Sagimet Announces Positive 52-Week Data from License Partner Ascletis' Open-Label Phase 3 Clinical Trial Evaluating the Long-Term Safety of ASC40 (Denifanstat) Tablets in Patients with Moderate to Severe Acne

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SAN MATEO, Calif., Feb. 02, 2026 (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 press release on January 29th reporting positive topline results in the open-label Phase 3 trial evaluating the long-term safety of ASC40 (denifanstat) tablets in patients with moderate to severe acne. Denifanstat is a once-daily oral small molecule fatty acid synthase (FASN) inhibitor being developed by Ascletis as ASC40 for acne in China and by Sagimet for MASH in the rest of the world. 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.

"The topline results from Ascletis' Phase 3 open-label acne trial in China build additional confidence in the clinical potential of FASN inhibition in acne," said David Happel, Chief Executive Officer of Sagimet. "These results demonstrate FASN inhibition's potential as a novel mechanism of action for the treatment of acne."

In June 2025, Ascletis announced that denifanstat (ASC40) met all primary, key secondary, and secondary endpoints in a 480-patient randomized, double-blind, placebo-controlled Phase 3 clinical trial (NCT06192264, ASC40-303) for the treatment of moderate to severe acne vulgaris (press release here).

"Following the 12-week data from the Phase 3 randomized double-blind denifanstat trial in moderate to severe acne patients, results from the 40-week open-label study are even more encouraging," said Dr. Neal Bhatia, Director of Clinical Dermatology at Therapeutics Clinical Research in San Diego and former Vice President of the American Academy of Dermatology. "For moderate to severe acne patients, who are currently underserved by older agents, the potential of a new therapeutic option would be a welcome addition to the current treatment armamentarium."

Clinical Results
The Phase 3 multi-center open-label clinical trial ASC40-304 (NCT06248008) was designed to determine the long-term safety of denifanstat in patients with moderate to severe acne vulgaris who were previously enrolled in the double-blind, randomized, placebo-controlled 12-week Phase 3 ASC40-303 trial. This open-label Phase 3 trial enrolled 240 subjects that received oral denifanstat 50 mg once daily for up to 40 weeks. Subjects who were originally randomized to denifanstat in ASC40-303 trial had a total of 52 weeks of denifanstat exposure.

Primary endpoints evaluated safety, and secondary endpoints evaluated efficacy, for up to 52 weeks of denifanstat treatment. Denifanstat was generally well tolerated, with the following:

- **Treatment-emergent adverse events (TEAEs):** Only two categories of TEAEs had an incidence rate of 5% or more, with dry eye syndrome in 5.5% of denifanstat-treated subjects and dry skin reported in 5.2% of denifanstat-treated subjects.
- **Adverse events (AEs):** All denifanstat-related AEs were mild or moderate; no denifanstat-related Grade 3 or 4 AEs; no AE-related permanent discontinuations; Grade 1 hair thinning in the study was experienced by only 1 denifanstat-treated patient (which resolved within eight weeks while remaining in study without a change in dose); no deaths were reported.
- **Serious adverse events (SAEs):** No denifanstat-related SAEs; 2 non-denifanstat-related SAEs (1 breast lump, 1 contusion), both resolved.

Subjects treated with denifanstat showed improvements in all efficacy endpoints (secondary endpoints of the trial) beyond those observed at 12 weeks. The endpoints were the number of subjects with an IGA[1] score decrease by at least 2 points, the number of subjects dropping from an IGA score of 3 down to 0 or 1, the percentage reduction in total skin lesion count, and the percentage reduction in inflammatory skin lesion count. Data are planned to be shared in upcoming congresses and publications.

1. Investigator's Global Assessment (IGA) score. IGA score 0: clear; IGA score 1: almost clear

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 was tested in a Phase 1 PK clinical trial and is planned to be developed for patients with MASH cirrhosis (F4). 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.

About FASN Inhibition and Acne
Over 50 million people suffer from acne in the U.S., with 5.1 million acne patients treated by dermatologists annually, making it one of the most prevalent skin diseases addressed by physicians.[1,2] There is no cure for acne; and due to its pathology, most patients require chronic management

and multiple annual courses of treatment for flare control. Adherence to topical therapies is lower than with oral agents, with an estimated 30% to 40% of patients not adhering to their topical treatments.[3]

Patients with acne vulgaris have increased sebum production compared to non-acne populations which contributes to the pathogenesis of the disease. Increased sebum production is due to increased de novo lipogenesis (DNL) locally in the sebocytes. FASN is the last committed step in the DNL pathway which produces the majority (>80%) of key sebum lipids such as palmitate and sapienic acid in acne, and FASN also contributes to inflammatory pathways, making the inhibition of FASN a potentially impactful approach to address acne.

1. Bickers DR, et al. *J Am Acad Dermatol*. 2006;55(3):490-500.
2. American Academy of Dermatology. Burden of Skin Disease. 2017. www.aad.org/BSD.
3. Purvis CG, Balogh EA, Feldman SR. Clascoterone: How the Novel Androgen Receptor Inhibitor Fits Into the Acne Treatment Paradigm. Ann Pharmacother. 2021;55(10):1297-1299. doi:10.1177/1060028021992055.

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 timelines and 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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