Endo Announces Approval of XCOPRI™ (cenobamate tablets) in Canada

June 29, 2023

DUBLIN and MONTREAL, June 29, 2023 /PRNewswire/ -- Endo International plc (OTC: ENDPQ) announced today that Paladin Labs Inc., an Endo operating company, received Health Canada's approval of XCOPRI ™ (cenobamate tablets) for adjunctive therapy in the management of partial-onset seizures in adults with epilepsy who are not satisfactorily controlled with conventional therapy.

"Many adults with partial-onset seizures are not able to control their seizures, even with the availability of many anti-seizure medications," said Livio Di Francesco, Vice President & General Manager of Paladin Labs Inc. "Paladin is dedicated to addressing unmet medical needs, and we are proud to achieve this approval—a milestone in epilepsy treatment."

Paladin Labs is working collaboratively with the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Institut national d'excellence en santé et en services sociaux (INESSS) to ensure appropriate patients have access to XCOPRI ™.

Paladin Labs expects to launch XCOPRI ™ in December 2023.

About Epilepsy[1-3]
Epilepsy is a chronic neurological condition affecting ~300,000 Canadians. It is characterized by recurrent, unprovoked seizures. While there are many different types of seizures, they can be grouped into two broad categories based on the location of the brain in which the seizure activity starts: generalized seizures and focal seizures. Focal seizures (also called partial-onset seizures) affect ~60% of people with epilepsy. While many people with epilepsy will respond to anti-seizure medication, ~30% of patients continue to experience seizures despite treatment with currently available medication options.

About XCOPRI ™
XCOPRI ™ (cenobamate tablets) is indicated as adjunctive therapy in the management of partial-onset seizures in adults with epilepsy who are not satisfactorily controlled with conventional therapy. It is taken orally, once-daily.

XCOPRI ™ is an anti-seizure medication (ASM) discovered and developed by SK Biopharmaceuticals and SK life science. It is a novel small molecule with a dual mechanism of action. In pre-clinical studies, XCOPRI ™ has been demonstrated to reduce repetitive neuronal firing by inhibiting voltage-gated sodium currents. It is also a positive allosteric modulator of the γ-aminobutyric acid (GABAA) ion channel.[4-6] The efficacy and safety of XCOPRI ™ for the treatment of adults with partial-onset seizures (also known as focal-onset seizures) were assessed in two randomized, placebo-controlled, double-blind clinical trials (C013 and C017).[7,8] Long-term safety of cenobamate in this population has been studied in open-label safety study (C021).[9]

XCOPRI ™ is currently marketed in the US as XCOPRI® and Europe under the trademark ONTOZRY®.

About Endo International plc and Paladin Labs
Endo (OTC: ENDPQ) is a specialty pharmaceutical company committed to helping everyone we serve live their best life through the delivery of quality, life-enhancing therapies. Our decades of proven success come from passionate team members around the globe collaborating to bring treatments forward. Together, we boldly transform insights into treatments benefiting those who need them, when they need them. Learn more at www.endo.com or connect with us on LinkedIn.

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, medical 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. For more information visit www.paladin-labs.com.

Cautionary Note Regarding Forward-Looking Statements

Certain information in this press release may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and any applicable Canadian securities legislation including, but not limited to, the statements by Mr. Di Francesco, any statements relating to product efficacy, regulatory approvals, expected launch dates, potential treatments or indications, therapeutic outcomes or treatment responses, and any statements that refer to expected, estimated or anticipated future results or that do not relate solely to historical facts. Statements including words or phrases such as "believe," "expect," "anticipate," "intend," "estimate," "plan," "will," "may," "look forward," "intend," "guidance," "future," "potential" or similar expressions are forward-looking statements. All forward-looking statements in this communication reflect the Company's current views as of the date of this communication about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to it and on assumptions it has made. Actual results may differ materially and adversely from current expectations based on a number of factors, including, among other things, the outcome of the Company's contingency planning and restructuring activities; the timing, impact or results of any pending or future litigation, investigations, proceedings or claims, including opioid, tax and antitrust related matters; any actual or contingent liabilities; settlement discussions or negotiations; the Company's liquidity, financial performance, cash position and operations; the risks and uncertainties associated with chapter 11 proceedings; the time, terms and ability to confirm a sale of the Company's businesses under Section 363 of the U.S. Bankruptcy Code; the risk that the Company's chapter 11 cases may be converted to cases under chapter 7 of the Bankruptcy Code; the adequacy of the capital resources of the Company's businesses and the difficulty in forecasting the liquidity requirements of the operations of the Company's businesses; the unpredictability of the Company's financial results; the Company's ability to discharge claims in chapter 11 proceedings; negotiations with the holders of the Company's indebtedness and its trade creditors and other significant creditors; the risks and uncertainties with performing under the terms of the restructuring support agreement and any other arrangement with lenders or creditors while in chapter 11 proceedings; the performance, including the approval, introduction, and consumer and physician acceptance of new products and the continuing acceptance of currently marketed products; and the Company's ability to obtain and successfully manufacture, maintain and distribute a sufficient supply of products to meet market demand in a timely manner. The Company expressly disclaims any intent or obligation to update these forward-looking statements, except as required to do so by law.

Additional information concerning risk factors, including those referenced above, can be found in press releases issued by the Company, as well as the Company's public periodic filings with the U.S. Securities and Exchange Commission and with securities regulators in Canada, including the discussion under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q or other filings with the U.S. Securities and Exchange Commission.

References:

1. Canadian Epilepsy Alliance. https://www.canadianepilepsyalliance.org/about-epilepsy/. Accessed May 26, 2023.
2. Public Health Agency of Canada. Epilepsy in Canada. 2021. https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/diseases-conditions/64-03-17-2021-Epilepsy-in-Canada-EN-FINAL.pdf. Accessed April 20, 2023.
3. Epilepsy Canada. https://www.epilepsy.ca/what-is-epilepsy. Accessed May 26, 2023.
4. Guignet M, Campbell A, White HS. *Epilepsia*. 2020;61(11):2329-2339.
5. Nakamura M, et al. *Eur J Pharmacol*. 2019;855:175-182.
6. Sharma R, et al. *Eur J Pharmacol.* 2020;879:173117.
7. Chung SS, et al. *Neurology.* 2020;94:e2311-2322.
8. Krauss GL, et al. *Lancet Neurol.* 2020;19:38-48.
9. Sperling MR et al. *Epilepsia* 2020;61(6):1099-1108.

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