



Paladin Labs Inc. Announces Launch of New Indication for XIAFLEX® (Collagenase Clostridium Histolyticum), Broadening Its Use to the Treatment of Appropriate Patients with Peyronie's Disease

April 23, 2018

MONTREAL, April 23, 2018 /CNW/ -- Paladin Labs Inc., a subsidiary of Endo International plc (NASDAQ: [ENDP](#)) today announced the launch of a new indication for XIAFLEX® (collagenase clostridium histolyticum), the first and only Health Canada-approved treatment for appropriate patients with Peyronie's Disease. XIAFLEX®, distributed and promoted by Paladin Labs, is available nationwide in Canada.

XIAFLEX®, an in-office biologic, was approved by Health Canada in January 2018 for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy. The Health Canada review and approval was based on the results of safety and efficacy data from the pivotal IMPRESS (The Investigation for **M**aximal **P**eyronie's **R**eduction **E**fficacy and **S**afety **S**tudies) trials, the Phase 3 double-blinded placebo-controlled studies that assessed XIAFLEX® for the treatment of Peyronie's disease.

"We are pleased to announce the commercial availability of XIAFLEX® in Canada for its new indication. As the only Health Canada-approved Peyronie's disease treatment, XIAFLEX® is available to address a critical unmet need for men living with this distressing and sometimes painful condition," said Livio Di Francesco, VP & General Manager of Paladin Labs Inc. "The launch of the new indication for XIAFLEX® builds on Paladin's legacy of leadership in Men's Healthcare and exemplifies our focus on enhancing therapeutic options for patients and healthcare providers in this arena. It also demonstrates our capacity and commitment to successfully bring new treatments to market."

About Peyronie's Disease

Peyronie's Disease is a condition that involves the development of collagen plaque, or scar tissue, on the shaft of the penis. The scar tissue, known as a Peyronie's plaque, may harden and reduce flexibility, which may cause bending or arching of the penis during erection. Peyronie's disease can result in varying degrees of penile curvature deformity and disease "bother" (encompassing concern about erection appearance, erection pain and the impact of Peyronie's disease on intercourse and on frequency of intercourse). Peyronie's disease is a disease with an initial inflammatory component. This inflammatory phase is poorly understood with a somewhat variable disease course and spontaneous resolution occurring in less than 13 percent of cases. After approximately 12 months of disease, the disease is reported to often develop into a more chronic, stable phase. The incidence of Peyronie's disease is estimated between 3 and 9 percent; however the disease is thought to be underdiagnosed and undertreated.

About XIAFLEX®

XIAFLEX® (collagenase clostridium histolyticum) is a biologic approved for the treatment of adult Dupuytren's contracture patients with a palpable cord, and for the treatment of adult men with Peyronie's disease with a palpable plaque and penile curvature deformity of at least 30 degrees at the start of therapy. XIAFLEX® consists of a combination of two subtypes of collagenase, derived from Clostridium histolyticum. Together, the collagenase sub-types are thought to work synergistically to break the bonds of the triple helix collagen structure.

About Paladin Labs Inc.

Paladin Labs Inc., headquartered in Montreal, Canada, is a specialty pharmaceutical company focused on acquiring or in-licensing innovative pharmaceutical products for the Canadian market. Paladin has a focused marketing and sales organization that has helped it evolve into one of Canada's leading specialty pharmaceutical companies. Paladin is an operating company of Endo International plc (NASDAQ: [ENDP](#)), a highly focused generics and specialty branded pharmaceutical company delivering quality medicines to patients in need through excellence in development, manufacturing and commercialization. Learn more at www.endo.com or www.paladin-labs.com.

Forward-Looking Statements

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including the statements of Mr. Di Francesco, within the meaning of the Private Securities Litigation Reform Act of 1995 and Canadian securities legislation. 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, 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 securities regulators in the United States and Canada including under the caption "Risk Factors" in Endo's Form 10-K, Form 10-Q and Form 8-K filings with the Securities and Exchange Commission and with securities regulators in Canada on 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 forward-looking statements contained in Endo's Annual Report on Form 10-K. The forward-looking statements in this press release are qualified by these risk factors. These are factors that, individually or in the aggregate, could cause Endo's actual results to differ materially from expected and historical results. 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 law.