



Paladin Labs Inc. Announces Approval of Envarsus PA™ (tacrolimus prolonged-release tablets) in Canada

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MONTREAL, Feb. 22, 2019 /CNW/ -- Paladin Labs Inc. and Endo Ventures Limited, subsidiaries of Endo International plc (NASDAQ: ENDP), today announced Health Canada's approval of Envarsus PA™ (tacrolimus prolonged-release tablets) for the prophylaxis of organ rejection in kidney or liver transplant adult patients (in combination with other immunosuppressants). Envarsus PA™ is marketed in Canada by Paladin Labs Inc.

"We are pleased to announce Health Canada's approval of Envarsus PA™ in Canada," said Livio Di Francesco, Vice President & General Manager of Paladin Labs Inc. "We believe the launch of Envarsus PA™ will provide kidney or liver transplant patients with an important alternative in immunosuppression, enhancing therapeutic options for those patients and for healthcare providers. We are committed to supporting continued innovation in transplantation to help Canadian patients with unmet needs."

About Transplantation

The kidney and liver are the two most transplanted organs in Canada, representing over 76% of all organ transplants performed each year¹. In patients with end-stage organ failure, organ transplantation is the only curative option and has been established as a life-saving intervention that can have a profound effect on patient outcomes, including health-related quality of life (HRQoL) and survival.²⁻⁴ The most serious complication of transplantation is organ rejection and controlling the anti-transplant immune response is essential for a successful outcome.

About ENVARUSUS PA™

ENVARUSUS PA™ (tacrolimus prolonged-release tablets) is indicated for the prophylaxis of organ rejection in allogeneic kidney or liver transplant adult patients in combination with other immunosuppressants. Envarsus is currently marketed in Europe and in the US.

About Endo International plc and Paladin Labs

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.

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 Labs Inc. has a focused marketing and sales organization that has helped it evolve into one of Canada's leading specialty pharmaceutical companies.

Endo Ventures Limited and Paladin Labs Inc. are operating companies of Endo International plc. Learn more at www.endo.com or www.paladin-labs.com.

Forward-Looking Statements

Cautionary Note Regarding Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Canadian securities legislation, including, but not limited to, the statements by Mr. Di Francesco. 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.

¹ CORR e-Statistics Report on Transplant, Waiting List and Donor Statistics, 2017 Summary Statistics, January 1 to December 31, 2017.

² Onghena L, Develtere W, Poppe C, et al. Quality of life after liver transplantation: State of the art. *World J Hepatol.* 2016;8(18):749-756.

³ Landreneau K, Lee K, Landreneau MD. Quality of life in patients undergoing hemodialysis and renal transplantation—a meta-analytic review. *Nephrol Nurs J.* 2010;37(1):37-44.

⁴ Grinyo JM. Why is organ transplantation clinically important? *Cold Spring Harb Perspect Med.* 2013;3(6).

SOURCE Endo International plc