GlycoMimetics Announces First Cohort Dosed in Human Phase 1a Study of GMI-1687

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- GMI-1687, a highly potent E-selectin antagonist, is being developed as a potential point-of-care treatment for inflammatory diseases with initial focus on sickle cell disease (SCD)
- Single ascending dose study is expected to randomize approximately 40 healthy volunteers on GMI-1687 vs placebo with endpoints for safety, tolerability, and pharmacokinetics
- Initial results expected by end Q1 2024

ROCKVILLE, Md.--(BUSINESS WIRE)--Sep. 6, 2023-- GlycoMimetics, Inc. (Nasdaq: GLYC), a late clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers and inflammatory diseases, today announced dosing of the first cohort of healthy volunteers in a Phase 1a study of GMI-1687 to evaluate safety, tolerability, and pharmacokinetics.

“We are excited to progress our pipeline and advance GMI-1687, a highly potent, second-generation E-selectin antagonist, into clinical development, “said Harout Semerjian, Chief Executive Officer of GlycoMimetics. “GMI-1687 demonstrates our leadership in advancing the clinical application of E-selectin antagonism for inflammatory diseases, applying valuable insights learned from the sickle cell disease patient community to potentially create a point-of-care treatment option for vaso-occlusive crisis.”

This Phase 1a study is a double-blind, single-center, randomized, placebo-controlled, sequential, single ascending dose trial in healthy adult volunteers. It is expected to enroll approximately 40 subjects. Eligible subjects will receive a single dose of GMI-1687 or placebo (6:2 ratio) via subcutaneous injection. Safety, tolerability, and pharmacokinetics of up to five dose levels (3.3, 10, 20, 40, and 80 mg) will be evaluated.

About SCD

SCD is the most common inherited blood disorder in the United States, impacting approximately 100,000 people. Worldwide, approximately 100 million people carry the SCD trait and an estimated five million people live with the disease. While the majority are of African descent, the disease can affect all ethnic groups, especially those from areas where malaria is or was endemic, such as the Middle East, India and the Southern Mediterranean. Acute pain crises, or vaso-occlusive crises (VOCs), are the most common clinical manifestation of SCD. A VOC occurs when sickled red blood cells irritate the lining of blood vessels and cause an inflammatory response leading 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 has been shown in animal models to be bioavailable after subcutaneous administration. This second-generation compound has potential application in inflammatory diseases, and the initial development focus will be on SCD. E-selectin is believed to play a major role in VOCs, the vascular clots and blockages that cause pain crises in people living with SCD. Administration of GMI-1687 by subcutaneous injection, if successfully developed in the clinic, may enable this study drug to be approved as a point-of-care treatment option at the onset of a VOC.

About GlycoMimetics, Inc.

GlycoMimetics is a late clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers, including AML, and for inflammatory diseases. The company’s science is based on an understanding of the role that carbohydrates play in cell recognition. Its specialized chemistry platform is being deployed to discover small molecule drugs--known as glycomimetics--that alter carbohydrate-mediated recognition in diverse disease states, including cancers and inflammation. 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 data from clinical trials, planned or potential clinical development, 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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