U.S. FDA Accepts Regulatory Submission for Tanezumab, a Potential First-in-Class Treatment for Patients with Chronic Pain Due to Moderate-to-Severe Osteoarthritis

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Pfizer Inc. (NYSE:PFE) and Eli Lilly and Company (NYSE:LLY) today announced that the U.S. Food and Drug Administration (FDA) accepted for review a Biologics License Application (BLA) for tanezumab 2.5 mg administered subcutaneously (SC), which is being evaluated for patients with chronic pain due to moderate-to-severe osteoarthritis (OA) who have experienced inadequate pain relief with other analgesics. Tanezumab is a monoclonal antibody that is part of an investigational class of non-opioid chronic pain medications known as nerve growth factor (NGF) inhibitors.

More than 27 million Americans are living with OA, 11 million of whom have moderate-to-severe OA. Currently available treatment options for moderate-to-severe OA do not meet the needs of all patients, and many cycle through multiple therapies to find relief from their pain. The Prescription Drug User Fee Act (PDUFA) goal date for the FDA to make a decision on the tanezumab application is in December 2020. In its acceptance letter, the FDA stated that it is currently planning to hold an Advisory Committee meeting to discuss this application.

"The FDA acceptance of the tanezumab application represents a significant milestone, and the breadth of our regulatory submission reflects the extensive clinical data we have gathered for tanezumab over the course of its development," said Ken Verburg, tanezumab development team leader, Pfizer Global Product Development. "There is an

urgent need for innovation in the treatment of osteoarthritis, as there have been no new classes of medicines available for this debilitating condition in more than a decade. If approved, tanezumab would be a first-in-class treatment for patients suffering from chronic pain due to moderate-to-severe osteoarthritis who have experienced inadequate pain relief with other analgesics."

"Osteoarthritis patients face a significant burden – due to the physical pain they experience, nearly every aspect of their lives can be impacted. This pain can affect their ability to participate in daily activities, which can have significant psychological, social and societal consequences," said Patrik Jonsson, president, Lilly Bio-Medicines. "We look forward to working closely with the FDA to potentially bring tanezumab to patients living with moderate-to-severe osteoarthritis."

The tanezumab regulatory submission encompasses data from 39 Phase 1-3 clinical studies evaluating the safety and efficacy of tanezumab among more than 18,000 patients, including three Phase 3 studies evaluating SC administration of tanezumab in patients with moderate-to-severe OA.

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.

The Pfizer-Lilly Alliance In 2013, Pfizer and Lilly entered into a worldwide collaboration to develop and commercialize tanezumab, a monoclonal antibody that is part of an investigational class of non-opioid pain medications known as NGF inhibitors. Tanezumab has the potential to address significant unmet needs in moderate-to-severe OA, a condition that can have life-altering physical, social, psychological and economic impacts. We are driven by our shared mission to improve the lives of the millions of people who are suffering from chronic pain. Together, we are leveraging our deep clinical expertise with the goal of delivering scientific innovation in chronic pain management and making a meaningful difference for people around the world.

Pfizer Inc.: 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 150 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. P-LLY

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of March 2, 2020. 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 patients with chronic pain due to moderate-to-severe osteoarthritis who have experienced inadequate pain relief with other analgesics, 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; 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, 2019 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 chronic pain due to moderate-to-severe osteoarthritis 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 future study results will be consistent with the results to date or that tanezumab will receive regulatory approvals. 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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