GlycoMimetics Announces Positive Initial Safety and Pharmacokinetic Results from Phase 1a Healthy Volunteer Study of GMI-1687

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- First in human trial evaluating highly potent E-selectin antagonist, GMI-1687, met its primary and secondary endpoints with no dose-limiting toxicities or safety signals
- Single ascending dose study confirmed that subcutaneous dosing generated linear pharmacokinetics and achieved target plasma concentrations across all dosing levels
- GMI-1687 is being developed as a potential patient-controlled point-of-care treatment for inflammatory diseases, with initial focus on sickle cell disease (SCD)
- Data analysis is ongoing, with full study results to be presented at an upcoming medical meeting

ROCKVILLE, Md.--(BUSINESS WIRE)--Jan. 4, 2024-- GlycoMimetics, Inc. (Nasdaq: GLYC), a late clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers and inflammatory diseases, today announced positive initial safety, tolerability, and pharmacokinetic results from a Phase 1a study of GMI-1687 in healthy volunteers.

“These positive results represent an important milestone in the development of GMI-1687 as a potential point-of-care treatment option intended to help people living with sickle cell disease when they need it most, at the onset of pain crises,” said Harout Semerjian, Chief Executive Officer of GlycoMimetics. “Our Phase 1a data confirm this highly potent, second-generation E-selectin antagonist has an excellent profile for further development, with no dose-limiting toxicities or safety signals observed along with linear pharmacokinetics. We look forward to completing analysis of the study and advancing partner and financing discussions that support further development of this potentially important new therapeutic option for SCD.”

This double-blind, single-center, randomized, placebo-controlled, sequential, single ascending dose Phase 1a trial in healthy adult volunteers enrolled 40 subjects. Eligible subjects received a single subcutaneous injection of GMI-1687 or placebo (6:2 ratio). Five dose levels were evaluated, including 3.3, 10, 20, 40, and 80 mg. The study met its primary and secondary endpoints of safety/tolerability and pharmacokinetics. There were no observed dose limiting toxicities or safety signals. Subcutaneous dosing achieved target therapeutic plasma concentration and linear pharmacokinetics with rapid renal clearance across all dosing levels. Analysis of data is ongoing with full results expected to be presented at an upcoming medical conference.

About Sickle Cell Disease

SCD is the most common inherited blood disorder in the United States, afflicting approximately 100,000 people. Worldwide, about 100 million people carry the SCD trait, and an estimated five million live with the disease. While a majority are of African descent, SCD can affect all ethnic groups, in particular those from areas of endemic malaria, including the Southern Mediterranean, Middle East, and India. Acute pain crises, or vaso-occlusive crises (VOCs), are the most common clinical manifestation of SCD. VOCs occur when sickled red blood cells irritate the lining of blood vessels and cause an inflammatory response that leads to vascular occlusion, tissue ischemia and pain.

About GMI-1687

Discovered and developed by GlycoMimetics, GMI-1687 is a highly potent E-selectin antagonist that is bioavailable after subcutaneous administration. This second-generation compound has potential application in inflammatory diseases, and the company’s initial clinical development will focus on SCD. E-selectin is believed to play a major role in VOCs, vascular clots and blockages that cause pain crises in people living with the disease. Administration of GMI-1687 by subcutaneous injection, if successfully developed in the clinic, may enable this study drug to be approved as a patient controlled, point-of-care treatment option at time of VOC onset. There currently exists no FDA approved treatment for acute onset of painful and debilitating VOCs.

About GlycoMimetics, Inc.

GlycoMimetics is a late clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers, including Acute Myeloid Leukemia, and for inflammatory diseases. GlycoMimetics’ science is based on an understanding of the role that carbohydrates play in cell recognition. The company’s specialized chemistry platform is being deployed to discover small molecule drugs--known as glycomimetics--that alter carbohydrate-mediated recognition in diverse disease states. As a leader in this science, GlycoMimetics leverages this unique approach to advance its pipeline of wholly-owned drug candidates with the goal of developing transformative therapies for diseases with high unmet medical need. GlycoMimetics is headquartered in Rockville, MD in the BioHealth Capital Region. Learn more at www.glycomimetics.com.

Forward-Looking Statements

This press release contains forward-looking statements. These forward-looking statements may include, but are not limited to, statements regarding the conduct of and results from clinical trials, including presentation of data from such studies; planned or potential clinical development, partnering or financing opportunities; and the potential benefits and impact of the company’s drug candidate, GMI-1687. Actual results may differ materially from those described in these forward-looking statements. For a further description of the risks associated with these statements, as well as other risks facing GlycoMimetics, please see the risk factors described in the Company’s Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 29, 2023, and other filings GlycoMimetics makes with the SEC from time to time. Forward-looking statements

speak only as of the date of this release, and GlycoMimetics undertakes no obligation to update or revise these statements, except as may be required by law.

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