



# Pfizer and Lilly Receive FDA Fast Track Designation for Tanezumab

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Global Phase 3 program is studying potential new treatment option for millions of people living with chronic pain associated with osteoarthritis and chronic low back pain Acts in a different manner than opioids and other analgesics

Pfizer Inc. (NYSE:PFE) and Eli Lilly and Company (NYSE:LLY) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for tanezumab for the treatment of chronic pain in patients with osteoarthritis (OA) and chronic low back pain (CLBP). Tanezumab is an investigational humanized monoclonal antibody that selectively targets, binds to and inhibits nerve growth factor (NGF). It is the first NGF inhibitor to receive Fast Track designation, a process designed to facilitate the development and expedite the review of new therapies to treat serious conditions and fill unmet medical needs.

“If approved, tanezumab would be the first in a new class of non-opioid chronic pain medications,” said Ken Verburg, Chief Development Officer, Neuroscience & Pain, Pfizer Global Product Development. “We believe it would represent an important medical advance in the treatment of debilitating osteoarthritis and chronic low back pain for patients who do not experience adequate pain relief or cannot tolerate currently available pain medications.”

The Phase 3 global clinical development program for tanezumab is currently ongoing and includes six studies in approximately 7,000 patients with OA, CLBP or cancer pain who did not experience adequate pain relief with approved therapies. Results are projected to begin reporting out in 2018. All studies are investigating subcutaneous administration of tanezumab by a health care provider once every eight weeks for treatment periods ranging from 16 to 56 weeks, followed by a 24-week safety follow-up period.

"It is estimated that there are more than 27 million Americans currently living with osteoarthritis and 23 million living with chronic low back pain, many of whom fail to achieve adequate pain relief despite treatment with various types of pain medications," said Christi Shaw, Senior Vice President and President, Lilly Bio-Medicines. "We are committed to offering innovative solutions to people suffering from chronic pain conditions, and look forward to working closely with the FDA to facilitate the development of tanezumab."

For more information on ongoing clinical trials of tanezumab, visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **About Tanezumab**

Tanezumab is an investigational humanized monoclonal antibody, which 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).

In 2013, Pfizer and Lilly entered into a worldwide co-development and co-commercialization agreement for the advancement of tanezumab.

### **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](http://www.pfizer.com). In addition, to learn more, please visit us on [www.pfizer.com](http://www.pfizer.com) and follow us on Twitter at @Pfizer and @Pfizer\_News, LinkedIn, YouTube and like us on Facebook at [Facebook.com/Pfizer](https://www.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](http://www.lilly.com) and <http://newsroom.lilly.com/social-channels>.

**PFIZER DISCLOSURE NOTICE:** The information contained in this release is as of June 13, 2017. 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 involve 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, without limitation, 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; whether and when new drug applications may be filed in any jurisdictions for tanezumab; whether and when 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; 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, 2016 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](http://www.sec.gov) and [www.pfizer.com](http://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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