



Sagimet Biosciences to Present Additional Biomarker Phase 2 Data on Denifanstat (TVB-2640) in NASH Patients at DDW 2022

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Company Adopts Denifanstat as Non-Proprietary Name for TVB-2640

San Mateo, California, May 4, 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 expanded clinical biomarker data on denifanstat (formerly known as TVB-2640), its lead product candidate for the potential treatment for nonalcoholic steatohepatitis (NASH). The data will be shared via a Poster of Distinction at [Digestive Disease Week](#) (DDW) 2022, which will be held virtually and in San Diego from May 21-24, 2022.

“I am looking forward to presenting data from the FASCINATE-1 Phase 2 clinical trial with denifanstat, a first-in-class FASN inhibitor for the treatment of NASH, showing a positive impact on circulating fatty acids that have been associated with benefit in cardiovascular disease,” said Stephen Harrison, MD, medical director, Pinnacle Clinical Research. “Continued assessment of predictive biomarkers in ongoing studies should enhance the ability to identify patients who will most benefit from treatment.”

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. As presented at The Liver Meeting of the American Association for the Study of Liver Diseases (AASLD) in November 2021, 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/lipototoxicity, 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.

Based on the strength of those results, the company launched a Phase 2b liver biopsy-based clinical trial, FASCINATE-2, in NASH patients with moderate to severe fibrosis (Stage 2 or 3), which began enrolling patients in August 2021. An interim analysis of data is expected by the end of 2022. Additional information about FASCINATE-2 [NCT04906421] can be found at [ClinicalTrials.gov](#).

Poster presentation details are as follows:

Title: Novel, first-in-class, fatty acid synthase (FASN) inhibitor TVB-2640: efficacy, safety, and biomarker results from a global phase 2 randomized placebo-controlled NASH trial, FASCINATE-1.

Presenter: Stephen A. Harrison, MD, medical director, Pinnacle Clinical Research

Poster Session: NAFLD and NASH Therapeutics: Pharmacologic and Other, Session 9215, Poster #Tu1320

Date/Time: May 24, 2022, 12:30 PM to 1:30 PM PDT

About Denifanstat

Sagimet recently designated denifanstat as the non-proprietary name for TVB-2640, based on guidance from the World Health Organization's International Nonproprietary Names expert group and the United States Adopted Name (USAN) Council. The expert group created a new suffix '-fanstat' for designation of this first-in-class FASN inhibitor, TVB-2640, and future FASN inhibitors. 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.

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