# Endo Announces U.S. FDA Approval of Ephedrine Sulfate Injection, USP

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DUBLIN, Jan. 30, 2017 /PRNewswire/ -- Endo International plc (NASDAQ / TSX: ENDP) announced today that one of its operating companies, Par Pharmaceutical has received final approval from the U.S. Food and Drug Administration for its New Drug Application for ephedrine sulfate injection, a drug administered parenterally as a pressor agent to address clinically important hypotension in surgical settings. According to IMS Health data, U.S. sales of ephedrine sulfate injection products were approximately $177 million for the 12 months ended November 30, 2016.

Ephedrine sulfate for injection is packaged in cartons of twenty-five 50mg/mL, 1mL single use vials.  Par expects to start shipping the product in February 2017.

**Important Safety Information**

**WARNINGS AND PRECAUTIONS**

- Pressor Effects with Concomitant Use with Oxytocic Drugs: Pressor effect of sympathomimetic pressor amines is potentiated (5.1)
- Tachyphylaxis and Tolerance: Repeated administration of ephedrine may cause tachyphylaxis (5.2)

**ADVERSE REACTIONS**
Most common adverse reactions during treatment: nausea, vomiting, and tachycardia.

**About Endo International plc**
Endo International plc (NASDAQ / TSX: ENDP) is a global specialty pharmaceutical company focused on improving patients' lives while creating shareholder value. Endo develops, manufactures, markets and distributes quality branded and generic pharmaceutical products as well as over-the-counter medications through its operating companies. 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**
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Canadian securities legislation. Because these statements reflect Endo's current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties. Although Endo believes that these forward-looking statements and information are based upon reasonable assumptions and expectations, readers should not place undue reliance on them, or any other forward-looking statements or information in this news release. Investors should note that many factors, as more fully described in the documents filed by Endo with the Securities and Exchange Commission ("SEC") and with securities regulators in Canada on the System for Electronic Document Analysis and Retrieval ("SEDAR), and as otherwise enumerated herein or therein, could affect Endo's future financial results and could cause Endo's actual results to differ materially from those expressed in this communication. The forward-looking statements in this press release are qualified by these risk factors. Endo does not assume any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise, except as may be required under applicable securities laws.

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