

## Helsinn signs exclusive distribution and license agreements with Blanver and Varifarma for Pracinostat in South America

**Lugano, Switzerland, São Paulo, Brazil, and Buenos Aires, Argentina, August 30<sup>th</sup>, 2019** – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, together with Blanver Farmoquímica e Farmacêutica S.A., a Brazilian company focused on innovative products with high quality medicines and active pharmaceutical ingredients, committed to expand patient access, and Laboratorio Varifarma SA, a company focused on complex therapies and orphan diseases, and devoted to improving the patient’s quality of life today announce they have signed exclusive distribution and licensing agreements for Pracinostat in South America.

Under the terms of the agreements, São Paulo-based Blanver will register, promote, distribute and commercialize Pracinostat in Brazil, while Varifarma, located in Buenos Aires, will cover Argentina, Bolivia, Chile, Colombia, Ecuador, Paraguay, Peru, and Uruguay. Helsinn will retain all international development rights, including clinical development activities, and the supply of Pracinostat.

Blanver and Varifarma recently agreed a strategic alliance in Latin America, in order to create a portfolio of medicines for the treatment of diverse pathologies, including hematology and oncology.

Pracinostat is a pan histone deacetylase inhibitor. The compound is currently under development in a multi-national phase III trial in combination with Azacitidine for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) who are unfit for intensive induction chemotherapy; Pracinostat is also being tested in an open label phase II study in combination with Azacitidine for the treatment of naïve patients with high risk myelodysplastic syndromes (MDS).

**Riccardo Braglia, Helsinn Group Vice Chairman and CEO, commented:** “We’re delighted to have signed these agreements with two expert partners in Latin America, with the local market experience to help to broaden the potential reach of Pracinostat to the patients who need it most. A key factor when choosing our partners is to make sure they share our principles, values and

ethics and they have a focus on quality, results orientation and social responsibility – both Blanver and Varifarma share this vision and we look forward to working with them.”

**Sergio Frangioni, Blanver Group CEO, commented:** “Innovation is part of Blanver's DNA, with this characteristic, we are proud to bring Pracinostat and honored to have Helsinn as our partner in Brazil, where we share the same values and strategic vision, bringing innovative treatments that will surely benefit patients.”

**Marcelo Conti, Laboratorio Varifarma Director, commented:** “It is a great satisfaction for Varifarma to have been chosen to represent Helsinn and its product Pracinostat, for Argentina, Bolivia, Chile, Colombia, Ecuador, Paraguay, Peru and Uruguay. We take this challenge with great commitment and the responsibility we use to work with. Sharing the same values and ethics, we look forward to start a successful venture together providing care and novel products to more patients in our region.”

## **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 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)

### **About Blanver**

A Brazilian company, founded in 1984, which develops, manufactures and commercializes medicines and active pharmaceutical ingredients (APIs). In medicines, we develop and manufacture high quality products in the HIV, hepatitis and osteoporosis segments. In Hematology and Oncology, we have established strategic alliances with international partners of recognized quality, to license and commercialize innovative and established products. Blanver develops, produces and incorporates quality and competitive innovative products, always seeking to promote people's health, quality of life and wellbeing. We are based in Sao Paulo, with a corporate headquarters and two production plants: pharmaceutical and API unit.

### **About Varifarma**

Focused on complex therapies and orphan diseases, Varifarma is a company which is devoted to improving the patient's quality of life. It is our continuous commitment is with innovation and the search of new effective therapies what has placed us as market reference. We are renowned

for our product's high quality and our sustained commitment with the medical and scientific community. For over two decades, we have counted with distinguished professionals who have actively contributed to the search for the best solutions to patients, as well as for new challenges.

***For more information:***

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