Sagimet Biosciences Announces Completion of Patient Enrollment in Phase 2b 'FASCINATE-2' Clinical Trial with Denifanstat (TVB-2640), a First-in-Class Fatty Acid Synthase Inhibitor, in Non-alcoholic Steatohepatitis

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San Mateo, California, September 13, 2022 – Sagimet Biosciences, a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic pathways, announced today that it has completed enrollment of its Phase 2b liver biopsy-based clinical trial ("FASCINATE-2") with denifanstat, a fatty acid synthase (FASN) inhibitor, in non-alcoholic steatohepatitis (NASH) patients.

"Completing patient enrollment in the FASCINATE-2 trial with denifanstat is an important milestone that puts Sagimet firmly on track to report results of interim analyses in the fourth quarter of 2022," said Eduardo Martins, MD, DPhil, chief medical officer. "Denifanstat's unique mechanism of action directly targets the primary drivers of NASH by reducing excess liver fat, decreasing inflammation and blunting fibrosis."

The Phase 2b FASCINATE-2 study, which began enrolling patients in August 2021, is a double-blind, placebo-controlled trial of 168 NASH patients with moderate-to-severe fibrosis (Stage F2 or F3). Patients are randomized to receive oral, once-daily 50mg doses of denifanstat or placebo for 52 weeks. The interim analysis will include measurement of liver fat, assessed by MRI-PDFF, and serum biomarkers of inflammation, fibrosis and liver injury in a subset of patients at 26 weeks of treatment. An analysis of the full patient population at 52 weeks will evaluate the impact of denifanstat treatment or placebo as assessed by biopsy, with primary efficacy endpoints that include improvement in NASH activity score or improvement in fibrosis. Sagimet anticipates sharing top-line liver biopsy data in the fourth quarter of 2023.

About Sagimet
Sagimet is a clinical-stage biopharmaceutical company developing novel therapeutics
targeting dysfunctional metabolic pathways in diseases such as nonalcoholic steatohepatitis, certain cancers and acne. Sagimet compounds are designed to inhibit fatty acid synthase, an enzyme involved in the production of fatty acids normally used for energy storage. In NASH, the activity of FASN enzyme is upregulated, resulting in excess accumulation of liver fat, inflammation and fibrosis. FASN dysregulation has also been implicated in multiple cancers with lipogenic phenotypes.

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