# Endo Announces Anticipated Further Stay of Compounding Litigation Due to Lapse of Government Appropriations

December 31, 2018

DUBLIN, Dec. 31, 2018 /PRNewswire/ -- Endo International plc ("Endo"; NASDAQ: ENDP) today announced that, due to the ongoing federal government shutdown, the U.S. Food and Drug Administration (the "FDA") has requested a further stay of Endo's ongoing litigation against the FDA for the duration of the shutdown. That litigation challenges the FDA's authorization of the bulk compounding of drugs, including vasopressin, that have not satisfied the legal requirements under Section 503B of the Drug Quality and Security Act amendments to the Federal Food, Drug, and Cosmetic Act. One of Endo's subsidiaries, Par Sterile Products, LLC ("Par"), manufacturers the only vasopressin product currently approved by the FDA, Vasostrict®. The suit was most recently stayed until December 31, 2018 and the FDA had committed to use its best efforts to issue a final clinical need determination for vasopressin on or before that date. The FDA has now filed a motion, which Endo did not oppose, seeking a further stay of the suit for the period of time in which the government lacks appropriations. According to the FDA's motion, absent an appropriation, Department of Justice attorneys and the FDA employees responsible for handling Endo's litigation and the clinical need determination, respectively, are prohibited from working, even on a voluntary basis, except in very limited circumstances. If the FDA's motion is granted, the litigation will be stayed for as long as the appropriations lapse continues and Endo is not at this time aware when appropriations may resume.

Two Endo subsidiaries, Par and Endo Par Innovation Company, LLC, sued the FDA in the U.S. District Court for the District of Columbia in October 2017 challenging the agency's "Interim Policy" on bulk compounding under Section 503B as unlawful because it authorized bulk compounding of drugs, including vasopressin, where the applicable legal requirements (including a determination of clinical need) were not satisfied. In January 2018 and March 2018, the parties agreed to stay the case while the FDA took initial steps to comply with the statutory framework. The parties then agreed in September 2018 to another stay of the litigation based on the FDA's representation that it would use its best efforts to finalize its clinical need determination for vasopressin by December 31, 2018. Endo and other interested parties have submitted comments on the FDA's proposed vasopressin determination. In light of the appropriations lapse, however, that determination will now not occur by December 31, 2018.

**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, statements relating to the status and outcome of litigation and the 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.



SOURCE Endo International plc

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