# Pfizer Announces FDA Acceptance for Review of a New Drug Application for ALO-02 (oxycodone hydrochloride and naltrexone hydrochloride)

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Pfizer Inc. (NYSE:PFE) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for ALO-02 (oxycodone hydrochloride and naltrexone hydrochloride), extended-release capsules, an abuse-deterrent formulation (ADF) opioid for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. ALO-02 is an extended-release oxycodone specifically designed to reduce abuse via the oral, intranasal (i.e., snorting) and intravenous (IV) routes when crushed.

Prescription opioids are an important treatment option for patients with chronic pain, but the misuse, abuse, and diversion of these agents remains a serious and persistent problem. In 2013, according to the National Survey on Drug Use and Health, nearly 10 million U.S. adults reported prescription pain reliever use for non-medical purposes in the previous year1. Abuse deterrent opioid medications incorporate technology designed to make the product difficult to abuse, yet when used appropriately, provide patients with intended pain relief. Pfizer believes that abuse deterrent formulation opioids, including ALO-02, are an important step toward helping to address the growing public health issue of opioid abuse in the U.S. Pfizer supports the appropriate use of opioid pain medications and is committed to research in this field. If approved, ALO-02 would become Pfizer’s second abuse deterrent formulation opioid.

Pfizer’s submission to the FDA is based on the results of two Phase 3 trials in patients with moderate-to-severe, non-cancer chronic pain. In addition, Pfizer conducted three

abuse-potential studies in recreational opioid users, comparing the abuse potential of crushed ALO-02 with immediate-release oxycodone when taken by the oral, intranasal or intravenous (the combination of oxycodone and 12% naltrexone was used to simulate crushed ALO-02 in the IV study) routes.

About ALO-02

ALO-02 capsules contain 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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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 February 13, 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, ALO-02, including its potential benefits, that involves 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 possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; whether and when any applications may be filed with

regulatory authorities in other jurisdictions for ALO-02; whether and when the FDA may approve the new drug application and whether and when regulatory authorities in other jurisdictions may approve any such other applications, 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 ALO-02; 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, 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 andwww.pfizer.com.

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1 Substance Abuse and Mental Health Services Administration, Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-48, HHS Publication No. (SMA) 14-4863. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

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