Endo Announces FDA Decision Not to Include Vasopressin on 503B Bulks List

March 1, 2019

DUBLIN, March 1, 2019 /PRNewswire/ -- Endo International plc ("Endo") (NASDAQ: ENDP) today announced that the U.S. Food and Drug Administration (FDA) has determined that there is no clinical need to compound vasopressin under Section 503B of the Drug Quality and Security Act. As a result, it will be unlawful for outsourcing facilities to sell compounded vasopressin products unless they manufacture those products using an FDA-approved vasopressin product, rather than bulk vasopressin, or if vasopressin were to be added to the FDA's drug shortage list. Par Sterile Products, LLC ("Par"), a subsidiary of Endo, is the manufacturer of Vasostrict®, the only vasopressin product approved by the FDA. Par and another Endo subsidiary are plaintiffs in a lawsuit against the FDA challenging a previously issued "interim policy" that authorized bulk compounding of vasopressin in violation of the applicable statute.

"Endo is incredibly pleased that the FDA has correctly concluded that bulk compounding using vasopressin is inappropriate," said Matthew J. Maletta, Executive Vice President and Chief Legal Officer of Endo. "We appreciate that the FDA is addressing the concerns which prompted our litigation by continuing its efforts to comply with the Drug Quality and Security Act, and we anticipate discussing with the FDA the impact of this decision on our pending litigation in the near future."

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 may be considered "forward-looking statements," within the meaning of the Private Securities Litigation Reform Act of 1995 and any applicable Canadian securities legislation including, but not limited to, the statements by Mr. Maletta and other statements relating to the status and outcome of litigation and the potential impact of the FDA's clinical need determination for vasopressin. All forward-looking statements in this press release reflect Endo's current expectations of future events based on information available to Endo as of the date of this press release. 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, 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; the outcome of litigation, settlement discussions or other adverse 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, including current reports on Form 8-K, quarterly reports on Form 10-Q and annual reports on Form 10-K.

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