Paladin Labs Announces Health Canada's Filing Acceptance of Cenobamate Tablets as an Adjunctive Therapy for the Management of Partial-Onset Seizures in Adults with Epilepsy

MONTREAL, August 8, 2022 – Paladin Labs Inc., a subsidiary of Endo International plc (NASDAQ: ENDP), announced today that Health Canada has accepted its New Drug Submission (NDS) for cenobamate tablets as an adjunctive therapy for the management of partial-onset seizures in adults with epilepsy who are not satisfactorily controlled with conventional therapy. A decision from Health Canada as to whether cenobamate tablets can be marketed and sold in Canada under this NDS is expected mid-2023.

"This is an important step in our journey to address the unmet needs of adult patients diagnosed with partial-onset seizures," said Livio Di Francesco, Vice President and General Manager of Paladin. "Paladin Labs is committed to working collaboratively with regulatory, pricing and reimbursement authorities in order to provide cenobamate to appropriate patients as quickly as possible."

The regulatory submission includes efficacy information from two pivotal studies (C013 and C017)[1, 2], which enrolled a total of 658 patients. The evaluation of safety was conducted over the course of the two pivotal studies, and their respective open-label extensions, and is complemented by a long-term open-label Phase III safety study (C021)[3], also presented in the regulatory submission. A total of 1,944 patients with epilepsy have been treated with cenobamate in the clinical development program.

Endo Ventures Limited, a subsidiary of Endo, and SK Biopharmaceuticals signed a licensing agreement in December 2021 granting Endo Ventures Limited the exclusive right to commercialize cenobamate in Canada. Under the terms of this agreement, Paladin Labs is responsible for all commercial activities in Canada related to cenobamate.

About Cenobamate

Cenobamate is a novel small molecule with a dual mechanism of action under investigation for treating seizures.[4, 5,6] Cenobamate, at clinically relevant concentrations, acts both as a positive allosteric modulator of the γ-aminobutyric acid (GABAA) ion channel and inhibits voltage-gated sodium currents.[2,3] Long-term data of cenobamate has been 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 partial-onset seizures. 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).[7]

Cenobamate was discovered by SK Biopharmaceuticals and SK life science, and is an anti-seizure medication for the adjunctive or monotherapy 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 passionate team members around the globe 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. https://www.clinicaltrials.gov/ct2/show/NCT01397968

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3. https://www.clinicaltrials.gov/ct2/show/NCT02535091

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

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

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7. https://www.clinicaltrials.gov/ct2/show/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 statements by Mr. Di Francesco and any statements relating to regulatory approval or the development, registration, supply, commercialization, distribution or launch of any product. 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, proceedings or claims, including opioid, tax and antitrust matters; actual or contingent liabilities; settlement discussions or negotiations; the impact of competition including loss of exclusivity and generic competition; our ability to satisfy judgments or settlements or to pursue appeals including bonding requirements; our ability to adjust to changing market conditions; 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 refinance our outstanding indebtedness; and 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. 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 any 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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