Hepagene Therapeutics Initiates the RISE Study, a Phase IIa Clinical Trial of HPG1860 in Patients with NASH

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Hepagene Therapeutics, Inc, a clinical stage biopharmaceutical company focusing on innovative therapies for patients with liver diseases, today announced that it has screened the first patient in the USA for the RISE study, a Phase IIa clinical trial of HPG1860 in patients with non-alcoholic steatohepatitis (NASH). HPG1860, a non-bile acid, potent, selective and full farnesoid X receptor (FXR) agonist, is under development for the treatment of NASH and cholestatic hepatitis.

"We are thrilled to initiate the HPG1860 phase IIa RISE trial in NASH patients. We have recently reported positive phase I data of HPG1860 at the 2021 AASLD meeting. HPG1860 displayed a benign safety profile with robust target engagement through C4 reduction and FGF19 activation." Said Que Liu M.D. Ph.D., Chief Medical Officer of Hepagene. "We look forward to assessing safety and efficacy of HPG1860 in the RISE study and advancing HPG1860 as a potential therapy for NASH patients."

The RISE study is a 12-week, randomized, double-blind, placebo-controlled multi-center Phase IIa clinical trial evaluating the safety, tolerability, and efficacy in NASH patients who receive placebo or 3mg, 5mg and 8 mg doses of HPG1860. The trial will enroll 80 patients (20 patients/cohort) in the USA. Each study drug (placebo or HPG1860) will be given once daily by oral administration. The primary endpoint for the study is the safety and tolerability of HPG1860, while the secondary endpoint is to assess changes in liver fat content (LFC) after treatment with HPG1860. Other endpoints include changes in biomarkers and pharmacokinetic profile of HPG1860 in NASH patients.

"Initiating RISE phase IIa trial in NASH patients represents an important milestone for Hepagene." said Michael X. Xu Ph.D., CEO of Hepagene. "Our focus is on liver diseases, and we anticipate multiple novel mechanism compounds for both NASH and HBV entering clinical trials in the near future. At the same time, we are actively advancing pipelines utilizing in house developed novel siRNA delivery platform."

About HPG1860

HPG1860 is an investigational potent and selective full FXR agonist with a non-bile acid scaffold. Through regulation of gene expression of bile acids, FXR serves as a key controller of bile acid homeostasis. HPG1860 exhibited strong target engagement and benign safety profile in both preclinical research and Phase I clinical trial.