Endo Announces Approval of First Generic Orfadin® in U.S.

September 4, 2019

DUBLIN, Sept. 4, 2019 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) today announced that Novitium Pharma, LLC, a partner of Endo's subsidiary Endo Ventures Limited, received approval from the U.S. Food and Drug Administration for a room temperature stable, AB-rated, generic equivalent of Swedish Orphan Biovitrum's Orfadin® (nitisinone capsules). Endo's operating company Par Pharmaceutical, Inc. expects to distribute the product through specialty pharmacies beginning this month.

Nitisinone capsules are indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

"We are pleased to offer this rare patient population suffering from HT-1 the first and only bioequivalent and therapeutically equivalent option to Orfadin® capsules. Additionally, the product can be stored at room temperature which is an added convenience to patients," said Domenic Ciarico, Executive Vice President and Chief Commercial Officer, Sterile and Generics. "We are proud to continue our tradition at Par of providing high quality, affordable medicines to patients."

"Novitium has a history of impressive development and execution skills and we are pleased to have several products under development with them," said Brandon Rockwell, Senior Vice President of Business Development. "This first time generic approval is another example of Par's strategic investment in business development and execution on first-to-market and first-to-file products."

According to Swedish Orphan Biovitrum, global sales for Orfadin® were approximately $85M over the last four quarters.

About HT-1

Hereditary Tyrosinemia type-1 (HT-1) is a rare and serious inherited metabolic disease caused by the inability to metabolise the amino acid tyrosine. Left untreated, HT-1 can cause hepatic, renal and peripheral nerve damage. HT-1 affects at least 1 in 100,000 patients worldwide, with approximately 150 patients in the United States.

About Endo International plc

Endo International plc (NASDAQ: ENDP) is a highly focused generics and specialty branded pharmaceuticals 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.

About Par Pharmaceutical

Par Pharmaceutical, headquartered in Chestnut Ridge, NY, develops, manufactures and markets safe, innovative and cost-effective generic pharmaceutical and branded injectable products that help improve patient quality of life. Par, among the top leaders in the U.S. generics industry, possesses a portfolio that includes sterile injectables, alternative dosage forms and many other differentiated products. Par is advancing a robust research and development (R&D) pipeline of potential products. Par is an operating company of Endo International plc. Learn more at www.endo.com or www.parpharm.com.

Forward Looking Statements

This press release may contain certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Canadian securities legislation, including the statements from Messrs. Ciarico and Rockwell and other statements regarding research and development outcomes, regulatory, marketing and reimbursement approvals, efficacy, adverse reactions, market and product potential and product availability. Statements including words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may," "look forward," "intend," "guidance," "future" or similar expressions are forward-looking statements. Because these statements reflect Endo's current views, expectations and beliefs concerning future events, they 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 and with securities regulators in Canada on the System for Electronic Document Analysis and Retrieval, including under the caption "Risk Factors" in Endo's Form 10-K, Form 10-Q and Form 8-K filings, and as otherwise enumerated herein or therein, could affect Endo's future results and could cause Endo's actual results to differ materially from those expressed in forward-looking statements contained in this communication. The forward-looking statements in this press release are qualified by these risk factors. Endo assumes no 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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