Seal Rock Therapeutics

Seal Rock Therapeutics Announces Initiation of Phase 1 Clinical Trial of ASK1 Inhibitor SRT-015 for NASH

June 23, 2021, Seattle, WA – Seal Rock Therapeutics, Inc., a clinical stage biotechnology company developing a platform of first-in-class and best-in-class therapeutic kinase inhibitors for treatment of severe fibrotic and inflammatory diseases with limited or no available therapies, today announced dosing of the first healthy volunteer in a Phase 1 clinical trial of SRT-015, a next-generation, liver-selective inhibitor of apoptosis signal-regulating kinase 1 (ASK1) for non-alcoholic steatohepatitis (NASH) and other liver diseases such as Alcoholic Hepatitis (AH) .

"We are thrilled to reach this significant milestone of beginning the first-in-human trial of SRT-015. This clinical study allows us to build upon the extremely promising safety and efficacy findings demonstrated in our preclinical studies, including gold-standard NASH models," said Neil McDonnell, Chief Executive Officer of Seal Rock Therapeutics.

This randomized, double-blind, placebo-controlled trial (Clinicaltrials.gov Identifier: #NCT04887038) will evaluate SRT-015 in up to 96 healthy volunteers to assess safety, tolerability and pharmacokinetics. The trial will be conducted in three parts. The first part will evaluate single ascending doses of SRT-015 or placebo. The second part will evaluate repeat ascending doses of SRT-015 or placebo. The third part will evaluate for possible food effect on treatment.

Completion of these Phase 1 studies, anticipated by the end of this year, will be followed by a Ph 2a "proof of clinical activity" trial in presumed NASH patients where a suite of non-invasive biomarkers will allow an early clinical assessment of SRT-015's unique trimodal mechanism of action and it's direct anti-fibrotic, anti-inflammatory, and cell protecting activities.

Previously reported data presented at the Annual Meeting of the American Association for the Study of Liver Diseases (The Liver Meeting® 2020) demonstrated superior pharmacological properties and efficacy of SRT-015 compared to other ASK1 inhibitors, including Gilead Sciences' ASK1 inhibitor selonsertib, which was found to be no more efficacious than placebo in two clinical trials in NASH. Data presented by Seal Rock showed substantial improvement of SRT-015-treated animals in the gold standard DIO-NASH mouse model. In contrast, selonsertib, at a clinically relevant dose, showed no efficacy (Link to Poster). Additional data showed consistent inhibition of inflammation, fibrosis, and apoptosis with SRT-015 that was not observed with other ASK1 inhibitors, including selonsertib (Link to poster).

About SRT-015

SRT-015 is the next generation inhibitor of ASK1, developed internally by Seal Rock Therapeutics with the goal to overcome liabilities that limited the clinical efficacy of selonsertib, the first ASK1 inhibitor to reach clinical development. Optimized to

overcome such liabilities including a liver-preferential distribution, the excellent preclinical safety profile of SRT-015 positions it as a first-in-class product candidate for NASH and also AH.

About Seal Rock Therapeutics

Led by an experienced management team with a long track record of successful drug discovery, development and commercialization, Seal Rock Therapeutics is a privately held, clinical stage company based in Seattle, WA focused on developing a platform of well-validated first-in or best-in-class kinase inhibitors. Its lead clinical indication is NASH while the company's R&D pipeline offers additional compelling high unmet need disease opportunities, including alcoholic hepatitis, chronic kidney disease, heart failure and Parkinson's disease. Seal Rock is currently raising Series A funding to complete all phase 2-readiness activities for SRT-015 and continuing advancement of its other pipeline products. For more information, please visit www.sealrocktx.com

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