



Sagimet Announces Positive Full 52-Week Results from License Partner Ascleitis' Phase 3 Open-Label Extension Clinical Trial of Denifanstat in Acne Presented at EADV 2026

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- In the Phase 3 open-label extension clinical trial (OLE), patients with moderate to severe acne received denifanstat for up to 52 weeks, including prior placebo patients
- Denifanstat showed progressive and sustained improvements across all efficacy endpoints in the OLE, including Investigator's Global Assessment (IGA) success with a response rate of 57%, 72% reduction in total lesions, and 77% reduction in inflammatory lesions, and was generally well-tolerated, with no adverse event-related permanent discontinuations
- Patient screening for AURORA U.S. Phase 3 clinical trial expected to begin in October 2026
- Sagimet to host a KOL event and webcast September 30, 2026 at 1 PM ET

FOSTER CITY, Calif., Sept. 30, 2026 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic and fibrotic pathways, today announced positive 52-week results from the Phase 3 ASC40-304 OLE clinical trial of denifanstat in patients with moderate to severe acne vulgaris, conducted by license partner Ascleitis BioScience Co. Ltd. (Ascleitis) in China. The results were presented at the European Academy of Dermatology and Venereology Congress (EADV) in Vienna by Ascleitis. 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.

The Phase 3 OLE clinical trial, ASC40-304, evaluated the long-term safety of denifanstat in patients with moderate to severe acne vulgaris who were previously enrolled in the 12-week randomized, double-blind, placebo-controlled Phase 3 ASC40-303 clinical trial, conducted in China by Ascleitis. 240 patients rolled over into the OLE trial, for a total trial duration of up to 52 weeks. 116 of those patients had received denifanstat, and 124 patients had received placebo in the original 12-week double-blind ASC40-303 trial. Primary endpoints evaluated safety, and secondary endpoints evaluated efficacy, including reduction in IGA from baseline and reduction in total lesion count and inflammatory lesion count from baseline.

Phase 3 Open-Label Extension Results

The baseline characteristics of the OLE cohorts were consistent with the overall study population, as shown below:

Baseline Characteristics of ASC40-304 OLE Cohorts at ASC40-303 Baseline

Baseline Characteristics	ASC40-304 Denifanstat/Denifanstat (n=116)	ASC40-304 Placebo/Denifanstat (n=124)	ASC40-303 Total (n=480)
Age, years, mean (SD)	22.5 (4.1)	22.3 (3.3)	22.6 (3.8)
Male, n (%)	31 (26.7)	47 (37.9)	150 (31.3)
Female, n (%)	85 (73.3)	77 (62.1)	330 (68.8)
IGA=3 (moderate), n (%)	101 (87.1)	106 (85.5)	412 (85.8)
IGA=4 (severe), n (%)	15 (12.9)	18 (14.5)	68 (14.2)
Total lesion count, mean (SD)	102.8 (25.3)	103.2 (24.4)	102.1 (24.8)
Inflammatory lesion count, mean (SD)	42.0 (12.2)	43.5 (11.8)	42.6 (11.9)
Non-Inflammatory lesion count, mean (SD)	60.8 (19.3)	59.7 (20.9)	59.5 (19.9)

Treatment success was defined as at least a 2-point reduction from baseline in Investigator's Global Assessment (IGA) score with a score of 0 (clear) or 1 (almost clear). At the end of the trial, treatment success rates and mean percentage changes, compared to the ASC40-303 baseline, were:

Efficacy Endpoints	Denifanstat 12wk / Denifanstat 40wk (n=116)	Placebo 12wk / Denifanstat 40wk (n=124)	Total (n=240)
Treatment success rate	57.8%	55.6%	56.7%
Mean % change in total lesion count	-73.0%	-70.7%	-71.8%
Mean % change in inflammatory lesion count	-78.1%	-75.8%	-76.9%
Mean % change in non-inflammatory lesion count	-68.3%	-65.5%	-66.9%

Note: Total skin lesion counts and inflammatory skin lesion counts reduced by approximately 75% and 80%, respectively, compared to ASC40-303 baseline for patients who completed the OLE trial.

Denifanstat was generally well-tolerated in the OLE with patients receiving up to 52 weeks of exposure, with no permanent discontinuations of study drug due to adverse events and no drug-related serious adverse events among patients treated with denifanstat. Only two categories of treatment-related adverse events had an incidence of more than 5% over the 52-week period: dry skin in 7.1% and dry eye in 5.9%.

"The positive results presented today at EADV reinforce our confidence in denifanstat as we prepare to begin patient screening for our U.S. AURORA Phase 3 clinical trial in October, with first patient enrollment expected shortly thereafter," said David Happel, Chief Executive Officer of Sagimet.

"Annually approximately ten million people in the U.S. live with moderate to severe acne. Denifanstat, if approved, could offer a convenient, once-daily oral medication for this underserved patient population, and would be the first oral treatment with a novel mechanism of action approved for acne in more than forty years."

"The open-label extension trial provides important data to support our AURORA Phase 3 program," said Andreas Grauer, MD, Chief Medical Officer of Sagimet. "It is particularly encouraging that patients continued to improve with longer treatment, and denifanstat remained generally well-tolerated through the open-label extension trial, with exposure to denifanstat up to 52 weeks. Notably, patients who crossed over from placebo achieved treatment success rates similar to those treated with denifanstat from the start. Together, these results provide meaningful long-term experience with the 50 mg denifanstat dose we are taking forward in AURORA."

Virtual Key Opinion Leader Conference Call Information

Sagimet Biosciences will host a virtual KOL event with Julie Harper, MD, Founding Director and past President of the American Acne and Rosacea Society on September 30, 2026 at 1 PM ET.

Dr. Harper will join company management for a review of the 52-week data from license partner Ascleitis' Phase 3 open-label extension clinical trial of denifanstat in moderate to severe acne vulgaris in China and an update on the company's planned U.S. Phase 3 AURORA clinical trial of denifanstat for the treatment of moderate to severe acne. Live webinar available: [LINK](#)

About the Ascleitis Phase 3 Clinical Trial and Open-Label Extension

ASC40-303 (NCT06192264) was a randomized, double-blind, placebo-controlled 12-week Phase 3 clinical trial of denifanstat in 480 patients with moderate to severe acne vulgaris, conducted in China by Ascleitis. Patients were randomized 1:1 to denifanstat 50 mg or placebo once daily. Denifanstat met all primary and secondary endpoints and was generally well-tolerated.

ASC40-304 (NCT06248008) was a multi-center, open-label Phase 3 extension evaluating the long-term safety of denifanstat in patients with moderate to severe acne vulgaris who were previously enrolled in the double-blind, randomized, placebo-controlled 12-week Phase 3 ASC40-303 trial. This open-label Phase 3 trial enrolled 240 subjects that received oral denifanstat 50 mg once daily for up to 40 weeks. Subjects who were originally randomized to denifanstat in ASC40-303 trial had a total of up to 52 weeks of denifanstat exposure. Primary endpoints evaluated safety, and secondary endpoints evaluated efficacy, including reduction in IGA from baseline and reduction in total lesion count and inflammatory lesion count from baseline for up to 52 weeks of denifanstat treatment. Denifanstat was generally well-tolerated. Subjects treated with denifanstat showed improvements in all efficacy endpoints (secondary endpoints of the trial) beyond those observed at 12 weeks.

About the AURORA Phase 3 Clinical Trial

The AURORA 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 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 in patients with moderate to severe acne. 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 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, 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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