New Data from Sagimet's Phase 2 FASCINATE-1 Clinical Trial Demonstrate TVB-2640's Positive Effect Across Patients with NASH in the U.S. and China

11/12/2021 at 8:00 AM EST

FOR IMMEDIATE RELEASE

- *Rohit Loomba to share consolidated results on November 14 in an oral presentation at American Association for the Study of Liver Diseases' (AASLD) The Liver Meeting 2021*
- *Data from the global Phase 2 trial showed TVB-2640's positive efficacy across diverse populations of patients in the U.S. and China*
- *Confirmed 50 mg as optimal dose based on potent efficacy and excellent safety profile*
- *Identified panel of blood metabolites that predicts changes in liver fat*

San Mateo, California, November 12, 2021 – Sagimet Biosciences, a clinical-stage biotechnology company, announced today that Rohit Loomba, MD, MHSc, Director, NAFLD Research Center, University of California San Diego, will give an oral presentation on consolidated results from the Phase 2 FASCINATE-1 trial of Sagimet's lead clinical candidate TVB-2640 in patients in the U.S. and China with nonalcoholic steatohepatitis (NASH) on November 14 at The Liver Meeting 2021. The presentation is 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."

Dr. Loomba, who serves as the trial's Coordinating Principal Investigator, noted, "We are encouraged that despite different patient populations, the results were consistent between U.S. and Chinese cohorts including reduction in liver fat, which has been shown in multiple studies to correlate with histological response. Through the Phase 2 FASCINATE-1 clinical trial, we conducted a robust program to determine the optimal dose of TVB-2640. We now have confidence that 50 mg is the appropriate dose of TVB-2640 to assess in our larger, ongoing Phase 2b FASCINATE-2 liver biopsy-based clinical trial."

"Identifying patients that respond to your drug is a goal for both clinical trials and commercial programs. We have identified a panel of blood metabolites that predicts changes in liver fat in patients treated with TVB-2640," said George Kemble, PhD, Sagimet Chief Executive Officer. "We will continue to refine the panel to establish a correlation with histological endpoints and outcomes."

Among the key findings from the presentation are:

- TVB-2640 demonstrated consistent improvement across key NASH biomarkers, including decreased liver fat and serum biomarkers of liver injury, fibrosis and inflammation, with an excellent safety and tolerability profile.

	Location	Subjects (n)	Arms	Relative liver fat change (mean)
Cohort 1 (RCT)	US	99	25 mg 50 mg placebo	-9.6% -28.1% +4.5%
Cohort 2 (RCT)	China	30	50 mg placebo	-28.2% -11.1%
Cohort 3 (open label)	US	13	75 mg	-35.0%

- At the optimal dose of 50 mg, TVB-2640 demonstrated a combined 28% relative reduction in liver fat, representing a 56% responder rate across U.S. and China cohorts. TVB-2640 also improved levels of alanine aminotransferase (ALT) by -24% and low-density lipoprotein (LDL) cholesterol by -4%. These decreases indicate improved liver function and metabolic health.
- Across all populations and doses, all drug-related adverse events (AEs) were Grade 1/2 and reversible. At the 75 mg dose level, clinicians observed an increased rate of on-target AEs.
- Metabolomic analysis on baseline samples from the 50 mg US cohort revealed a novel panel of predictive biomarkers that correlated to liver fat changes in patients treated with TVB-2640. This panel includes bile acid, amino acid and lipid derivatives.

About the FASCINATE-1 trial
FASCINATE-1 is a Phase 2 clinical trial designed to evaluate the safety and efficacy of TVB-2640 in participants with NASH across three cohorts. Cohort 1 (U.S.) and cohort 2 (China) are part of a multi-center, randomized, single-blind, placebo-controlled trial, where participants received either TVB-2640 or placebo. In cohort 3, participants received only open-label 75 mg of TVB-2640. Following enrollment, participants in all cohorts

completed a 12-week treatment period. Additional details about FASCINATE-1 [NCT03938246] can be found at ClinicalTrials.gov.

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 2 clinical trial, TVB-2640 demonstrated statistically significant improvements across steatosis, inflammation/lipotoxicity, 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.

###

Media Contact
Jamie Lacey-Moreira, PressComm PR
+1 410-299-3310
jamielacey@presscommpr.com