

Endo Pharmaceuticals to Launch Three New Dosage Strengths of OPANA(R) ER

Intermediate Strengths Provide Additional Dosing Options for Physicians Treating Patients With Moderate-to-Severe Chronic Pain

CHADDIS FORD, PA, Mar 03, 2008 (MARKET WIRE via COMTEX News Network) -- Endo Pharmaceuticals Inc., a market leader in pain management and a wholly owned subsidiary of Endo Pharmaceuticals Holdings Inc. (NASDAQ: ENDP), today announced that the U.S. Food and Drug Administration has approved three new dosage strengths of OPANA(R) ER (oxymorphone HCl) extended-release tablets CII. The new strengths -- 7.5 mg, 15 mg, and 30 mg -- will be available on April 1, 2008 and will join previously approved OPANA ER dosage strengths of 5 mg, 10 mg, 20 mg, and 40 mg. An opioid analgesic, OPANA ER is indicated for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time. (See Important Safety Information below.)

"The addition of three new dosage strengths of OPANA ER, complementing the currently available strengths, will make it easier for physicians to titrate patients to the optimal level of pain relief," said David A. Lee, M.D., Ph.D., Chief Scientific Officer. "The new strengths will also facilitate clinicians' ability to convert patients to OPANA ER from other opioid analgesics to which they may not have had an adequate clinical response. Further, the introduction of these new strengths underscores Endo's long-term commitment to the OPANA franchise and to providing physicians with additional treatment options for their appropriate chronic pain patients."

The approval is based on studies demonstrating the safety and efficacy of OPANA ER in its four original strengths. Because the new dosages fall between the available strengths, FDA did not require new safety or efficacy studies.

About OPANA ER Tablets

OPANA ER tablets were formulated using oxymorphone hydrochloride, a semisynthetic, pure μ -opioid agonist that had been available previously only as an injectable formulation. The product has been proven to achieve effective relief in multiple moderate-to-severe chronic pain models, in opioid-naïve and opioid-experienced patients. All OPANA ER strengths are available by prescription only.

Important Safety Information

OPANA ER is an opioid agonist and Schedule II controlled substance with an abuse liability similar to morphine. OPANA ER can be abused in a manner similar to other opioid agonists, legal or illicit.

WARNING:

OPANA ER contains oxymorphone, which is a morphine-like opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics.

Oxymorphone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OPANA ER in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OPANA ER is an extended-release oral formulation of oxymorphone indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

OPANA ER is NOT intended for use as a prn analgesic.

OPANA ER TABLETS are to be swallowed whole and are not to be broken, chewed, dissolved, or crushed. Taking broken, chewed, dissolved, or crushed OPANA ER TABLETS leads to rapid release and absorption of a potentially fatal dose of oxymorphone.

Patients must not consume alcoholic beverages, or prescription or non-prescription medications containing alcohol, while on OPANA ER therapy. The co-ingestion of alcohol with OPANA ER may result in increased plasma levels and a potentially fatal overdose of oxymorphone.

OPANA ER is not indicated for pain in the immediate post-operative period (12-24 hours following surgery), or if pain is mild or not expected to persist for an extended period of time.

OPANA ER is contraindicated in patients with a known hypersensitivity to oxymorphone hydrochloride, morphine analogs such as codeine, or any of the other ingredients of OPANA ER; in patients with moderate or severe hepatic impairment or in any situation where opioids are contraindicated.

Respiratory depression is the chief hazard of OPANA ER, particularly in elderly or debilitated patients.

The most common adverse drug reactions (greater than or equal to 10%) in all clinical trials for OPANA ER were nausea, constipation, dizziness (excluding vertigo), vomiting, pruritus, somnolence, headache, increased sweating, and sedation.

