MEI Pharma Announces Updated Clinical Data from ME-401 Phase 1b Study in Patients with Indolent B-cell Malignancies

Oct 03 2019

SAN DIEGO, Oct. 3, 2019 /PRNewswire/ -- MEI Pharma, Inc. (NASDAQ: MEIP), a late-stage pharmaceutical company focused on advancing potential new therapies for cancer, today announced updated data from the ongoing Phase 1b study of investigational ME-401, a selective oral inhibitor of PI3K delta. These new data will be presented at MEI's Investor and Analyst Event being held tomorrow, October 4, 2019, at 8:00 am ET.

Highlights of the ME-401 updated data include:

- Overall response rates of 78% in relapsed or refractory (r/r) follicular lymphoma (FL) and 89% in r/r chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL).
- Rates of Grade 3 adverse events of special interest related to ME-401 exposure were observed in <10% of patients dosed on an intermittent schedule (IS).
- Median duration of response not yet reached in patients with FL or CLL/SLL on the IS regimen. Median follow-up for FL and CLL/SLL patients is 9.2 months (range 3.4-20.7 months) and 7.4 months (range 2.6-14.7 months), respectively.

At the Investor and Analyst event MEI will also review progress across the pipeline of its four clinical-stage oncology candidates with a focus on voruciclib, a cyclin-dependent kinase (CDK) inhibitor with potent CDK9 inhibition. Voruciclib is in a Phase 1b study in patients with r/r B-cell malignancies or Acute Myeloid Leukemia (AML) after failure of prior standard therapies. In addition, we plan to evaluate voruciclib in combination with venetoclax (marketed as Venclexta®), a B-cell lymphoma (Bcl) 2 inhibitor, in patients with r/r AML.

"ME-401 continues to exceed expectations in the Phase 1b study; the overall response rate remains high at 81% with 73 evaluable FL and CLL/SLL patients being followed for treatment,"
Daniel P. Gold, Ph.D., president and chief executive officer of MEI Pharma. "Currently, our primary focus is the ME-401 Phase 2 TIDAL study evaluating patients with relapsed or refractory follicular lymphoma, which may support an accelerated approval of a marketing application with FDA, as well as the continuing exploration of various combination regimens with ME-401."

Dr. Gold continued: "More broadly, MEI has a strong foundation to build value through advancing our pipeline, evaluating drug combination opportunities across the B-cell malignancy landscape, and continuing to create and explore strategic opportunities to most effectively leverage the potential of the pipeline. Each of our four clinical-stage oncology candidates is well positioned for continued clinical development."

Investor and Analyst Event Information

Date: Friday, October 4, 2019
Time: 8 am -11 am ET

The investor event will feature presentations from the following MEI Pharma executives:

- **Dan Gold, Ph.D.**, President and Chief Executive Officer, MEI Pharma.
- **Robert Mass, M.D.**, Chief Medical Officer, MEI Pharma.
- **Richard Ghalie, M.D.**, Senior Vice President, Clinical Development, MEI Pharma.

The event will also feature presentations by the following guest speakers:

- **Lewis C. Cantley, Ph.D.**, Meyer Director of the Sandra and Edward Meyer Cancer Center at Weill Cornell

Medical College, Professor of Cancer Biology in Medicine.

- **Nishitha M. Reddy, M.D., M.B.B.S.,** Associate Professor of Medicine at Vanderbilt University Medical Center.

- **Matthew J. Matasar, M.D.**, Medical Director, Memorial Sloan Kettering Bergen.

You can access the live webcast under the investor relations section of MEI's website on the "Events and Presentation" page at: www.meipharma.com. A replay of the webcast will be archived for at least 30 days after the conclusion of the live event.

The full Investor and Analyst Event presentation will be available on the home page of the Investor Relations section of MEI Pharma's website at: https://investor.meipharma.com/

About MEI's Clinical-Stage Oncology Pipeline

About ME-401
ME-401 is an oral, once-daily, selective phosphatidylinositol 3-kinase (PI3K) delta inhibitor in clinical development for the treatment of B-cell malignancies. MEI owns worldwide rights in all geographies except Japan, which we licensed to Kyowa Kirin Company (formerly "Kyowa Hakko Kirin Co., Ltd.") in 2018.

MEI is conducting two ongoing studies evaluating ME-401. The first is a Phase 2 clinical trial evaluating ME-401 as a monotherapy for the treatment of adults with relapsed or refractory follicular lymphoma ("FL") after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. Subject to the results, upon completion of the Phase 2 clinical trial, we are planning a submission with the FDA to support an accelerated approval of a marketing application under 21 CFR Part 314.500, Subpart H. The second is a multi-arm, open-label, Phase 1b dose escalation and expansion trial evaluating ME-401 as a monotherapy and in combination with other therapies or investigational agents in patients with relapsed or refractory B-cell malignancies.

About Voruciclib
Voruciclib is an orally administered cyclin-dependent kinase (CDK) inhibitor differentiated by its potent in vitro inhibition of CDK9, in addition to CDK6, 4 and 1. Voruciclib is currently being evaluated in a Phase 1b dose ranging trial in patients with relapsed and/or refractory B-cell malignancies or acute myeloid leukemia (AML) after failure of prior standard therapies.

About ME-344
ME-344 is our novel and tumor selective, isoflavone-derived mitochondrial inhibitor drug candidate. It directly targets the OXPHOS complex 1, a pathway involved in ATP production in the mitochondria. ME-344 was recently studied in an investigator-initiated, multi-center, randomized clinical trial in combination with the vascular endothelial growth factor (VEGF) inhibitor bevacizumab (marketed as Avastin ®) in a total of 42 patients with HER2 negative breast cancer. The data established significant biologic activity in the ME-344 treatment group as measured by Ki67 reductions (a measure of cell proliferation that is highly correlated with tumor response).

About Pracinostat
Pracinostat is an oral histone deacetylase (HDAC) inhibitor being evaluated in a pivotal Phase 3 global registration clinical trial for the treatment of adults with newly diagnosed AML who are unfit to receive intensive chemotherapy. Pracinostat is also being evaluated in a Phase 2 trial in patients with high or very high-risk myelodysplastic syndrome (MDS). In August 2016, we entered into an exclusive worldwide license, development, manufacturing and commercialization agreement with Helsinn Healthcare SA, a Swiss pharmaceutical corporation for pracinostat in AML, MDS and other potential indications.

About MEI Pharma
MEI Pharma, Inc. (Nasdaq: MEIP) is a late-stage pharmaceutical company focused on developing potential new therapies for cancer. Our portfolio of drug candidates contains four clinical-stage assets, including one candidate in an ongoing global registration trial and another candidate in a Phase 2 clinical trial which may support an accelerated approval marketing application with the U.S. Food and Drug Administration. Each of our pipeline candidates leverages a different mechanism of action with the objective of developing therapeutic options that are: (1) differentiated, (2) address unmet medical needs and (3) deliver improved benefit to patients

either as standalone treatments or in combination with other therapeutic options. For more information, please visit www.meipharma.com.

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.

View original content to download multimedia:http://www.prnewswire.com/news-releases/mei-pharma-announces-updated-clinical-data-from-me-401-phase-1b-study-in-patients-with-indolent-b-cell-malignancies-300930938.html

SOURCE MEI Pharma, Inc.

ORIGINAL NASDAQ-SMALL:MEIP PR Newswire