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Helsinn gives exclusive rights to Menarini for Pracinostat

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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



Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, and Menarini, an Italian biopharmaceutical Group active in 136 countries worldwide, 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."