Endo Agrees to FDA's Request to Seek Temporary Litigation Stay

January 24, 2018

DUBLIN, Jan. 24, 2018 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) today announced that it has agreed to a request by the U.S. Food and Drug Administration (FDA) to seek a temporary stay of the litigation initiated against FDA in October 2017 by the Company's subsidiaries, Par Sterile Products, LLC and Endo Par Innovation Company, LLC (collectively, "Endo"). The litigation, filed in the U.S. District Court for the District of Columbia, 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 its intent to alter its compounding policy and comply with the DQSA, as well as subsequent discussions among the parties' counsel, Endo has agreed to FDA's proposed litigation stay until March 30, 2018, subject to, among other things: (1) FDA using its best efforts to issue further clarification of the proposed conditions for bulk compounding by that date; and (2) Endo retaining the ability to terminate the litigation 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 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. FDA's recent public statements indicate that it is now taking steps to comply with the DQSA and that it plans to announce further details by the end of March 2018. Those statements, in conjunction with subsequent discussions among the parties' counsel, have led Endo to conclude that a temporary stay of its litigation against FDA is appropriate and therefore agree to FDA's request," said Matthew J. Maletta , Executive Vice President and Chief Legal Officer of Endo. In its recently issued *2018 Compounding Policy Priorities Plan*, FDA explains that:

- "Because of the profound public health implications, the FDA's compounding program is a priority for the agency and the FDA is committed to implementing the DQSA framework";
- FDA intends "to prioritize review of situations that could adversely impact the public health and premarket approval process, such as compounding using a bulk drug substance to produce a product that can otherwise be made by diluting an FDA-approved drug according to its labeled instructions"; and
- "The FDA's decisions will be guided by the conditions set forth in the statute, so that bulk drug substances are placed on the 503B bulks list only when there is clinical need to compound drugs using these substances. This protects patient health and the drug approval process, for example, by helping to ensure that outsourcing facilities do not compound using a bulk drug substance when an FDA-approved drug can be used to meet patient medical needs."

"We look forward to continuing our dialog with FDA," said Mr. Maletta, "and we are hopeful that the policy changes FDA has described, once effective, will address the multiple concerns that led Endo to file this case."

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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