Endo Files Federal Lawsuit to Obtain FDA Compliance with Drug Quality and Security Act of 2013

October 26, 2017

DUBLIN, Oct. 26, 2017 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) today announced that its subsidiaries, Par Sterile Products, LLC and Endo Par Innovation Company, LLC, filed suit in the United States District Court for the District of Columbia against the U.S. Food and Drug Administration (FDA) seeking a declaration that the FDA's current framework allowing for the bulk compounding of numerous products is unlawful under the Drug Quality and Security Act of 2013 (DQSA) amendments to the Federal Food, Drug, and Cosmetic Act (FDCA). The lawsuit also seeks the immediate removal of vasopressin from the FDA's Category 1 nominations list to assure that non-sterile-to-sterile outsourcing facilities cannot engage in bulk compounding of vasopressin. Endo filed the suit based on legislative provisions contained in the DQSA amendments requiring FDA to implement a regulatory framework regarding bulk compounding that serves to protect the public health.

"Endo welcomes FDA Commissioner Gottlieb's September 2017 press statement that FDA is working on a new compounding policy which we hope will include the legally required changes to FDA's regulatory framework," said Matthew J. Maletta, Executive Vice President and Chief Legal Officer of Endo. "Nevertheless, because we believe the status quo is unlawful and because we have no certainty about FDA's plans, we feel compelled to bring this action in an effort to protect the public health and safety, together with our own investments in product development and the integrity of the new drug approval process established by the Hatch-Waxman amendments to the FDCA."

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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SOURCE Endo International plc

Endo International plc: Investors/Media: Stephen Mock, (845) 364-4833; Media: Heather Zoumas-Lubeski, (484) 216-6829; Investors: Nina Goworek, (484) 216-6657