

MEI Pharma and Helsinn Group Announce Successful Interim Analysis of Pracinostat/Azacitidine Phase 2 Combination Study in Higher Risk Myelodysplastic Syndrome (MDS) Patients

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SAN DIEGO and LUGANO, Switzerland, May 31, 2018 /PRNewswire/ -- 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, and Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, today announced that a planned interim analysis in the ongoing Phase 2 study of pracinostat and azacitidine in higher risk MDS patients successfully met a predefined patient retention threshold. The positive outcome supports continuation of the study.

Importantly, only 10% of patients discontinued from the study due to adverse events in the first 3 cycles of therapy. The 10% rate is consistent with the established discontinuation rate for azacitidine given as a monotherapy, and it meets the predefined threshold to continue enrollment in the study. Based on the positive interim analysis announced today, Helsinn and MEI are expanding open-label enrollment to a total of up to 60 MDS patients. The goal of this expanded cohort is to gain an estimate of the response rate and overall survival in this patient population to better inform the design of a global registration study.

"Patients with higher risk MDS currently face limited treatment options and poor outcomes," stated Ehab Atallah, M.D., Study Chair, Associate Professor of Medicine, Medical College of Wisconsin. "Given the substantial need among this patient group, I am very encouraged by my experience to date in this study investigating pracinostat in combination with azacitidine. Frequently, higher risk MDS develops into AML. The potential to offer patients a novel combination therapy that is generally well tolerated with the prospect for improved outcomes in MDS and possibly AML is exciting."

The ongoing Phase 2 open-label study is evaluating a 45 mg dose of pracinostat in higher risk MDS patients in order to improve tolerability and retain patients in study longer than in an earlier Phase 2 study evaluating a 60 mg dose. A prolonged treatment may result in a systemic exposure to pracinostat sufficient to achieve the desired treatment effect, unlike in the earlier study.

The Phase 2 Study

The ongoing Phase 2 dose optimization study is investigating a 45 mg dose of pracinostat in combination with the standard dose of azacitidine in patients with high and very high-risk MDS who are previously untreated with hypomethylating agents. 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 pre-planned interim analysis of the study established a 10% discontinuation rate among the first 20 evaluable patients treated, beating a predefined threshold in the first 3 treatment cycles. Having met this threshold, the study is expanding open-label enrollment to 60 patients. Patients will be followed for one year to evaluate safety and efficacy. If the expanded open-label study is successful, the companies intend to initiate a global registration study. To date 29 patients have completed at least one cycle of therapy.

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) response rate, clinical benefit rate (defined as rate of CR + PR + HI + Marrow CR), rate of cytogenetic complete response/remission, duration of response, rate of leukemic transformation, event-free survival, progression-free survival and overall survival.

The study as initially designed included 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 predefined discontinuation threshold in the first stage. The study design is being amended by substituting stage 2 with an expanded open-label portion of the study to obtain data intended to better inform 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 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 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

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

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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.

For more information, please visit www.helsinn.com and follow us on [Twitter](#), [LinkedIn](#) and [Vimeo](#)



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