Sagimet Biosciences Announces Successful Completion of End-of-Phase 2 Interactions with FDA on the Development of Denifanstat for MASH; Phase 3 Program Initiation Expected by End of 2024

10/29/2024 at 7:00 AM EDT

- The planned registration program consists of two double-blind, placebo-controlled multicenter Phase 3 trials, FASCINATE-3 and FASCINIT, to evaluate the safety and efficacy of denifanstat in patients with MASH and MASLD

SAN MATEO, Calif., Oct. 29, 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 the successful completion of end-of-Phase 2 interactions with the U.S. Food and Drug Administration (FDA), supporting the advancement of denifanstat into Phase 3 in metabolic-dysfunction associated steatohepatitis (MASH). The planned program will include two Phase 3 trials: FASCINATE-3, evaluating patients with F2/F3 (non-cirrhotic) MASH, and FASCINIT, evaluating patients with suspected or confirmed diagnosis of metabolic dysfunction-associated steatotic liver disease (MASLD)/MASH. The Phase 3 program is expected to initiate by the end of 2024.

“Following the recent Breakthrough Therapy designation for denifanstat for treatment of non-cirrhotic MASH, we are pleased with the outcome of our end-of-Phase 2 interactions with the FDA and are appreciative of the agency’s support and guidance on our Phase 3 program for denifanstat in MASH,” said Dave Happel, Chief Executive Officer of Sagimet. “The agency supports our strategy to conduct two Phase 3 trials to assess the safety and efficacy of denifanstat in F2/F3 MASH, a complex disease where treatments with novel/differentiated mechanisms of action that directly target the three main drivers of liver injury: fat accumulation, inflammation, and fibrosis are urgently needed.”

Based on ongoing discussions with the FDA, the planned Phase 3 program will consist of two double-blind, placebo-controlled multicenter registrational trials:

- FASCINATE-3 in patients with F2/F3 (non-cirrhotic) MASH: The trial will evaluate the efficacy and safety of denifanstat in this population, with primary endpoints being liver biopsy and 4.5-year clinical outcomes.
- FASCINIT in patients with suspected or confirmed diagnosis of MASLD/MASH: The trial will evaluate the efficacy and safety of denifanstat in this population, with primary endpoints being safety and tolerability. Non-invasive biomarkers will be assessed as part of the secondary endpoints, and there will be no end-of-treatment liver biopsy.

The Phase 3 program is designed to comprise a minimum of 1,800 patients exposed to denifanstat.

About MASH

Metabolic-dysfunction associated steatohepatitis (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.

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 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.

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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Source: Sagimet Biosciences Inc.