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GlycoMimetics' GMI-1271 Receives FDA Breakthrough Therapy Designation for Adult Relapsed/Refractory Acute Myeloid Leukemia

ROCKVILLE, Md.--(BUSINESS WIRE)-- GlycoMimetics, Inc. (NASDAQ: GLYC) today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for treatment of adult relapsed/refractory acute myeloid leukemia (AML) to the company's drug candidate GMI-1271, an E-selectin antagonist currently being evaluated in the Phase 2 portion of a Phase 1/2 clinical trial in patients with AML. The U.S. Food and Drug Administration (FDA) had previously granted Orphan Drug designation and Fast Track Status for GMI-1271 in AML.

In the ongoing clinical trial, GMI-1271 is being administered, along with chemotherapy, to patients with relapsed or refractory AML as well as those 60 years of age and older with newly diagnosed disease. Data from this trial were presented in 2016 at meetings of the European Hematology Association (EHA) and the American Society of Hematology (ASH). In the trial, patients treated with GMI-1271 achieved higher than expected remission rates and lower than expected 30- and 60-day mortality rates in early evaluations of patients with relapsed/refractory AML as well as in newly diagnosed patients. In March 2017, the Company announced that the first of two patient cohorts in the Phase 2 portion of the trial of GMI-1271 had completed enrollment. In April 2017, the Company announced plans to present further data updates on both patient populations in the ongoing AML trial at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting in June.

The FDA grants Breakthrough Therapy designation to companies to help accelerate development and review of drug candidates when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies. The designation is designed to expedite the development and review of designated therapies, without changing FDA standards for new drug approval.

"The FDA's granting to GMI-1271 of Breakthrough Therapy designation will further help GlycoMimetics to accelerate the development of GMI-1271 as a treatment for this very difficult-to-treat patient population," said Helen Thackray, MD, Chief Medical Officer of GlycoMimetics. "We believe GMI-1271 when combined with chemotherapy has the potential to address an unmet therapeutic need for individuals living with AML. We are encouraged by our clinical results to date, and look forward to working closely with the FDA to bring this novel therapy to patients as quickly as possible."

About AML

Acute myeloid leukemia (AML) is a cancer of the blood and bone marrow. AML is the most common type of acute leukemia in adults. Each year in the United States, about 19,900 people (usually older than 45 years of age) are diagnosed, and about 10,400 people die from all forms of the disease, according to the American Cancer Society. Unlike other cancers that start in an organ and spread to the bone marrow, AML is known for rapid growth of abnormal white blood cells that gather in the bone marrow, getting in the way of normal blood cell production. The lack of normal blood cells can cause some of the symptoms of AML, including anemia (shortage of red blood cells resulting in tiredness and weakness), neutropenia (shortage of white blood cells that may lead to increased infections), and thrombocytopenia (shortage of platelets in the blood that may lead to excessive bleeding). Current treatment options for AML consist of reducing and eliminating cancer cells mainly through chemotherapy, radiation therapy, and stem cell transplantation.

About GlycoMimetics, Inc.

GlycoMimetics is a clinical-stage biotechnology company focused on cancer and sickle cell disease. GlycoMimetics' most advanced drug candidate, rivipansel, a pan-selectin antagonist, is being developed for the treatment of vaso-occlusive crisis in sickle cell disease and is being evaluated in a Phase 3 clinical trial being conducted by its strategic collaborator, Pfizer. GlycoMimetics' wholly-owned drug candidate, GMI-1271, an E-selectin antagonist, is being evaluated in an ongoing Phase 1/2 clinical trial as a potential treatment for AML and in a Phase 1 clinical trial in multiple myeloma. GlycoMimetics has also recently initiated a clinical trial with a third drug candidate, GMI-1359, a combined CXCR4 and E-selectin antagonist. GlycoMimetics is located in Rockville, MD in the BioHealth Capital Region. Learn more at www.glycomimetics.com.

Forward-Looking Statements

This press release contains forward-looking statements regarding GlycoMimetics' planned activities with respect to the clinical development of its drug candidate, GMI-1271. Actual results may differ materially from those indicated by such

forward-looking statements as a result of various important factors, including the availability and timing of data from ongoing clinical trials, the uncertainties inherent in the initiation of future clinical trials, whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical trials will be indicative of the results of future trials, expectations for regulatory approvals, availability of funding sufficient for GlycoMimetics' foreseeable and unforeseeable operating expenses and capital expenditure requirements, other matters that could affect the availability or commercial potential of GlycoMimetics' drug candidates and other factors discussed in the "Risk Factors" section of GlycoMimetics' Annual Report on Form 10-K that was filed with the U.S. Securities and Exchange Commission on March 1, 2017 and other filings GlycoMimetics makes with the Securities and Exchange Commission from time to time. In addition, the forward-looking statements included in this press release represent GlycoMimetics' views as of the date hereof. GlycoMimetics anticipates that subsequent events and developments may cause its views to change. However, while GlycoMimetics may elect to update these forward-looking statements at some point in the future, GlycoMimetics specifically disclaims any obligation to do so, except as may be required by law. These forward-looking statements should not be relied upon as representing GlycoMimetics' views as of any date subsequent to the date hereof.

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GlycoMimetics, Inc.
Investor Contact:
Shari Annes, 650-888-0902
sannes@annesassociates.com
or
Media Contact:
Jamie Lacey-Moreira, 410-299-3310
jamielacey@presscommpr.com

Source: GlycoMimetics, Inc.