Sagimet Biosciences Announces Completion of Enrollment of 120 Patients for Phase 3 Clinical Trial by Its Partner Ascletis of Denifanstat Combined with Bevacizumab for Treatment of Recurrent Glioblastoma

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SAN MATEO, Calif., Sept. 27, 2023 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic pathways, today announced that its license partner, Ascletis Bioscience Co. Ltd. (Ascletis), has enrolled 120 patients in its Phase 3 registration clinical trial of denifanstat combined with bevacizumab for treatment of recurrent glioblastoma (rGBM). Ascletis anticipates that this number of study subjects will provide sufficient events for its planned interim analysis of progression-free survival (PFS). Denifanstat is an oral, selective small molecule inhibitor of fatty acid synthase (FASN), a key enzyme which regulates de novo lipogenesis (DNL). Sagimet licensed the rights to develop and commercialize denifanstat in the People's Republic of China, Hong Kong, Macau and Taiwan to Ascletis in January 2019.

Sagimet's FASCINATE-2 Phase 2b clinical trial for denifanstat in liver biopsy-confirmed F2-F3 nonalcoholic steatohepatitis (NASH) patients is fully enrolled and biopsy results are expected in the first quarter of 2024. Sagimet also expects to report Phase 1 clinical trial results characterizing the pharmacokinetic profile of denifanstat in patients with impaired hepatic function in the first quarter of 2024.

"We congratulate Ascletis on achieving this important patient enrollment milestone in its Phase 3 clinical trial of denifanstat being conducted in China in patients with recurrent glioblastoma," stated David Happel, Chief Executive Officer of Sagimet. "Sagimet looks forward to reporting biopsy results and other key endpoints from our Phase 2 FASCINATE-2 trial for denifanstat in patients with NASH in the first quarter of 2024, and, if the data is positive, potentially advancing the program into a registrational Phase 3 trial."

About Sagimet Biosciences

Sagimet is a clinical-stage biopharmaceutical company developing novel therapeutics called fatty acid synthase (FASN) inhibitors that 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 nonalcoholic steatohepatitis (NASH), for which there are no treatments currently approved in the United States or Europe. Denifanstat is currently being tested in FASCINATE-2, a Phase 2b clinical trial in NASH with liver biopsy as the primary endpoint. 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, including its FASCINATE-2 Phase 2b clinical trial; 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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