Denifanstat Achieved All Endpoints in the Treatment of Moderate to Severe Acne in Phase 3 Clinical Trial in Acne in China: A Presentation at the 2025 Fall Clinical Dermatology Conference

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Denifanstat met all primary and secondary endpoints versus placebo and was generally well tolerated in a Phase 3 clinical trial in acne in China conducted by license partner Ascletis

Ascletis announced completion of its pre-NDA consultation with China's NMPA and its plans to submit an NDA for denifanstat in China

SAN MATEO, Calif., Oct. 24, 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 for China, Ascletis Bioscience Co. Ltd. (Ascletis), will be presented at the 2025 Fall Clinical Dermatology Conference taking place October 24-26, 2025, in Las Vegas, Nevada. 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.

In October, Ascletis announced that it completed the pre-New Drug Application (NDA) consultation with China National Medical Products Administration (NMPA) for denifanstat for the treatment of moderate-to-severe acne vulgaris and plans to submit an NDA soon.

2025 Fall Clinical Dermatology Conference Poster Presentation Details:

Title:	FASN Inhibitor Denifanstat Achieved All Endpoints in the Treatment of Acne Vulgaris: Results from a Phase III Randomised Placebo-Controlled Trial
Presenting authors:	**Neal Bhatia**, MD, FAAD, Director of Clinical Dermatology at Therapeutics Clinical Research, Kearny Mesa, San Diego, CA
	Leon H. Kircik, MD, FAAD, Clinical Professor of Dermatology, Icahn School of Medicine at Mount Sinai, New York, NY; Adjunct Clinical Professor of Dermatology, Indiana University School of Medicine, Indianapolis, IN; Medical Director, Physicians Skin Care, PLLC and DermResearch, PLLC, Louisville, KY
Date/Time:	October 25 - 26, 2025
Location:	The Wynn Hotel, Las Vegas, Nevada

Key Presentation Highlights: Once daily oral 50 mg denifanstat achieved highly statistically significant and clinically meaningful improvements across all primary and secondary efficacy endpoints when analyzed using an intent-to-treat (ITT) analysis. At Week 12, treatment success rates with denifanstat were more than double those of placebo, with marked reductions in both inflammatory and non-inflammatory lesions. Denifanstat was generally well-tolerated.

"Denifanstat's Phase 3 results in acne demonstrate FASN inhibition's potential as a novel mechanism of action for the treatment of acne, a condition that impacts more than 50 million people in the U.S. annually and has seen limited innovation over the past 40 years," said David Happel, Chief Executive Officer of Sagimet. "In June 2025, we initiated a Phase 1 first-in-human clinical trial with a second FASN inhibitor, TVB-3567, that we plan to develop 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 pharmacokinetic (PK) clinical trial of a combination of denifanstat and resmetirom that is planned to be developed for patients living with MASH. Sagimet has also 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 for 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 or combination therapies 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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