Sagimet Biosciences Announces Positive Results from the Phase 1 PK Clinical Trial of Denifanstat and Resmetirom Combination

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- *The combination of denifanstat and resmetirom was generally well-tolerated*
- *Pharmacokinetic (PK) results support further development of the combination*
- *A Phase 2 trial of a denifanstat/resmetirom combination in F4 MASH patients is planned to initiate in 2H 2026*

SAN MATEO, Calif., Dec. 18, 2025 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic and fibrotic pathways, today announced positive results in the Phase 1 pharmacokinetic (PK) trial of a combination of its oral once-daily fatty acid synthase (FASN) inhibitor, denifanstat, and a thyroid hormone receptor beta (THR-β) agonist, resmetirom.

The Phase 1 PK trial (NCT07216313) of denifanstat and resmetirom was an open-label, 2-cohort study that enrolled 40 healthy adult participants. The objectives were to evaluate multiple-dose and single-dose pharmacokinetics, identify any potential drug-drug interactions (DDIs), and assess the safety and tolerability of the combination.

The combination of denifanstat and resmetirom was generally well-tolerated over the duration of the study, with no safety signals. No Serious Adverse Events (SAEs) occurred, and there were no clinically significant laboratory results, and no treatment discontinuations.

Sagimet plans to use these data to advance the development of the combination into a Phase 2 proof-of-concept efficacy trial for patients living with metabolic dysfunction-associated steatohepatitis (MASH) with F4 fibrosis, subject to consultation with regulatory authorities.

“The successful completion of the Phase 1 PK trial is an important step in our journey to develop a new, potentially synergistic combination treatment for MASH. Patients with cirrhosis of the liver associated with MASH currently have no approved options and our goal is to combine two therapies with complementary mechanisms of action into a single tablet to address this underserved medical need,” said David Happel, Chief Executive Officer of Sagimet. “Our recent presentations at AASLD demonstrated denifanstat’s ability to address advanced fibrosis in MASH patients, including in fibrosis stage qF4 as defined by AI-based digital pathology, and we previously have presented preclinical data demonstrating the synergistic effect of a FASN inhibitor combined with resmetirom on important liver disease markers. With these Phase 1 data in hand, we plan to consult with regulators on the design of a proof-of-concept Phase 2 study, which we plan to initiate in the second half of 2026. Following our recent announcement of a global license agreement with TAPI, a TEVA affiliate, we look forward to drawing on the licensed innovative forms of resmetirom API to develop a convenient, once-daily pill fixed dose combination product to test in Phase 3 for patients living with liver cirrhosis.”

Denifanstat, Sagimet's lead product candidate, is an oral, once daily selective FASN inhibitor in development for the treatment of MASH. Its anti-fibrotic mechanism of action coupled with its inhibition of liver fat synthesis and inflammation may be complementary to a fat oxidizer molecule such as resmetirom. Resmetirom is commercially available as Rezdiffra for the treatment of non-cirrhotic MASH with moderate to advanced fibrosis (F2 to F3). Pre-clinical data presented at EASL in 2024 showed in two mouse models of MASH that the combination of a FASN inhibitor (TVB-3664, a mouse surrogate for denifanstat) and resmetirom had a synergistic effect on important markers of liver disease, including improvement of NAS (NAFLD Activity Score) by histologic analysis and more robust improvement in hepatic collagen content compared to the single agents.

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 was tested in a Phase 1 PK clinical trial and is planned to be developed for patients with MASH cirrhosis (F4). 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

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 timelines and 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 Ascletis, 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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