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MEI Pharma, KHK to develop and commercialize ME-401

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MEI is planning to initiate a Phase 2 study to evaluate patients with follicular lymphoma that is intended to support an accelerated approval marketing application with the U.S. Food and Drug Administration.

MEI Pharma, Inc. and Kyowa Hakko Kirin Co., Ltd. (KHK), have announced the execution of a license agreement granting KHK exclusive rights to develop and commercialize ME-401 in Japan. ME-401 is MEI's phosphatidylinositol 3-kinase (PI3K) delta inhibitor being developed by MEI for the treatment of patients with B-cell malignancies. MEI is planning to initiate a Phase 2 study to evaluate patients with follicular lymphoma that is intended to support an accelerated approval marketing application with the U.S. Food and Drug Administration.

Under the terms of the License Agreement, MEI will receive a $10 million upfront payment and is eligible to receive additional development and commercialization milestones totaling up to $87.5 million. MEI is also eligible to receive tiered double-digit royalties extending into the mid-teens. The agreement grants Kyowa Hakko Kirin exclusive rights to ME-401 to develop and commercialize ME-401 in Japan. The initial indication for development and regulatory approval under the agreement is relapsed or refractory follicular lymphoma.