Sagimet Biosciences Receives FDA “Study May Proceed” Letter and IND Clearance for Phase 3 Trial in Acne in Adolescent and Adult Patients

08/13/2026 at 7:00 AM EDT

Phase 3 clinical trial of denifanstat in moderate to severe acne patients in the U.S. on track to initiate in second half of 2026

FOSTER CITY, Calif., Aug. 13, 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 the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application and issued a “Study May Proceed” letter for the company’s Phase 3 clinical trial of fatty acid synthase (FASN) inhibitor denifanstat in moderate to severe acne. The Phase 3 clinical trial is on track to initiate in the second half of 2026.

“This letter marks an important regulatory milestone for denifanstat,” said Andreas Grauer, MD, Chief Medical Officer of Sagimet. “The Phase 3 clinical trial is intended to enroll approximately 800 US patients, with 450 expected to be adolescents, using well-accepted co-primary endpoints that will be assessed at the end of the 12-week randomized double-blind period, followed by a 40-week open-label extension to evaluate long-term safety. We appreciate the FDA's review and look forward to advancing into Phase 3 this year.”

“Clearance of the IND and receipt of the “Study May Proceed” letter is a decisive step in our clinical development of denifanstat for acne,” said David Happel, Chief Executive Officer of Sagimet. “We are on track to initiate the trial and start dosing patients this year. As an oral once-daily FASN inhibitor, denifanstat offers a novel mechanism of action to treat acne, and we look forward to offering this novel treatment option, if approved, to a currently underserved patient population.”

About the Phase 3 Clinical Trial

The multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical trial of denifanstat in moderate to severe acne is intended 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 has three co-primary endpoints 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. 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 our license partner, Ascletis BioScience Co. Ltd. (Ascletis) 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 Phase 3 clinical trial evaluating its long-term safety in patients with moderate to severe acne. Denifanstat is being developed by Ascletis 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 developing novel FASN inhibitors designed to target dysfunctional metabolic and fibrotic pathways in conditions resulting from the overproduction of the fatty acid, palmitate. FASN is a regulator of lipid synthesis, and a key pathway implicated in multiple diseases, such as acne, MASH and certain FASN-dependent tumor types. 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 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 Ascletis, 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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