Sagimet Biosciences and TAPI Announce Global License Agreement for Innovative Forms of Resmetirom API for Sagimet's Fixed Dose Combination Program

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- *License Agreement grants Sagimet a global, exclusive license to innovative forms of resmetirom active pharmaceutical ingredient (API) developed by TAPI and covered by TAPI patent applications*
- *Collaboration supports Sagimet's fixed-dose combination (FDC) program currently in clinical development*
- *Sagimet's Phase 1 pharmacokinetic (PK) trial of combination of denifanstat and resmetirom is underway with topline data anticipated by the end of 2025*
- *Sagimet anticipates selecting one of the innovative forms of resmetirom licensed from TAPI for combination with denifanstat in a fixed dose combination (FDC) tablet for use in Phase 3*

SAN MATEO, Calif., Dec. 17, 2025 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Sagimet, Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic and fibrotic pathways for metabolic and fibrotic diseases, today announced entry into a license agreement with Assia Chemical Industries Ltd. (Assia), doing business as TAPI Technology & API Services (TAPI), a subsidiary of Teva Pharmaceutical Industries Ltd.

Under the agreement, TAPI has granted Sagimet a global, exclusive license to certain intellectual property rights covering innovative forms of TAPI's resmetirom active pharmaceutical ingredient (API) for Sagimet's technical evaluation and manufacture, and, if elected by Sagimet, further development of a fixed-dose combination product containing denifanstat and resmetirom. Pending patent applications filed by Sagimet and TAPI cover the FDC and the innovative resmetirom forms, respectively.

In September 2025, Sagimet announced that it has dosed the first participants in a Phase 1 PK trial of a combination of its oral once-daily fatty acid synthase (FASN) inhibitor, denifanstat, and a thyroid hormone receptor beta (THR-β) agonist, resmetirom. The trial objectives are to evaluate multiple-dose and single-dose pharmacokinetics, identify any potential drug-drug interactions (DDI), and assess the safety and tolerability of the combination. Topline data from this trial are anticipated by the end of 2025 and, if positive, are planned to be used to advance the development of the combination for F4 patients living with metabolic dysfunction-associated steatohepatitis (MASH) into Phase 2, estimated to start in the second half of 2026, subject to consultation with regulatory authorities.

"Our Phase 1 PK trial is an important step in the development of a new, potentially synergistic combination of denifanstat and resmetirom for the treatment of MASH. The license agreement with TAPI provides us the pathway to combine these two therapies with complementary mechanisms of action into a single once-daily tablet to improve clinical outcomes of patients who are living with cirrhosis of the liver and currently have no approved options," said David Happel, Chief Executive Officer of Sagimet. "We have already initiated our evaluation of the innovative forms of resmetirom licensed to us by TAPI and intend to select one of these forms to manufacture a single tablet including denifanstat for our FDC program in MASH. We anticipate using a single FDC tablet including TAPI's innovative form of resmetirom in our Phase 3 study, and are excited about making this convenient, once-daily oral option, which we anticipate will not require weight-based dosing, available to patients."

Sagimet's combination program builds upon preclinical data presented by the company at the European Association for the Study of Liver (EASL) Congress 2024 that observed the synergistic effect of a FASN inhibitor combined with resmetirom on important liver disease markers. Denifanstat previously demonstrated significant improvements in liver fibrosis in the Phase 2b FASCINATE-2 clinical trial in a subset of MASH patients who were digitally diagnosed with cirrhosis.

Dr. R. Ananthanarayanan, CEO of TAPI, said "We are excited to announce the license agreement with Sagimet for their FDC development program, contributing TAPI's deep experience in the development and manufacturing of APIs. APIs are essential components used in the production of medications, and TAPI has long been recognized as an industry leader in their development and manufacturing. With this collaboration with Sagimet, we are excited to contribute our innovative intellectual property and manufacturing know how to Sagimet's development of a product in an area of high medical need, cirrhosis of the liver, where there are currently no approved therapies."

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. Denifanstat, an oral, once-daily pill, met all primary endpoints in its Phase 2b FASCINATE-2 clinical trial in MASH as well as all primary and secondary endpoints in Sagimet's license partner for China's Phase 3 clinical trial in moderate-to-severe acne. A combination of denifanstat and resmetirom is currently being tested in a Phase 1 PK clinical trial and is planned to be developed for cirrhotic patients living with F4-stage MASH. TVB-3567, a second oral FASN inhibitor which is planned to be developed for acne, is currently being tested in a Phase 1 first-in-human clinical trial. For additional information about Sagimet, please visit www.sagimet.com.

About TAPI

TAPI is a global leader in the development and manufacturing of active pharmaceutical ingredients (APIs), building blocks and key starting materials (KSM's) providing one of the industry's most comprehensive API portfolios. TAPI also offers customized CDMO services, utilizing their extensive expertise in a wide range of technologies to meet the diverse needs of partners, ensuring flexibility and excellence in every project. With 4,100

employees, a global footprint in 100+ countries, 13 sites worldwide, and a robust portfolio of 350+ high-quality products, TAPI's operations are integral to the delivery of high-quality, safe and effective medications to patients worldwide, supported by a sophisticated supply chain, focused innovative manufacturing, regulatory and quality excellence and a commitment to sustainability. For more information about how TAPI is advancing health from the core, visit www.tapi.com

About MASH

Metabolic dysfunction-associated steatohepatitis (MASH) is a progressive and severe liver disease which is estimated to impact more than 265 million people worldwide. MASH is characterized by the build-up of fat in the liver and various degrees of inflammation and fibrosis along with systemic metabolic changes including dyslipidemia (increased fat levels in blood) and insulin resistance. Patients with moderate to severe disease who have advanced fibrosis (F3) or cirrhosis (F4) have the highest risk of liver-related outcomes such as decompensation, hepatocellular carcinoma, and liver transplantation. There are few approved treatments for non-cirrhotic MASH (stages F1, F2 and F3 fibrosis) and no approved treatments for MASH cirrhosis (F4).

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, Sagimet's cash and financial resources and expected cash runway 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 Sagimet may develop; 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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