

MEI Pharma Announces New Clinical Data from First-in-Human Study of ME-401, A Next Generation Oral PI3K Delta Inhibitor

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SAN DIEGO, April 20, 2016 /PRNewswire/ -- MEI Pharma, Inc. (Nasdaq: MEIP), an oncology company focused on the clinical development of novel therapies for cancer, announced new clinical data from a first-in-human study of MEI Pharma's investigational drug candidate, ME-401, a next generation oral PI3K delta inhibitor. The data, presented today at the American Association for Cancer Research (AACR) Annual Meeting in New Orleans, suggest that ME-401 has an excellent pharmacokinetic (PK) and pharmacodynamic (PD) profile and the potential for an improved therapeutic window compared to other PI3K delta inhibitors, including the approved drug idelalisib (marketed as Zydelig[®]), with a half-life that supports once-daily dosing.

Logo - <http://photos.prnewswire.com/prnh/20140805/133834>

A copy of the poster presentation, entitled, "Clinical Pharmacokinetics and Pharmacodynamics of ME-401, an Oral, Potent, and Selective Inhibitor of Phosphatidylinositol 3-Kinase P110 δ , Following Single Ascending Administration to Healthy Volunteers," is now available at www.meipharma.com.

"PI3K delta is a class of drugs that has shown great promise in the treatment of B-cell malignancies, but with certain toxicities," said

Daniel P. Gold, Ph.D., President and Chief Executive Officer of MEI Pharma. "We believe this provides an opportunity for a next-generation drug that can produce therapeutic responses at a safe, effective dose. Thus far, ME-401 has demonstrated all of the attributes we had hoped to see, including linear PK and on-target activity at very low concentrations. Now the goal of our upcoming Phase Ib study will be to show a large therapeutic window in cancer patients. We expect to dose the first patient in this study by the end of June and look forward to providing an update later this year."

The Phase I study was designed to assess the safety and tolerability of ME-401 after single ascending oral doses in healthy volunteers to select the most appropriate dose for further clinical evaluation. The open label study enrolled a total of 15 healthy volunteers in 10, 30, 60, 90 and 150 mg dose levels. ME-401 was well tolerated at all dose levels. One subject experienced two treatment-emergent adverse events that were considered drug-related: pain and headache, graded as mild, after a 60 mg dose.

The first-in-human study of ME-401 was conducted using Quotient Clinical's Translational Pharmaceuticals[®] platform, which collected PK/PD data immediately after each dose and allowed for real-time decision making and manufacturing between dose groups.

About ME-401

ME-401 (formerly PWT143) is an orally bioavailable, potent and selective inhibitor of phosphatidylinositol 3 kinase (PI3K) delta, a molecular target that has been shown to play a critical role in the proliferation and survival of certain hematologic cancer cells. ME-401 has a distinct chemical structure from other PI3K delta inhibitors, including idelalisib. Data presented at the American Society of Hematology Annual Meeting in December 2012 demonstrated that ME-401 has superior pre-clinical activity compared to idelalisib. In March 2015, the U.S. Food and Drug Administration approved an Investigational New Drug application for ME-401 in B-cell malignancies. MEI Pharma expects to initiate a Phase Ib dose-escalation study of ME-401 in patients with relapsed/refractory chronic lymphocytic leukemia (CLL) or follicular non-Hodgkin's lymphoma (fNHL) in June 2016. The study is expected to enroll 42-84 patients at approximately 10 sites, with a starting dose of 60 mg.

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 lead drug candidate is Pracinostat, a potential best-in-class, oral HDAC inhibitor that showed positive results in a Phase II clinical study in combination with azacitidine (marketed as Vidaza[®]) in elderly patients with newly diagnosed acute myeloid leukemia (AML). The Company

expects to initiate a Phase III study of Pracinostat in the second half of 2016. MEI Pharma's portfolio of drug candidates also includes ME-401, a highly selective oral PI3K delta inhibitor that is expected to enter a Phase Ib study in patients with recurrent CLL or fNHL in June 2016. The Company is also developing ME-344, a novel mitochondrial inhibitor that is prepared to begin an investigator-sponsored study in combination with bevacizumab (marketed as Avastin[®]) in HER2-negative breast cancer. 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.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/mei-pharma-announces-new-clinical-data-from-first-in-human-study-of-me-401-a-next-generation-oral-pi3k-delta-inhibitor-300253984.html>

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