Endo Announces Successful Culmination of Litigation Regarding FDA Compounding Policy

September 30, 2019

DUBLIN, Sept. 30, 2019 /PRNewswire/ -- Endo International plc ("Endo") (NASDAQ: ENDP) today announced the successful culmination of two litigation matters before the U.S. District Court for the District of Columbia regarding the unlawful compounding of vasopressin from bulk drug substances.

In October 2017, Endo initiated a lawsuit against the U.S. Food and Drug Administration ("FDA") challenging the FDA's interim policy authorizing the bulk compounding of drugs. That policy relied on "enforcement discretion" to allow bulk compounding of vasopressin, the active ingredient in Vasostrict®, which is manufactured by Endo's subsidiary Par Sterile Products, LLC. Endo's lawsuit alleged that the FDA's interim policy violated Section 503B of the Drug Quality and Security Act ("DQSA") and other provisions of the Federal Food, Drug, and Cosmetic Act which allow bulk compounding only if FDA first makes a determination that there is a genuine "clinical need" for compounding from a particular bulk drug substance.

Shortly after Endo filed its lawsuit, the FDA began to take significant steps to implement the requirements of the DQSA, and in particular issued proposed guidance regarding the statutory "clinical need" requirement which was consistent with the claims in Endo's Complaint. At FDA's and the Department of Justice's request, Endo stayed its lawsuit to allow FDA time to complete this process. FDA ultimately finalized its new guidance and issued a thorough, well-reasoned administrative decision that bulk compounders of vasopressin competing with Vasostrict® could not satisfy the statutory "clinical need" requirement.

Soon thereafter, a bulk compounder of vasopressin, Athenex, Inc., and two related entities (collectively, "Athenex"), sued the FDA—also in the U.S. District Court in the District of Columbia—seeking to invalidate the FDA's decision regarding vasopressin. Endo intervened in the Athenex lawsuit to defend the case alongside the FDA and the Department of Justice. The defense was successful, with the Court concluding on August 1, 2019 that the "FDA's exclusion of vasopressin from the 'clinical need' list was not arbitrary and capricious," a decision that "forecloses [Athenex] from selling their product." The Court also denied Athenex's subsequent motion for a stay of its ruling pending appeal. Although Athenex initially appealed the Court's ruling, it recently filed a motion to withdraw that appeal.

Given FDA's determination removing bulk compounded vasopressin from the market, and FDA's and Endo's success in the Athenex litigation, Endo has agreed with the FDA and the Department of Justice to voluntarily dismiss without prejudice its initial lawsuit against the FDA. That case has been stayed since February 2019, and Endo has now filed with the Court a stipulation to voluntarily dismiss the suit.

"Endo congratulates FDA on the successful and well-reasoned implementation of Section 503B of the DQSA, and was very pleased to assist in the subsequent defense of separate litigation regarding those actions," said Matthew J. Maletta, Executive Vice President and Chief Legal Officer of Endo. "In light of FDA's determination that bulk compounding of vasopressin is impermissible under Section 503B and the Court's decision to uphold that determination, we have agreed with the Department of Justice and the FDA to voluntarily dismiss Endo's lawsuit."

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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