Sagimet Biosciences Doses First Patient in FASCINATE-2 Phase 2b Trial in NASH Patients with Moderate to Advanced Fibrosis

08/16/2021 at 8:30 AM EDT

SAN MATEO, Calif., Aug. 16, 2021 /PRNewswire/ -- Sagimet Biosciences, a clinical-stage biotechnology company focused on developing a portfolio of internally-discovered, selective fatty acid synthase (FASN) inhibitors, announced today that clinicians recently dosed the first patient with nonalcoholic steatohepatitis (NASH) in its FASCINATE-2 Phase 2b clinical trial.

Eduardo Bruno Martins, MD, DPhil, Sagimet's chief medical officer, said, "The initiation of the Phase 2 clinical trial marks an important milestone for the evaluation of our lead candidate TVB-2640. Building from the data seen in our FASCINATE-1 Phase 2a clinical trial, we believe TVB-2640 has the potential to make a meaningful difference for patients with NASH, the most aggressive form of nonalcoholic fatty liver disease (NAFLD), for which there are no FDA-approved therapies."

"After the robust and encouraging results from the Phase 2a study of TVB-2640, we are very excited to be enrolling individuals with NASH in the Phase 2b trial," stated said Rohit Loomba, MD, MHSc, director, NAFLD Research Center, University of California San Diego, and coordinating investigator of the study. "The current standard of care for patients with NASH is suboptimal, and we anticipate the data from FASCINATE-2 will support advancing TVB-2640 into late-stage clinical trials."

Stephen A. Harrison, MD, medical director for Pinnacle Clinical Research, San Antonio, Texas, and visiting professor of Hepatology, University of Oxford, who is an investigator in this trial, noted, "The well-designed FASCINATE-2 study will generate important biomarker and imaging data to support the global research efforts to replace liver biopsy, the current gold-standard, with non-invasive tests that may be useful to diagnose and follow patients in both routine care and clinical trials."

About the FASCINATE-2 Clinical Trial
FASCINATE-2 is a randomized, double-blind, placebo-controlled Phase 2b clinical trial of approximately 330 NASH patients with moderate to advanced fibrosis (F2-F3). This trial will evaluate the impact of oral, once-daily doses of TVB-2640 for 52 weeks as assessed by biopsy. Patients will initially be randomized to receive placebo or 50mg of TVB-2640. A 75mg dose level of TVB-2640 is planned to be added following an ongoing open-label cohort in the FASCINATE-1 Phase 2a clinical trial expected to complete in the fourth quarter of 2021.

Primary efficacy endpoints in FASCINATE-2 are:

1. ≥ 2-point improvement in NAS (Nonalcoholic fatty liver disease (NAFLD) Activity Score) that results from reduction of necro-inflammation (inflammation or ballooning), or
2. improvement in fibrosis.

The U.S. Food and Drug Administration (FDA) accepts these two endpoints for Phase 2b studies in NASH. Liver biopsy data will also be evaluated to assess NASH resolution without worsening of fibrosis and/or improvement in fibrosis without worsening of NASH, both of which are endpoints accepted by the FDA for accelerated approval following Phase 3 studies. The study will also measure liver fat, assessed by MRI-PDFF, and other serum biomarkers of inflammation, fibrosis, and liver injury in a portion of patients at 26 weeks of treatment in an interim analysis. Sagimet anticipates sharing interim results in the second half of 2022 and top-line liver biopsy results in 2023.

About TVB-2640
Sagimet is developing TVB-2640 as an oral, once-daily selective FASN inhibitor for the treatment of NASH, an aggressive form of nonalcoholic fatty liver disease (NAFLD). It is the company's lead drug candidate selected from more than 1,200 compounds in Sagimet's library of FASN inhibitors. TVB-2640 has been studied in over 300 subjects, including healthy volunteers and patients with NASH or cancer. In the FASCINATE-1 Phase 2a clinical trial, TVB-2640 demonstrated statistically significant improvements across steatosis, inflammation/lipotoxicity, fibrosis and metabolic biomarkers important in NASH, and was well-tolerated. Sagimet received FDA Fast Track designation for TVB-2640 for the treatment of NASH in March 2021.

About Sagimet
Sagimet Biosciences Inc. is a clinical-stage biopharmaceutical company focused on developing a portfolio of internally-discovered, selective FASN inhibitors for treatment in several therapeutic areas of high unmet medical need including liver disease and specific cancers targeting dysfunctional metabolic pathways. The company has unique expertise in FASN biology and has created a pipeline of proprietary FASN inhibitors. www.sagimet.com.

SOURCE Sagimet Biosciences