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Glycomine Receives FDA Fast Track Designation for GLM101 for the Treatment of PMM2-CDG

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SAN CARLOS, Calif.--(BUSINESS WIRE)--Glycomine, Inc., a biotechnology company focused on developing new therapies for orphan diseases, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for GLM101, a mannose-1-phosphate replacement therapy in development for the treatment of patients with phosphomannomutase 2-congenital disorder of glycosylation (PMM2-CDG).

“Fast Track Designation for GLM101 highlights its potential to meet the serious unmet medical need of patients with PMM2-CDG,” said Rose Marino, M.D., Chief Medical Officer of Glycomine. “As we continue to enroll pediatric patients in our Phase 2 clinical study, we are encouraged by our initial data showing promising evidence of clinical benefit with GLM101. We look forward to progressing development of GLM101 within the Fast Track framework.”

The GLM101-002 Phase 2 clinical study has enrolled 10 adult and five adolescent patients with PMM2-CDG in the U.S. and Spain (ClinicalTrials.gov Identifier: NCT05549219). Study participants have completed treatment with GLM101 at either 10 mg/kg (n=3), 20 mg/kg (n=3), or 30 mg/kg (n=9) for up to 24 weeks. More than 350 doses of GLM101 have been administered to PMM2-CDG patients. The drug appears to be well tolerated with no serious adverse events, and only mild to moderate adverse events reported to date. The study is planned to continue enrollment in pediatric patients ≥ 2 years of age.

The FDA’s Fast Track program is designed to facilitate the development and expedite the review of novel potential therapies intended to treat serious conditions and address significant unmet medical needs. Companies whose programs are granted Fast Track designation are eligible for more frequent interactions with the FDA during clinical development and potentially accelerated approval and/or priority review, if relevant criteria are met.

About GLM101

GLM101 is a mannose-1-phosphate replacement therapy in development to treat phosphomannomutase 2-congenital disorder of glycosylation (PMM2-CDG), previously known as CDG Type Ia. GLM101 has received Orphan Drug Designation in the U.S. and Europe and Rare Pediatric Disease Designation in the U.S. PMM2-CDG is caused by genetic mutations that lead to a deficiency of the enzyme phosphomannomutase 2 (encoded by the PMM2 gene). GLM101 is designed to deliver mannose-1-phosphate directly into cells and thereby bypass the PMM2 enzyme deficiency and address disease-causing PMM2 mutations to restore pathway function.

About Glycomine, Inc.

Glycomine is a clinical-stage biotechnology company developing novel drugs for serious rare disorders of metabolism and protein misfolding for which no other therapeutic options exist. The company's approach is to use replacement therapies – substrates, enzymes, or proteins – and to target those molecules to clinically relevant cellular compartments. The company is based in San Carlos, California and supported by leading international life sciences investors. For more info visit www.glycomine.com.

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