Sagimet Biosciences Provides Strategic and Corporate Updates

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

First-in-human Phase 1 clinical trial of FASN inhibitor TVB-3567 ongoing

Further MASH development to be undertaken only upon securing non-dilutive funding

Sagimet to host a KOL event and webcast, April 30 at 2 pm ET

SAN MATEO, Calif., April 27, 2026 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic and fibrotic pathways, today provided strategic and corporate updates.

“Building on the recent successful Phase 3 clinical trial in China of our lead molecule denifanstat in moderate to severe acne, we have taken the strategic decision to advance denifanstat in acne for the U.S., starting with a Phase 3 clinical trial expected to begin in the second half of 2026,” said David Happel, Chief Executive Officer of Sagimet. “We believe the large moderate to severe acne patient population is underserved by the currently approved treatments. Denifanstat, if approved, would be a convenient, once-daily oral medication and the first innovative oral treatment for acne in more than forty years.”

Fatty acid synthase (FASN) inhibition, with its ability to reduce sebum production and address local inflammation, represents a potential novel approach to treat moderate to severe acne vulgaris, a condition impacting an estimated 10 million people in the U.S. annually. The Company recently announced positive topline results in the open-label Phase 3 clinical trial conducted and reported by its license partner that evaluated the long-term safety of denifanstat tablets in patients with moderate to severe acne in China.

“We are prioritizing our dermatology franchise in our capital allocation,” said Thierry Chauche, Chief Financial Officer, “and we plan to pursue non-dilutive funding options for our MASH program.”

Recent Corporate Highlights

- Sagimet plans to initiate a Phase 3 clinical trial of denifanstat in moderate to severe acne patients for the U.S. in the second half of 2026, subject to Investigational New Drug (IND) clearance.
- In January 2026, positive topline results were reported in the open-label Phase 3 trial (n=240) evaluating the long-term safety of 50 mg once-daily denifanstat in patients with moderate to severe acne in China by Sagimet’s license partner Ascletis Bioscience Co. Ltd. (Ascletis). Denifanstat was generally well-tolerated, and subjects treated with denifanstat showed improvements in all efficacy endpoints measured at 52 weeks (secondary endpoints of the trial).
- First-in-human Phase 1 clinical trial of FASN inhibitor TVB-3567 is ongoing.
- The Company also plans to develop a topical formulation of a FASN inhibitor for the potential treatment of acne.
- In relation to its development program for the combination of denifanstat and resmetirom in metabolic dysfunction associated steatohepatitis (MASH), the Company reported the completion of its Phase 1 PK clinical trial in December 2025. The Company anticipates that the denifanstat and resmetirom combination program will be ready to advance into Phase 2 in the second half of 2026. The Company will undertake no further clinical development in MASH until non-dilutive financing is achieved.
- In April 2026, Sagimet announced the appointment of Andreas Grauer, MD, as Chief Medical Officer, and the retirement of its former Chief Medical Officer, Eduardo Bruno Martins, MD, DPhil. Dr. Grauer brings more than two decades of global biopharmaceutical leadership experience, with deep expertise spanning clinical development, medical affairs, and regulatory strategy across multiple therapeutic areas.

Publications and Presentations

- In April 2026, Sagimet presented analyses from the Phase 2b FASCINATE-2 trial of denifanstat in MASH of bile acid biomarkers to measure denifanstat response at the Fueling MASH: Metabolic Drivers and Inflammatory Crosstalk Keystone Symposium.

Anticipated Upcoming Milestones

- The Company plans to file an IND application for denifanstat for the treatment of moderate to severe acne in mid-2026.
- Following IND clearance, Sagimet anticipates advancing denifanstat into a registrational Phase 3 clinical trial in moderate to severe acne patients in the second half of 2026.
- Upon completion of the Phase 1 clinical trial of TVB-3567, subject to consultation with regulatory authorities, Sagimet plans to initiate a Phase 2 clinical trial with TVB-3567 in moderate to severe acne patients in the second half of 2026.

Conference Call Information

Sagimet Biosciences will host a virtual KOL event with Dr. Julie Harper to discuss its planned development of denifanstat for acne on April 30, 2026 at 2pm ET.

Live webcast available: https://lifescievents.com/event/ha9t02g/

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.

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.

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 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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