Sagimet Biosciences Announces Dosing of First Participants in Phase 1 PK Clinical Trial for Denifanstat and Resmetirom Combination

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- *Dosing has successfully commenced with healthy volunteers*
- *Primary endpoints for the Phase 1 trial include safety, tolerability, and pharmacokinetic (PK) profile of the combination*
- *Topline data are anticipated in the first half of 2026*

SAN MATEO, Calif., Oct. 01, 2025 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Sagimet, Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic and fibrotic pathways, today announced that the Company has dosed the first participants in a 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. Topline data from this trial are anticipated in the first half of 2026 and, if positive, are planned to be used to advance the development of the combination for patients living with metabolic dysfunction-associated steatohepatitis (MASH) into Phase 2, subject to consultation with regulatory authorities.

The Phase 1 PK trial of denifanstat and resmetirom is an open-label, 2-cohort study and will enroll approximately 40 healthy adult participants. The objectives are to evaluate multiple-dose and single-dose pharmacokinetics, identify any potential drug-drug interactions (DDI), and assess the safety and tolerability of the combination. Results from this Phase 1 PK trial will be used to inform the optimal dose levels of denifanstat and resmetirom to evaluate in a Phase 2 combination proof-of-concept efficacy trial in F4 MASH patients.

“The initiation of the Phase 1 PK trial is an important step in the development of a new, potentially synergistic combination treatment for MASH. As we look ahead, our goal is to combine two therapies with complementary mechanisms of action into a single tablet that will improve clinical outcomes of patients who are living with cirrhosis of the liver and who currently have no approved options,” said David Happel, Chief Executive Officer of Sagimet. “At EASL 2024, we presented preclinical data that observed the synergistic effect of a FASN inhibitor combined with resmetirom on important liver disease markers. Furthermore, denifanstat previously demonstrated significant improvements in liver fibrosis in our Phase 2b FASCINATE-2 clinical trial in a subset of MASH patients who were digitally diagnosed as having cirrhosis.”

“I anticipate that combination therapy may become the standard of care in cirrhosis due to MASH in the future, and offers the potential to improve outcomes of disease including in the most advanced F4 patients, as there are currently no approved therapies for these patients,” said 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, who serves as a scientific advisor for Sagimet on its ongoing development of denifanstat. “It’s exciting to see Sagimet initiate development of a combination of denifanstat and resmetirom with this Phase 1 PK trial which could answer important questions about the compatibility of these two molecules in humans. Results of this Phase 1 trial, if successful, could lead to further development of a combination of Sagimet’s fat synthesis inhibitor, denifanstat, with a fat oxidizer, resmetirom, in MASH patients, potentially including those with stage 4 fibrosis.”

Denifanstat, Sagimet's lead product candidate, is an oral, once daily selective FASN inhibitor in development for the treatment of MASH, whose strong 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. Pre-clinical data presented at EASL in 2024 for two mouse models of MASH showed 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 fatty acid synthase (FASN) inhibitors that are designed to target dysfunctional metabolic and fibrotic pathways in diseases resulting from the overproduction of the fatty acid, palmitate. Sagimet’s lead drug candidate, denifanstat, is an oral, once-daily pill and selective FASN inhibitor in development for the treatment of metabolic dysfunction associated steatohepatitis (MASH). FASCINATE-2, a Phase 2b clinical trial of denifanstat in MASH with liver biopsy-based primary endpoints, was successfully completed with positive results. Denifanstat has been granted Breakthrough Therapy designation by the FDA for the treatment of non-cirrhotic MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis), and end-of-Phase 2 interactions with the FDA have been successfully completed, supporting the advancement of denifanstat into further development. Sagimet has recently initiated a Phase 1 first-in-human clinical trial with a second oral FASN inhibitor drug candidate, TVB-3567, that is planned to be developed for acne for the U.S. 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 Sagimet may develop; 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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