Paladin Labs Announces the Launch of Xydalba® (dalbavancin for injection) in Canada

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The new antibiotic treatment is for adult patients with acute bacterial skin and skin structure infections (ABSSSI)[3]

MONTREAL, Jan. 17, 2022 /PRNewswire/ -- Paladin Labs Inc., a subsidiary of Endo International plc (NASDAQ: ENDP), announced today the launch of Xydalba® (dalbavancin for injection), a 30-minute intravenous (IV) therapy for acute bacterial skin and skin structure infections (ABSSSI) that can be administered as a single- or two-dose regimen. Xydalba® is now available to patients nationwide in Canada.

"We are pleased to launch Xydalba® in Canada and provide this new product to appropriate Canadian patients," says Livio Di Francesco, Vice President and General Manager of Paladin. "It offers healthcare providers an important option to treat ABSSSI."

Xydalba® was approved by Health Canada in September 2018 for the treatment of ABSSSI in adults caused by susceptible isolates of multiple gram-positive microorganisms, including methicillin resistant Staphylococcus aureus (MRSA).[3] In April 2021, ADVANZ PHARMA Corp. Limited and Endo announced that Endo subsidiary Endo Ventures Limited had entered into a definitive agreement with Correvio International Sàrl, a subsidiary of ADVANZ PHARMA, to commercialize Xydalba® in Canada on an exclusive basis.

About Xydalba®
Xydalba® for injection is a second-generation, semi-synthetic lipoglycopeptide, antibiotic. Xydalba® is indicated for treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI), caused by susceptible isolates of the following gram-positive microorganisms: Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant strains), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus group (including Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus) and Enterococcus faecalis (vancomycin susceptible strains).

About ABSSSI
Acute bacterial skin and skin structure infections (ABSSSIs) include cellulitis, erysipelas, wound infection and major cutaneous abscesses. World-wide, the most common cause of ABSSSI is Staphylococcus aureus, including the methicillin resistant S. aureus (MRSA). The spread of MRSA has made the management of ABSSSIs more challenging. Patients with ABSSSI commonly present to emergency departments in Canada and this can lead to an average of five days in hospital[1,2]. ABSSSI due to MRSA may lead to longer lengths of stay [1,2].

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 has a focused marketing 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.

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 product launch or availability. 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.

References

1. Kaye KS, Patel DA, Stephens JM, et al. Rising United States hospital admissions for acute bacterial skin and skin structure infections: recent trends and economic impact. PLoS One. 2015;10(11):e0143276.
2. Lee BY, Singh A, David MZ, et al. The economic burden of community-associated methicillin-resistant Staphylococcus aureus (CA-MRSA). Clin Microbiol Infect. 2013;19(6):528-536.
3. XYDALBA® (dalbavancin for injection) Product Monograph. Markham, Ontario, Canada: Endo Ventures Ltd.; 2021:1–33.

SOURCE Endo International plc