For full prescribing information, visit www.OPANA.com

Endo's Commitment to Responsible Pain Management: PROMISE(R)

Endo is committed to providing healthcare professionals and patients with safe and effective opioid analgesic medications and support programs that will better ensure their appropriate and responsible use. Through extensive experience with opioid analgesics and working with the FDA and industry experts, Endo has developed a comprehensive risk minimization action plan for OPANA ER. Evolving from the risk minimization plan is a program to further help reduce the inherent risk of misuse, abuse and diversion of opioid analgesics: The Partnership for Responsible Opioid Management through Information, Support, and Education (PROMISE(R)) initiative contains essential information and guidance to healthcare professionals so that they can prescribe opioids to patients responsibly and appropriately. PROMISE includes educational support and practical patient management tools. For patients, the program raises the level of knowledge of those suffering from moderate-to-severe pain and empowers them to manage their condition with the help of their healthcare professional. More information about the PROMISE initiative is available at www.endopromise.com.

OPANA(R) is a registered trademark of Endo Pharmaceuticals Inc.

The PROMISE(R) initiative is a registered trademark of Endo Pharmaceuticals Inc.

About Endo

A wholly owned subsidiary of Endo Pharmaceuticals Holdings Inc., Endo Pharmaceuticals is a fully integrated specialty pharmaceutical company with market leadership in pain management products. The company researches, develops, produces and markets a broad product offering of branded and generic pharmaceuticals, meeting the needs of healthcare professionals and consumers alike. More information, including this and past press releases of Endo Pharmaceuticals Holdings Inc., is available online at www.endo.com.

Forward-Looking Statements

This press release contains information that includes or is based on "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements, including estimates of future net sales, future expenses, future net income and future earnings per share, are subject to risks and uncertainties. Forward-looking statements include the information concerning the company's possible or assumed results of operations. Also, statements including words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may" or similar expressions are forward-looking statements. Endo has based these forward-looking statements on its current expectations and projections about the growth of its business, its financial performance and the development of its industry. Because these statements reflect Endo's current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors could affect Endo's future financial results and could cause its actual results to differ materially from those expressed in forward-looking statements contained in this press release. Important factors that could cause its actual results to differ materially from the expectations reflected in the forward-looking statements in this press release include, but are not limited to: its ability to successfully develop, commercialize and market new products; timing and results of pre-clinical or clinical trials on new products; its ability to obtain regulatory approval of any of its pipeline products; competition for the business of its branded and generic products, and in connection with its acquisition of rights to intellectual property assets; market acceptance of its future products; government regulation of the pharmaceutical industry; its dependence on a small number of products; its dependence on outside manufacturers for the manufacture of its products; its dependence on third parties to supply raw materials and to provide services for certain core aspects of its business; new regulatory action or lawsuits relating to its use of narcotics in most of its core products; its exposure to product liability claims and product recalls and the possibility that the company may not be able to adequately insure itself; its ability to protect its proprietary technology; the successful efforts of manufacturers of branded pharmaceuticals to use litigation and legislative and regulatory efforts to limit the use of generics and certain other products; its ability to successfully implement its acquisition and in-licensing strategy; regulatory or other limits on the availability of controlled substances that constitute the active ingredients of some of its products and products in development; the availability of third-party reimbursement for its products; the outcome of any pending or future litigation or claims by the government; its dependence on sales to a limited number of large pharmacy chains and wholesale drug distributors for a large portion of its total net sales; significant litigation expenses to defend or assert patent infringement claims; any interruption or failure by its suppliers, distributors and

collaboration partners to meet their obligations pursuant to various agreements with Endo; a determination by a regulatory agency that Endo is engaging in inappropriate sales or marketing activities, including promoting the "off-label" use of its products; existing suppliers become unavailable or lose their regulatory status as an approved source, causing an inability to obtain required components, raw materials or products on a timely basis or at commercially reasonable prices; the loss of branded product exclusivity periods and related intellectual property; and its exposure to securities that are subject to market risk.

The company does not undertake any obligation to update its forward-looking statements after the date of this Report for any reason, even if new information becomes available or other events occur in the future. You are advised, however, to consult any further disclosures we make on related subjects in our 10-K, 10-Q and 8-K reports to the Securities and Exchange Commission (or SEC). Also note that Endo provides the preceding cautionary discussion of risks, uncertainties and possibly inaccurate assumptions relevant to its business. These are factors that, individually or in the aggregate, the company believes could cause its actual results to differ materially from expected and historical results. Endo notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the preceding to be a complete discussion of all potential risks or uncertainties.

SOURCE: Endo Pharmaceuticals