Endo Receives Paragraph IV Notification on Vasostrict®

April 17, 2018

DUBLIN, April 17, 2018 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) today announced that its subsidiaries, Par Pharmaceutical, Inc. and Par Sterile Products, LLC, have received a Notice Letter dated April 16, 2018 (the "Notice Letter") advising that Eagle Pharmaceuticals, Inc. (Eagle) has submitted an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) seeking approval from the FDA to manufacture and market a generic version of Vasostrict® (vasopressin injection, USP) 1 mL, in the United States.

The Notice Letter also contains "Paragraph IV" certifications alleging invalidity and non-infringement with respect to five patents which Endo has listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for Vasostrict®. Endo is assessing the details of the Notice Letter and formulating its legal strategy. Endo intends to vigorously protect its intellectual property, which may include initiating a patent infringement lawsuit against Eagle within 45 days of receiving the Notice Letter. If a lawsuit is filed within that timeframe, it will trigger a stay of FDA approval of Eagle's generic version of Vasostrict® for up to 30 months pursuant to the Hatch-Waxman Act.

About Endo International plc
Endo International plc (NASDAQ: ENDP) is a highly focused generics and specialty branded pharmaceutical company delivering quality medicines to patients in need through excellence in development, manufacturing and commercialization. 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
Certain information in this press release contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and any applicable 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. All forward-looking statements in this press release reflect Endo's current analysis of existing information and represent Endo's judgment only as of the date of this press release. We cannot predict the outcome of litigation. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results, including the outcome of litigation, could vary materially from Endo's expectations. 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, including regulatory decisions, product recalls, withdrawals and other unusual items; 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; settlement discussions or other proceedings; 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.

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