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ASIA EDITION

Pfizer and Lilly announce top-line results of Tanezumab

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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

Pfizer and Eli Lilly have 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.

As per the company statement, “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.

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.

Ken Verburg, tanezumab development team leader, Pfizer Global Product Development said, “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. We look forward to sharing data from additional ongoing studies evaluating tanezumab for osteoarthritis pain and chronic low back pain in the coming months.”

Christi Shaw, president, Lilly Bio-Medicines said, “For many people, living with osteoarthritis pain can limit their ability to function, which can force them to make compromises in everyday life. 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 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).