Sagimet to Present Data from Phase 2 FASCINATE-1 Trial of TVB-2640 in NASH at AASLD's The Liver Meeting Digital Experience™ 2020

10/06/2020 at 9:00 AM EDT

SAN MATEO, Calif., Oct. 6, 2020 /PRNewswire/ -- Sagimet Biosciences, a clinical-stage biotechnology company, announced today that new results from its Phase 2 FASCINATE-1 trial of TVB-2640 in nonalcoholic steatohepatitis (NASH) will be shared in an oral presentation at The Liver Meeting Digital Experience™ 2020 of the American Association for the Study of Liver Diseases (AASLD) to be held November 13 - 16. In this randomized, placebo-controlled trial, a novel, first-in-class, FASN inhibitor, TVB-2640 significantly decreased liver fat and serum biomarkers of liver injury, fibrosis and inflammation with an excellent safety profile and tolerability.

Rohit Loomba, M.D., M.H.Sc., 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 clinically significant reduction in liver fat by MRI-PDFF, and ALT in NASH: a Phase 2 randomized placebo-controlled trial (FASCINATE-1)."

"The potent liver fat reduction, measured by an advanced MRI method called MRI-PDFF, combined with the additional biomarkers demonstrates that TVB-2640 is positively impacting multiple pathological mechanisms causing liver damage in NASH patients," said Dr. Loomba. "MRI-PDFF response is an accurate and reliable biomarker that correlates with histological response in NASH and also has been shown to predict NASH resolution. The treatment response seen in TVB-2640 treated subjects in this study along with the additional biomarkers increases our confidence to embark upon a larger Phase 2b liver biopsy based clinical trial in NASH patients with stage 2-3 fibrosis."

Additional information about the Phase 2 study [NCT03938246] can be found at ClinicalTrials.gov.

Presentation details are as follows:

Abstract Title: Novel, first-in-class, fatty acid synthase (FASN) inhibitor, TVB-2640 demonstrates clinically significant reduction in liver fat by MRI-PDFF, and ALT in NASH: a phase 2 randomized placebo-controlled trial (FASCINATE-1)
Abstract number: 67
Presenting Author: Dr. Rohit Loomba
Session Title: Parallel 9: NAFLD and NASH: Therapeutics
Session Broadcast Date and Time: Sunday, November 15, 2020, 10:30 AM ET

About TVB-2640

TVB-2640 is an orally bioavailable, first-in-class FASN inhibitor. FASN is a key enzyme in the de novo lipogenesis (DNL) pathway that is responsible for the synthesis of excess fat and activation of fibrogenic and inflammatory mechanisms in the liver of patients with NASH. Sagimet's approach targets these key drivers of NASH. The company announced in June 2020 initial results of a randomized, placebo-controlled Phase 2 trial, FASCINATE-1, which evaluated the impact of TVB-2640 in 99 NASH patients in the United States. The company, along with partner Ascletis Pharma Inc., is currently enrolling an additional 25-30 NASH patients in China. Based upon the strength of this Phase 2 imaging and biomarker data, Sagimet expects to initiate a Phase 2b biopsy trial in 1H 2021. The company has demonstrated in preclinical models that blocking FASN not only reduces liver fat, but directly reduces fibrosis and inflammation– addressing three major drivers of NASH.

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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