

Helsinn Group and MEI Pharma Announce First Patient Dosed in Phase 2 Dose-Optimization Study of Pracinostat and Azacitidine in Myelodysplastic Syndrome

Two-stage study designed to evaluate tolerability and efficacy of pracinostat combined with azacitidine in patients with high and very high risk MDS

Data from first stage expected in first quarter of 2018

Lugano, Switzerland and San Diego, USA, June 14, 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 that the first patient has been dosed in a Phase 2 dose-optimization study of pracinostat in combination with azacitidine in patients with higher risk myelodysplastic syndromes (MDS) who are previously untreated with hypomethylating agents (HMAs).

The two-stage study will be conducted at approximately 25 sites and is expected to enroll up to 120 patients with high and very high risk MDS per the Revised International Prognostic Scoring System (IPSS-R). 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, respectively¹. The cost of this study will be shared by Helsinn and MEI Pharma. Data from the first stage is expected in the first quarter of 2018.

*“Based on our clinical experience with the combination, we believe that a reduced dose of pracinostat has the potential to improve tolerability in patients with higher risk MDS, thereby improving efficacy of the combination compared to azacitidine alone,” said **Robert D. Mass, MD, Chief Medical Officer of MEI Pharma**. “We look forward to working with the study’s investigators and Helsinn to evaluate this hypothesis in the clinic while we await the outcome of our pivotal Phase 3 study of the combination in acute myeloid leukemia (AML).”*

¹ Blood. 2012 Sep 20;120(12):2454-65

Sergio Cantoreggi, PhD., Helsinn Group Chief Scientific Officer said, *“We are pleased to announce that the first patient with higher risk myelodysplastic syndromes has been dosed in this Phase 2 dose-optimization study of pracinostat in combination with azacitidine. Pracinostat is a promising late-stage asset and a key part of Helsinn’s broadened focus into therapeutic clinical development and we look forward to seeing the results in early 2018.”*

In a recently published, placebo-controlled Phase 2 study (MEI-003) conducted in 102 patients with intermediate-2 and high risk MDS, pracinostat (60mg) and azacitidine failed to increase the complete response rate, the study’s primary endpoint, compared to azacitidine and placebo². Drug discontinuation within the first two months of treatment, due to poor tolerability (primarily fatigue and myelosuppression), occurred twice as frequently in the pracinostat group compared to placebo. A sensitivity analysis, including 54 patients who received at least four cycles of study therapy (pracinostat or placebo) and azacitidine showed a trend for better progression-free survival and overall survival (hazard ratio = 0.37 and 0.59, respectively) compared to the control group. These data suggest that insufficient exposure to treatment may have limited the overall efficacy of the combination and are consistent with recently presented findings from an analysis of patients in a Phase 2 study of pracinostat and azacitidine in AML which showed that continued treatment increases the rate of minimal residual disease clearance³.

This two-stage, Phase 2 study will investigate a pracinostat dose of 45 mg, 25% lower than the dose used in study MEI-003, in combination with the standard dose of azacitidine to determine whether lowering the pracinostat dose in a higher risk patient population can improve the tolerance of the combination while achieving a clinically meaningful improvement in efficacy.

The first stage of the study will be open-label, single arm in up to 40 patients to assess if the lower pracinostat dose will result in a discontinuation rate that approximates the rate that was observed with azacitidine alone in study MEI-003 (10%). If results from the first stage support expansion of enrollment, the second stage will be randomized and placebo-controlled to confirm the discontinuation rate in a blinded setting and to provide data on safety and efficacy.

² Cancer. 2017 May 15;123(6):994-1002

³ J Clin Oncol 35, 2017 (suppl; abstr 7034)

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.

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 regimens⁴. 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 year⁵.

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. The deal provides the complementary resources from both organizations to advance pracinostat into Phase 3 clinical development in AML and expand into additional areas of clinical development, including MDS. Pracinostat is an investigational agent and is not approved for commercial use in the U.S.

⁴ Lancet Oncol. 2009 Mar;10(3):223-32

⁵ J Clin Oncol. 2011 Aug 20;29(24):3322-7

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.

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. 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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