Helsinn Group and MEI Pharma Report Correlation between Mutations in DNA Methylation Pathway and Clinical Response in Phase II Study of Pracinostat and Azacitidine in Acute Myeloid Leukemia

- ***Analysis shows statistically significant CR rate (p=0.027) in patients with mutations in DNA methylation pathway, including DNMT3A, IDH1, IDH2 and TET2, most common mutations in study***

- ***Mutation profile generally typical of older AML and MDS patients***

- ***Equivalent overall survival in patients with mutations typically associated with secondary AML (17.7 months) and de novo AML (18.1 months)***

- ***Continued treatment increases rate of minimal residual disease clearance***

Lugano, Switzerland and San Diego, USA, June 5, 2017 – 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 findings from a genetic mutation analysis of patients in a Phase II clinical study of the investigational drug pracinostat and azacitidine in acute myeloid leukemia (AML), including a significant correlation between genetic mutations in the DNA methylation pathway and clinical response. These data are being presented today at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.

Available samples from 41 of the 50 patients enrolled in the Phase II study were sequenced to characterize the genetic mutation profile of these patients. The overall mutation profile of the patients in this study appear to be generally typical of an older population with AML[1] and are also common in myelodysplastic syndrome (MDS)[2]. The most frequent mutations, occurring in 37% of samples studied (15/41), were found in the DNA methylation pathway, including

[1] N Engl J Med. 2015;373(12):1136–1152
[2] N Engl J Med. 2017;376(6):536–547

DNMT3A, IDH1, IDH2 and TET2. Patients with these mutations had a complete response (CR) rate of 60%, a significant improvement (p=0.027) over patients with the wild-type genes (22%).

Notably, the phase II analysis also showed that median overall survival was roughly equivalent in patients with mutations typically associated with *de novo* AML (18.1 months) and secondary AML (17.7 months). In a recent study, the standard-of-care regimen of cytarabine and daunorubicin (7+3) in patients with secondary AML showed a median overall survival of 5.95 months[3].

"This mutational analysis enabled us to identify frequently occurring genetic abnormalities that may predict outcomes in older AML patients treated with the combination of pracinostat and azacitidine," said Dr. Guillermo Garcia-Manero, MD Anderson Cancer Center, principal investigator of the study. "In addition, we confirmed that the mutation profile in the Phase II AML study was representative not only of the larger population of older AML patients, but common in MDS patients as well. Finally, longitudinal sequencing analyses showed that continued treatment with pracinostat and azacitidine increases the rate of minimal residual disease clearance. These findings combine to support the upcoming Phase III study of pracinostat plus azacitidine in AML as well as the Phase II dose-optimization study of pracinostat and azacitidine in high and very high MDS."

A copy of the poster, entitled "Correlation Between Mutation Clearance and Clinical Response in Elderly Patients with Acute Myeloid Leukemia (AML) Treated with Azacitidine and Pracinostat," is now available at www.meipharma.com. These data will also be presented at the European Hematology Association (EHA) Annual Congress in Madrid on Friday, June 23, 2017.

Results from the Phase II study of pracinostat and azacitidine in elderly patients with AML 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%. CR rate and overall survival were consistent across patient subsets. Responses were durable (median CR+CRi 17.2 months), blast clearance was rapid (median 8 weeks) and maximum clinical benefit required prolonged therapy (> 6 months) in some patients.

[3] J Clin Oncol 34, 2016 (suppl; abstr 7000)

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. These results were presented at the American Society of Hematology (ASH) Annual Meeting in December 2016.

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. Site recruitment is ongoing for a global Phase III study of pracinostat and azacitidine in newly diagnosed AML patients who are ≥75 years of age or unfit for intensive induction chemotherapy. A Phase II dose-optimization study of pracinostat and azacitidine in patients with high and very high risk MDS is expected to initiate this month. Pracinostat is an investigational agent and is not approved for commercial use in the U.S.

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 and the US, a representative office in 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 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. 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 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. MEI Pharma's clinical development pipeline also includes ME-401, a potent and highly selective oral PI3K delta inhibitor currently in a Phase Ib study in patients with relapsed/refractory CLL or follicular lymphoma. 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.

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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