



Maze Therapeutics Announces FTC Action Seeking to Block Collaboration and License Agreement with Sanofi Regarding MZE001, a Potential Oral Substrate Reduction Therapy for Pompe Disease

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SOUTH SAN FRANCISCO, Calif.—(BUSINESS WIRE)—Maze Therapeutics, a company translating genetic insights into new precision medicines, today announced the U.S. Federal Trade Commission (FTC) has filed a complaint seeking to block Sanofi’s exclusive worldwide license agreement for Maze’s glycogen synthase 1 (GYS1) program, including clinical candidate MZE001, which is in development for the treatment of Pompe disease and other potential indications. The agreement was originally announced in May 2023 with closing subject to review under the Hart-Scott-Rodino (HSR) Act.

“People with Pompe disease are in need of new treatment options, and as a global healthcare leader with deep experience with the Pompe patient community, Sanofi is an ideal partner to bring the MZE001 program forward.”

“At Maze, our commitment is to the patients around the world that we believe can benefit from our work. We are disappointed to learn of the FTC’s unprecedented challenge to our license agreement with Sanofi for our investigational GYS1 program—to our knowledge this is the first time ever the FTC has moved to block a license of a Phase 1 investigational medicine,” said Jason Coloma, Ph.D., chief executive officer of Maze Therapeutics. “People with Pompe disease are in need of new treatment options, and as a global healthcare leader with deep experience with the Pompe patient community, Sanofi is an ideal partner to bring the MZE001 program forward.”

Dr. Coloma continued, “We respectfully disagree with this decision and believe that the FTC’s complaint lacks any legal basis. With positive preclinical and Phase 1

data, MZE001 has the potential to be the first oral therapeutic option to address Pompe disease, providing a new option for patients suffering from Pompe disease. We entered into this deal with Sanofi because we believed, and continue to believe, that Sanofi has the optimal resources, expertise and motivation to advance the program forward, and its stewardship of MZE001 is in the best interest of patients suffering from Pompe disease. We are currently reviewing the FTC’s complaint and evaluating our legal and business options.”

Importantly, Maze will continue to advance its lead programs addressing common diseases, including MZE829, an APOL1 inhibitor for APOL1-mediated kidney disease, which largely impacts individuals in the black community and is on track to enter clinical development by the end of this year. Maze’s second undisclosed program in chronic kidney disease is scheduled to commence clinical trials in the second half of 2024.

About MZE001

Maze has advanced MZE001 through Phase 1 development. In the first-in-human, double-blind, placebo-controlled, single and multiple ascending dose clinical trial, MZE001 was well-tolerated at doses up to 720 mg twice daily. Response to MZE001 was evaluated in patients using a novel biomarker, peripheral blood mononuclear cell (PBMC) glycogen, and demonstrated exposure-dependent reductions in PBMC glycogen across dose levels 10 days after administration, confirming target engagement with GYS1. These results were further confirmed in a muscle biopsy cohort, that showed equivalent reductions in muscle glycogen with MZE001.

About Maze Therapeutics

Maze Therapeutics is a biopharmaceutical company harnessing the power of human genetics to transform the lives of patients. The Company is committed to developing breakthrough precision medicines for common diseases with large unmet medical needs. Maze has developed Maze Compass™, a proprietary, purpose-built platform to leverage genetic variation and integrate the critical step of variant functionalization into each stage of therapeutic development. Utilizing Maze Compass, the Company’s strategy is to develop its therapies independently, in collaboration with major pharmaceutical companies, and through company formation. For more information, please visit mazetx.com, or follow us on [LinkedIn](#) and [X](#). (formerly Twitter).

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