MEI Pharma Announces Acceptance of Abstract for Presentation at ASH 2023

November 2, 2023

SAN DIEGO--(BUSINESS WIRE)--Nov. 2, 2023-- MEI Pharma, Inc. (Nasdaq: MEIP), a clinical-stage pharmaceutical company focused on advancing new therapies for cancer, today announced that an abstract highlighting clinical data from the monotherapy dose escalation stage of the ongoing Phase 1 study evaluating voruciclib, a selective oral cyclin-dependent kinase 9 (CDK9) inhibitor, alone and in combination with venetoclax (Venclexta®), a B-cell lymphoma 2 ("BCL2") inhibitor, in patients with acute myeloid leukemia (AML) or B-cell malignancies, will be presented during a poster session at the upcoming 65th American Society of Hematology (ASH) Annual Meeting and Exposition to be held December 9 – 12, 2023.

Presentation Title: A Phase 1 Study of the Oral CDK9 Inhibitor Voruciclib in Relapsed/Refractory (R/R) B-Cell Lymphoma (NHL) or Acute Myeloid Leukemia (AML)
Session Title: Acute Myeloid Leukemias: Investigational Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster III (616)
Presenter: Mathew Davids, MD, MMSc., Director, Clinical Research, Division of Lymphoma, Dana Farber Cancer Institute
Date: Monday, December 11, 2023, 6:00-8:00 PM (Pacific Time)
Publication Number: 4286

About the Phase 1 Study

The Phase 1 study is a two stage, open-label, 3+3 dose escalation and expansion study evaluating voruciclib, a CDK9 inhibitor, as a monotherapy and in combination with venetoclax (marketed as Venclexta®), a BCL2 inhibitor. Inhibition of CDK9 blocks the production of Mcl-1, which is an established resistance mechanism to the BCL2 inhibitor venetoclax. The primary objectives of the study are to determine the safety and biologic effective dose of voruciclib monotherapy or voruciclib in combination with venetoclax. Secondary objectives of the study include assessing the preliminary efficacy, pharmacokinetics, pharmacodynamics, and biomarkers of voruciclib monotherapy or voruciclib in combination with venetoclax.

The first stage of the study, evaluating the dose and schedule of voruciclib as a single-agent in patients with relapsed and refractory (“R/R”) acute myeloid leukemia (“AML”) or B-cell malignances after failure of standard therapies, is now completed and the final results presented in the abstract. Stage 2 of the study is evaluating voruciclib in combination with standard dose venetoclax in patients with R/R AML.

About Voruciclib

Voruciclib is an orally administered cyclin-dependent kinase 9 (“CDK9”) inhibitor with potential to treat both hematological malignancies and solid tumors. It is in clinical development for acute myeloid leukemia and B-cell malignancies. Applications in solid tumors are also being considered.

The CDK family of proteins are important cell cycle regulators responsible for the control of cell proliferation, differentiation, apoptosis, and DNA repair. CDK9, one of several members of the CDK family of proteins, functions as a gene transcription controller and is also involved in regulating protein degradation. Specifically, CDK9 is a promising target to treat a range of cancers because of its role in controlling two other proteins often dysregulated in cancerous cells: myeloid leukemia cell differentiation protein ("Mcl-1") and the MYC proto-oncogene protein ("MYC")

Mcl-1 is a member of the family of anti-apoptotic proteins which, when elevated, may prevent the cell from undergoing

cell death. Inhibition of CDK9 blocks the production of Mcl-1, which is an established resistance mechanism to the B-cell lymphoma 2 ("BCL2") inhibitor venetoclax (marketed as Venclexta®).

MYC regulates cell proliferation and growth. Upregulation of MYC is implicated in many human cancers and is frequently associated with poor prognosis and unfavorable patient survival. CDK9, in addition to being a transcription factor for MYC, also decreases phosphorylation of MYC protein that is implicated in stabilizing MYC in KRAS mutant cancers. Targeting MYC directly has historically been difficult, but CDK9 is a promising approach to target this oncogene.

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. 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; 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; the impact of geopolitical tensions, 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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