Sagimet Receives FDA Breakthrough Therapy Designation for Denifanstat in MASH

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Supported by positive data from Phase 2b FASCINATE-2 trial of denifanstat in patients with MASH

Preparations are ongoing to initiate Phase 3 program for denifanstat by the end of 2024

SAN MATEO, Calif., Oct. 01, 2024 (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 U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to denifanstat for treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

“The FDA’s Breakthrough Therapy designation for denifanstat underscores the global incidence of MASH and the continuing need for new therapies,” said David Happel, Chief Executive Officer of Sagimet. “As the only fat synthesis inhibitor that directly targets the three main drivers of MASH— fat accumulation, inflammation, and fibrosis— we believe denifanstat is well-positioned to offer a leading treatment option for patients living with MASH.”

Treatments that receive Breakthrough Therapy designation must target a serious or life-threatening disease and preliminary clinical evidence must indicate that the drug may demonstrate a substantial improvement over existing therapies on one or more clinically significant endpoints. Drugs that receive Breakthrough Therapy designation are eligible for all the benefits of Fast Track designation, as well as intensive guidance by FDA on an efficient drug development program and organizational commitment involving FDA senior managers.

Breakthrough Therapy designation of denifanstat was supported by positive data from the Phase 2b FASCINATE-2 clinical trial in biopsy-confirmed MASH patients with stage 2 or stage 3 fibrosis. In the trial, denifanstat showed statistically significant improvements relative to placebo on both primary endpoints of MASH resolution without worsening of fibrosis with ≥2-point reduction in Nonalcoholic Fatty Liver Disease (NAFLD) Activity Score (NAS), and ≥2-point reduction in NAS without worsening of fibrosis. Denifanstat-treated patients also showed statistically significant fibrosis improvement by ≥ 1 stage with no worsening of MASH, and a statistically significantly greater proportion of MRI-derived proton density fat fraction (MRI-PDFF) ≥30% responders relative to placebo. In the intent to treat (ITT) population, denifanstat achieved statistically significant results on primary and secondary liver biopsy endpoints, including both histology endpoints recommended in the FDA draft guidance for accelerated approval in MASH. Safety data showed that denifanstat was generally well tolerated. The Company plans to initiate the Phase 3 clinical program for denifanstat in MASH by the end of 2024.

About Sagimet Biosciences

Sagimet is a clinical-stage biopharmaceutical company developing novel fatty acid synthase (FASN) inhibitors that are designed to target dysfunctional metabolic 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 MASH. FASCINATE-2, a Phase 2b clinical trial of denifanstat in MASH with liver biopsy-based primary endpoints, was successfully completed with positive results. 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 115 million people worldwide, for which there is only one recently approved treatment in the United States and no currently approved treatments in Europe. In 2023, global liver disease medical societies and patient groups formalized the decision to rename non-alcoholic fatty liver disease (NAFLD) to metabolic dysfunction-associated steatotic liver disease (MASLD) and nonalcoholic steatohepatitis (NASH) to MASH. Additionally, an overarching term, steatotic liver disease (SLD), was established to capture multiple types of liver diseases associated with fat buildup in the liver. The goal of the name change was to establish an affirmative, non-stigmatizing name and diagnosis.

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. 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 or any other drug candidates Sagimet may develop; Sagimet’s ability to advance drug candidates into and successfully complete clinical trials within anticipated timelines, including its Phase 3 denifanstat program; 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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