

Helsinn Group and MEI Pharma Enter Strategic Agreement for the Development and Commercialization of Pracinostat for the Treatment of Acute Myeloid Leukemia and Other Hematologic Diseases

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LUGANO, Switzerland and SAN DIEGO, Aug. 8, 2016 /PRNewswire/ -- Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, and MEI Pharma, Inc. (Nasdaq: MEIP), an oncology company focused on the clinical development of novel therapies for cancer, today announced that they have entered into an exclusive licensing, development and commercialization agreement for Pracinostat, a Phase III-ready drug candidate for the treatment of acute myeloid leukemia (AML) and other potential indications. The deal provides the complementary resources from both organizations to rapidly advance Pracinostat into Phase III clinical development and expand into additional indications, including high-risk myelodysplastic syndrome (MDS).

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Under the terms of the agreement, Helsinn will get exclusive worldwide rights, including manufacturing and commercialization rights, and will be responsible for funding the global development of Pracinostat. As compensation for such grant of rights, MEI Pharma will receive near-term payments of \$20 million, comprised of a \$15 million upfront payment and a \$5 million payment upon dosing of the first patient in the upcoming Phase III study of Pracinostat in newly diagnosed AML patients unfit to receive induction therapy. In addition, MEI Pharma will be eligible to receive up to \$444 million in potential development, regulatory and sales-based milestone payments, along with additional tiered royalty payments in selected territories.

As part of the development and commercialization agreement, Helsinn and MEI Pharma will also collaborate to explore an optimal dosing regimen of Pracinostat in combination with azacitidine for the treatment of high-risk MDS. This clinical study is expected to commence in the first half of 2017. In a related transaction, Helsinn will make a \$5 million equity investment in MEI Pharma.

Riccardo Braglia, Helsinn Group Vice Chairman and CEO, said: "Helsinn is delighted to be entering into this agreement with MEI Pharma for the exclusive rights on Pracinostat, a promising late-stage novel asset. In the first instance we will target acute myeloid leukemia (AML), an area of huge unmet medical need. As part of the development, we will also target additional indications. Helsinn is committed to helping people to survive cancer and offer a better quality of living with cancer.

"This agreement broadens our focus beyond cancer supportive care products and into the development of oncology therapeutics. Helsinn Therapeutics (HTU), our US sales organization, will allow us to accelerate the development and commercialization of this product, once approved, as we will be able to leverage our clinical and regulatory expertise coupled with our existing oncology specialist sales organization."

"Helsinn is an ideal strategic partner to entrust the development of Pracinostat," said Daniel P. Gold, Ph.D., President and Chief Executive Officer of MEI Pharma. "Helsinn has a strong commercial presence in the United States and, globally, has been able to create and skillfully coordinate a solid and significant network of 70 commercial partners in 90 countries. Helsinn's antiemetic, Aloxi®, is a market leader and is often used by patients receiving azacitidine, so their commercial organization is well positioned to market Pracinostat for the treatment of AML and MDS. Helsinn shares our enthusiasm for bringing Pracinostat to patients in need, and we look forward to a successful partnership for the development of the program."

Dr. Gold added: "Including MDS along with AML in the development plans was a critical component to this deal, as it significantly increases the market opportunity for Pracinostat. With this agreement in place, we are now in a great position to move forward with the Phase III study in AML, optimize the development path in MDS, and maintain lucrative economics on future commercial success."

This transaction has been approved by the boards of both companies. Destum Partners acted as an advisor to MEI Pharma on the transaction.

MEI Pharma Conference Call and Webcast

MEI Pharma's management team will host a conference call with simultaneous webcast today, August 8, 2016, at 9:00 a.m. Eastern time to discuss the license, development and commercialization agreement with Helsinn. To access the live call, please dial 888-357-5399 (toll-free) or 440-996-5704 (international), conference ID 62028037. The conference call will also be webcast live and can be accessed at www.meipharma.com. A replay of the webcast will be available approximately one hour after the conclusion of the call.

