Paladin Labs Inc. Announces Approval of Wakix® (pitolisant) in Canada

MONTREAL, June 9, 2021 -- Paladin Labs Inc., a subsidiary of Endo International plc (NASDAQ: ENDP), today announced Health Canada's approval of Wakix® (pitolisant) for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy.

"With the approval of Wakix® by Health Canada, we are pleased to be able to provide appropriate Canadians who suffer from narcolepsy with an option to manage their EDS or to treat their cataplexy attacks," said Livio Di Francesco, Vice President & General Manager of Paladin Labs Inc. "Paladin Labs is committed to offering innovative treatment options to help support the unmet needs of Canadian patients."

Paladin plans to work 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 patients have access to Wakix® as soon as possible.

In 2018 Endo Ventures Limited, a subsidiary of Endo International plc, entered into an agreement with Bioprojet SCR to register, commercialize, and distribute pitolisant on an exclusive basis in Canada. Paladin Labs Inc., an operating company of Endo, is commercializing pitolisant in Canada.

About Narcolepsy

Narcolepsy is a rare but serious sleep disorder that significantly impacts the lives of those affected. It is estimated that this chronic condition affects up to 25,000 people in Canada[1], most commonly starting during adolescence though proper diagnosis can often take several years. [2][3][4] Current treatment options remain limited and often target either one of the two main symptoms of narcolepsy: EDS and cataplexy. EDS is the inability to stay awake and alert during the day, resulting in periods of an irrepressible need for sleep or unintended lapses into drowsiness or sleep, and is present in all people

[1] Ohayon MM. Epidemiology of narcolepsy. In: Bassetti C, Mignot E, Billard M, editors. Narcolepsy and hypersomnia. New York: Taylor and Francis; 2007. p. 125–32.
[2] Silber MH, Krahn LE, Olson EJ, Pankratz VS. The epidemiology of narcolepsy in Olmsted County, Minnesota: a population-based study. Sleep. 2002;25(2):197–202.
[3] Thorpy MJ, Krieger AC. Delayed diagnosis of narcolepsy: characterization and impact. Sleep Med. 2014;15(5):502–7.
[4] Thorpy M. Recently Approved and Upcoming Treatments for Narcolepsy. CNS Drugs (2020) 34:9–27

living with narcolepsy.[5,6] Cataplexy, characterized by sudden loss of muscle tone that is often triggered by strong emotions such as excitement, laughter or anger, can be present in up to 60% of narcolepsy patients.[7]

About Wakix®

Wakix® (pitolisant 4.5mg and 18mg tablets) is the first and only Health Canada approved treatment for adult patients experiencing both excessive daytime sleepiness and cataplexy symptoms associated with narcolepsy. Wakix® is a first-in-class highly selective histamine 3 (H_3) receptor antagonist/inverse agonist that works through a novel mechanism of action to increase the levels of histamine and other wakefulness promoting neurotransmitters in the brain.[8] It is a once-daily tablet taken in the morning upon waking. Wakix® is the only treatment approved by Health Canada for cataplexy which is not a controlled drug. Wakix® is currently marketed in Europe and the United States and is a registered trademark of Bioprojet Europe Ltd.

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

This press release contains forward-looking statements, including the statements by Mr. Di Francesco and other statements relating to regulatory, marketing and reimbursement approvals, efficacy, adverse reactions, market and product potential and product availability of Wakix®, 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 current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties and 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 International plc with securities regulators in the United States and Canada including under the caption "Risk Factors" in Endo's Form 10-K, Form

---

[5] Kornum BR, Knudsen S, Ollila HM, Pizza F, Jennum PJ, Dauvilliers Y, et al. Narcolepsy. Nat Rev Dis Prim. 2017;3:16100.

[6] Szabo ST, Thorpy MJ, Mayer G, Peever JH, Kilduff TS. Neurobiological and immunogenetic aspects of narcolepsy: implications for pharmacotherapy. Sleep Med Rev. 2019;43:23–36.

[7] Dauvilliers Y, Siegel JM, Lopez R, Torontali ZA, Peever JH. Cataplexy– clinical aspects, pathophysiology and management strategy. Nat Rev Neurol. 2014;10(7):386–95.

[8] Wakix® product Monograph. Paladin Labs Inc. May 25, 2021

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 any forward-looking statements. The forward-looking statements in this press release are qualified by these risk factors which, 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.

Endo International plc:

Media:	*Investors:*
Heather Zoumas-Lubeski	Pravesh Khandelwal
(484) 216-6829	(845) 364-4833
media.relations@endo.com	relations.investor@endo.com

###