Pfizer and Lilly Announce Top-Line Results From Second Phase 3 Study of Tanezumab in Osteoarthritis Pain

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NEW YORK & INDIANAPOLIS--(BUSINESS WIRE)--Jan. 29, 2019-- Pfizer Inc. (NYSE:PFE) and Eli Lilly and Company (NYSE:LLY) today announced positive top-line results from a Phase 3 study evaluating tanezumab 2.5 mg or 5 mg in patients with moderate-to-severe osteoarthritis (OA) pain. The tanezumab 5 mg treatment arm met all three co-primary endpoints at 24 weeks, demonstrating a statistically significant improvement in pain, physical function and the patients' overall assessment of their OA compared to those receiving placebo. The tanezumab 2.5 mg treatment arm met two of the three protocol-defined co-primary efficacy endpoints compared to placebo, demonstrating a statistically significant improvement in pain and physical function, while patients' overall assessment of their OA was not statistically different than placebo. Tanezumab is a humanized monoclonal antibody that is part of an investigational class of non-opioid pain medications known as nerve growth factor (NGF) inhibitors.

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In this study, subcutaneous (SC) administration of tanezumab 2.5 mg or 5 mg was evaluated every eight weeks, for a total of 24 weeks, in patients with moderate-to-severe OA pain. Patients enrolled in the study had experienced inadequate pain relief from or intolerance to at least three different classes of analgesics, and on average had OA for more than six years. They also reported significant impact of their pain on their ability to function in everyday life. Preliminary safety data showed that tanezumab was generally well tolerated during the 24-week treatment period, with similarly low rates of treatment discontinuations due to adverse events observed among patients taking tanezumab and placebo. The trial also included a 24-week safety follow-up period, for a total of 48 weeks of observation.

Overall, rapidly progressive osteoarthritis (RPOA) was observed in 2.1 percent of tanezumab-treated patients and was not observed in the placebo arm. The ratio of RPOA type 1 (accelerated joint space narrowing) to RPOA type 2 (damage or deterioration of the joint) was 2:1, consistent with the ratio from the previously reported SC Phase 3 study in OA pain (A4091056). There was one event of osteonecrosis and one event of subchondral insufficiency fracture observed in tanezumab-treated patients, and no events were observed in the placebo arm. The rate of total joint replacement was similar across the tanezumab treatment groups and placebo. Detailed efficacy and safety results from this study will be submitted to a future medical congress.

"These findings build on the previously reported positive Phase 3 results in patients with osteoarthritis pain and add to the growing body of evidence supporting tanezumab as a potential innovative treatment option for this difficult-to-treat patient population," said Ken Verburg, PhD, tanezumab development team leader, Pfizer Global Product Development. "We look forward to sharing data from additional ongoing studies evaluating tanezumab for osteoarthritis pain and chronic low back pain in the coming months."

"For many people, living with osteoarthritis pain can limit their ability to function, which can force them to make compromises in everyday life," said Christi Shaw, president, Lilly Bio-Medicines. "Lilly and Pfizer have a shared commitment to advance the care of people living with chronic pain, and we see the potential of tanezumab as an innovative, non-opioid option to improve the treatment of osteoarthritis pain, a debilitating, progressive condition."

More than 27 million Americans are living with OA, a progressive joint disease that can be life-altering and cause debilitating physical, emotional and social effects. Approximately 11 million of these patients suffer from moderate-to-severe OA pain. Currently available treatment options for OA pain do not meet the needs of all patients, and many cycle through multiple therapies to find relief from their pain. Tanezumab has a novel mechanism that acts in a different manner than other analgesics, including opioids and nonsteroidal anti-inflammatory drugs (NSAIDs), and in studies to date, tanezumab has not demonstrated a risk of addiction, misuse or dependence.

This is the second readout from the ongoing Phase 3 global clinical development program for tanezumab, which includes six studies in approximately 7,000 patients with OA pain, chronic low back pain (CLBP) and cancer pain (due to bone metastases). Results from the first Phase 3 OA study (A4091056) evaluating SC administration of tanezumab for 16 weeks were previously reported. That study met all three co-primary efficacy endpoints, demonstrating that among patients with moderate-to-severe OA pain of the knee or hip, both dosing regimens of tanezumab (2.5 mg and 2.5/5 mg) resulted in a statistically significant improvement in pain, physical function and patients' overall assessment of their OA, compared to placebo.

About the Study

The Phase 3 OA study (A4091057) was a randomized, double-blind, placebo-controlled, multicenter, parallel-group trial evaluating the efficacy and safety of SC tanezumab compared to placebo for 24 weeks in patients with moderate-to-severe OA pain of the knee or hip. The trial was conducted in Europe and Japan.

Patients enrolled in the study had experienced inadequate pain relief from or intolerance to at least three different classes of analgesics, and on average had OA for more than six years. At the beginning of the study, they reported significant impact of their pain on their ability to function in everyday life. A total of 849 patients were randomized to three treatment groups in a 1:1:1 ratio to receive three SC injections over the 24-week treatment period, once every eight weeks. One group received three doses of tanezumab 2.5 mg, the second group received three doses of tanezumab 5 mg, and the third group received three doses of placebo. The efficacy of tanezumab versus placebo was measured by changes from baseline at 24 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. The trial also included a 24-week safety follow-up period.

About Tanezumab

Tanezumab is an investigational humanized 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 a different manner than opioids and other analgesics, including 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. 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. If approved, tanezumab would be a first-in-class treatment for OA pain and CLBP.

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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 https://www.lilly.com/newsroom/social-channels.

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of January 29, 2019. 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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