MEI Pharma to Present Design of Ongoing Clinical Study Evaluating ME-344 at ASCO GI Cancers Symposium 2024

January 16, 2024

– Ongoing Phase 1b Study Evaluating ME-344 Plus Avastin® in Patients with Metastatic Colorectal Cancer: Combination Intended to Create Metabolic Synthetic Lethality –

SAN DIEGO--(BUSINESS WIRE)--Jan. 16, 2024-- MEI Pharma, Inc. (Nasdaq: MEIP), a clinical-stage pharmaceutical company evaluating novel drug candidates to address known resistance mechanisms to standard-of-care cancer therapies, today announced the design of the ongoing Phase 1b study of the mitochondrial oxidative phosphorylation (OXPHOS) inhibitor ME-344 in combination with bevacizumab (Avastin®) in refractory metastatic colorectal cancer patients will be presented during a poster session at the 2024 ASCO Gastrointestinal Cancers Symposium to be held January 18 – 20, 2024.

Presentation Title: A Phase 1b Study of the OXPHOS Inhibitor ME-344 in Combination with Bevacizumab in Refractory Metastatic Colorectal Cancer
Session Title: Trials in Progress Poster Session C: Cancers of the Colon, Rectum, and Anus
Presenter: Patrick M. Boland
Date: Saturday, January 20, 2024, 6:30-7:45 AM (Pacific Time)
Abstract Number: TPS222

The poster can be viewed on the MEI Pharma website here:
https://meipharma.com/ASCO2024enocuyg.html#

About the Phase 1b Study

The ongoing Phase 1b study is evaluating ME-344 plus bevacizumab across two cohorts in patients with metastatic colorectal cancer after failure of standard therapies. The combination of ME-344 and bevacizumab is intended to create metabolic synthetic lethality by leveraging the ability of antiangiogenics like bevacizumab to reduce glycolysis, forcing tumors to switch to mitochondrial respiration via OXPHOS, which is inhibited by ME-344.

In the first cohort of approximately 20 patients ME-344 is administered at 10 mg/kg once weekly for 3 weeks in combination with bevacizumab every two weeks, with cycles repeated every 4 weeks. If the rate of non-progression in Cohort 1 reaches a predetermined progression free survival threshold, Cohort 2 will enroll an additional 20 patients. Patients will be treated until disease progression or intolerability. The primary endpoint of the study is progression free survival. Secondary endpoints include overall response rate, duration of response, overall survival and safety.

The study is being conducted at member centers of the Academic GI Cancer Consortium (AGICC), an oncology consortium dedicated to identifying new drugs to treat gastrointestinal (GI) cancers.

About ME-344

ME-344 is a novel drug candidate that inhibits mitochondrial oxidative phosphorylation (OXPHOS), a fundamental metabolic pathway involved in the production of adenosine triphosphate (ATP) in the mitochondria. ATP provides energy to drive many metabolic cell processes, including division, proliferation, and growth. By disrupting the production of ATP, ME-344 has been shown to induce cancer cell death in nonclinical models and was associated with antitumor activity in clinical studies.

The two main sources of ATP production in cells are OXPHOS and glycolysis; the latter is highly active in most tumors. Anti-angiogenics, like the vascular endothelial growth factor (VEGF) inhibitor bevacizumab (AVASTIN®), have the potential to normalize vasculature and decrease reliance on glycolysis. The resulting reduction in glycolysis may trigger an increased dependence on mitochondrial ATP production for energy to support continued tumor proliferation.

In such cases of tumor plasticity, the combination of ME-344 and bevacizumab may induce metabolic synthetic lethality, providing a novel therapeutic strategy. Specifically, leveraging the ability of antiangiogenics like bevacizumab to reduce glycolysis and force tumor cells to switch to mitochondrial respiration via OXPHOS, which is inhibited by ME-344, may reduce access to ATP needed for cell division and growth in tumors.

This approach was first clinically evaluated in a multicenter, investigator-initiated, randomized, open-label, window of opportunity clinical study, evaluating ME-344 (3 doses) plus bevacizumab (1 dose) in 42 women with early HER2-negative breast cancer. Study results demonstrated significant biological antitumor activity as measured by a reduction in the proliferative biomarker Ki-67 compared to placebo. The combination appeared to be generally well tolerated. The data from this study were consistent with preclinical data suggesting that combining ME-344 can augment anti-angiogenic therapy and provided validation for continued evaluation of the combination of ME-344 with bevacizumab and other VEGF inhibitors.

An earlier Phase 1 clinical study evaluating ME-344 as a single-agent in patients with refractory solid tumors also demonstrated anti-tumor activity, further validating the potential of mitochondrial inhibition as a promising therapeutic modality.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a clinical-stage pharmaceutical company committed to developing novel and differentiated cancer therapies. We build our pipeline by acquiring promising cancer agents and creating value in programs through development, strategic partnerships, out-licensing and commercialization, as appropriate. Our approach to oncology drug development is to evaluate our drug candidates in combinations with standard-of-care therapies to overcome known resistance mechanisms and address clear medical needs to provide improved patient benefit. The drug candidate pipeline includes voruciclib, an oral cyclin-dependent kinase 9 ("CDK9") inhibitor, and ME-344, an intravenous small molecule mitochondrial inhibitor targeting the oxidative phosphorylation pathway. For more information, please visit www.meipharma.com. Follow us on X (formerly Twitter) @MEI_Pharma and on LinkedIn.

Forward-Looking Statements

Certain information contained 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 including, without limitation, statements regarding: the potential, safety, efficacy, and regulatory and clinical progress of our product candidates, including the anticipated timing for initiation of clinical trials and release of clinical trial data and our expectations surrounding potential regulatory submissions, approvals and timing thereof, our business strategy and plans; the sufficiency of our cash, cash equivalents and short-term investments to fund our operations; and our ability to fund future capital returns. 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; the availability or appropriateness of utilizing the FDA's accelerated approval pathway for our product candidates; final data from our pre-clinical studies and completed clinical trials may differ materially from reported interim data from ongoing studies and trials; 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; uncertainty regarding the impact of rising inflation and the increase in interest rates as a result; potential economic downturn; geopolitical conflicts; activist investors; 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. 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.

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