Pfizer Reports Top-Line Results From ALO-02 Phase 3 Study

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Pfizer Inc. (NYSE: PFE) announced today top-line results from a Phase 3 study of investigational agent ALO-02 (oxycodone hydrochloride and naltrexone hydrochloride extended-release capsules) in patients with moderate-to-severe chronic low back pain. In this study, ALO-02 met the primary efficacy endpoint, demonstrating a statistically significant difference from placebo.

This was a 12-week, double-blind, placebo-controlled, randomized withdrawal design efficacy and safety study in patients with moderate-to-severe chronic low back pain. Patients who achieved a stable and effective dose of ALO-02 (10-80 mg twice per day) during the 4-to-6 week, open-label titration period were randomized (n=281) to the 12-week, double-blind period in which they were either maintained on their current dose regimen of ALO-02 (n=147) or were tapered to placebo (n=134). The primary efficacy endpoint of the study was defined as the difference between ALO-02 and placebo in the mean change in the daily average pain numerical rating scale (NRS-Pain) scores from baseline (just prior to randomization) to the final two weeks of the double-blind treatment period. Pain was self-reported daily on an 11-point numeric rating scale (daily NRS; 0=no pain, 10=worst possible pain). Mean changes in the primary endpoint, NRS-Pain scores from baseline to the final 2 weeks, were significantly different between ALO-02 and placebo.

The most common adverse events with ALO-2 during the double-blind period in this study were nausea, vomiting and diarrhea.

Results from this study will be submitted for presentation at upcoming medical congresses and submitted for publication in a peer-reviewed journal.

About ALO-02

ALO-02 contains pellets that consist of extended-release oxycodone hydrochloride, an opioid agonist, that surrounds sequestered naltrexone hydrochloride, an opioid receptor antagonist. When used as directed, the naltrexone remains sequestered and patients receive oxycodone in an extended release manner. When the pellets are crushed in an attempt to misuse or abuse ALO-02, naltrexone is released and is designed to counteract the effects of oxycodone.

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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.

DISCLOSURE NOTICE: The information contained in this release is as of January 23, 2014. 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, ALO-02, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the possibility of unfavorable clinical trial results; whether and when any drug applications may be filed in any jurisdictions for ALO-02; whether and when any such applications may be approved by regulatory authorities, as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K/A for the fiscal year ended December 31, 2012 and in its reports on Form 10-Q and Form 8-K.

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