Positive Phase 3 Results for Denifanstat for the Treatment of Moderate to Severe Acne to be Presented at the EADV Congress 2025 by Partner Ascletis

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Denifanstat met all primary and secondary endpoints versus placebo

Denifanstat was generally well tolerated

Sagimet initiated first-in-human Phase 1 clinical trial of a second FASN inhibitor, TVB-3567, for development in acne

SAN MATEO, Calif., Sept. 17, 2025 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic and fibrotic pathways, today reported that data from a Phase 3 clinical trial for the treatment of moderate to severe acne vulgaris conducted by Sagimet's license partner Ascletis Bioscience Co. Ltd. (Ascletis) will be presented at the European Academy of Dermatology and Venerology (EADV) 2025 Congress taking place September 17-20, 2025 in Paris, France. 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 world.

The Phase 3 clinical trial was a randomized, double-blind, placebo-controlled, multicenter clinical trial in China to evaluate the safety and efficacy of denifanstat for the treatment of patients with moderate to severe acne, defined as Investigator's Global Assessment (IGA) scores of 3 and 4. This trial enrolled 480 patients who were randomized 1:1 into two treatment arms to receive denifanstat 50mg or placebo, once daily for 12 weeks. Primary endpoints included the percentage of treatment success (defined as an IGA score of 0 (clear) or 1 (almost clear) with at least a 2-point decrease from baseline), the percentage change in total lesion count, and the percentage change in inflammatory lesion count. Denifanstat met all primary and secondary endpoints and was generally well tolerated.

EADV Oral Presentation Details:

Title:	First-in-Class FASN Inhibitor Denifanstat Achieved All Endpoints in the Treatment of Acne Vulgaris: Results from a Phase III Randomised Placebo Controlled Trial
Presenter:	Leihong Flora Xiang, M.D., Ph.D. Professor & Vice Chair, Department of Dermatology, Huashan Hospital, Fudan University, Shanghai, China
Session:	Late Breaking Session / Oral Presentation
Date/Time:	Wednesday, September 17, 4:45 - 5:00 PM CEST
Location:	Room Paris Nord, Paris Expo Porte de Versailles

Key Presentation Highlights: Once daily 50 mg denifanstat achieved highly statistically significant and clinically meaningful improvements across all efficacy endpoints. In particular, denifanstat showed 18.6% placebo-adjusted increase in treatment success rate, 22.0% placebo-adjusted reduction in total lesions and 20.2% placebo-adjusted reduction in inflammatory lesions. Denifanstat was also generally well-tolerated.

"FASN inhibition represents a novel mechanism of action for the treatment of acne, a condition that impacts more than 50 million people in the U.S. annually, with limited innovation over the last 40 years," said David Happel, Chief Executive Officer of Sagimet. "While Ascletis continues to advance denifanstat for approval in China, Sagimet initiated a Phase 1 first-in-human clinical trial with a second FASN inhibitor, TVB-3567, that we plan to develop as a novel therapeutic option for patients with moderate to severe acne."

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 further development. Sagimet has recently initiated a Phase 1 first-in-human clinical trial with a second oral FASN inhibitor drug candidate, TVB-3567, that is planned to be developed for acne in the U.S. For additional information about Sagimet, please visit www.sagimet.com.

About Acne

There are 5.1 million acne patients treated by dermatologists annually in the U.S., and a total U.S. acne market of over 50 million people.[1,2] There is no cure for acne; and due to its pathology, most patients require chronic management and multiple courses of treatment for flare control annually. Additionally, 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]

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 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 Sagimet may develop; 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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