Endo Agrees to Extend Temporary Stay of FDA Litigation

April 2, 2018

DUBLIN, April 2, 2018 /CNW/ -- Endo International plc (NASDAQ: ENDP) today announced that it has agreed to extend 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.

Based on the January 18, 2018 public statements from FDA reflecting FDA's intent to alter its compounding policy and comply with the DQSA, as well as subsequent discussions among the parties' counsel, Endo previously agreed to FDA's request to stay the litigation until March 30, 2018. On March 23, 2018, FDA issued draft guidance describing the procedures that FDA intends to follow, and the criteria that FDA intends to apply, to implement the requirements of the DQSA for use of bulk drug substances in compounding under Section 503B. In the new draft guidance, FDA interprets the DQSA's requirement that there be a "clinical need" for compounding from bulk substances, stating, among other things, that because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.

In the new draft guidance, FDA also announced that if a "bulk drug substance is a component of an FDA-approved drug," prior to authorizing bulk compounding using that substance, "FDA intends to conduct a threshold review" to determine both (1) whether "an attribute of the FDA-approved drug product makes it medically unsuitable to treat certain patients" and "the drug product proposed to be compounded is intended to address that attribute," and (2) whether there is "a basis to conclude that the drug product proposed to be compounded must be produced from a bulk drug substance rather than from an FDA-approved drug product." Only if both those criteria are satisfied will FDA proceed to conduct a multi-factor "balancing test" to determine whether to include the substance on a list of bulk drug substances that may be used for compounding under Section 503B.

As a result of the draft guidance and further discussions among the parties' counsel, Endo has agreed to extend the temporary litigation stay for an additional 180 days while FDA works toward implementation of the new compounding policy. Under the terms of the proposed stay, Endo will retain 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.

"As we have previously stated, Endo brought this lawsuit because FDA violated the DQSA by issuing an improper 'Interim Policy' and by listing vasopressin as a 'Category 1' substance that outsourcing facilities could use in bulk compounding under Section 503B," said Matthew J. Maletta, Executive Vice President and Chief Legal Officer of Endo. "In light of FDA'sMarch 23 draft guidance and further discussions among the parties' counsel, we believe that extending the temporary litigation stay for an additional 180 days to allow FDA to implement its new compounding policy is appropriate. We very much appreciate FDA's recent efforts, and we are hopeful that the new policy, once implemented, will address the multiple concerns that resulted in our initiating the litigation," said Mr. Maletta.

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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