

Pfizer Announces FDA Advisory Committees' Recommend ALO-02 (oxycodone hydrochloride and naltrexone hydrochloride) Extended-Release Capsules for Approval

Wednesday, June 08, 2016 - 03:15pm

"management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration (FDA) Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee voted (9 to 6) in favor of approval of ALO-02 (oxycodone hydrochloride and naltrexone hydrochloride) extended-release capsules for its proposed indication, "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

The Committees recommended the inclusion of abuse-deterrent labeling for intranasal (11 to 4) and intravenous (9 to 6) routes of abuse. They voted against inclusion of abuse-deterrent labeling for the oral route (6 to 9). The FDA will take the Committees' recommendations into consideration before taking action on the New Drug Application for ALO-02.

"Pfizer believes the ALO-02 data support approval with abuse-deterrent labeling and we look forward to ongoing discussions with the FDA," said Ken Verburg, PhD, Chief Development Officer, Neuroscience and Pain, Pfizer Inc. "Abuse-deterrent opioids are an important part of a multi-faceted approach to help address the growing abuse epidemic."

About ALO-02 Technology

ALO-02 is the first investigational oxycodone formulated with sequestered naltrexone technology designed to help deter oral and non-oral abuse when crushed. ALO-02 extended-release capsules contain pellets that consist of oxycodone hydrochloride, an opioid agonist, which surround sequestered naltrexone hydrochloride, an opioid antagonist. When taken as directed, the naltrexone is intended to remain sequestered and patients receive oxycodone in an extended-release manner. Studies demonstrate that when the pellets are crushed, up to 100 percent of the sequestered naltrexone is released and is available to counteract the effects of oxycodone.

About 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. For more information, please visit us at www.pfizer.com. In addition, to learn more, follow us on Twitter at [@Pfizer](https://twitter.com/Pfizer) and [@Pfizer_News](https://twitter.com/Pfizer_News), [LinkedIn](#), [YouTube](#) and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

DISCLOSURE NOTICE: The information contained in this release is as of June 8, 2016. 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 the FDA may approve the new drug application for ALO-02, which will depend on the assessment by the FDA of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling (including whether the FDA will approve abuse-deterrent 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, 2015 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

Media: Allyanna Anglim, (212) 733-4945 Allyanna.Anglim@pfizer.com or Investor: Ryan Crowe, (212) 733-8160 Ryan.Crowe@pfizer.com