



## Paladin Labs Announces Approval of WAKIX® (pitolisant hydrochloride tablets) For Use in Pediatric Patients in Canada

March 28, 2024

***Indication Includes Children Ages 6 Years and Older and Weighing at Least 30 kg***

**MONTREAL, 28 March 2024** – Paladin Labs Inc., a subsidiary of Endo International plc (OTC: ENDPQ), today announced Health Canada's approval of WAKIX® (pitolisant hydrochloride tablets) for the treatment of excessive daytime sleepiness (EDS) or cataplexy in pediatric patients aged 6 years and older and weighing at least 30 kg with narcolepsy.

"Health Canada's approval of WAKIX® for appropriate pediatric patients with narcolepsy marks a significant milestone. We are proud to offer an option for Canadians struggling with narcolepsy's debilitating symptoms, EDS and cataplexy, and potentially empowering caregivers to help manage their condition," 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 medical needs of Canadian patients."

In 2018, Endo Ventures Limited, a subsidiary of Endo International plc, entered into an agreement with Bioprojet SCR to register, commercialize, and distribute pitolisant hydrochloride on an exclusive basis in Canada. Paladin Labs Inc., an operating company of Endo, is commercializing pitolisant hydrochloride 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<sup>1</sup>, most commonly starting during adolescence though proper diagnosis can often take several years.<sup>234</sup> Presently, pediatric patients face a void in Health Canada approved treatment options. Compounding this challenge is the fact that other approved treatments singularly address either excessive daytime sleepiness (EDS) or cataplexy, leaving a critical need for comprehensive treatment. 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 living with narcolepsy.<sup>56</sup> 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.<sup>2</sup>

### **About WAKIX®**

WAKIX® is the first and only Health Canada approved treatment for children 6 years of age and older and weighing at least 30 kg experiencing excessive daytime sleepiness or cataplexy symptoms associated with narcolepsy. WAKIX® was approved in 2021 for the treatment of excessive daytime sleepiness or cataplexy in adult patients with narcolepsy. WAKIX® is a first-in-class highly selective histamine 3 (H<sub>3</sub>) 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.<sup>7</sup> 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 also 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 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](http://www.endo.com) or [www.paladin-labs.com](http://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," "outlook," "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. Actual results may differ materially and adversely from current expectations based on a number of factors, including, among other things, the company's restructuring activities and its ability to complete its plan of reorganization; the timing, impact or results of any pending or future litigation, investigations, proceedings or claims; the company's liquidity, financial performance, cash position and operations; supply chain interruptions or difficulties; changes in competitive or market conditions; changes in legislation or regulatory developments; product recalls,

withdrawals and other unusual items; health care and cost containment reforms; and the Company's ability to advance its strategic priorities. Investors should note that these and many other factors, as more fully described in the documents filed 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 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.

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<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> Thorpy MJ, Krieger AC. Delayed diagnosis of narcolepsy: characterization and impact. *Sleep Med*. 2014;15(5):502–7.

<sup>4</sup> Thorpy M. Recently Approved and Upcoming Treatments for Narcolepsy. *CNS Drugs* (2020) 34:9–27

<sup>5</sup> Kornum BR, Knudsen S, Ollila HM, Pizza F, Jennum PJ, Dauvilliers Y, et al. Narcolepsy. *Nat Rev Dis Prim*. 2017;3:16100.

<sup>6</sup> 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.

<sup>7</sup> WAKIX® product Monograph. Paladin Labs Inc. January 25,2024

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