

Sep 3, 2025 9:00 AM Eastern Daylight Time

Glycomine Initiates Dosing in a Global, Randomized, Placebo-Controlled Phase 2b Study of GLM101 for the Treatment of PMM2-CDG

Share      

SAN CARLOS, Calif.--(BUSINESS WIRE)--Glycomine, Inc. announced today that the first participant has been dosed in the global Phase 2b study, called POLAR. This randomized placebo-controlled multi-center clinical trial is designed to assess the safety and efficacy of GLM101, an investigational mannose-1-phosphate substrate replacement therapy for the treatment of phosphomannomutase 2 congenital disorder of glycosylation (PMM2-CDG), a rare genetic disorder leading to serious neurological and multi-systemic impairments.

"We've been encouraged by the improvements in ataxia seen in our Phase 2 open-label study, and we are excited to bring GLM101 forward into this next phase of clinical development to further assess its safety and efficacy," said Dr. Marino, Glycomine's CMO.

Share

"Dosing the first patient with PMM2-CDG in our global Phase 2b study marks a critical step forward for GLM101 and for the PMM2-CDG community, who currently have no approved treatment options," said Rose Marino, MD, Chief Medical Officer at Glycomine. "We've been encouraged by the improvements in ataxia seen in our Phase 2 open-label study, and we are excited to bring GLM101 forward into this next phase of clinical development to further assess its safety and efficacy."

POLAR (ClinicalTrials.gov Identifier: NCT06892288) plans to enroll approximately 50 adults and children ≥4 years of age living with PMM2-CDG across a planned 16

sites and 10 countries. The trial will consist of two phases. Part A is a 24-week randomized, double-blind, placebo-controlled treatment period designed to evaluate the primary efficacy of GLM101 compared to placebo. Participants will be randomized 1:1 to receive weekly intravenous infusions of 30 mg/kg GLM101 or placebo for 24 weeks before transitioning into Part B of the study. Part B is a 24-week open-label extension phase in which all participants will receive weekly IV infusions of GLM101.

The primary outcome assessment, evaluated after Part A of the study, is improvement in ataxia as measured by the International Cooperative Ataxia Rating Scale (ICARS), a clinical tool to assess the severity of ataxia. Ataxia is a hallmark of PMM2-CDG and has been reported to be a key driver of disease burden. Additional secondary and exploratory endpoints include clinical assessments of gross motor function, cognition, strength, and patient and clinician-reported global impressions of change.

The POLAR study design has been informed by results of an ongoing open-label Phase 2 study in pediatric and adult patients with PMM2-CDG, which has demonstrated encouraging clinical improvements in ataxia as measured by the ICARS and a favorable safety and tolerability profile.

About PMM2-CDG

Phosphomannomutase 2-congenital disorder of glycosylation (PMM2-CDG), previously known as CDG-1a, is the most prevalent congenital disease of glycosylation. PMM2-CDG is caused by a genetic mutation in phosphomannomutase 2 (PMM2), which results in the protein having reduced activity. PMM2 is an enzyme that converts mannose-6-phosphate to mannose-1-phosphate, which is required to insert the mannose sugar building block into developing glycans that are crucial for proper protein structure and function. The deficiency of mannose-1-phosphate disrupts the process of N-glycosylation and causes a wide array of clinical symptoms and, in many cases, can be life-threatening.

About Glycomine, Inc.

Glycomine is a clinical-stage biotechnology company that is advancing treatments for serious rare diseases with no other therapeutic options. The Company's lead investigational drug candidate GLM101 is a mannose-1-phosphate replacement therapy in development to treat PMM2-CDG. GLM101 is designed to deliver

mannose-1-phosphate into cells and thereby bypass disease-causing PMM2 mutations to restore pathway function. GLM101 has received Orphan Drug Designation in the U.S. and E.U. and Rare Pediatric Disease Designation and Fast Track Designation in the U.S. The company is based in San Carlos, California, and supported by leading international life sciences investors. For more info visit www.glycomine.com.

Contacts

Corporate Contact: Peter McWilliams, Ph.D., info@glycomine.com

Media Contact: Jessica Yingling, Ph.D., [Little Dog Communications Inc.](http://LittleDogCommunicationsInc.com), jessica@litldog.com

Industry: [Science](#) [Biotechnology](#) [Research](#) [Pharmaceutical](#)
[General Health](#) [Health](#) [Genetics](#) [Clinical Trials](#)



GLYCOMINE, INC.

RELEASE SUMMARY

Glycomine Initiates Dosing in a Global, Randomized, Placebo-Controlled Phase 2b Study of GLM101 for the Treatment of PMM2-CDG

RELEASE VERSIONS

English

HASHTAGS

[#CDG](#)

[#CDGResearch](#)

[#CDGawareness](#)

[#PMM2CDG](#)

[#clinicaltrial](#)

[#glycans](#)

[#glycoprotein](#)

[#glycoscience](#)

[#glycosylated](#)

[#glycosylation](#)

[#raredisease](#)

[#rarediseases](#)

CONTACTS

Corporate Contact: Peter McWilliams, Ph.D., info@glycomine.com

Media Contact: Jessica Yingling, Ph.D., [Little Dog Communications Inc.](mailto:jessica@litldog.com),
jessica@litldog.com

SOCIAL MEDIA PROFILES

 [Glycomine on LinkedIn](#)

 [Glycomine on Twitter](#)

More News From Glycomine, Inc.

 [Get RSS Feed](#)

Glycomine Announces \$115 Million Series C Financing to Advance Lead Drug Candidate, GLM101, into a Phase 2b Clinical Trial for PMM2-CDG

SAN CARLOS, Calif.--(BUSINESS WIRE)--Glycomine Announces \$115 Million Series C Financing to Advance Lead Drug Candidate, GLM101, into a Phase 2b Clinical Trial for PMM2-CDG...