Sagimet Biosciences Announces Positive Interim Phase 2b Clinical Trial Data with Denifanstat (TVB-2640), a First-in-Class Fatty Acid Synthase Inhibitor, in Moderate-to-Severe Non-alcoholic Steatohepatitis (NASH) Patients

11/03/2022 at 8:00 AM EDT

Denifanstat Showed Statistically Significant Improvements Across Key Disease Markers in FASCINATE-2 Study After 26 Weeks of Treatment

Highlights to be Included in Oral Presentation Session at The Liver Meeting on Sunday, November 6th at 2 pm EST

San Mateo, California, November 3, 2022 – Sagimet Biosciences, a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic pathways, announced today positive interim data from its Phase 2b clinical trial (FASCINATE-2) with denifanstat, a fatty acid synthase (FASN) inhibitor, in non-alcoholic steatohepatitis patients. Data showed statistically significant improvements across key markers of NASH, reinforcing results observed in earlier studies, including statistically significant reductions in markers of liver fat, inflammation and fibrosis.

"These denifanstat non-invasive data in biopsy-confirmed NASH patients are very encouraging and among the strongest results to date for an oral treatment, including significant improvements in liver fat, markers of fibrosis and inflammation, and a favorable safety profile," said Stephen Harrison, M.D., FAASLD, visiting professor, University of Oxford, and medical director of Pinnacle Research Center. Dr. Harrison will include interim data highlights in an oral presentation at The Liver Meeting of the American Association for the Study of Liver Diseases (AASLD), being held November 4-8 in Washington, DC.

Presentation details:

Abstract Title (#99): Correlation Between AI-based Digital Pathology and Non-invasive Tests (NITS) of NASH Fibrosis Stage: Baseline Data from the FASCINATE-2 Phase 2B Clinical Study of Denifanstat in Patients with F2/F3 NASH
Session: Nash Therapeutics & Omics
Date: Sunday, November 6
Time: Session 2-3:30 pm EST; Dr. Harrison presentation at 3 pm EST
Location: Room 146, Walter E. Washington Convention Center

The Phase 2b FASCINATE-2 study is a randomized, double-blind, placebo-controlled trial of 168 NASH patients with moderate-to-severe fibrosis (Stage F2 or F3), as confirmed by liver biopsy. In the planned interim analysis, 52 patients were evaluated after 26 weeks of treatment with either 50 mg denifanstat or placebo.

Improvement across biomarkers after 26 weeks of treatment:

	Denifanstat 50 mg (n=30)	**Placebo (n=22)**	**P-value vs placebo**
Relative reduction in liver fat	– 34.1%	– 1.5%	p<0.002
≥30% reduction of liver fat (responder rate)	67%	18%	p<0.002
ALT (U/L)	– 16.5	– 4.0	p<0.05
Enhanced liver fibrosis (ELF) score*	– 0.41	– 0.01	p<0.05
LDL cholesterol (mg/dL)	-12.4	0.0	p<0.05

** based upon available data (denifanstat n=20, placebo=15)*

There were no treatment-related serious adverse events, with the majority of adverse events mild to moderate in nature (Grade 1 and 2). Additional interim data are expected in early 2023.

"We are pleased to report such robust and durable results across a range of biomarkers in the interim analysis of our FASCINATE-2 study," said David Happel, chief executive officer, Sagimet. "These data underscore the potential of denifanstat to treat a broad NASH patient population and reinforce our commitment to addressing this emerging health epidemic. We look forward to the complete trial readout with biopsy data in the fourth quarter of 2023, and subsequent launch of a pivotal Phase 3 trial."

The FASCINATE-2 study, which was fully enrolled in August 2022, is on track for final analysis of the total patient population at 52 weeks as assessed by biopsy by the end of 2023. Primary efficacy endpoints include histological (liver biopsy) improvement in NAFLD activity score (NAS) without worsening of fibrosis OR resolution of steatohepatitis without worsening of fibrosis; as well as secondary endpoints measuring biomarkers of inflammation, fibrosis and liver injury.

About Denifanstat
Denifanstat is an oral, selective, first-in-class fatty acid synthase inhibitor that directly targets the primary drivers of NASH by reducing excess liver fat (steatosis), decreasing inflammation and blunting fibrosis. In addition to the FASCINATE-2 trial, denifanstat is being tested in a Phase 3 clinical trial for recurrent glioblastoma and a Phase 2 study for moderate to severe acne, both in China under exclusive license by Ascletis Pharma Inc. through its

subsidiaries.

About Sagimet
Sagimet is a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic pathways in diseases such as nonalcoholic steatohepatitis, certain cancers and acne. Sagimet compounds are designed to inhibit fatty acid synthase, an enzyme involved in the production of fatty acids normally used for energy storage. In NASH, the activity of FASN enzyme is upregulated, resulting in excess accumulation of liver fat, inflammation and fibrosis. FASN dysregulation has also been implicated in multiple cancers with lipogenic phenotypes.

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