Lilly's OVERCOME Study Reveals Nearly 80% of People Reported Improvement in Their Migraine Since Starting a CGRP Monoclonal Antibody for Preventive Treatment

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- Largest Real-World Study of Patient-Reported Outcomes in People with Migraine Shows the Use of Novel CGRP Monoclonal Antibody Class May Improve Migraine

INDIANAPOLIS, Oct. 9, 2020 /PRNewswire/ -- Nearly 80% of people taking calcitonin gene-related peptide monoclonal antibodies (CGRP mAbs) for the preventive treatment of migraine reported their migraine as "better" overall since starting their medication, according to a web-based population survey. Close to two-thirds (62.6%) said they also used an additional recommended migraine preventive medication with their CGRP mAbs. Eli Lilly and Company (NYSE: LLY) announced today the results, which are among the first real-world, population-based, patient-reported outcomes from people using CGRP mAbs as a migraine preventive treatment and suggest these novel medications lead to improvement in how patients perceive their migraine. The latest findings from Lilly's OVERCOME study are being presented virtually at the 18th Migraine Trust International Symposium (MTIS 2020).

"It is very encouraging that nearly 4 out of 5 people in the survey taking a CGRP monoclonal antibody felt better and reported their migraine had improved," said Sait Ashina, M.D., Department of Neurology and Department of Anesthesia, Critical Care and Pain Medicine, and Harvard Medical School, Beth Israel Deaconess Medical Center, and scientific advisor to the OVERCOME study. "It is also notable that the OVERCOME survey reported the clinically meaningful distinction between individuals who reported no change in their migraine with those who said their migraine worsened. This distinction can enhance conversations between the healthcare provider and the patient regarding treatment expectations when considering the use of these novel migraine preventive medications."

Patient's Assessment of Their Migraine After Taking a CGRP mAb for Preventive Treatment

Of the 586 people who reported using a CGRP mAb for the preventive treatment of migraine in the past three months, 79.2% reported perception of their migraine as "better," 11.3% indicated "no change" and 9.6% said it was "worse." These findings were relatively consistent across groups: 80.3% (0-3 headache days per month), 80.8% (4-7 headache days per month), 79.8% (8-14 headache days per month) and 74.6% (≥15 headache days per month). Data was obtained from participants in Q4 2019 and represented 2.8% of the 20,782 participants in the U.S. OVERCOME 2019 survey. Patients' perception of improvement in their migraine were measured using the Patient Global Impression of Improvement (PGI-I) scale. PGI-I responses were categorized as better, no change, or worse.

Use of Additional Recommended Migraine Preventive Medication

Among respondents who used a CGRP mAb in the previous 3 months, 62.6% used an additional recommended migraine preventive medication. This finding is consistent with the 2018 position statement of the American Headache Society (AHS) on integrating new migraine treatments into clinical practice and with patients' existing treatment plans.

"Given the AHS position statement and these exciting results that people reported their migraine as 'better' overall after taking novel CGRPs mAbs, Lilly believes the new data informs HCPs of the role CGRP mAbs can play as part of a comprehensive treatment plan for migraine," said Michael Cobas Meyer, M.D., vice president, global medical affairs, bio-medicines, Eli Lilly and Company.

Use of an additional migraine preventive medication was generally higher for patients with more frequent migraine headache days per month: 56.8% (0-3 headache days per month), 64.6% (4-7 headache days per month), 70.9% (8-14 headache days per month) and 70.2% (≥15 headache days per month). Recommended preventive medications for migraine were defined by the guidelines of the American Academy of Neurology (AAN) as well as the AHS position statement, and included topiramate, divalproex sodium/valproate sodium, metoprolol, propranolol, timolol, atenolol, nadolol, amitriptyline, nortriptyline, venlafaxine, duloxetine and onabotulinumtoxinA.

"We are pleased to share the latest insights from OVERCOME, which will enroll 100,000 people with migraine from around the globe and make it the largest population-based study of its kind by including U.S. patients who are studied over time. OVERCOME is focused on assessing the unmet needs of patients with migraine and how novel therapies, including the class of CGRP monoclonal antibodies, are influencing migraine treatment and patient-reported outcomes in this unprecedented era of treatment innovation for migraine," said Michael Cobas Meyer. "At Lilly we believe it's important to go beyond controlled clinical trials to better understand how patients manage their migraine including medicines in real life, and how they report the impact on their outcomes. We believe these insights will be useful for patients and healthcare providers when discussing treatment."

For additional information, read about Lilly's commitment to go beyond clinical trials to advance findings for migraine here.

About the OVERCOME Study

The **O**bser**v**ational Survey of the **E**pidemiology, T**r**eatment and **C**are **o**f **M**igrain**e** (OVERCOME) study 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.

OVERCOME is a prospective, web-based patient survey and will enroll 100,000 individuals with migraine from regions across the globe. U.S. OVERCOME will enroll more than 60,000 individuals with migraine using a prospective, multi-cohort, longitudinal study design to follow U.S. population samples with migraine for two years following their enrollment. In addition, nearly 40,000 individuals with migraine from other regions across the globe will complete a cross-sectional survey. In parallel, OVERCOME will also include 24,000 people who did not have migraine, providing

a unique perspective about how migraine is perceived by those who do not have the disease. OVERCOME began enrollment in Q4 2018.

About the U.S. OVERCOME Scientific Advisory Board

The U.S. OVERCOME study is being conducted by Kantar on behalf of Eli Lilly and Company with expert guidance provided by some of the leading voices in migraine research today, including:

- Richard B. Lipton, M.D., (Study Chair), Department of Neurology, Albert Einstein College of Medicine and Director, Montefiore Headache Center, Montefiore Health System
- Sait Ashina, M.D., Department of Neurology and Department of Anesthesia, Critical Care and Pain Medicine, and Harvard Medical School, Beth Israel Deaconess Medical Center
- Dawn C. Buse, Ph.D., Department of Neurology, Albert Einstein College of Medicine, Clinical Health Psychology Doctoral Program of the Ferkauf Graduate School of Psychology, Yeshiva University
- Susan Hutchinson, M.D., Orange County Migraine and Headache Center
- Michael L. Reed, Ph.D., President, Vedanta Research
- Robert E. Shapiro, M.D., Department of Neurological Sciences, Larner College of Medicine, University of Vermont

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.

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This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about the OVERCOME study and its assessment of the unmet needs of patients with migraine and the use of novel therapies, including the class of CGRP monoclonal antibodies, and reflects Lilly's current beliefs. There are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that future study results will be consistent with the results to date or that Lilly will receive additional regulatory approvals. For further discussion of these and other risks and uncertainties, see Lilly's most recent respective 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.

Refer to:Jen Dial; dial_jennifer_kay@lilly.com; 317-220-1172 (Lilly Bio-Medicines)
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