



Endo Announces OPANA® ER Regulatory Update

August 12, 2016

DUBLIN, Aug. 12, 2016 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) (TSX: ENL) announced today that based on an August 11, 2016 discussion with the U.S. Food and Drug Administration (FDA), the Company has decided to withdraw its supplemental New Drug Application (sNDA) relating to specific abuse deterrent labeling for OPANA® ER without prejudice to re-filing. The Company plans to continue collecting and analyzing epidemiological data relating to OPANA® ER. Endo's financial projections for 2016 did not assume approval of the sNDA.

"We anticipate the generation of additional data and we will seek collaboration with FDA to appropriately advance OPANA® ER," said Sue Hall, Ph.D., Executive Vice President, Chief Scientific Officer and Global Head of Research & Development and Quality at Endo. "We believe in the ability of OPANA® ER to continue making a difference in the lives of appropriate patients and remain committed to safely and effectively addressing the needs of the pain patient community."

OPANA® ER is an opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock opioid treatment and for which alternative treatment options are inadequate. The sNDA for OPANA® ER, which is formulated using INTAC® Technology, included studies designed to evaluate the abuse deterrence of the formulation. INTAC® Technology increases tablet hardness using a high molecular weight polymer (polyethylene oxide).

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 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.

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements," including, but not limited to, the statements by Dr. Hall. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from Endo's expectations and projections. Risks and uncertainties include, among other things, general industry and market conditions; technological advances and patents attained by competitors; challenges inherent in the research and development and regulatory processes; challenges related to product marketing, such as the unpredictability of market acceptance for new products and/or the acceptance of new indications for such products; inconsistency of treatment results among patients; potential difficulties in manufacturing; general economic conditions; and governmental laws and regulations affecting domestic and foreign operations. Endo expressly disclaims any intent or obligation to update these forward-looking statements except as required by law. Additional information concerning these and other risk factors can be found in Endo's periodic reports filed with the U.S. Securities and Exchange Commission and in Canada on the System for Electronic Data Analysis and Retrieval ("SEDAR"), including current reports on Form 8-K, quarterly reports on Form 10-Q and annual reports on Form 10-K. Additional information about Endo is available on the World Wide Web at www.endo.com or you can contact the Endo Investor Relations department by calling (484) 216-0000.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/endo-announces-opana-er-regulatory-update-300312835.html>

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