

# Pfizer And Lilly Preparing To Resume Phase 3 Chronic Pain Program For Tanezumab

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Pfizer Inc. (NYSE:PFE) and Eli Lilly and Company (NYSE:LLY) announced today that they are preparing to resume the Phase 3 clinical program for tanezumab. As a result, Pfizer expects to receive a \$200 million upfront payment from Lilly in accordance with their collaboration agreement. This announcement follows a decision by the U.S. Food and Drug Administration (FDA) to lift the partial clinical hold on the tanezumab development program after a review of a robust body of nonclinical data characterizing the sympathetic nervous system response to tanezumab. The data were submitted to the FDA in February 2015.

In the prior clinical studies of more than 11,000 patients, tanezumab demonstrated clinically meaningful efficacy vs. placebo and other select commonly used pain medicines. A partial clinical hold has been in place for tanezumab and all other anti-nerve growth factor antibodies since December 2012 due to adverse changes in the sympathetic nervous system of mature animals. Studies in terminal cancer pain were allowed to proceed.

“We are pleased with the FDA’s decision as chronic pain remains an area of significant unmet medical need and we believe tanezumab has potential to offer a new, non-narcotic option,” said Steve Romano, MD, senior vice president and head of Global Medicines Development at Pfizer’s Global Innovative Pharmaceuticals Business.

“We’re pleased to work with Pfizer to resume the Phase 3 program, and we’re confident that tanezumab, if approved, can be an innovative treatment with the potential to help millions suffering from painful conditions,” said David Ricks, Lilly senior vice president and president, Lilly Bio-Medicines.

It is estimated that nearly one in five adults suffer from chronic pain.

## About Tanezumab

Tanezumab is a humanized monoclonal antibody that selectively targets nerve growth factor (NGF), a regulator of pain processing and sensitivity. NGF levels increase as a result of injury or inflammation and in chronic pain states. Tanezumab selectively binds to NGF, thereby inhibiting this protein from activating pain-signaling neurons.

## 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, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at [www.pfizer.com](http://www.pfizer.com).

### **About Eli Lilly and Company (NYSE: LLY)**

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 March 23, 2015. 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 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, 2014 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC 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 about tanezumab as a potential treatment for patients with osteoarthritis, chronic low back pain, and cancer pain. It reflects Lilly's current beliefs; however, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug development, regulatory review, and commercialization. There is no guarantee that future study results will be consistent with study findings to date, or that tanezumab will receive regulatory approvals or, if approved, will be commercially successful. For further discussion of these and other risks and uncertainties, please see Lilly's latest Forms 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.*

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