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Joint FDA Advisory Committee Votes on Application for Tanezumab for the Treatment of Osteoarthritis Pain

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NEW YORK & INDIANAPOLIS--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) and Eli Lilly and Company (NYSE:LLY) today announced the outcome of the U.S. Food and Drug Administration (FDA) Joint Arthritis Advisory Committee and Drug Safety and Risk Management Advisory Committee on tanezumab. There was a single voting question focused on whether the proposed risk evaluation and mitigation strategy (REMS) for tanezumab will ensure its benefits outweigh its risks, and the Committee voted 1 in favor and 19 against. Tanezumab 2.5 mg administered subcutaneously (SC) every eight weeks is being evaluated for the treatment of moderate-to-severe osteoarthritis (OA) pain in adult patients for whom use of other analgesics is ineffective or not appropriate. Tanezumab is an investigational monoclonal antibody in a new class of medicines called nerve growth factor (NGF) inhibitors, which work in a different manner than currently available treatments such as opioids, nonsteroidal anti-inflammatory drugs (NSAIDs) and other analgesics. In studies to date, tanezumab has not demonstrated a risk of addiction, misuse or dependence.

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“While we are disappointed with today’s outcome, we continue to believe that tanezumab has a positive benefit-risk profile for patients with moderate-to-severe osteoarthritis pain for whom current treatments are ineffective or not appropriate. Many of these patients have exhausted available therapies, have not had a new class of medications available to them in more than a decade and are eager for new, non-opioid options,” said Ken Verburg, tanezumab development team leader, Pfizer Global Product Development. “We will continue to work with the FDA as the agency continues its review of our application.”

The Advisory Committee’s discussions were based on the Biologics License Application (BLA) currently under review by the FDA. The BLA includes data from 20 Phase 1-3 clinical studies evaluating the safety and efficacy of tanezumab administered intravenously or SC in patients with OA, including three pivotal Phase 3 SC studies involving more than 4,500 patients with moderate-to-severe OA.

“The dialogue during the open public forum of this week’s Advisory Committee meeting reinforced the urgent need for innovation for people living with moderate-to-severe osteoarthritis pain – many of whom cycle through three to four therapies each year without adequate relief. The unresolved pain can impact all aspects of their lives, creating physical, emotional, social and financial hardships,” said Ilya Yuffa, president, Lilly Bio-Medicines.

Advisory Committees provide the FDA with independent opinions and recommendations from outside medical experts during the regulatory review process; however, the recommendations are not binding.

“Osteoarthritis is the most common type of arthritis and poses unique challenges for patients,” said Steven Taylor, executive vice president, mission & strategic initiatives for the Arthritis Foundation. “Despite its far-reaching impact, many patients still live with debilitating pain and have exhausted or are unable to take or tolerate currently available therapies. That is why the Arthritis Foundation advocates for innovative treatment solutions and a patient-centered approach to managing chronic pain for those with osteoarthritis.”

About Tanezumab

Tanezumab is an investigational monoclonal antibody that works by selectively targeting, binding to and inhibiting NGF. NGF levels increase in the body as a result of injury, inflammation or in chronic pain states. By inhibiting NGF, tanezumab may help to keep pain signals produced by muscles, skin and organs from reaching the spinal cord and brain. Tanezumab has a novel mechanism that acts in the periphery in a different manner than opioids and other analgesics, including nonsteroidal anti-inflammatory drugs (NSAIDs), and in studies to date, tanezumab has not demonstrated a risk of addiction, misuse or dependence.

About Osteoarthritis

OA is a chronic, progressive and disabling disease of the joint that is a leading cause of chronic pain. In the United States, OA impacts an estimated 31 million people, 11 million of whom have moderate-to-severe OA and have been living with the condition for an average of nine years. OA places a significant burden on these patients – the pain can limit their ability to function, which can force compromises in everyday life, negatively impacting their roles and relationships and causing feelings of isolation, frustration and anxiety. OA can also impact their ability to function in the workplace. There is a need for innovation, as currently available treatment options for moderate-to-severe OA do not meet the needs of all patients.

About the Pfizer-Lilly Alliance

In 2013, Pfizer and Lilly entered into a collaboration to develop and commercialize tanezumab. If approved, the companies will jointly commercialize tanezumab in the U.S. and Pfizer will be responsible for commercialization activities outside of the U.S. Pfizer and Lilly are driven by our shared mission to improve the lives of the millions of people who are suffering from moderate-to-severe OA pain, and together, we are leveraging our deep clinical expertise to make a meaningful difference for patients.

About Pfizer: Breakthroughs That Change Patients’ Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

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 www.lilly.com and lilly.com/newsroom.

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of March 25, 2021. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a product candidate, tanezumab and a potential indication in the U.S. for the treatment of moderate-to-severe OA pain in adult patients for whom use of other analgesics is ineffective or not appropriate, including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications for any potential indications for tanezumab may be filed in any other jurisdictions; whether and when the FDA may approve the pending application for the potential indication and whether and when regulatory authorities in any jurisdictions may approve any such other applications that may be filed for tanezumab, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether tanezumab will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of tanezumab; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

LILLY DISCLOSURE NOTICE: This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about tanezumab as a potential treatment for patients with moderate-to-severe OA pain for whom the use of other analgesics is ineffective or inappropriate and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of research, development, and commercialization. Among other things, there can be no guarantee that future study results will be consistent with the results to date, that tanezumab 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.

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