Endo Agrees to Additional Stay of FDA Litigation Following FDA's Commitment to Use Best Efforts to Finalize Vasopressin Clinical Need Determination By Year End

September 24, 2018

DUBLIN, Sept. 24, 2018 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) today announced that it has agreed to an additional stay of its litigation against the U.S. Food and Drug Administration (FDA) until December 31, 2018. 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 503 B 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. Shortly after Endo commenced the litigation, FDA took initial steps to comply with the DQSA and Endo agreed to FDA's prior stay requests in January 2018 and April 2018.

In August 2018, an outsourcing facility announced it would commence bulk compounding of vasopressin and intervened in the litigation. Endo promptly lifted the litigation stay and filed a motion for preliminary injunction. Seven days after Endo filed its motion, FDA published a proposed clinical need determination for vasopressin in the *Federal Register* indicating that it "find[s] no basis to conclude that there is a clinical need for an outsourcing facility to compound using the bulk drug substance vasopressin" and initiated a 60-day comment period. If FDA finalizes its proposed clinical need determination following the comment period, bulk compounding of vasopressin will be illegal and subject to FDA enforcement.

During discussions between Endo's and FDA's respective counsel on September 20, 2018, FDA advised Endo that FDA would commit to use its best efforts to finalize its clinical need determination for vasopressin by December 31, 2018 if Endo agreed to again stay the litigation until such date. Based on FDA's commitment, Endo agreed to the proposed stay and the parties jointly moved the court for approval on September 21, 2018. The motion was unopposed by the intervenor outsourcing facility. If the court approves the proposed stay, Endo's motion for preliminary injunction will be held in abeyance and the hearing on such motion that is currently scheduled for October 3, 2018 will be taken off calendar.

"Endo reiterates its prior statement that bulk compounding of vasopressin by outsourcing facilities 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. "In light of FDA's commitment to Endo that FDA will use its best efforts to reach a final clinical need determination for vasopressin by December 31, 2018, we believe that a brief additional stay of our litigation is appropriate to allow FDA to complete its rulemaking process. Without FDA's best efforts commitment, we would not have agreed to the additional stay. We very much appreciate FDA's proposed determination and we are hopeful that such determination, once finalized, will address multiple concerns that prompted 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," 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 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.

View original content:http://www.prnewswire.com/news-releases/endo-agrees-to-additional-stay-of-fda-litigation-following-fdas-commitment-to-use-best-efforts-to-finalize-vasopressin-clinical-need-determination-by-year-end-300717351.html

SOURCE Endo International plc

Endo International plc: Investors/Media: Laure Park, (845) 364-4862; Media: Heather Zoumas-Lubeski, (484) 216-6829