Sagimet Biosciences Receives Fast Track Designation from U.S. Food and Drug Administration for FASN Inhibitor TVB-2640 in NASH

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In a recent Phase 2a trial, TVB-2640 improved serum biomarkers of liver injury in patients with nonalcoholic steatohepatitis (NASH)

SAN MATEO, Calif., March 16, 2021 /PRNewswire/ -- Sagimet Biosciences Inc., a clinical-stage biotechnology company focused on developing a portfolio of internally-discovered, selective fatty acid synthase (FASN) inhibitors, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to TVB-2640 for the treatment of patients with NASH.

TVB-2640, is a wholly-owned, oral, selective inhibitor of FASN, a key enzyme involved in the production of saturated fatty acids in the liver and other organs, and is the only enzyme in the human body capable of converting metabolized sugars into palmitate. In patients with NASH, increased FASN-mediated palmitate synthesis in the liver is the source of three key drivers of the disease: excess accumulation of liver fat, inflammation and fibrosis.

In a recent Phase 2 randomized placebo-controlled trial (FASCINATE-1), TVB-2640 demonstrated statistically significant improvement across steatosis, inflammation/lipotoxicity, fibrosis and metabolic biomarkers important in NASH. NASH is currently the leading cause of liver transplantation in women and second only to alcoholic liver disease in men and is expected to become the leading indication for liver transplantation in the United States.[1]

George Kemble, Ph.D., Sagimet's chief executive officer, said, "The FDA's Fast Track designation for TVB-2640 demonstrates recognition of TVB-2640's potential to address unmet needs of NASH patients. There are currently no FDA-approved therapies on the market to treat NASH.[2] This designation brings us one step closer to a potential treatment for patients with this critical unmet need."

Fast Track designation is designed to facilitate drug development and expedite the review of drugs that are developed to treat serious conditions and fill an unmet medical need. The FDA defines filling an unmet medical need as providing a therapy where none exists or providing one that may offer advantages over currently available therapy. A company whose drug receives Fast Track designation may be eligible for more frequent meetings and written communications with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval; eligibility for Accelerated Approval and Priority Review, if relevant criteria are met; and eligibility for rolling review of a New Drug Application (NDA), where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted.

About Sagimet

Sagimet Biosciences Inc. is a clinical-stage biopharmaceutical company focused on developing novel therapeutics to treat important diseases such as the liver disease NASH and specific cancers, with focus on targeting dysfunctional metabolic pathways. The company has unique expertise in FASN biology and has created a pipeline of proprietary FASN inhibitors. For more information, please visit www.sagimet.com.

[1] Noureddin et al. 2018. doi: 10.1038/s41395-018-0088-6

[2] https://www.niddk.nih.gov/health-information/liver-disease/nafld-nash/treatment

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