



## Helsinn and Endo Announce Agreement for Paladin Labs Inc. to Commercialize Pracinostat in Canada

July 31, 2019

DUBLIN and LUGANO, Switzerland, July 31, 2019 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) and Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, are pleased to announce today that Endo International plc's subsidiary Endo Ventures Limited has entered into definitive agreements with Helsinn to register, commercialize, and distribute Pracinostat on an exclusive basis in Canada upon receipt of the required regulatory approval.

Under the terms of the agreement, Paladin Labs Inc., an operating company of Endo, will be responsible for the registration, distribution, sales, marketing, medical affairs, pricing and reimbursement activities in connection with Pracinostat in Canada. Helsinn will be responsible for supplying the drug to Paladin and will retain all international development rights, including clinical development activities.

Pracinostat is a novel oral histone deacetylase (HDAC) inhibitor that is in a pivotal Phase 3 study in combination with Azacitidine for the treatment of adults with newly diagnosed acute myeloid leukemia (AML) who are unfit for intensive chemotherapy. It is also being evaluated in a Phase II study in naïve patients with high or very high-risk myelodysplastic syndrome (MDS). The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for Pracinostat in combination with Azacitidine for the treatment of patients with newly diagnosed AML who are  $\geq 75$  years of age or unfit for intensive chemotherapy.

AML is a cancer of the blood and bone marrow that is caused by the uncontrolled proliferation of a blood progenitor cell of myeloid lineage. It is the most common type of acute leukemia in adults. Pracinostat is thought to act as an epigenetic cell cycle regulator in cancerous cells. The clinical study combination of Pracinostat and Azacitidine is being evaluated for the effect in reverse gene silencing, leading to cell apoptosis and differentiation.

"Our collaboration with Paladin demonstrates our commitment to advancing the quality of cancer care for patients around the world. Paladin has a very successful 24-year track record of commercializing innovative pharmaceutical products in Canada and our partnership with them will be an invaluable component of our strategy to ensure global access to Pracinostat," said Riccardo Braglia, Helsinn Group Vice Chairman and CEO.

"Pracinostat has shown potential as a possible treatment for AML and MDS in an elderly population with otherwise limited therapeutic options," said Rahul Garella, Senior Vice President, International Pharmaceuticals of Endo. "We are excited to partner with Helsinn and add this important medicine to our leukemia cancer care product offering in Canada."

### **About Pracinostat:**

Pracinostat is an oral HDAC that is in a pivotal Phase III study in combination with Azacitidine for the treatment of adults with newly diagnosed acute myeloid leukemia ("AML") who are unfit for intensive induction chemotherapy. It is also being evaluated in a Phase II study in patients with high risk myelodysplastic syndromes ("MDS"). The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for Pracinostat in combination with Azacitidine for the treatment of patients with newly diagnosed AML who are  $\geq 75$  years of age or unfit for intensive chemotherapy.

In 2016 Helsinn obtained global rights to Pracinostat from MEI Pharma, Inc. under an exclusive license, development and commercialization agreement, the terms of which are not altered by the sublicense agreement, which also included the right for Helsinn to grant sublicenses to third parties.

Exclusive licensing rights for all territories excluding US, Canada, Japan and South America were granted to Menarini, the Italian biopharmaceutical group, in December 2018.

Pracinostat is an investigational agent and is not approved for commercial use in the U.S. and any other country worldwide.

### **About AML:**

AML is a disorder of the blood and bone marrow caused by the uncontrolled proliferation of an abnormal hematopoietic cell of myeloid lineage. This results in a high circulating number of immature blood cells and replacement of normal bone marrow by malignant cells. AML has eight different subtypes, which are based on the type of cell from which the leukemia developed. It is typically a disease of older patients, with a median age at diagnosis of 67 years. Although the cure rate for AML patients 60 years and younger with intensive chemotherapy is 35 to 40%, it remains poor in older patients, typically not exceeding 15%.

### **About MDS:**

Myelodysplastic Syndrome is a type of blood cancer in which the bone marrow does not make enough healthy blood. MDS is normally a disease of the elderly and sometimes may progress into AML, which is a more rapidly growing cancer.

### **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 the Helsinn Group

Helsinn is a privately owned pharmaceutical group with an extensive portfolio of marketed cancer care products and a robust drug development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality. The Group works across pharmaceuticals, biotechnology, medical devices and nutritional supplements and has expertise in research, development, manufacture and the commercialization of therapeutic and supportive care products for cancer, pain and inflammation and gastroenterology. In 2016, Helsinn created the Helsinn Investment Fund to support early-stage investment opportunities in areas of unmet patient need. The company is headquartered in Lugano, Switzerland, with operating subsidiaries in Switzerland, Ireland, the U.S., Monaco and China, as well as a product presence in approximately 190 countries globally.

To learn more about Helsinn Group please visit [www.helsinn.com](http://www.helsinn.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 Messrs. Riccardo Braglia and Rahul Garella and other statements relating to the registration, distribution, sales, marketing, medical affairs, pricing, reimbursement activities, commercialization, research and development, efficacy, adverse reactions, market and product potential and product availability of Pracinostat. 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.

For more information, please visit [www.helsinn.com](http://www.helsinn.com) and follow us on [Twitter](#), [LinkedIn](#) and [Vimeo](#)

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