Sagimet Biosciences Announces Clearance of IND for FASN Inhibitor TVB-3567, to be Developed for the Treatment of Acne

03/11/2025 at 8:00 AM EDT

TVB-3567 is the Company's second fatty acid synthase (FASN) inhibitor

First-in-human Phase 1 trial initiation planned in 2025

SAN MATEO, Calif., March 11, 2025 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Sagimet, Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic and fibrotic pathways, today announced the clearance of its Investigational New Drug (IND) application for TVB-3567, the Company's second fatty acid synthase (FASN) inhibitor. TVB-3567 is a potent and selective small molecule FASN inhibitor, planned to enter clinical development for the treatment of acne. The IND with the U.S. Food and Drug Administration's Division of Dermatology and Dentistry allows the Company to initiate a first-in-human Phase 1 clinical trial of TVB-3567, planned in 2025.

"The clearance of the TVB-3567 IND marks a significant milestone for Sagimet, as we advance our second FASN inhibitor into the clinic and expand our therapeutic presence into dermatology," said David Happel, Chief Executive Officer of Sagimet. "FASN inhibition is a highly attractive target in the treatment of acne, addressing acne's most significant contributor, sebum. We are excited about bringing TVB-3567 into the clinic, building upon compelling data from the denifanstat program in acne, including the favorable sebum lipid composition changes demonstrated in the Phase 1 clinical trial conducted by Sagimet, and the significant decreases in inflammatory and non-inflammatory lesion counts after 12 weeks of treatment shown in a Phase 2 clinical trial conducted by our license partner Ascletis BioScience in patients with moderate to severe acne vulgaris in China. Based on both its mechanism of action and strong preclinical profile, we believe TVB-3567 has the potential to offer a differentiated treatment option for acne. We look forward to initiating enrollment of the first-in-human study of TVB-3567 in 2025."

Over 50 million people suffer from acne in the US, making it one of the most prevalent skin diseases that physicians address annually. Acne's pathogenesis is highly associated with increased sebum production in the skin. FASN is the last committed step in the de novo lipogenesis pathway which produces approximately 80% of sebum lipids, including the fatty acids palmitate and sapienate. Previous pre-clinical and clinical studies have demonstrated that a FASN inhibitor can favorably alter sebum composition and significantly reduce acne lesions. FASN inhibition therefore represents a therapeutic target within acne and a significant commercial opportunity, if approved.

The planned Phase 1 clinical trial will be a randomized double-blind placebo-controlled trial designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of TVB-3567 in healthy participants with or without acne. The trial is expected to be comprised of several parts, including single ascending dose cohorts and multiple ascending dose cohorts in participants without acne, followed by testing in participants with acne including evaluation of pharmacodynamic biomarkers.

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 Phase 3 development in MASH. 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 anticipated development milestones, Sagimet's cash and financial resources and expected cash runway. 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 or any other drug candidates Sagimet may develop; Sagimet's ability to advance drug candidates into and successfully complete clinical trials within anticipated timelines, including its Phase 3 denifanstat program and Phase 1 acne program; 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.

Contact:
Joyce Allaire
LifeSci Advisors
jallaire@lifesciadvisors.com

Source: Sagimet Biosciences Inc.