Phase 2 Interim Data Evaluating the Combination of Pracinostat and Azacitidine in Patients with Myelodysplastic Syndrome Presented at the 2018 American Society of Hematology Annual Meeting

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LUGANO, Switzerland and SAN DIEGO, Dec. 3, 2018 /PRNewswire/ -- 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 announced interim data from a Phase 2 study evaluating pracinostat, a histone deacetylase inhibitor, in combination with azacitidine for the treatment of patients with IPSS-R high/very high-risk of Myelodysplastic Syndrome (MDS). The data demonstrate a 9% discontinuation rate due to adverse events, a substantially lower rate than observed in an earlier study, as well as an encouraging 36% complete response rate among patients receiving at least 6 cycles of treatment. These data are being presented today at the 2018 American Society of Hematology (ASH) Annual Meeting.

The ongoing Phase 2 open-label study is evaluating a 45 mg dose of pracinostat in combination with azacitidine in order to improve safety/tolerability and retain patients in study longer than in an earlier Phase 2 study evaluating a 60 mg dose. Prolonged treatment is envisaged to result in a systemic exposure to pracinostat sufficient to achieve the desired treatment effect. The data reported today reinforce results from a planned May 2018 interim analysis meeting a predefined discontinuation threshold and suggest a reduced dose of pracinostat may allow MDS patients to remain on treatment longer and thereby increase the likelihood of a treatment response. If the current Phase 2 open-label study is successful, Helsinn intends to initiate a global registration study.

Ehab Atallah, M.D., Study Chair, Associate Professor of Medicine, Medical College of Wisconsin, said: *"Treatment options for patients with a higher risk of MDS are still limited and following diagnosis the survival rate is less than 18 months with the current standard of care. At the time of the Phase 2 data announced this year in May, I was excited to see that this treatment demonstrated that it can be offered to patients as a combination therapy and potentially improve outcomes. We're pleased that the threshold for expansion of this study has been met, and I look forward to continuing to observe the progress of this combination treatment."*

Ruben Giorgino, M.D. Ph.D. Helsinn Group Head of Clinical Development at Helsinn, commented: *"Helsinn bolsters its commitment in developing pracinostat in combination with hypomethylating agents in patients with AML and with high risk MDS. Moving forward to the second stage of this really important Phase 2 clinical trial in MDS patients represents an important next step in our efforts to understand the potential benefit of pracinostat in these patients with poor prognosis and modest response to hypomethylating monotherapy".*

Richard Ghalie, M.D., Senior Vice President, Clinical Development at MEI Pharma, commented: *"The interim data demonstrating a 9% discontinuation rate due to adverse events, a substantially lower rate than observed in the earlier study, as well as an encouraging complete response rate to date of 36% of patients reaching the first disease assessment at 6 months, represents an opportunity to advance a promising new treatment for patients with high/very high-risk disease that currently have limited options."*

The Phase 2 Study

The ongoing Phase 2 study is open-label and is investigating a 45 mg dose of pracinostat in combination with the standard dose of azacitidine in up to 60 patients with high and very high-risk MDS previously untreated with hypomethylating agents. The primary endpoints of the study are 1) safety and tolerability and 2) overall response rate, defined as complete remission (CR), partial remission (PR) and marrow CR. Secondary endpoints include CR rate, overall hematologic improvement (HI) progression-free survival and overall survival, among others.

As of the end of October 2018, 55 patients have completed at least one cycle of therapy. The data demonstrate a 9% discontinuation rate due to adverse events, 4% of which were early discontinuations (within the first 3 treatment cycles). Of note, 15% of patients discontinued because they advanced to Stem Cell Transplantation. The discontinuation rate reported today continues to meet the pre-defined threshold from the planned interim analysis conducted in May 2018 and is consistent with the discontinuation rate for azacitidine administered as a single agent.

In the group patients receiving at least 6 cycles of treatment, the complete response rate is 36%. The median duration on therapy is 4.7 months (range 0.5-13 months).

The 45 mg dose of pracinostat being evaluated in the Phase 2 is better tolerated than the 60 mg dose evaluated in a prior Phase 2 study. Treatment in the current Phase 2 study was generally well-tolerated: adverse events ≥ Grade 3 reported in 20% or more of patients are febrile neutropenia, anemia, neutropenia and thrombocytopenia. It is notable that patients in the current study were diagnosed with higher-risk MDS than in the prior study.

The study was initially designed with two stages: the completed first stage that met the predefined discontinuation rate threshold, and a randomized and placebo-controlled second stage triggered upon meeting the pre-defined discontinuation threshold in the first stage. Based on the discontinuation rate meeting the pre-defined threshold in a planned interim analysis in May 2018, the study design was amended by substituting stage 2 with an expanded open-label portion to enroll up to 60 patients to obtain data to support the design of a registration study upon successful completion of the Phase 2 study.

About Higher Risk MDS
Higher risk MDS (high and very high risk in the IPSS-R classification) is a serious medical condition, with median survival of less than 18 months. The high and very high-risk groups represent the highest unmet need in MDS, with median survival estimates of only 1.6 years and 0.8 years, respectively.

The only curative therapy is allogeneic stem cell transplantation (SCT), however most patients with MDS are not candidates for SCT given their typically advanced age, comorbidities and lack of a suitable donor. Standard therapy with HMAs in higher risk MDS provides modest responses, though azacitidine has been shown to improve survival when compared to conventional care regimens. Patients who do not respond to HMAs or progress after therapy with HMAs have a very poor outcome, with a median survival of less than one year.

About Pracinostat
Pracinostat is an oral histone deacetylase ("HDAC") inhibitor that is in a pivotal Phase 3 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 2 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 costs 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.

To learn more about Helsinn Group 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 1b 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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