Pfizer Announces Top-Line Results From A Phase 3 Long-Term Safety Study Of ALO-02:

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An Investigational Agent Comprised Of Oxycodone Hydrochloride And Naltrexone Hydrochloride Extended-Release Capsules, In Subjects With Moderate-To-Severe Chronic Non-cancer Pain

"These top-line data provide evidence of the long-term safety of ALO-02 in patients with moderate-to-severe non-cancer pain regardless of prior prescription opioid treatment,"

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced top-line results today from a Phase 3 open-label long-term safety study of investigational agent ALO-02 (oxycodone hydrochloride and naltrexone hydrochloride extended-release capsules) in patients with moderate-to-severe chronic, non-cancer pain. The primary objective of the study was to evaluate the safety of ALO-02 administered for up to 12 months. The study showed that the adverse event profile was as expected based on similar long-term safety studies with other extended-release opioid formulations; the most common adverse events were nausea, constipation, vomiting and headache. The study supports the safety profile of this investigational analgesic.

ALO-02 uses technology designed to encourage use as intended. The technology may discourage common methods of tampering associated with prescription opioid misuse and abuse and consists of extended-release oxycodone pellets that surround a sequestered core of naltrexone. When used as directed, the naltrexone core remains sequestered and patients receive oxycodone in an extended release manner. When the pellets are crushed, the naltrexone is released and is designed to counteract the effects of oxycodone.

“These top-line data provide evidence of the long-term safety of ALO-02 in patients with moderate-to-severe non-cancer pain regardless of prior prescription opioid treatment,”

said Steven J. Romano, M.D., senior vice president, head, Medicines Development Group, Global Primary Care Business Unit, Pfizer Inc.

Study ALO-02-10-3001 included adult patients with moderate-to-severe chronic non-cancer pain lasting at least 3 months and requiring a continuous around-the-clock opioid analgesic for an extended period of time. Before enrolling in the study, subjects could be receiving a prescription opioid for the management of chronic pain or could be opioid-naïve. The primary objective of this single-arm, multicenter, safety study was to evaluate the long-term safety of ALO-02 administered once or twice daily for up to 12 months. The study enrolled 395 patients, the majority of whom – 77 percent – were opioid-experienced. The majority of patients had chronic lower back pain (61 percent) and 18 percent had pain from osteoarthritis. Patients enrolled in the study had pain for an average of nine years. A total of 193 (48.9%) patients received ALO-02 for approximately 6 months and 105 (26.6%) patients for approximately one year.

The most common treatment-emergent adverse events (>10%) while on ALO-02 were nausea, constipation, vomiting and headache. The most common serious adverse events were acute myocardial infarction, non-cardiac chest pain, pneumonia, convulsion, and kidney stones, each of which occurred in 2 patients. A total of 237 (60%) patients discontinued from the study over the one-year study period, with 19 percent of patients reporting adverse events as the primary reason for discontinuation. The adverse events that most commonly (>2%) lead to discontinuation were nausea and constipation. The discontinuation rate was within the expected range based on similar long-term safety studies with other extended-release opioid formulations.

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DISCLOSURE NOTICE: The information contained in this release is as of October 11, 2012. 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; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for ALO-02 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 for the fiscal year ended December 31, 2011 and in its reports on Form 10-Q and Form 8-K.

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