Sagimet's License Partner Ascletis Announced Acceptance of New Drug Application for Denifanstat for the Treatment of Moderate to Severe Acne by China's National Medical Products Administration

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SAN MATEO, Calif., Dec. 10, 2025 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic and fibrotic pathways, today announced that Ascletis Pharma Inc. issued a December 10 statement that China's National Medical Products Administration (NMPA) has accepted its New Drug Application (NDA) for denifanstat for the treatment of moderate to severe acne. Sagimet has granted an exclusive license to denifanstat for China to Ascletis Bioscience Co. Ltd. (Ascletis), of which Ascletis Pharma Inc. is the parent company.

Denifanstat is a once-daily oral small molecule fatty acid synthase (FASN) inhibitor being developed by Ascletis for acne in China as ASC40, and by Sagimet for metabolic dysfunction associated steatohepatitis (MASH) in the rest of world. The NDA is based on data from Ascletis' successful Phase 3 clinical trial of denifanstat for the treatment of moderate to severe acne vulgaris, in which denifanstat met all primary and secondary endpoints and was generally well tolerated.

About Sagimet Biosciences

Sagimet is a clinical-stage biopharmaceutical company developing novel FASN inhibitors designed to target dysfunctional metabolic and fibrotic pathways in conditions resulting from the overproduction of the fatty acid, palmitate. Denifanstat, an oral, once-daily pill, met all primary endpoints in its Phase 2b FASCINATE-2 clinical trial in MASH as well as all primary and secondary endpoints in Sagimet's license partner for China's Phase 3 clinical trial in moderate-to-severe acne. A combination of denifanstat and resmetirom is currently being tested in a Phase 1 PK clinical trial and is planned to be developed for cirrhotic patients living with F4-stage MASH. TVB-3567, a second oral FASN inhibitor which is planned to be developed for acne, is currently being tested in a Phase 1 first-in-human clinical trial. 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 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 developed by Sagimet; 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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