



Sagimet Biosciences Presents Two Denifanstat Posters at AASLD—The Liver Meeting® 2025

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A secondary analysis of FASCINATE-2 Phase 2 trial demonstrated denifanstat improved fibrosis, inflammation and steatosis in advanced qF4 MASH patients as measured by artificial intelligence (AI) digital pathology

In a second poster, spatial computational histology relying on baseline fibrosis features was used to predict response to denifanstat

SAN MATEO, Calif., Nov. 10, 2025 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic and fibrotic pathways, today announced the presentation of two posters at the American Association for the Study of Liver Disease (AASLD) - The Liver Meeting® 2025, taking place November 7-11, 2025 in Washington, DC:

- A Poster of Distinction titled “*Denifanstat elicited a significant ≥ 2 -stage improvement in fibrosis in F3 MASH patients, and improved liver fibrosis and biomarkers in qFibrosis stage 4 MASH patients: secondary analysis of phase 2b FASCINATE-2 trial*” was presented by Rohit Loomba, M.D., M. H.Sc., Professor of Medicine, Chief, Division of Gastroenterology and Hepatology, and Director, MASLD Research Center, University of California San Diego, and primary investigator of the FASCINATE-2 trial
- “*Spatial Computational Histology Stratified Denifanstat Responders in the Phase 2b FASCINATE-2 MASH Trial,*” was presented by Vlad Ratziu, M.D., Ph.D., Professor of Hepatology, Sorbonne Université and the Hôpital Pitié-Salpêtrière Medical School

“Our presentations at AASLD this year demonstrate denifanstat’s impressive ability to address advanced fibrosis in MASH patients,” said David Happel, Chief Executive Officer of Sagimet. “A secondary analysis of denifanstat treatment in MASH patients with advanced liver fibrosis stage defined as qF4 by AI-based digital pathology reproduced and further detailed denifanstat’s anti-fibrotic and anti-inflammatory benefits.”

The first poster, “*Denifanstat elicited a significant ≥ 2 -stage improvement in fibrosis in F3 MASH patients, and improved liver fibrosis and biomarkers in qFibrosis stage 4 MASH patients: secondary analysis of phase 2b FASCINATE-2 trial,*” was presented by Dr. Loomba. In a secondary analysis of the Phase 2b FASCINATE-2 clinical trial, AI-based digital pathology was used to identify a subpopulation of MASH patients with advanced fibrosis, defined as qFibrosis stage 4 (qF4), and to explore liver histology improvement with denifanstat in this subset. In this qF4 subgroup, denifanstat treatment improved fibrosis by 1-2 qFibrosis stages with a response rate for ≥ 1 qFibrosis stage regression of 85% (11/13) for denifanstat vs. 33% (1/3) in placebo-treated patients.

Additional findings:

- In F3 MASH patients, using clinical research network (CRN) scoring, the response rate for fibrosis improvement by ≥ 2 stages without worsening of MASH was 34% (16/47) for denifanstat, vs. 4% (1/23) in placebo-treated patients (p value = 0.0065).
- In qF4 MASH patients, using MASH CRN scoring, the response rate for fibrosis improvement by ≥ 1 stage was 39% (5/13) for denifanstat, of which 4/5 patients had 2 stages of improvement, vs. 0% (0/3) in placebo-treated patients.
- Several noninvasive biomarkers were decreased by denifanstat in qF4 patients (mean change at week 52 from baseline), in particular:
 - FibroScan (kPa): -29% vs. Placebo +26%
 - FAST score: denifanstat -45% vs. placebo +9%
 - MRI-PDFF (% liver fat): denifanstat -34% vs. placebo +14%
 - ALT: denifanstat -43% vs. placebo +5%
 - AST: denifanstat -37% vs. placebo -1%
 - ELF: denifanstat -0.3 vs. placebo +0.02

The second poster, “*Spatial Computational Histology Stratified Denifanstat Responders in the Phase 2b FASCINATE-2 MASH Trial,*” was presented by Dr. Ratziu. In this analysis, spatial computational histology relying on baseline fibrosis features was used to predict response to denifanstat. Quantitative single-fiber traits and clustering revealed fibrosis phenotypes that predicted denifanstat response, supporting that computational pathology could be leveraged for response stratification.

About Sagimet Biosciences

Sagimet is a clinical-stage biopharmaceutical company developing novel FASN inhibitors designed to target dysfunctional metabolic and fibrotic pathways in conditions resulting from the overproduction of the fatty acid, palmitate. Denifanstat, an oral, once-daily pill, met all primary endpoints in its Phase 2b FASCINATE-2 clinical trial in MASH as well as all primary and secondary endpoints in Sagimet’s license partner for China’s Phase 3 clinical trial in moderate-to-severe acne. A combination of denifanstat and resmetirom is currently being tested in a Phase 1 PK clinical trial and is planned to be developed for cirrhotic patients living with F4-stage MASH. TVB-3567, a second oral FASN inhibitor which is planned to be developed for acne, is currently being tested in a Phase 1 first-in-human clinical trial. For additional information about Sagimet, please visit www.sagimet.com.

About MASH

Metabolic dysfunction-associated steatohepatitis (MASH) is a progressive and severe liver disease which is estimated to impact more than 265 million people worldwide. MASH is characterized by the build-up of fat in the liver and various degrees of inflammation and fibrosis along with systemic metabolic changes including dyslipidemia (increased fat levels in blood) and insulin resistance. Patients with moderate to severe disease who have advanced fibrosis (F3) or cirrhosis (F4) have the highest risk of liver-related outcomes such as decompensation, hepatocellular carcinoma, and liver transplantation. There are few approved treatments for non-cirrhotic MASH (stages F1, F2 and F3 fibrosis) and no approved treatments for MASH cirrhosis (F4).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of, and made pursuant to the safe harbor provisions of, The Private Securities Litigation Reform Act of 1995. All statements contained in this press release, other than statements of historical facts or statements that relate to present facts or current conditions, including but not limited to, statements regarding: the expected timing of the presentation of data from ongoing clinical trials, Sagimet's clinical development plans and related anticipated development milestones, Sagimet's cash and financial resources and expected cash runway are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause Sagimet's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, these statements can be identified by terms such as "may," "might," "will," "should," "expect," "plan," "aim," "seek," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "forecast," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this press release are only predictions. Sagimet has based these forward-looking statements largely on its current expectations and projections about future events and financial trends that Sagimet believes may affect its business, financial condition and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond Sagimet's control, including, among others: the clinical development and therapeutic potential of denifanstat, TVB-3567 or any other drug candidates or combination therapies developed by Sagimet; Sagimet's ability to advance drug candidates into and successfully complete clinical trials within anticipated timelines; Sagimet's relationship with Ascleptis, and the success of its development efforts for denifanstat; the accuracy of Sagimet's estimates regarding its capital requirements; and Sagimet's ability to maintain and successfully enforce adequate intellectual property protection. These and other risks and uncertainties are described more fully in the "Risk Factors" section of Sagimet's most recent filings with the Securities and Exchange Commission and available at www.sec.gov. You should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in these forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, Sagimet operates in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that Sagimet may face. Except as required by applicable law, Sagimet does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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