Sagimet Biosciences Announces Presentation of Additional Phase 2 Data on Denifanstat Identifying a Predictive Metabolic Signature in NASH Patients at EASL's International Liver Congress (ILC) 2022

06/08/2022 at 8:00 AM EDT

San Mateo, California, June 8, 2022 – Sagimet Biosciences, a clinical-stage biotechnology company focused on developing a portfolio of internally discovered, selective fatty acid synthase (FASN) inhibitors, announced today that it will present additional Phase 2 data on denifanstat (formerly TVB-2640) identifying a predictive 'metabolic signature' in nonalcoholic steatohepatitis (NASH) patients. Denifanstat, an oral, selective FASN inhibitor, is the company's lead product candidate for the potential treatment of nonalcoholic steatohepatitis. The data will be shared in a poster session at the International Liver Congress 2022, the annual meeting of the European Association for the Study of the Liver (EASL), being held in London and online June 22-26.

Poster presentation details are as follows:

Abstract #: FRI045
Title: A baseline signature of metabolites involving the gut-liver axis predicts MRI-PDFF response to FASN inhibitor TVB-2640: results from the FASCINATE-1 study
Presenter: Rohit Loomba, MD, MHSc, Director, NAFLD Research Center, University of California, San Diego
Poster session: NAFLD: Diagnostics and non-invasive assessment
Date and time: June 24, 2022, 09:00 – 18:00 GMT
https://easl.eu/event/international-liver-congress-2022/

In the analysis, Sagimet profiled baseline blood samples from patients in the Phase 2 FASCINATE-1 trial and identified a 6-metabolite signature for patients most likely to respond to denifanstat treatment, as measured by liver fat changes on magnetic resonance imaging derived proton density fat fraction (MRI-PDFF).

The FASCINATE-1 Phase 2 clinical trial evaluated the safety and efficacy of denifanstat in NASH patients across three cohorts in the U.S. and China. The trial met both primary endpoints of efficacy and safety, including a combined 28% relative reduction in liver fat at the optimal dose of 50 mg, representing a 56% responder rate, as well as statistically significant improvements in inflammation/lipotoxicity, fibrosis and metabolic biomarkers. The drug was well-tolerated across all populations and doses, with all drug-related adverse events (AEs) grade 1/2 and reversible. Results were initially published in *Gastroenterology* in July 2021.

Denifanstat is currently being evaluated in a Phase 2b liver biopsy-based clinical trial ("FASCINATE-2") in NASH patients with moderate-to-severe fibrosis (Stage F2 or F3). An interim analysis of data is expected by the end of 2022. Additional information about FASCINATE-2 [NCT04906421] can be found at ClinicalTrials.gov.

About Denifanstat
Denifanstat is a wholly owned, oral, selective inhibitor of FASN, a key enzyme involved in the production of saturated fatty acids in the liver and other organs. FASN is also the only enzyme in the human body capable of converting metabolized sugars into palmitate. In patients with NASH, increased FASN-mediated palmitate synthesis in the liver is the source of three major drivers of the disease: excess accumulation of liver fat, inflammation and fibrosis.

About Sagimet
Sagimet Biosciences Inc. is a clinical-stage biopharmaceutical company focused on developing a portfolio of internally discovered, selective FASN inhibitors for the treatment of 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.

Contact:
Susan Kinkead
susan@kinkeadcomm.com
415-509-3610