

Helsinn Group Grants Exclusive Licensing Rights to Menarini for Pracinostat

- Licensing rights are worldwide excluding US, Canada, Japan and South America

Lugano, Switzerland and Florence, Italy, December 21, 2018: Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, and Menarini, an Italian biopharmaceutical Group active in 136 countries worldwide, today announced that Berlin Chemie AG, the German company of the Menarini Group, has been granted exclusive licensing rights to commercialize Pracinostat worldwide (excluding US, Canada, Japan and South America).

Pracinostat is an inhibitor of class I, II, and IV histone deacetylase. The compound is currently in development with a multiregional 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 syndrome (MDS).

Under the terms of the agreement, Helsinn will retain all international development rights, including clinical development activities, and the supply of Pracinostat. Menarini will promote, distribute and commercialize Pracinostat in all countries of the assigned territories. Helsinn will retain the right to co-promote Pracinostat in the province of Shanghai, China, alongside Menarini, who will exclusively access the rest of China. Pursuant to certain clauses of the agreement, Menarini will have the opportunity to exploit any potential further oncology indication in the same territories.

Riccardo Braglia, Helsinn Group Vice Chairman and CEO, said: “We are pleased to have signed this agreement with Menarini, granting them exclusive licensing rights to promote and sell Pracinostat in AML, the prognosis of which remains dismal in those patients unfit to intensive induction chemotherapy.

We believe this global agreement will help to broaden the reach of Pracinostat to those patients who need it. Pracinostat, is now in Phase III clinical development. As Helsinn expands its focus into cancer therapeutics, we’re delighted to have a new, trusted partner like Menarini on board.”

“Finding new therapies against cancer, and precisely, against leukemia, is one of the goals of Menarini, which is strongly investing in Research and Development with the aim of discovering

new products – said **Lucia and Alberto Giovanni Aleotti, shareholders of the Menarini Group** – We are extremely pleased to have signed this agreement with Helsinn, one of the recognized pharmaceutical companies in the field of cancer care products.”.

About Pracinostat

Pracinostat is an oral histone deacetylase (“HDAC”) inhibitor 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 syndrome (“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 ≥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.

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

About Menarini Group and Berlin-Chemie Menarini

Berlin-Chemie Menarini is a company of The Menarini Group, an Italian pharmaceutical company, 13th in Europe out of 5,345 companies, and 35th company in the world out of 21,587 companies, with a turnover of more than 3.6 billion Euro and 17,000 employees. The Menarini Group has always pursued two strategic objectives: research and internationalization, and has a strong commitment to oncology research and development. As part of such commitment to oncology, Menarini, is developing four investigational new oncological drugs. Two of them are biologics, namely the anti CD157 antibody MEN1112, and the toxin-conjugated, anti CD205 antibody MEN1309. In addition, Menarini has recently added two small molecules to its oncology pipeline, the dual PIM and FLT3 kinase inhibitor MEN1703, and the PI3K inhibitor MEN1611, in clinical development for the treatment of a variety of hematological and/or solid tumors. Menarini is active commercially in the most important therapeutic areas with products for cardiology, gastroenterology, pneumology, infectious diseases, diabetology, inflammation, and analgesia.

With 16 production sites and 7 Research and Development centers, the Menarini Group has a strong presence throughout Europe and Asia, Africa, Central and South America. Menarini Group products are available in 136 countries worldwide.

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