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Pfizer, Lilly's osteoarthritis drug succeeds in phase III trials

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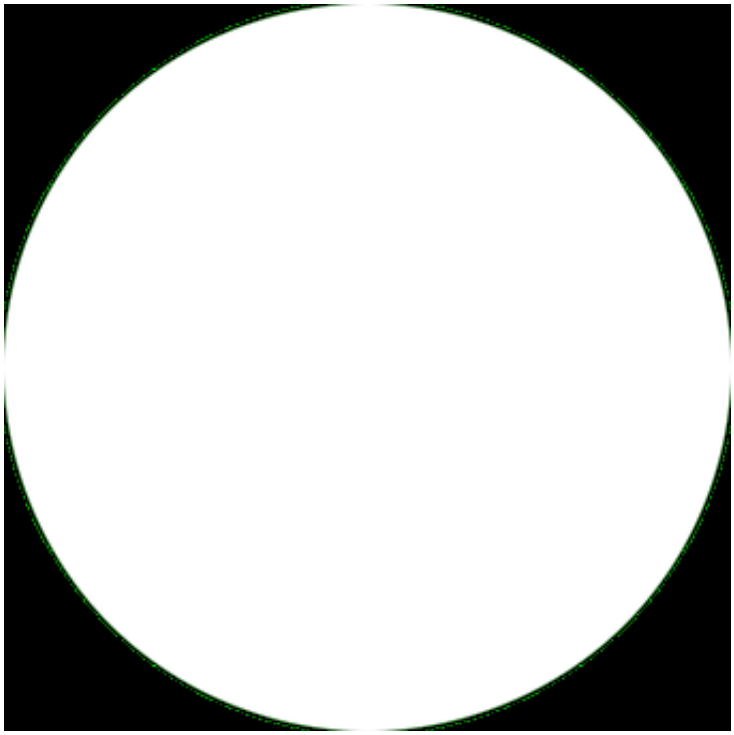

Pfizer and Eli Lilly and Company recently announced that a 16-week Phase 3 study in patients with osteoarthritis (OA) pain evaluating subcutaneous administration of tanezumab, an investigational humanized monoclonal antibody, met all three co-primary endpoints.

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.