Sagimet Biosciences Announces Upcoming Presentations at EASL Congress 2025

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SAN MATEO, Calif., April 23, 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 three poster presentations featuring additional analyses from the Phase 2b FASCINATE-2 study of denifanstat in MASH will be presented at the European Association for the Study of Liver (EASL) Congress 2025 being held May 7-10, 2025 in Amsterdam, Netherlands.

EASL Presentation Details:

Title: Assessment of the metabolic dysfunction-associated steatohepatitis resolution index and component biomarkers in prediction of histology response to denifanstat in the FASCINATE-2 trial
Presenter: Rohit Loomba, MD, University of California, San Diego School of Medicine, San Diego
Session: Poster – MASLD: Diagnostics and non-invasive assessment
Date/Time: Wednesday, May 7, 2025, 8:30 AM CEST
Location: Poster area, RAI Convention Centre, Amsterdam

Key Poster Highlights: This retrospective analysis evaluated the performance of the MASH Resolution Index (MR-I), a non-invasive biomarker score, in detecting histologic resolution of MASH in the Phase 2b FASCINATE-2 trial of denifanstat. Results demonstrated that, in patients treated with denifanstat, MR-I can predict MASH resolution and potentially can predict non-responders. Additional analyses of the MR-I results are underway to identify an alternative endpoint to the more invasive liver biopsy.

Title: Denifanstat-mediated reduction of plasma glycine- and taurine-conjugated bile acids correlates with histological improvements in denifanstat-treated metabolic dysfunction-associated steatohepatitis patients in phase 2b FASCINATE-2 study
Presenter: Rohit Loomba, MD, University of California San Diego School of Medicine, San Diego
Session: Poster – MASLD: Diagnostics and non-invasive assessment
Date/Time: Wednesday, May 7, 2025, 8:30 AM CEST
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Key Poster Highlights: Elevated serum bile acid levels have been associated with metabolic disorders, such as MASH and type 2 diabetes. In MASH patients from the Phase 2b FASCINATE-2 trial treated with denifanstat, glycine- and taurine-conjugated bile acids were significantly reduced at 26 weeks in histological responders for both fibrosis regression and MASH resolution. These data suggest that these circulating bile acid levels may be leveraged as a response biomarker in patients treated with denifanstat.

Title: Denifanstat improves multiple qFibrosis-based collagen features linked to major adverse liver outcomes in patients with metabolic dysfunction-associated steatohepatitis and high polygenic risk
Presenter: Mary E. Rinella, MD, University of Chicago Pritzker School of Medicine, Chicago U.S.
Session: Poster – MASLD: Therapy
Date/Time: Saturday, May 10, 2025, 8:30 AM CEST
Location: Poster area, RAI Convention Centre, Amsterdam

Key Poster Highlights: Denifanstat demonstrated antifibrotic effect in qFibrosis-based collagen features previously linked to major adverse liver outcomes (MALO) using digital pathology techniques. Pronounced antifibrotic effects were observed with denifanstat treatment in the difficult-to-treat population with several risk variants associated with MALO.

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 Phase 3 development in MASH. 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 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 and Phase 1 acne 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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