



Helsinn Group and MEI Pharma Report Prolongation of Survival Results from Phase 2 Clinical Study of Pracinostat and Azacitidine in Acute Myeloid Leukemia

Phase 2 study results presented at American Society of Hematology Annual Meeting on Saturday, December 3, 2016

Global Phase 3 study site recruitment is ongoing

Lugano, Switzerland and San Diego, USA, December 5, 2016 – 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, announced final results from a Phase 2 clinical study of the investigational drug candidate Pracinostat and azacitidine in elderly patients with acute myeloid leukemia (AML) who were not eligible for induction chemotherapy, including evidence of prolongation of survival in the overall population and across a number of patient subgroups.

In an oral presentation at the American Society of Hematology (ASH) Annual Meeting on Saturday, Dr. Guillermo Garcia-Manero, MD Anderson Cancer Center, principal investigator of the study, reported a median overall survival of 19.1 (95%CI: 10.7-26.5) months, one-year survival of 62% and a complete response (CR) rate of 42%.

"The results from this study of Pracinostat and azacitidine in elderly patients deemed unfit for intensive therapy are particularly encouraging," said Dr. Garcia-Manero. "Despite recent advances in the treatment of AML, options for these elderly unfit patients remain limited. The combination of Pracinostat and azacitidine appears to show a long-term survival benefit in this population, including an unprecedented two-year survival rate of 41% in this study. Furthermore, the prolongation of survival over what is generally expected for azacitidine alone is observed not only in the overall population, but across virtually every defined patient subset, including cytogenetic risk group, *de novo* or secondary AML, age and ECOG performance status."





A copy of the presentation, entitled "A Phase 2 Study of Pracinostat and Azacitidine in Elderly Patients with Acute Myeloid Leukemia (AML) Not Eligible for Induction Chemotherapy: Response and Long-Term Survival Benefit," is available at www.meipharma.com.

The open-label Phase 2 study enrolled a total of 50 patients at 15 centers across the U.S. Median age in the study was 75 years. Patients received 60 mg of Pracinostat orally three times a week for three weeks followed by one week of rest and 75 mg/m2 of azacitidine via subcutaneous injection or intravenous infusion for the first seven days of each 28-day cycle. The combination of Pracinostat and azacitidine had no unexpected toxicities. The most common grade 3/4 treatment-emergent adverse events reported in >10% of all patients included thrombocytopenia, febrile neutropenia, neutropenia, fatigue and anemia.

Site recruitment is ongoing for the global Phase 3 study of Pracinostat and azacitidine in newly diagnosed AML patients who are ≥75 years of age or unfit for intensive induction chemotherapy.

About Pracinostat

Pracinostat is a potential best-in-class, oral histone deacetylase (HDAC) inhibitor. 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 licensing, development and commercialization agreement for Pracinostat in AML and other potential indications. The deal provides the complementary resources from both organizations to rapidly advance Pracinostat into Phase 3 clinical development and expand into additional indications, including high and very high risk myelodysplastic syndrome (MDS).

Pracinostat is an investigational agent and is not approved for use in the U.S.

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 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 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. 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, an oral HDAC inhibitor that is partnered with Helsinn Healthcare, SA for its development and commercialization in AML and other potential indications, including MDS. The Company's clinical development pipeline also includes ME-401, an oral PI3K delta inhibitor currently in a Phase Ib study in patients with recurrent chronic lymphocytic leukemia or follicular non-Hodgkin's lymphoma, and ME-344, a 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.

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.

MEI Pharma Contacts

Investors:

Pete De Spain Vice President, Investor Relations (858) 792-3729 pdespain@meipharma.com

Media:

Jason Spark
Canale Communications
(619) 849-6005
jason@canalecomm.com

Helsinn Group Contact:

Paola Bonvicini Head of Communication & Press Office +41 91-985-21-70 info-hhc@helsinn.com