



Sagimet to Present Data from Phase 2 FASCINATE-1 Trial of TVB-2640 in NASH at AASLD's The Liver Meeting 2021

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SAN MATEO, Calif., Oct. 4, 2021 /PRNewswire/ -- Sagimet Biosciences, a clinical-stage biotechnology company, announced today that consolidated results from its Phase 2 FASCINATE-1 trial of TVB-2640 in patients with nonalcoholic steatohepatitis (NASH) in the U.S. and China will be shared at The Liver Meeting 2021 of the American Association for the Study of Liver Diseases (AASLD) to be held virtually November 12-15, 2021. Rohit Loomba, MD, MHS, Director, NAFLD Research Center, University of California San Diego, and Coordinating Principal Investigator of the study, will present the results in an oral presentation entitled "Novel, first-in-class, fatty acid synthase (FASN) inhibitor TVB-2640 demonstrates robust clinical efficacy and safety in a global phase 2 randomized placebo-controlled NASH trial (FASCINATE-1) conducted in the U.S. and China." Details about the Phase 2 study [NCT03938246] can be found at [ClinicalTrials.gov](https://clinicaltrials.gov).

In this randomized, placebo-controlled trial, TVB-2640, a novel, first-in-class, FASN inhibitor, significantly decreased liver fat and serum biomarkers of liver injury, fibrosis and inflammation with an excellent safety and tolerability profile.

"I am encouraged that despite different patient populations, the readouts were consistent between U.S. and Chinese cohorts including reduction in liver fat, measured by MRI-PDFF, which has been shown in multiple studies to correlate with histological response. Additional biomarker analyses showed improvements among several pathways in NASH and identified a metabolite signature predicting response to therapy," said Dr. Loomba. "In addition, we will share results from a small, open label cohort evaluating the impact of a 75 mg dose. All these data give us confidence that we have chosen the appropriate dose of TVB-2640 to assess its efficacy relative to placebo on liver histology in the larger, ongoing FASCINATE-2 Phase 2b liver biopsy-based clinical trial in patients with NASH who have stage 2 or 3 fibrosis."

Oral presentation details are as follows:

Abstract Title: Novel, first-in-class, fatty acid synthase (FASN) inhibitor TVB-2640 demonstrates robust clinical efficacy and safety in a global phase 2 randomized placebo-controlled NASH trial (FASCINATE-1) conducted in the U.S. and China

Abstract number: 141

Presenting Author: Dr. Rohit Loomba

Session Title: Parallel 21: NAFLD and NASH: Clinical Trials of Novel Therapeutics

Session Broadcast Date and Time: Sunday, November 14, 2021, 6:30 – 8:00 p.m. ET

About NASH

NASH is an aggressive form of non-alcoholic fatty liver disease, a condition where an excessive amount of fat (known as steatosis) accumulates in the liver, and for which no treatments have been approved in the United States or European Union. In the United States, the prevalence of NASH was estimated to total about 17.3 million people in 2016, of which about 5.7 million have NASH with advanced fibrosis (F2-F3), and the disease continues to be a vast and growing global healthcare burden. NASH is currently the leading cause of liver transplantation in women and is expected to become the leading cause in men, which is currently alcoholic liver disease.

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). In patients with NASH, increased FASN-mediated palmitate synthesis in the liver is the source of three key drivers of the disease: excess accumulation of liver fat, inflammation and fibrosis. TVB-2640 has been studied in over 300 subjects, including healthy volunteers and patients with NASH or cancer. In the global FASCINATE-1 Phase 2a clinical trial, TVB-2640 demonstrated statistically significant improvements across steatosis, inflammation/lipototoxicity, fibrosis and metabolic biomarkers important in NASH, and was well-tolerated. Based upon the strength of these data, Sagimet initiated the FASCINATE-2 Phase 2b biopsy trial in August 2021. TVB-2640 received FDA Fast Track designation for the treatment of NASH in March 2021.

About Sagimet

Sagimet Biosciences is a clinical-stage biopharmaceutical company focused on developing novel therapeutics to treat important diseases such as the liver disease NASH and specific cancers, with focus on targeting dysfunctional metabolic pathways. The company has unique expertise in FASN biology and has created a pipeline of proprietary FASN inhibitors. For more information, please visit www.sagimet.com.

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