MEI Pharma's Pracinostat Receives Breakthrough Therapy Designation from FDA for Treatment in Combination with Azacitidine of Patients with Newly Diagnosed Acute Myeloid Leukemia Unfit for Intensive Chemotherapy

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SAN DIEGO, Aug. 1, 2016 /PRNewswire/ -- MEI Pharma, Inc. (Nasdaq: MEIP), an oncology company focused on the clinical development of novel therapies for cancer, announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for the investigational drug Pracinostat in combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are ≥75 years of age or unfit for intensive chemotherapy. In addition, agreement has been reached with the FDA on the Company's proposed Phase III study design.

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The Breakthrough Therapy Designation is supported by data from a Phase II study of Pracinostat plus azacitidine in elderly patients with newly diagnosed AML, not candidates for induction chemotherapy, which showed a median overall survival of 19.1 months and a complete response (CR) rate of 42% (21 of 50 patients). These data compare favorably to a Phase III study of azacitidine (AZA-AML-001[1]), which showed a median overall survival of 10.4 months with azacitidine alone and a CR rate of 19.5% in a similar patient population. The combination of Pracinostat and azacitidine was generally well tolerated, with no unexpected toxicities. The most common grade 3/4 treatment-emergent adverse events included febrile neutropenia, thrombocytopenia, anemia and fatigue.

"This designation speaks to both the serious unmet need for AML patients unfit to receive intensive chemotherapy and the promise of Pracinostat to address this need," said
Daniel P. Gold, Ph.D., President and Chief Executive Officer of MEI Pharma. "With this designation, the FDA recognizes that our preliminary clinical data demonstrate that Pracinostat may result in a substantial improvement in the lives of AML patients over available therapy. We have worked closely with the FDA to get to this point and now focus on executing our Phase III study and bringing Pracinostat to market as quickly and efficiently as possible."

According to the FDA, Breakthrough Therapy Designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. A Breakthrough Therapy Designation has all the benefits of the fast track program together with more intensive guidance on an efficient drug development program and an organizational commitment involving senior managers.

About Pracinostat

Pracinostat is a potent oral inhibitor of a group of enzymes called histone deacetylases, or HDACs. HDACs belong to a larger set of proteins collectively known as epigenetic regulators that can alter gene expression by chemically modifying DNA or its associated chromosomal proteins. Abnormal activity of these regulators is believed to play an important role in cancer and other diseases. Pracinostat has been tested in multiple Phase I and Phase II clinical studies in advanced hematologic diseases and solid tumor indications. The results of these studies suggest that Pracinostat has potential best-in-class pharmacokinetic properties when compared to other oral HDAC inhibitors, with side effects often associated with drugs of this class, including fatigue and myelosuppression.

About AML

Acute myeloid leukemia (also known as acute myelogenous leukemia) is the most common acute leukemia affecting adults, and its incidence is expected to continue to increase as the population ages. The American Cancer Society estimates about 20,830 new cases of AML per year in the U.S., with an average age of about 67

years. Treatment options for AML remain virtually unchanged for nearly 40 years. Front line treatment consists primarily of chemotherapy, while the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology recommend hypomethylating agents azacitidine or decitabine as low intensity treatment options for AML patients over the age of 60 who are unsuitable for induction therapy.

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 has been granted Breakthrough Therapy Designation from the FDA in combination with azacitidine for the treatment of patients with newly diagnosed AML who are ≥75 years of age or unfit for intensive chemotherapy. MEI Pharma's portfolio of drug candidates also includes ME-401, a highly selective oral PI3K delta inhibitor, and ME-344, a novel mitochondrial inhibitor. For more information, please visit www.meipharma.com.

MEI Pharma 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. 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.

[1] Dombret H et al. International phase 3 study of azacitidine vs conventional care regimens in older patients with newly diagnosed AML with >30% blasts. Blood. 2015 May 18.