MEI Pharma Announces Exclusive License Agreement with Presage Biosciences for Voruciclib, An Oral, Selective CDK Inhibitor

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SAN DIEGO and SEATTLE, Sept. 5, 2017 /PRNewswire/ -- MEI Pharma, Inc. (Nasdaq: MEIP), an oncology company focused on the clinical development of novel therapies for cancer, today announced that it has entered into a license agreement with Presage Biosciences, Inc. for voruciclib, a clinical-stage, oral and selective cyclin-dependent kinase (CDK) inhibitor. Under the terms of the agreement, MEI Pharma receives exclusive worldwide rights to develop, manufacture and commercialize voruciclib. In exchange, Presage will receive near-term payments of $2.9 million and additional potential payments of up to $181 million upon the achievement of certain development, regulatory and commercial milestones. Presage will also receive mid-single-digit tiered royalties on the net sales of any product successfully developed.

"We are very excited by this opportunity to add voruciclib to our growing pipeline of clinical-stage oncology drug candidates," said
Daniel P. Gold, Ph.D., President and Chief Executive Officer of MEI Pharma. "Voruciclib is a selective CDK inhibitor, a class of drugs that has recently demonstrated significant clinical and commercial value, and is differentiated by its potent inhibition of CDK9. This is an attractive asset that comes with an established clinical safety profile, along with compelling pre-clinical data showing suppression of MCL1, a known mechanism of resistance to BCL2 inhibitors, and synergy with the FDA-approved BCL2 inhibitor venetoclax. We believe this provides a clear and efficient clinical development path forward in combination with venetoclax. We appreciate that Presage put their trust in us to execute this plan and we are eager to get started."

Voruciclib (formerly P1446A) has been tested in more than 70 patients in multiple Phase 1 studies and has been associated with manageable side effects consistent with other drugs in its class, including nausea, vomiting and diarrhea. In pre-clinical studies, voruciclib alone induces cell death in multiple patient-derived chronic lymphocytic leukemia (CLL) samples[1]. In addition, voruciclib shows dose-dependent suppression of MCL1 at concentrations achievable with doses that appeared to be generally well tolerated in the Phase 1 studies. Studies have shown that MCL1 is an established resistance mechanism to the B-cell lymphoma 2 (BCL2) inhibitor venetoclax (marketed as Venclexta™)[2].

"Voruciclib is a promising drug candidate with the potential to overcome mechanisms of drug resistance and significantly improve patient outcomes," said
David Johnson, Chairman of Presage. "The management team at MEI Pharma has a proven track record in oncology therapeutic development and we believe they have the clinical, regulatory and CMC expertise to maximize the value of this asset. This transaction also enables us to focus our attention on identifying and advancing additional drug candidates and combinations using our powerful CIVO™ intratumoral microdosing platform."

There are currently two CDK inhibitors approved by the U.S. Food and Drug Administration, palbociclib (marketed as Ibrance®) and ribociclib (marketed as Kisqali®), both oral, selective CDK 4/6 inhibitors approved for the treatment of hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer in combination with hormonal therapy. A third, abemaciclib, was recently granted priority review by the FDA.

About Presage Biosciences

Presage Biosciences is an oncology company pioneering a new drug development approach to assess novel drugs and drug combinations directly in patient tumors with its patented CIVO™ intratumoral microdosing platform. The CIVO platform is a drug development tool intended to simultaneously assess responses to multiple drugs or drug combinations directly in a single solid tumor while still in a patient's body. Presage is using CIVO to develop a portfolio of promising oncology therapies to advance to the clinic. Presage also partners with oncology-focused pharmaceutical companies through strategic alliances to provide data to discover effective drug combinations. Presage is privately held and based in Seattle. For more information, visit

www.presagebio.com.

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 portfolio of drug candidates includes Pracinostat, an oral HDAC inhibitor that is partnered with Helsinn Healthcare, SA. Pracinostat has been granted Breakthrough Therapy Designation from the U.S. Food and Drug Administration for use in combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are unfit for intensive chemotherapy. Pracinostat is also being developed in combination with azacitidine for the treatment of patients with high and very high-risk myelodysplastic syndrome (MDS). MEI Pharma's clinical development pipeline also includes ME-401, a highly differentiated oral PI3K delta inhibitor currently in a Phase Ib study in patients with relapsed/refractory CLL or follicular lymphoma, and voruciclib, an oral, selective CDK inhibitor shown to suppress MCL1, a known mechanism of resistance to BCL2 inhibitors. The Company is also developing ME-344, a novel mitochondrial inhibitor currently in an investigator-sponsored study in combination with bevacizumab for the treatment of HER2-negative breast cancer. Pracinostat, ME-401, ME-344 and voruciclib are investigational agents and are not approved for use in the U.S. 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 ability to obtain sufficient funds to progress our clinical trials; risks relating to our collaboration agreement with Helsinn; changes in general economic conditions; costs and delays in the development and/or FDA approval, or the failure to obtain such approval, of our product candidates; our failure to satisfy foreign regulatory approval requirements; uncertainties or differences in interpretation in clinical study 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; our failure to successfully commercialize our product candidates; the effect of unfavorable pricing regulations, third-party reimbursement practices and health care regulations on our products; competitive factors; our reliance on third party clinical research organizations, suppliers and manufacturers; 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; 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; data security 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] PLoS One. 2015 Nov 25;10(11):e0143685
[2] Blood. 2016 Jun 23;127(25):3192-201

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