Pfizer and Lilly Announce Top-line Results From Phase 3 Study of Tanezumab in Chronic Low Back Pain

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NEW YORK and INDIANAPOLIS, Feb. 19, 2019 /PRNewswire/ -- Pfizer Inc. (NYSE: PFE) and Eli Lilly and Company (NYSE: LLY) today announced positive top-line results from a Phase 3 study evaluating tanezumab in patients with moderate-to-severe chronic low back pain (CLBP). In the study, treatment with tanezumab 10 mg met the primary endpoint, demonstrating a statistically significant improvement in pain at 16 weeks compared to placebo. The tanezumab 5 mg arm demonstrated a numerical improvement in pain, but did not reach statistical significance compared to placebo at the week 16 analysis. Full results from this study will be submitted for future scientific publication and presentation. Tanezumab is a monoclonal antibody that is part of an investigational class of non-opioid pain medications known as nerve growth factor (NGF) inhibitors.

In this study, CLBP was defined as low back pain that had persisted for more than three consecutive months. Patients enrolled suffered from moderate-to-severe pain and had experienced inadequate pain relief from or intolerance to at least three different classes of analgesics. On average, they had CLBP for 10 years, and they reported a significant impact of their pain on their ability to function in everyday life. An estimated 33 million Americans have CLBP, and approximately eight million of these patients suffer from moderate-to-severe CLBP. The condition is a leading cause of disability, and currently available treatment options for CLBP do not meet the needs of all patients.

Tanezumab 5 mg or 10 mg was administered subcutaneously (SC) every eight weeks. Preliminary safety data showed that tanezumab was generally well tolerated during the 56-week treatment period. The trial also included a 24-week safety follow-up period, for a total of 80 weeks of observation. Overall, rapidly progressive osteoarthritis (RPOA) was observed among 1.4 percent of patients receiving tanezumab and 0.1 percent of patients in the other treatment groups. The ratio of RPOA type 1 (accelerated joint space narrowing) to RPOA type 2 (damage or deterioration of the joint) observed with tanezumab in the study was 6:1. Subchondral insufficiency fracture and total joint replacement were observed in 0.4 percent and 0.7 percent of tanezumab-treated patients, respectively, and were not observed in the other treatment groups. There were no events of osteonecrosis in the study.

"This study demonstrates the potential of tanezumab to treat individuals suffering from moderate-to-severe chronic low back pain who have been unable to achieve relief with currently available medicines," said Ken Verburg, tanezumab development team leader, Pfizer Global Product Development. "This is one of the longest studies conducted to date in chronic low back pain. We look forward to further analyzing these results, and believe the data from this study will support our planned future global regulatory submissions in chronic low back pain."

"Many patients living with chronic low back pain suffer from constant pain, which significantly impacts their ability to perform everyday tasks," said Christi Shaw, president, Lilly Bio-Medicines. "Lilly and Pfizer recognize the unmet needs for those living with this life-altering and debilitating condition, and continue to advance tanezumab as an innovative non-opioid treatment for these patients."

In addition to CLBP, the ongoing Phase 3 program for tanezumab includes studies in osteoarthritis (OA) pain and cancer pain (due to bone metastases). Positive results from two Phase 3 OA pain studies evaluating 16 and 24 weeks of treatment with tanezumab were previously reported. One additional Phase 3 study in OA pain and one additional Phase 3 study in CLBP will read out this year.

About Chronic Low Back Pain (CLBP)

CLBP, or low back pain that lasts longer than three months, impacts an estimated 33 million Americans and is a leading cause of disability. Approximately eight million of these patients suffer from moderate-to-severe CLBP. The cause of CLBP is complex and not well understood, and management of the condition often requires medication in addition to non-pharmacologic treatment. Currently available treatment options for CLBP do not meet the needs of all patients, and many find themselves cycling through therapies to try to find relief from their pain. Living with CLBP can limit patients' ability to physically function, which can force compromises in everyday life and cause feelings of isolation, frustration and anxiety.

About the Study

Study A4091059 was a randomized, double-blind, placebo-and active-controlled, multicenter, parallel-group Phase 3 trial in subjects with moderate-to-severe CLBP. The study evaluated the efficacy and safety of SC administration of tanezumab compared to placebo for a total of 16 weeks, and oral tramadol prolonged release (PR) for a total of 56 weeks. The study was conducted in North America, Europe and Asia.

The primary endpoint evaluated change in the daily average Low Back Pain Intensity (LBPI) score from baseline to week 16, as measured by an 11-point numeric rating scale, for tanezumab vs. placebo. Secondary efficacy endpoints evaluated tanezumab treatment through 16 and 56 weeks, including comparisons to tramadol PR. The long-term safety of tanezumab through 80 weeks (56 weeks of treatment plus the 24-week safety follow-up period) was also evaluated.

Patients were not eligible to participate in the study if they met the American College of Rheumatology criteria for OA of the hip or knee, or had symptoms and radiographic findings consistent with OA of the shoulder. Patients with mild radiographic evidence of knee OA (Kellgren-Lawrence grade ≤ 2) but no pain, and patients with no or possible radiographic evidence of hip OA (Kellgren-Lawrence grade ≤1), were eligible to participate. Patients in the study had experienced inadequate pain relief from or intolerance to at least three different classes of analgesics. On average, these patients had CLBP for 10 years and reported significant impact of their pain on their ability to function in everyday life.

A total of 1,832 patients were randomized to one of four treatment groups in a 2:2:2:3 ratio: one group received placebo every eight weeks to week 16; at week 16, patients in this group who met the efficacy responder criteria were switched equally to either tanezumab 5 mg or tanezumab 10 mg every eight weeks to week 56; the second group received tanezumab 5 mg every eight weeks to week 56; the third group received tanezumab 10 mg every eight weeks to week 56; and the fourth group received oral tramadol PR daily to week 56.

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 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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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 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 jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any such applications, 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, 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.

Pfizer Media Contact:
Neha Wadhwa
212-733-2835
Neha.Wadhwa@pfizer.com

Eli Lilly Media Contact:
Jen Dial
317-220-1172
dial_jennifer_kay@lilly.com

Pfizer Investor Contact:
Ryan Crowe
212-733-8160
Ryan.Crowe@pfizer.com

Eli Lilly Investor Contact:
Kevin Hern
317-277-1838
hern_kevin_r@lilly.com





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