



MEI Pharma Initiates Strategic Realignment

December 5, 2022

– Company continuing development efforts on its two early clinical-stage oncology assets: voruciclib and ME-344 –

– MEI expects existing cash sufficient to fund through clinical data milestones for voruciclib and ME-344 –

SAN DIEGO--(BUSINESS WIRE)--MEI Pharma, Inc. (Nasdaq: MEIP), a clinical-stage pharmaceutical company focused on advancing new therapies for cancer, today announced that it plans to initiate a realignment of its clinical development efforts following the discontinuation of global development outside Japan of its PI3K delta inhibitor, zandelisib. As part of the realignment, the company plans to streamline its organization towards the development of two earlier clinical-stage assets, voruciclib and ME-344. Following completion of the workforce reductions, MEI expects its existing cash, cash equivalents and marketable securities will be sufficient to fund operations through clinical data milestones for both voruciclib and ME-344. The company further announced that it has engaged Torreya Partners as financial advisor to help explore additional strategic opportunities.

“In light of the determination we made with our global partner, Kyowa Kirin, to discontinue development of zandelisib outside of Japan after a recent meeting with FDA, we have had to make some tough decisions. We intend to continue development of our earlier-stage clinical assets, streamline MEI’s operations towards these efforts, and consider additional strategic opportunities,” said Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. “As we move forward with the planned development of voruciclib and ME-344, two investigational candidates representing potential treatments for various hematological and solid tumor cancers, I want to express my deep gratitude to the MEI team. I am very proud of our work, and the simply exemplary efforts, to develop zandelisib. I also want to recognize the collaborative efforts of our partner, Kyowa Kirin, and sincerely thank all the healthcare providers and patients that contributed to zandelisib’s development.”

Expected Drug Candidate Pipeline Developments

Voruciclib – Oral cyclin-dependent kinase 9 (CDK9) inhibitor for the treatment of B-cell malignancies and acute myeloid leukemia, as well as solid tumors.

- After initiating dosing of the first patient in November, continue advancing the dosing of patient cohorts evaluating voruciclib in combination with Venclexta® (venetoclax) in patients with acute myeloid leukemia in the ongoing Phase 1 study.
 - Provide a clinical data update in CY2023.
- Continue preclinical evaluation of the role CDK9 in cMYC regulation in solid tumors expressing KRAS mutations to support potential clinical development as a treatment for solid tumors.

ME-344 – Tumor selective mitochondrial inhibitor for the treatment of solid tumors.

- Initiate a Phase 1b study evaluating ME-344 plus Avastin® (bevacizumab) in relapsed colorectal cancer patients in the first half of calendar year 2023.

Strategic Realignment Overview

MEIP plans to streamline its organization towards the continued clinical development of voruciclib and ME-344. As a result, it plans to initiate a staggered workforce reduction, initially representing approximately 30% of the current workforce in connection with the wind down of the zandelisib development program outside of Japan, which costs are shared with Kyowa Kirin, our global development partner. Following completion of the zandelisib wind down and associated workforce reductions, MEI expects that, along with any additional workforce reductions to be determined to fully align resources going forward, its existing cash, cash equivalents and marketable securities will be sufficient to fund operations through clinical data milestones for both voruciclib and ME-344.

About Voruciclib

Voruciclib is an orally administered Cyclin-dependent kinase 9 (CDK9) inhibitor being clinically investigated for hematological malignancies. Potential applications in solid tumors are also being actively explored. CDK9 has important functions in cell cycle regulation, including the modulation of two therapeutic targets in cancer: myeloid leukemia cell differentiation protein ("MCL1") and the MYC proto-oncogene protein ("MYC") which regulates cell proliferation and growth. Voruciclib is currently being evaluated in a Phase 1b trial evaluating dose and schedule in patients with acute myeloid leukemia ("AML") and B-cell malignancies. Applications in solid tumors are also being considered where MYC is dysregulated.

About ME-344

ME-344 is a tumor selective mitochondrial inhibitor drug candidate targeting the OXPHOS pathway involved in the production of

adenosine triphosphate, or ATP, in the mitochondria. It is in clinical development to treat solid tumors. Although clinical investigation of ME-344 has demonstrated single agent activity in patients with solid tumors, using it in combination with other cancers therapies is thought to hold more significant potential for patients. Data reported at the 2018 ASCO conference from an investigator-initiated, multi-center, randomized study of ME-344 in combination with the VEGF inhibitor bevacizumab (Avastin®) in women with demonstrated biologic activity in the ME-344 treatment group supporting further clinical investigation.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a pharmaceutical company focused on developing potential new therapies for cancer. MEI Pharma's portfolio of drug candidates includes clinical stage candidates with differentiated mechanisms of action intended to address unmet medical needs and deliver improved benefit to patients, either as standalone treatments or in combination with other therapeutic options. For more information, please visit www.meipharma.com. Follow us on Twitter [@MEI_Pharma](https://twitter.com/MEI_Pharma) and on [LinkedIn](https://www.linkedin.com/company/meipharma).

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 including, without limitation, statements regarding: the potential, safety, efficacy, and regulatory and clinical progress of voruciclib, ME-344 and our other 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 through clinical data milestones for both voruciclib and ME-344; our ability to recognize the anticipated benefits of our planned strategic realignment; and our ability to identify and enter into potential future strategic opportunities. 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 develop 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; adverse effects on the Company's business as a result of the restatement of our previously issued financial statements; the impact of the COVID-19 pandemic on our industry and individual companies, including on our counterparties, the supply chain, the execution of our clinical development programs, our access to financing and the allocation of government resources; 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 realize the anticipated benefits of our planned strategic realignment; our inability to identify and enter into potential future strategic opportunities; 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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