



## **Bioprojet and Endo Jointly Announce Agreement for Paladin Labs Inc. to Commercialize Pitolisant in Canada**

July 25, 2018

DUBLIN, July 25, 2018 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP), announced today that its subsidiary Endo Ventures Limited has entered into definitive agreements with Bioprojet SCR to register, commercialize, and distribute pitolisant on an exclusive basis in Canada. Paladin Labs Inc., an operating company of Endo, will be commercializing pitolisant in Canada.

Pitolisant is a selective histamine H3-receptor antagonist/inverse agonist that enhances the activity of histaminergic neurons. The drug is approved in the European Union (EU) for the treatment of narcolepsy in adult patients with or without cataplexy and is distributed under the tradename WAKIX®, but is not approved in Canada. Pitolisant has an orphan designation in the EU and the US for the treatment of narcolepsy.

Narcolepsy is a serious, chronic disorder characterized by excessive daytime sleepiness (EDS), with some patients experiencing intermittent uncontrolled muscle weakness or paralysis (cataplexy). Pitolisant increases the release of the brain chemical histamine to increase a patient's wakefulness and alertness. The novel drug was developed after decades of research by Bioprojet co-founders Dr. Jeanne-Marie Lecomte and Prof. Jean-Charles Schwartz.

In accordance with the terms of the agreements, Paladin will be responsible for the registration distribution, sales, marketing, medical affairs, pricing and reimbursement activities in connection with pitolisant while Bioprojet will be responsible for supplying the drug to Paladin.

"Bioprojet is proud to partner with Endo and its affiliate, Paladin, which has more than a 20 year successful track record of commercializing innovative, much-needed specialty products in Canada. We believe this partnership will be expertly led by Paladin, bringing relief to patients suffering from this debilitating disease," said Prof. Schwartz.

"We are very pleased to work with Bioprojet to bring a new treatment option for Canadian narcolepsy patients," said Rahul Garella, Senior Vice President, International Pharmaceuticals of Endo. "This product complements Paladin's promoted specialty products portfolio and provides us with an additional pillar upon which to grow our portfolio of innovative treatments."

### **About Pitolisant:**

Pitolisant is a selective histamine H3-receptor antagonist/inverse agonist which enhances the activity of histaminergic neurons. The drug was approved by the EMA in 2016 for the treatment of narcolepsy in adults with or without cataplexy and is marketed in certain countries in Europe but is not approved in Canada. Pitolisant has an orphan designation in the EU and the US for the treatment of narcolepsy and a breakthrough designation by the U.S. Food and Drug Administration for treatment of cataplexy.

### **About Narcolepsy:**

Narcolepsy is a rare, chronic, debilitating neurological disorder characterized by excessive daytime sleepiness, cataplexy, a sudden loss of muscle control triggered by emotions, and hallucinations among other symptoms. Two types of narcolepsy are currently recognized according to the ICSD3 diagnostic criteria, Type 1 and 2. Type 1 is associated with cataplexy and a reduction in of hypocretin-1 levels, while Type 2 is not associated with cataplexy.

### **About Endo International plc and Paladin Labs Inc.**

Endo International plc (NASDAQ: ENDP) is a highly focused generics and specialty branded pharmaceuticals company delivering quality medicines to patients in need through excellence in development, manufacturing and commercialization. Endo has global headquarters in Dublin, Ireland, and U.S. headquarters in Malvern, PA. Learn more at [www.endo.com](http://www.endo.com).

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](http://www.endo.com) or [www.paladin-labs.com](http://www.paladin-labs.com)

### **About Bioprojet SCR**

Bioprojet SCR is a research-based pharmaceutical company. Bioprojet is headquartered in Paris, France and its Research Center located in Rennes, France. Its activity is focused on the design, synthesis and development of novel classes of drugs for unmet medical needs. For more information visit [www.bioprojet.com](http://www.bioprojet.com).

### **Cautionary Note Regarding Forward-Looking Statements**

Certain information in this press release contains certain "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, statements by Prof. Jean-Charles Schwartz and Mr. Rahul Garella and statements relating to the commercialization of pitolisant. 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 our current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described 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 in Canada on the System for Electronic Data Analysis and Retrieval and as otherwise enumerated herein or therein, could individually or in the aggregate affect Endo's future financial results and could cause Endo's actual

results to differ materially from those expressed in the forward-looking statements or from historical results. The forward-looking statements in this press release are qualified by these risk factors. 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 laws.

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