Endo Announces Agreement for Paladin Labs to Commercialize SK Biopharmaceuticals' XCOPRI® (Cenobamate) in Canada

December 23, 2021

DUBLIN, Dec. 23, 2021 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) announced today that its subsidiary Endo Ventures Limited has entered into definitive agreements with SK Biopharmaceuticals for the development, registration, supply, commercialization and distribution of cenobamate on an exclusive basis in Canada. Paladin Labs Inc., an operating company of Endo, will be responsible for all commercial activities in Canada related to cenobamate.

"We are very pleased to work with SK Biopharmaceuticals to possibly bring a new treatment option to the market for appropriate Canadian epilepsy patients," said Livio Di Francesco, Vice President and General Manager of Paladin. "This transaction continues to build our neurology franchise. Cenobamate has shown promising clinical evidence to address an unmet need and it has the potential to become a very important addition to our existing Canadian portfolio."

Cenobamate is a novel small molecule with a dual mechanism of action under investigation for treating seizures; it is not approved in Canada. [1, 2,3] Although its precise mechanism of action is unknown, cenobamate, at clinically relevant concentrations, acts both as a positive allosteric modulator of the γ-aminobutyric acid ($GABA_A$) ion channel and inhibits voltage-gated sodium currents.[2,3] Long-term data of cenobamate is being studied in the open-label extensions of the double-blind placebo control trials as well as the open-label safety study in adults with uncontrolled focal-onset seizures.[4] Additionally, cenobamate is being assessed in an ongoing randomized, double-blind, placebo-controlled trial evaluating its safety and efficacy as adjunctive therapy in patients with primary generalized tonic-clonic seizures (NCT03678753).[5]

About Cenobamate
Cenobamate was discovered by SK Biopharmaceuticals and SK life science and is an anti-seizure medication for the treatment of partial-onset seizures in adults (also known as focal-onset seizures). In November 2019, the U.S. Food and Drug Administration approved cenobamate tablets, marketed under the trademark XCOPRI® (cenobamate tablets) CV in the U.S., for such treatment. In March 2021, the European Commission granted marketing authorization for cenobamate tablets, marketed under the trademark ONTOZRY® in Europe, for such treatment.

IMPORTANT SAFETY INFORMATION AND INDICATION FOR XCOPRI® (cenobamate tablets) CV can be found on www.xcopri.com.

About Endo and Paladin Labs
Endo (NASDAQ: ENDP) 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 a global team of passionate employees collaborating to bring the best 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.endo.com or www.paladin-labs.com.

References
1. Guignet M, Campbell A, White HS, Epilepsia. 2020 Oct 16. doi: 10.1111/epi.16718. Online ahead of print

2. Nakamura M, et al. Eur J Pharmacol 2019;855:175-182.

3. Sharma R, et al. Eur J Pharmacol 2020;879:173117.

4. Sperling MR, et al. Epilepsia, Feb 2020;61:1099–1108.

5. Randomized, Double-Blind Study to Evaluate Efficacy and Safety of Cenobamate Adjunctive Therapy in PGTC Seizures NCT03678753.

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 statement by Mr. Di Francesco and other statements relating to the development, registration, supply, commercialization, distribution or market potential of cenobamate or any other products. Statements including words or phrases such as "believe," "expect," "anticipate," "intend," "estimate," "plan," "will," "may," "look forward," "intend," "future," "potential" or similar expressions are forward-looking statements. All forward-looking statements in this press release reflect Endo's current expectations of future events based on existing trends and information and represent Endo's judgment only as of the date of this press release. Actual results may differ materially and adversely from current expectations based on a number of factors affecting Endo's businesses, including, among other things, the following: the outcome of our strategic review, contingency planning and any potential restructuring; the timing, impact or results of any pending or future litigation, investigations or claims or actual or contingent liabilities, settlement discussions, negotiations or other adverse proceedings; our ability to satisfy judgments or settlements or pursue appeals including bonding requirements; our ability to adjust to changing market conditions; our ability to attract and retain key personnel; our inability to maintain compliance with financial covenants and operating obligations which would expose us to potential events of default under our outstanding indebtedness; our ability to incur additional debt or equity financing for working capital, capital expenditures, business development, debt service requirements, acquisitions or general corporate or other purposes; our ability to refinance our indebtedness; a significant reduction in our short-term or long-term revenues which could cause us to be unable to fund our operations and liquidity needs or repay indebtedness. The occurrence or possibility of any such result has caused us to engage, and may result in further engagement in strategic reviews that ultimately may result in our pursuing one or more significant corporate transactions or other remedial measures, including on a preventative or proactive basis. Those remedial measures could include a potential corporate reorganization, restructuring or bankruptcy filing involving all or a portion of our business, asset sales or other divestitures, cost-saving initiatives, corporate realignments or strategic partnerships. Some of these measures could take significant time to implement and others may require judicial or other third-party approval. Any such actions may be complex, could entail significant costs and charges or could otherwise negatively impact shareholder value, and there can be no assurance that we will be able to accomplish any of these alternatives on terms acceptable to us, or at all, or that they will result in their intended benefits. Therefore, the reader is cautioned not to rely on these forward-looking statements. Endo 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 Endo, as well as Endo'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 Endo'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.

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