



Endo Lifts Temporary Stay of FDA Litigation Following the Launch of a Bulk-Compounded Vasopressin Product by a Section 503B Outsourcing Facility

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DUBLIN, Aug. 15, 2018 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) today announced that it is lifting a temporary stay of its litigation against the U.S. Food and Drug Administration (FDA). The litigation, filed in the U.S. District Court for the District of Columbia in October 2017 by the Company's subsidiaries, Par Sterile Products, LLC and Endo Par Innovation Company, LLC (collectively, "Endo"), seeks a declaration that FDA's "Interim Policy" on compounding using bulk drug substances under Section 503B of the Drug Quality and Security Act of 2013 (DQSA) amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) is contrary to law because it authorizes bulk compounding of new drugs where the applicable DQSA requirements are not satisfied and because it is fundamentally inconsistent with the plain language and structure of the FDCA statutory regime for introducing new drugs. The litigation also seeks the immediate removal of vasopressin from FDA's Category 1 nominations list to assure that outsourcing facilities do not engage in bulk compounding of vasopressin-containing drug products under Section 503B.

In light of an outsourcing facility's recent announcement that it has launched a ready-to-use vasopressin product compounded using bulk drug substances under Section 503B, Endo is lifting the stay of its litigation against FDA. "Bulk compounding of vasopressin under Section 503B is inappropriate and undermines the longstanding new drug approval framework of the Federal Food, Drug, and Cosmetic Act," said Matthew J. Maletta, Executive Vice President and Chief Legal Officer of Endo. "We previously stated that in the event an entity were to commence bulk compounding of vasopressin under Section 503B prior to FDA's implementation of a new compounding policy, we would lift the stay of our litigation against FDA. Yesterday we did just that, and we will file a motion for preliminary injunction vacating the listing of vasopressin on FDA's Category 1 bulk drug substances list and preventing FDA from authorizing bulk compounding using vasopressin in a manner that does not comply with applicable laws."


In January 2018, following public statements from FDA reflecting FDA's intent to alter its compounding policy, and after discussions among the parties' counsel, Endo agreed to FDA's request to stay the parties' litigation until March 30, 2018. Under the terms of the litigation stay, Endo retained the ability to terminate the stay by notifying FDA that it believes that an entity has commenced or is likely to commence bulk compounding of any vasopressin-containing drug product under Section 503B. Endo later agreed to extend the temporary litigation stay for an additional 180 days following FDA's issuance in March 2018 of draft guidance describing the procedures that FDA intends to follow, and the criteria that FDA intends to apply, in implementing the requirements of the DQSA for use of bulk drug substances in compounding under Section 503B. In the draft guidance, FDA states, among other things, that because "compounded drug products are subject to a lower regulatory standard than FDA-approved drugs, they should only be used by patients whose medical needs cannot be met by an FDA-approved drug." FDA further explains that in certain situations, "compounding using the FDA-approved drug product instead of a bulk drug substance would meet patients' medical needs and present less risk," and specifically describes the dilution of FDA-approved drugs by outsourcing facilities to produce intravenous bags for hospitals as such a situation.

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," including, but not limited to, the statements by Mr. Maletta. 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 ("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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