



Endo Announces FDA Advisory Committee Meeting For OPANA® ER

June 15, 2016

DUBLIN, June 15, 2016 /PRNewswire/ -- Endo Pharmaceuticals Inc., a subsidiary of Endo International plc (NASDAQ: ENDP) (TSX: ENL), today announced that, based on discussions with the U.S. Food and Drug Administration (FDA), the Company has been notified that an Advisory Committee of the FDA will be convened in the fall of 2016 to review the Company's Supplemental New Drug Application (sNDA) for OPANA® ER. As a result of the Advisory Committee meeting, the current Prescription Drug User Fee Act (PDUFA) date of July 29, 2016 for the OPANA® ER sNDA will not be met and the action on the supplement is expected to be taken by the FDA as soon as possible following the Advisory Committee meeting.

"Endo believes in the ability of OPANA® ER to continue making a difference in the lives of appropriate patients," said Sue Hall, Ph.D., Executive Vice President, Chief Scientific Officer and Global Head of Research & Development and Quality at Endo. "Endo has been a long standing leader in treating pain and we are working to advance new options to safely and effectively address the unique 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, includes 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 (NASDAQ: ENDP) (TSX: ENL) 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 within the meaning of the Private Securities Litigation Reform Act of 1995 and Canadian securities legislation including, among others, the statements made by Dr. Hall. 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 the Securities and Exchange Commission ("SEC") and with securities regulators in Canada on the 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 this communication. The forward-looking statements in this press release are qualified by these risk factors. Endo does not assume any 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.

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SOURCE Endo International plc

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