Helsinn Group and MEI Pharma Announce that Pracinostat has Received Orphan Drug Designation from the European Medicines Agency for the Treatment of acute myeloid leukemia (AML)

Lugano, Switzerland, January 11, 2018 – 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 the European Medicines Agency (EMA) has granted Orphan Drug Designation to pracinostat, an investigational drug candidate currently in a Phase 3 study in combination with azacitidine for the treatment of acute myeloid leukemia (AML) in adult patients unfit to induction chemotherapy.

The orphan drug designation is based on the scarcity of treatments for patients suffering from AML and on positive Phase 2 study results (see below) that were presented at the American Society of Hematology (ASH) Annual Meeting, in December 2016.

The EMA orphan drug designation is a status assigned to a medicine intended for use against a rare condition in the European Union (prevalence of the condition in the European Union must not be more than 5 in 10,000). The designation allows pharmaceutical companies to benefit from incentives offered by the EU to develop a medicine for the treatment, prevention or diagnosis of a disease that is life threatening or a chronically debilitating rare disease. These include 10 years of market exclusivity once approved, alongside a range of other regulatory advantages.

Riccardo Braglia, Helsinn Group Vice Chairman and CEO, commented: "Helsinn is pleased with the decision of the EMA to grant orphan drug designation to Pracinostat. This decision encourages us to continuously dedicate significant resources to accelerate our clinical trial program, with a goal of helping patients who are fighting rare and difficult-to-treat diseases, such as AML and, at present, have very few treatment options. Following the positive Phase 2 clinical trials of Pracinostat for patients with AML, Helsinn has recently initiated the Phase 3 program."

"This designation from the EMA recognizes the potential that Pracinostat holds in addressing a significant unmet need for those suffering with AML," **said Daniel P. Gold, Ph.D., President and Chief Executive Officer of MEI Pharma.** "This represents another important milestone in the global development strategy for Pracinostat."

1st patient randomized in Phase 3 trial:

In August of 2017, Helsinn and MEI Pharma announced that the first patient has been dosed in the pivotal Phase 3 study of the investigational agent Pracinostat in combination with Azacitidine in adults with newly diagnosed acute myeloid leukemia (AML) who are unfit to receive intensive induction chemotherapy. The primary endpoint of the study is overall survival. Secondary endpoints include, among others, morphologic complete remission (CR) rate, cytogenetic complete remission and complete remission without minimal residual disease.

Phase 2 study results for Pracinostat for the treatment of AML:

Results from a Phase 2 open-label, single-arm, multicenter study of pracinostat and azacitidine in 50 patients aged ≥ 65 years with newly diagnosed AML not eligible for induction chemotherapy showed a median overall survival of 19.1 (95%CI: 10.0-26.5) months, one-year survival of 62% and a CR rate of 42%. These results were presented at the American Society of Hematology (ASH) Annual Meeting in December 2016.

About AML

AML 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 21,380 new cases and 10,590 deaths from AML in the U.S. for 2017; the average age of a patient with AML is about 67 years. According to the Surveillance of Rare Cancers in Europe project, the incidence of AML in Europe is 3.7 per 100,000. There are currently no drugs approved in the U.S. to treat AML in patients who are unfit for intensive induction chemotherapy, though hypomethylating agents are recommended by the National Comprehensive Cancer Network (NCCN) guidelines. In the EU, Azacitidine is approved for the treatment of adult patients who are not eligible for hematopoietic stem cell transplant (HSCT) with AML with >30% marrow blasts according to the World Health Organization (WHO) classification, and decitabine is approved the treatment of adult patients with newly diagnosed de novo or secondary AML,

according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.

About Pracinostat

Pracinostat is an oral histone deacetylase (HDAC) inhibitor that is in late-stage clinical development. The U.S. Food and Drug Administration has 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 August 2016, Helsinn and MEI Pharma entered into an exclusive license, development and commercialization agreement for pracinostat in AML and other potential indications. Under the terms of the agreement, Helsinn is granted a worldwide exclusive license to develop, manufacture and commercialize pracinostat, and is primarily responsible for funding its global development and commercialization. Pracinostat is under clinical investigation and has not been approved by any health authority 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. Since 2012, Helsinn has been coordinating clinical and regulatory activities in China from Beijing and in 2017 established an office in Shanghai to pursue commercial activities. The company is headquartered in Lugano, Switzerland, with operating subsidiaries in Switzerland, Ireland, and the U.S., as well as a product presence in approximately 190 countries globally.
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 portfolio of drug candidates includes pracinostat, a late-stage oral HDAC inhibitor that is partnered with Helsinn Healthcare, SA. MEI Pharma's clinical development pipeline also includes ME-401, a highly differentiated oral PI3K delta inhibitor currently in a Phase Ib study in patients with relapsed/refractory chronic lymphocytic leukemia (CLL) or follicular lymphoma, and voruciclib, an oral, selective CDK inhibitor shown to suppress MCL1, a known mechanism of resistance to BCL2 inhibitors. The Company is also developing ME-344, a novel mitochondrial inhibitor currently in an investigator-sponsored study in combination with bevacizumab for the treatment of HER2-negative breast cancer. For more information, please visit www.meipharma.com.

Helsinn Group and 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.

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