



Envarsus® PA Once-daily Immunosuppressive Therapy for Kidney and Liver Transplant Patients is Now Reimbursed in Ontario, Quebec, Manitoba and Saskatchewan

October 22, 2020

MONTREAL, Oct. 22, 2020 /CNW/ -- Paladin Labs Inc., a subsidiary of Endo International plc (NASDAQ: ENDP), announced today that Ontario, Quebec, Manitoba and Saskatchewan now cover the cost of Envarsus® PA for kidney and liver transplant adult patients who meet certain reimbursement criteria (see below) for the prophylaxis of organ rejection. This announcement follows an agreement signed in July between Paladin Labs and the pan-Canadian Pharmaceuticals Alliance (pCPA) on the terms of public reimbursement for Envarsus® PA.

"We are excited to announce that Envarsus® PA is now eligible for reimbursement in the majority of Canadian provinces," said Livio Di Francesco, Vice President & General Manager of Paladin Labs Inc. "This new milestone will ensure greater and more equitable access to an important alternative in immunosuppression for kidney and liver transplant patients. Envarsus® PA will expand therapeutic options for those patients and for healthcare providers."

With a focus on specialty therapeutic areas, including transplant immunology, Paladin Labs Inc. is committed to supporting innovation in transplantation.

Please visit the links below to the respective provincial formularies to see the exact reimbursement criteria:

- [Ontario Drug Benefit Formulary](#)
- [Quebec - Régie de l'assurance maladie du Québec – List of medications](#)
- [Manitoba Drug Benefits and Interchangeability Formulary](#)
- [Saskatchewan Drug Formulary](#)

About Envarsus® PA

Envarsus® PA (tacrolimus prolonged-release tablets) is a once-daily tablet indicated for the prophylaxis of organ rejection in allogenic kidney or liver transplant adult patients in combination with other immunosuppressants.¹ Envarsus® PA is formulated using the patented Meltdose® technology. The clinical development of Envarsus® PA comprised of pharmacokinetic (PK) study as well as clinical trials in both de novo or stable kidney or liver transplant patients.

Envarsus® is a registered trademark of Veloxis Pharmaceuticals A/S and is currently also marketed in Europe and in the USA.

About Kidney and Liver Transplantation

In Canada, the kidney and liver are the two most transplanted organs, accounting for over 76% of all organ transplants performed each year.³ To prevent organ rejection following transplantation, all kidney and liver transplant patients must take immunosuppressive medications. Major advancements in immunosuppressive therapies over the last decades significantly improved patient outcomes, including health-related quality of life (HRQoL).²⁻⁴ As of 2018, there are more than 17,000 Canadians (excluding Quebec) living with a functioning kidney transplant, and 5,900 with a functioning liver transplant.³

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 is an operating company of Endo International plc (NASDAQ: ENDP), a specialty pharmaceutical company committed to helping everyone we serve live their best life through the delivery of quality, life-enhancing therapies. Learn more at www.paladin-labs.com or endo.com

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including the statements by Mr. Di Francesco and other statements relating to reimbursement for Envarsus® PA, within the meaning of the Private Securities Litigation Reform Act of 1995 and the relevant 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 led 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.

References

¹ Envarsus® PA Product Monograph, updated on June 16, 2020

² The Canadian Liver Foundation. Liver Disease in Canada: A Crisis in the Making – An Assessment of Liver Disease in Canada. March 2013

³ Canadian Institute for Health Information. Annual Statistics on Organ Replacement in Canada: Dialysis, Transplantation and Donation, 2009 to 2018. Ottawa, ON: CIHI; 2019

⁴ The Canadian Kidney Foundation. Living with Kidney Failure. <https://kidney.ca/Kidney-Health/Living-With-Kidney-Failure/Transplantation>. Accessed on July 2020

SOURCE Endo International plc