Endo Announces U.S. District Court Ruling Upholding OPANA® ER Intellectual Property

August 14, 2015

DUBLIN, Aug. 14, 2015 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) (TSX: ENL) today announced that the U.S. District Court for the Southern District of New York has issued a ruling upholding two Endo patents covering OPANA® ER, the Company's opioid agonist indicated 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. The ruling also determined that Endo's patents had been infringed by all of the defendants. As a result, it is expected that the generic version of non-crush-resistant OPANA® ER currently sold by Actavis, the U.S. generics business of Allergan, Inc., will be removed from the market and additional approved but not yet marketed generic versions of the product developed by other generic companies will not be launched in the near term.

"Endo has long been dedicated to vigorously asserting and defending our patents for OPANA® ER," said Rajiv De Silva, President and CEO of Endo. "We are very happy with today's outcome and are reviewing the ruling in greater detail to determine its long-term impact. We remain committed to advancing OPANA® ER and to making it available to patients for responsible and appropriate use."

In December 2012, Endo filed a patent infringement complaint against Actavis in U.S. District Court for the Southern District of New York for patent infringement based on Actavis' sale of a non-crush-resistant generic version of OPANA® ER. In 2013, Endo filed similar suits in the U.S. District Court for the Southern District of New York against the following additional applicants for non-crush-resistant OPANA® ER: Par Pharmaceutical, Teva Pharmaceuticals, Mallinckrodt LLC, Sandoz, Roxane and Ranbaxy. The suits against Par Pharmaceutical and Mallinckrodt LLC have been dismissed pursuant to settlements and the suits against Teva Pharmaceuticals and Sandoz have been dismissed based on those companies' demonstration to Endo that they do not intend to pursue an ANDA for non-crush-resistant OPANA® ER.

About OPANA® ER
OPANA® ER is a strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require daily, around-the-clock, long-term treatment with an opioid, when other pain treatments such as, non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them. OPANA® ER is a long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed, you are at risk for opioid addiction, abuse, and misuse that can lead to death. OPANA® ER is not for use to treat pain that is not around-the-clock. It is not known if OPANA® ER is safe and effective in children under 18 years of age. The full prescribing information and Medication Guide for **OPANA® ER is available at www.opana.com. Also, read the boxed warning and additional safety information below.**

Important Safety Information for OPANA® ER
WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and INTERACTION WITH ALCOHOL

Addiction, Abuse, and Misuse
OPANA® ER exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing OPANA® ER, and monitor all patients regularly for the development of these behaviors or conditions.

Life-threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression may occur with use of OPANA® ER. Monitor for respiratory depression, especially during initiation of OPANA® ER or following a dose increase. Instruct patients to swallow OPANA® ER tablets whole; crushing, chewing, or dissolving OPANA® ER tablets can cause rapid release and absorption of a potentially fatal dose of oxymorphone.

Accidental Ingestion
Accidental ingestion of even one dose of OPANA® ER, especially by children, can result in a fatal overdose of oxymorphone.

Neonatal Opioid Withdrawal Syndrome
Prolonged use of OPANA® ER during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Interaction with Alcohol
Instruct patients not to consume alcoholic beverages or use prescription or non-prescription products that contain alcohol while taking OPANA® ER. The co-ingestion of alcohol with OPANA® ER may result in increased plasma levels and a potentially fatal overdose of oxymorphone.

Contraindications
OPANA® ER is contraindicated in patients with:

- Significant respiratory depression
- Acute or severe bronchial asthma or hypercarbia
- Known or suspected paralytic ileus and gastrointestinal obstruction
- Moderate and severe hepatic impairment
- Hypersensitivity (e.g. anaphylaxis) to oxymorphone, any other ingredients in OPANA® ER, or to morphine analogs such as codeine

About Endo International plc
Endo International plc is a global specialty pharmaceutical company focused on improving patients' lives while creating shareholder value. Endo develops, manufactures, markets and distributes quality branded pharmaceutical and generic pharmaceutical products as well as over-the-counter medications through its operating companies. Endo has global headquarters in Dublin, Ireland, and U.S. headquarters in Malvern, PA. Learn more at www.endo.com.

Safe Harbor Statement
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Canadian securities legislation. Statements including words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may," "look forward," "intend," "guidance," "future" or similar expressions are forward-looking statements. Because these statements reflect Endo's current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties. Although Endo believes that these forward-looking statements and information are based upon reasonable assumptions and expectations, readers should not place undue reliance on them, or any other forward-looking statements or information in this news release. Investors should note that many factors, as more fully described in the documents filed by Endo with securities regulators in the United States and Canada including under the caption "Risk Factors" in Endo's Form 10-K, Form 10-Q and Form 8-K filings with the Securities and Exchange Commission and with securities regulators in Canada on System for Electronic Document Analysis and Retrieval ("SEDAR") and as otherwise enumerated herein or therein, could affect Endo's future financial results and could cause Endo's actual results to differ materially from those expressed in forward-looking statements contained in Endo's Annual Report on Form 10-K. The forward-looking statements in this press release are qualified by these risk factors. These are factors that, individually or in the aggregate, could cause Endo's actual results to differ materially from expected and historical results. Endo assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise, except as may be required under applicable securities laws.

SOURCE Endo International plc

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