



Helsinn Group and MEI Pharma Announce Upcoming Presentation at ASCO 2018 on the design of the Phase III PRIMULA study of Pracinostat in combination with azacitidine for the treatment of Acute Myeloid Leukemia (AML) in adult patients unfit for standard induction chemotherapy

Lugano, Switzerland, May 30, 2018 – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, and MEI Pharma, Inc. (Nasdaq: MEIP), a pharmaceutical company focused on leveraging its extensive development and oncology expertise to identify and advance new therapies for cancer, today announce that the PRIMULA study design will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting 1 – 5 June, 2018 in Chicago.

The PRIMULA study is a Phase III, multiregional, double-blind, randomized study of pracinostat vs. placebo with azacitidine (AZA) as background therapy in patients ≥ 18 years of age with newly diagnosed acute myeloid leukemia (AML), unfit for standard induction chemotherapy.

- Abstract: TPS7078
- Poster Board #135b: A phase III, randomized study of pracinostat (PRAN) in combination with azacitidine (AZA) versus placebo in patients ≥18 years with newly diagnosed acute myeloid leukemia (AML) unfit for standard induction chemotherapy (IC)
- Date and time: Mon, Jun 04, 8:00 AM 11:30 AM
- Location: Hall A
- Poster Session: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant
- First Author: Guillermo Garcia-Manero, MD, The University of Texas MD Anderson Cancer Center

Guillermo Garcia-Manero, The University of Texas MD Anderson Cancer Center, commented: "Following encouraging survival and response data from a Phase II clinical trial of Pracinostat in 50 patients aged ≥ 65 years with newly diagnosed AML not eligible for induction





chemotherapy, the PRIMULA Phase III study has been initiated last summer, and we look forward to sharing an update on the trial progress."

Sergio Cantoreggi, Chief Scientific Officer of Helsinn Group, commented: "Though new therapies have been approved in 2017 for patients with Acute Myeloid Leukemia, this disease remains an area of highly unmet medical need especially for those patients with advanced age or clinically relevant comorbidities who are unfit to standard induction chemotherapies, Helsinn is fully committed to this program which currently represents one of the key priorities of our R&D organization."

1st patient randomized in Phase III trial:

In July 2017, the first patient has been dosed in the pivotal Phase III study of the investigational agent pracinostat in combination with azacitidine in adults with newly diagnosed acute myeloid leukemia (AML) who are unfit to intensive induction chemotherapy. The primary endpoint of the study is overall survival. Secondary endpoints include widely accepted bone marrow and hematologic response criteria

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. 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 MEI Pharma

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

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, 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 onetime 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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