Helsinn and MEI Pharma Announce Publication of Phase II Data for Pracinostat in Combination with Azacitidine in the Frontline Treatment of Older AML Patients Unfit for Intensive Chemotherapy, in *Blood Advances*

Lugano, Switzerland and San Diego, USA, February 14, 2019: Helsinn Group, 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 announce the publication in the medical journal, *Blood Advances*, published by the American Society of Hematology (ASH), the results from a Phase II study that evaluated the safety and efficacy of pracinostat, a potent oral pan-histone deacetylase inhibitor (HDACi), in combination with azacitidine, for the treatment of patients suffering from acute myeloid leukemia (AML), who cannot undergo treatment with intensive chemotherapy (IC).

AML is an haematological malignancy mostly diagnosed in older patients, with an average diagnosis age of 67 years of age. Although the cure rate for AML patients ≤60 years using intensive chemotherapy (IC) approaches 35% to 40%, it remains poor in older patients, typically not exceeding 15%.

The full article, just published online, *Pracinostat plus azacitidine in older patients with newly diagnosed acute myeloid leukemia: results of a phase II study, G. Garcia-Manero et al.*, shows the results of the Phase II study, assessing pracinostat combined with azacitidine in patients ≥65 years with newly diagnosed AML and ineligible for standard induction chemotherapy. This was a multicentre, open-label, single-arm, two-stage study enrolling 50 patients, evaluating the treatment with oral pracinostat 60 mg/day, 3 days/week, for 3 consecutive weeks plus intravenous azacitidine 75 mg/m^2 daily for 7 days in a 28-day cycle, until discontinuation due to progression, intolerable toxicity, intercurrent illness, or per patient request.

Primary endpoints for the Phase II study were the combined rates of complete remission (CR), CR with incomplete count recovery (CRi), and morphologic leukemia-free state (MLFS). Out of the 50 patients, 26 patients (52%) achieved the primary endpoint, with 42% achieving complete remission.

Ninety-four percent and 90% of patients had at least 1 TEAE related to pracinostat and azacitidine, respectively. The most common treatment-related AEs were nausea (56%), fatigue (40%), thrombocytopenia (38%), and neutropenia (30%).
Pracinostat plus azacitidine is a well-tolerated and active regimen in the frontline treatment of older patients with AML unfit for intensive therapy.

This investigational study showed that pracinostat in combination with azacitidine is active in the frontline treatment of older patients with AML, unfit for intensive therapy. The CR rate of 42%, the median overall survival (OS) of 19.1 months, a PFS of 12.6 months and 1-year OS rate of 62% have been evidenced in patients unfit for intensive therapy.

These data have shown that pracinostat in combination with azacitidine is a potential treatment option for the frontline treatment of older AML patients unfit for IC. Based on these results, a Phase III, multicenter, double-blind, randomized study of pracinostat with azacitidine vs placebo with azacitidine (NCT03151408) is ongoing to demonstrate an improvement of pracinostat in combination in this difficult-to-treat AML population.

Dr. Guillermo Garcia-Manero, MD Professor, Department of Leukemia, at MD Anderson Cancer Center in Houston, Texas, US, said: "We are thrilled to be in a position to outline the encouraging results of this Phase II study in Blood Advances, as the data is highly encouraging for older patients suffering from acute myeloid leukemia, and who cannot be treated with intensive chemotherapy. We look forward to continuing with our ongoing Phase III study with pacinostat to show improvement of the pracinostat combination vs azacitidine with placebo, in this difficult-to-treat AML patients population."

Sergio Cantoreggi, PhD, Chief Scientific Officer and Helsinn Group Head of R&D, commented: "The publication of this data in Blood Advances, shows the potential of pracinostat in combination with azacitidine as a safe and effective regimen for difficult-to-treat AML patients. There are only few treatment options for older patients suffering from AML and who are unfit for intensive chemotherapy treatment. We are committed to further investigate the effects of this drug combination in an ongoing Phase III study."

Richard Ghalie, M.D., Senior Vice President, Clinical Development at MEI Pharma added: "AML is a rapidly progressing, often fatal disease, with an urgent need for new treatment options. This Phase II study provided the rationale for our ongoing Phase III study

and show the potential for pracinostat, in combination with azacytidine, as a treatment option in this AML population. As such, we're delighted that these data are being published in Blood Advances."

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 chemotherapy. It is also being evaluated in a Phase II study in patients with high or very high-risk myelodysplastic syndrome ("MDS"). 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.

The agreement provides that Helsinn is primarily responsible for development and commercialization for pracinostat in AML and other indications, including MDS.

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.

For more information, please visit www.helsinn.com

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a San Diego-based pharmaceutical company focused on leveraging its extensive development and oncology expertise to identify and advance new therapies for cancer. The Company's portfolio of drug candidates includes pracinostat, an oral HDAC inhibitor that is partnered with Helsinn Healthcare, SA. Pracinostat has been granted Breakthrough Therapy Designation from the U.S. Food and Drug Administration for use in combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are unfit for intensive chemotherapy. Pracinostat is also being developed in combination with azacitidine for the treatment of patients with high and very high-risk myelodysplastic syndrome (MDS). 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 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-initiated study in combination with bevacizumab for the treatment of HER2-negative breast cancer. Pracinostat, ME-401, ME-344 and voruciclib are investigational agents and are not approved for use in the U.S. For more information, please visit www.meipharma.com

MEI Pharma and Helsinn Group 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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