



Sagimet Biosciences Announces First Patient Dosed in AURORA Phase 3 U.S. Clinical Trial of Denifanstat for Moderate to Severe Acne

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- *With first patient dosed in AURORA Phase 3 clinical trial, Sagimet advances denifanstat's U.S. registrational program, building on positive Phase 3 clinical results in China from license partner Ascleitis*
- *Pivotal trial designed to enroll approximately 800 U.S. patients, including 450 adolescents aged 12 and older*
- *If approved, denifanstat has the potential to address a significant unmet need among approximately 10 million Americans with moderate to severe acne*

FOSTER CITY, Calif., Oct. 22, 2026 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing inhibitors of fatty acid synthase (FASN), a key lipid synthesis regulator, for acne, today announced that the first patient has been dosed in AURORA, its pivotal U.S. Phase 3 clinical trial of denifanstat in adults and adolescents aged 12 years and older with moderate to severe acne. AURORA is intended to support a potential U.S. New Drug Application (NDA) submission. The trial builds on positive Phase 3 clinical results and subsequent 52-week open-label extension data generated by Sagimet's license partner Ascleitis BioScience Co. Ltd. (Ascleitis) in China. Denifanstat is a once-daily oral small molecule fatty acid synthase (FASN) inhibitor being developed by Ascleitis as ASC40 in China where it holds an exclusive license to denifanstat, and by Sagimet in the rest of the world.

"Dosing the first patient in our AURORA Phase 3 clinical trial marks a significant milestone for Sagimet," said David Happel, Chief Executive Officer of Sagimet. "Our focus is on advancing this registrational trial, with topline results expected in the second half of 2027. If approved, denifanstat would be the first once-daily oral acne treatment with a novel mechanism of action approved by the FDA for the treatment of acne in more than 40 years, offering a new treatment option for the approximately 10 million U.S. patients living with moderate to severe acne."

AURORA is a multicenter, randomized, double-blind, placebo-controlled registrational Phase 3 clinical trial designed to evaluate the efficacy and safety of denifanstat 50 mg once daily in approximately 800 U.S. patients aged 12 years and older, of which 450 are expected to be adolescents aged 12 to 17 years. The trial includes a 12-week double-blind treatment period followed by a 40-week open-label extension for eligible patients.

"As well as the positive Phase 3 data generated by our license partner Ascleitis, Sagimet's mechanistic non-clinical and clinical data provide further support for denifanstat's differentiated approach to targeting sebum production and inflammation, key drivers of acne," said Andreas Grauer, MD, Chief Medical Officer of Sagimet. "We look forward to conducting our registrational Phase 3 clinical trial and bringing denifanstat to patients and their families who we feel are currently underserved by the available treatment options."

The 52-week results from Ascleitis' Phase 3 open-label extension clinical trial were recently presented as posters at the European Academy for Dermatology and Venerology (EADV) Congress 2026 and the 2026 Fall Clinical Dermatology Conference. The posters are available in the Science section of Sagimet's website ([here](#)).

About the AURORA Phase 3 Clinical Trial

AURORA (NCT07863193) is a multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical trial of denifanstat in moderate to severe acne. AURORA is anticipated to enroll approximately 800 U.S. patients aged 12 years and older, of which 450 are expected to be adolescents aged 12 to 17 years. Patients will be randomized 2:1 to receive denifanstat 50 mg or placebo once daily for 12 weeks. The trial will have three co-primary endpoints that will be assessed at week 12: the proportion of patients achieving treatment success in a global assessment score, defined as at least a 2-point reduction from baseline with a score of 0 (clear) or 1 (almost clear); absolute change in inflammatory skin lesion counts from baseline; and absolute change in non-inflammatory skin lesion counts from baseline. A subset of approximately 530 patients completing the double-blind period will be eligible to enter a 40-week open-label extension evaluating the long-term safety of denifanstat.

About Denifanstat

Denifanstat is an oral, once-daily FASN inhibitor in development for the treatment of moderate to severe acne. In trials conducted by Sagimet's license partner, Ascleitis BioScience Co. Ltd. (Ascleitis) in China, denifanstat met all primary and secondary endpoints in a 12-week randomized, double-blind Phase 3 clinical trial in moderate to severe acne vulgaris and was generally well-tolerated and showed improvements in all efficacy endpoints measured at 52 weeks (secondary endpoints of the trial) in an open-label extension clinical trial evaluating denifanstat's long-term safety. Denifanstat is being developed by Ascleitis as ASC40 for acne in China and by Sagimet in the rest of world.

About Acne

Acne is one of the most common skin conditions in the U.S., with approximately 50 million Americans affected annually and more than 5 million seeking medical treatment for acne each year. Acne affects around 85% of persons between the ages of 12 and 24. Moderate to severe acne accounts for 20% of acne sufferers, or approximately 10 million people in the U.S. annually. 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.

About Sagimet Biosciences

Sagimet is a clinical-stage biopharmaceutical company advancing a portfolio of novel fatty acid synthase (FASN) inhibitors. FASN is a key regulator of the *de novo* lipogenesis pathway, which is overactive in acne and can cause elevated sebum and inflammation. FASN is also implicated in other diseases, including MASH and certain FASN-dependent tumor types. Denifanstat, Sagimet's lead drug candidate, is an oral, once-daily FASN inhibitor currently being evaluated in a U.S. Phase 3 registrational clinical trial for moderate to severe acne. For more information, 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 timelines and anticipated development milestones, 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 Asclethis, and the success of its development and registration 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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