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Pfizer And Lilly Announce Positive Top-Line Results From Phase 3 Trial Of Tanezumab For The Treatment Of Osteoarthritis (OA) Pain

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There is a substantial need for innovative new treatment options for osteoarthritis, as many patients are unable to find relief with currently available medicines and continue to suffer.

Pfizer Inc.(NYSE:PFE) and Eli Lilly and Company (NYSE:LLY) today announced that a 16-week Phase 3 study in patients with osteoarthritis (OA) pain evaluating subcutaneous administration of tanezumab, an investigational humanized monoclonal antibody, met all three co-primary endpoints. The study demonstrated that patients who received two doses of tanezumab separated by eight weeks experienced a statistically significant improvement in pain, physical function and the patients' overall assessment of their OA, compared to those receiving placebo. Tanezumab is part of an investigational class of pain medications known as nerve growth factor (NGF) inhibitors and in addition to OA pain, is being evaluated for chronic low back pain (CLBP) and cancer pain (due to bone metastases).

"There is a substantial need for innovative new treatment options for osteoarthritis, as many patients are unable to find relief with currently available medicines and continue to suffer," said Ken Verburg, tanezumab development team leader, Pfizer Global Product Development. "We are encouraged by these results, which speak to the potential of tanezumab as a non-opioid treatment option for pain reduction and improvement in physical function in people living with osteoarthritis pain."

Preliminary safety data showed that tanezumab was generally well tolerated, with approximately 1% of patients discontinuing treatment due to adverse events. Rapidly progressive osteoarthritis was observed in tanezumab-treated patients at a frequency of less than 1.5%, and was not observed in the placebo arm. There were no events of osteonecrosis observed in the trial. No new safety signals were identified.

"Worldwide, millions are living with osteoarthritis, a progressive disease that can significantly impact people's everyday lives," said Christi Shaw, senior vice president, Eli Lilly and Company and president, Lilly Bio-Medicines. "We look forward to continuing to advance tanezumab in our ongoing global Phase 3 development program, which includes six studies in approximately 7,000 patients with osteoarthritis, chronic low back pain and cancer pain."

In June 2017, Pfizer and Lilly announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for tanezumab for the treatment of OA pain and CLBP. Tanezumab is the first NGF inhibitor to receive Fast Track designation, a process designed to facilitate the development and expedite the review of new therapies that treat serious conditions and fill unmet medical needs.

About the Study

The Phase 3 OA study (A4091056) was a 16-week randomized, double-blind, placebo-controlled, multicenter, parallel-group trial evaluating the efficacy and safety of subcutaneous administration of tanezumab compared to placebo in patients with OA of the knee or hip. The trial included a 24-week safety follow-up period. In the study, patients were enrolled with moderate to severe OA pain who had experienced inadequate pain relief with other treatment options for OA pain or were unable to take other pain medications. A total of 698 patients were randomized to three treatment groups in a 1:1:1 ratio to receive two injections over the 16-week study, once every eight weeks. One group received two doses of placebo, the second group received two doses of tanezumab 2.5 mg, and the third group received one dose of tanezumab 2.5 mg followed by one dose of tanezumab 5 mg eight weeks later. The efficacy of tanezumab vs. placebo was measured by changes from baseline at 16 weeks in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Pain subscale, the WOMAC Physical Function subscale, and the patient's Global Assessment of OA. In the study, both tanezumab treatment arms met all three co-primary endpoints.

About Tanezumab

Tanezumab, an investigational humanized monoclonal antibody, is a potential first-in-class, non-opioid treatment being evaluated for OA pain, CLBP and cancer pain (due to bone metastases). Tanezumab 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 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.

In 2013, Pfizer and Lilly entered into a worldwide co-development and co-commercialization agreement for the advancement of tanezumab. The Phase 3 global clinical development program for tanezumab is currently ongoing and includes six studies in approximately 7,000 patients.

About Pfizer Inc.: Working together for a healthier world®

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. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. 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 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 http://newsroom.lilly.com/socialchannels.

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of July 18, 2018. 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, 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 trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when new drug applications may be filed in any jurisdictions for tanezumab; whether and when any such applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted and, if approved, whether tanezumab will be commercially successful; decisions by regulatory authorities regarding labeling and 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, 2017 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 osteoarthritis, chronic low back pain, and cancer pain, and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug development and commercialization. Among other things, there is no guarantee that future study results will be consistent with study findings to date, or that tanezumab will be approved by the U.S. FDA or other regulatory authorities on the anticipated timeline or at all, or that tanezumab 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.

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