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ALO-02 Demonstrates Significant Difference In Pain Scores In Chronic Low Back Pain Patients And Lower Abuse Potential Compared To Immediate-Release Oxycodone In Recreational Opioid Users

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Pfizer Inc. (NYSE:PFE) presented results today from three pivotal studies of investigational agent ALO-02 (oxycodone hydrochloride and naltrexone hydrochloride extended-release capsules). One of the studies demonstrates a statistically significant difference in pain scores in patients with moderate-to-severe chronic low back pain receiving ALO-02 versus placebo. The other studies demonstrate lower abuse potential of ALO-02 in recreational opioid users by oral and intranasal routes when compared to immediate-release oxycodone. Data from these three studies were presented at the 33rd Annual Meeting of the American Pain Society (APS) in Tampa, Florida.

“Chronic pain can have a profound negative impact on patients’ lives, and there continues to be a need for additional safe and effective treatment options,” said Dr. Steven Romano, senior vice president and head, Medicines Development Group, Pfizer Global Innovative Pharmaceutical Business. “These study results point to the potential of ALO-02 as an important treatment option, for appropriate patients, with abuse-deterrent features. Abuse of prescription opioids is a growing concern. Pfizer’s ongoing development of abuse-deterrent formulations, including ALO-02, demonstrates the company’s commitment to responsible use of opioid therapies.”

Phase 3 ALO-02 Study in Chronic Low Back Pain

One of the ALO-02 studies was a 12-week, double-blind, placebo-controlled, randomized withdrawal efficacy and safety Phase 3 study in patients with moderate-to-severe chronic low back pain. Patients who achieved a stable and effective dose of ALO-02 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). Mean changes in the primary endpoint, as measured by the numerical rating scale (NRS-pain) scores from baseline to the final two weeks, were statistically significant between ALO-02 and placebo. Of the patients in the ALO-02 group, 84 (57.5%) had at least a 30% decrease (improvement) in NRS-pain score from screening compared to 59 (44.0%) patients in the placebo group (p=0.0248). Of the patients in the ALO-02 group, 58 (39.7%) patients had at least a 50% decrease in NRS-pain score compared to 40 (29.9%) patients in the placebo group(p=0.0874).

The most common adverse events with ALO-2 during the double-blind period in this study were nausea (14.4% vs 3.7% with placebo), vomiting (6.2% vs 3%) and diarrhea (5.5% vs 4.5%).

ALO-02 Studies Demonstrate Lower Abuse Potential

The first of the two abuse-potential studies compared the abuse potential of ALO-02 and immediate-release (IR) oxycodone when taken orally. The randomized, double-blind, double-dummy, placebo- and active-controlled, 6-way crossover study in 41 healthy, non-dependent, recreational opioid users demonstrated that oral administration of 40 mg (crushed) and 60 mg ALO-02 (crushed or intact) resulted in statistically significant lower scores for Drug Liking and High than equivalent doses of crushed IR oxycodone.

The most common adverse events seen in this study included euphoric mood, itching (pruritus) and drowsiness (somnolence) and were more frequent with IR oxycodone than ALO-02.

A second abuse-potential study compared the abuse potential of crushed ALO-02 with crushed IR oxycodone and placebo when administered intranasally. The randomized, double-blind, placebo- and active-controlled, 4-way crossover study in 32 healthy, non-dependent, recreational opioid users demonstrated that intranasal administration of crushed 30 mg ALO-02 resulted in statistically significant lower scores for Drug Liking and High relative to crushed 30 mg IR oxycodone.

The most common adverse events seen in this study included euphoric mood, itching (pruritus) and drowsiness (somnolence) and were more frequent with IR oxycodone than ALO-02. Impaired sense of taste was also reported in six of 30 subjects following intranasal administration of ALO-02 and not with IR oxycodone.

About ALO-02

ALO-02 contains pellets that consist of extended-release oxycodone hydrochloride, an opioid agonist, which surround 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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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 for the fiscal year ended December 31, 2013 and in its subsequent reports on Form 10-Q and Form 8-K.

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