About Pracinostat

Pracinostat is a potential best-in-class, oral histone deacetylase (HDAC) inhibitor. The U.S. Food and Drug Administration (FDA) recently granted Breakthrough Therapy Designation for Pracinostat in combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are ≥ 75 years of age or unfit for intensive chemotherapy. The Breakthrough Therapy Designation is supported by data from a Phase II study of Pracinostat plus azacitidine in elderly patients with newly diagnosed AML, not candidates for induction chemotherapy, which showed a median overall survival of 19.1 months and a complete response (CR) rate of 42% (21 of 50 patients). These data compare favorably to a Phase III study of azacitidine (AZA-AML-001), which showed a median overall survival of 10.4 months with azacitidine alone and a CR rate of 19.5% in a similar patient population. The combination of Pracinostat and azacitidine was generally well tolerated, with no unexpected toxicities. The most common grade 3/4 treatment-emergent adverse events included febrile neutropenia, thrombocytopenia, anemia and fatigue.

About AML

Acute myeloid leukemia (also known as acute myelogenous leukemia) is the most common acute leukemia affecting adults, and its incidence is expected to continue to increase as the population ages. The American Cancer Society estimates about 20,830 new cases of AML per year in the U.S., with an average age of about 67 years. Treatment options for AML remain virtually unchanged for nearly 40 years. Front line treatment consists primarily of chemotherapy, while the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology recommend hypomethylating agents azacitidine or decitabine as low intensity treatment options for AML patients over the age of 60 who are unsuitable for induction chemotherapy.

About the Helsinn Group

Helsinn is a privately owned cancer supportive care pharmaceutical group with an extensive portfolio of marketed products and a broad development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality, through a unique integrated licensing business model working with long standing partners in pharmaceuticals, medical devices and nutritional supplement products. Helsinn is headquartered in Lugano, Switzerland, with operating subsidiaries in Ireland and the US, a representative office in China, as well as a product presence in about 90 countries globally.

In 2016, our 40th anniversary year, you can meet representatives from Helsinn at:

- ChemOutsourcing Conference (Parsippany, New Jersey, 19-21 September)
- CPhI Worldwide (Barcelona, Spain, 4-6 October)
- ESMO Congress (Copenhagen, Denmark, 7-11 October)
- BioEurope (Köln, Germany, 4-6 November)

For more information, please visit www.helsinn.com.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a San Diego-based oncology company focused on the clinical development of novel therapies for cancer. The Company's lead drug candidate is Pracinostat, a potential best-in-class, oral HDAC inhibitor that has been granted Breakthrough Therapy Designation from the FDA in combination with azacitidine for the treatment of patients with newly diagnosed AML who are ≥ 75 years of age or unfit for intensive chemotherapy. MEI Pharma's portfolio of drug candidates also includes ME-401, a highly selective oral PI3K delta inhibitor, and ME-344, a novel mitochondrial inhibitor. For more information, please visit www.meipharma.com.

MEI Pharma Forward-Looking Statements

Under U.S. law, a new drug cannot be marketed until it has been investigated in clinical studies and approved

by the FDA as being safe and effective for the intended use. Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. You should be aware that our actual results could differ materially from those contained in the forward-looking statements, which are based on management's current expectations and are subject to a number of risks and uncertainties, including, but not limited to, our failure to successfully commercialize our product candidates; costs and delays in the development and/or FDA approval, or the failure to obtain such approval, of our product candidates; uncertainties or differences in interpretation in clinical trial results; our inability to maintain or enter into, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any products; competitive factors; our inability to protect our patents or proprietary rights and obtain necessary rights to third party patents and intellectual property to operate our business; our inability to operate our business without infringing the patents and proprietary rights of others; general economic conditions; the failure of any products to gain market acceptance; our inability to obtain any additional required financing; technological changes; government regulation; changes in industry practice; and one-time events. We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.

To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/helsinn-group-and-mei-pharma-enter-strategic-agreement-for-the-development-and-commercialization-of-pracinostat-for-the-treatment-of-acute-myeloid-leukemia-and-other-hematologic-diseases-300309990.html>

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