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GlycoMimetics Initiates Phase 1/2 Clinical Trial of GMI-1271 as Potential Treatment for Acute Myeloid Leukemia in Combination with Chemotherapy

GAITHERSBURG, Md.--(BUSINESS WIRE)-- GlycoMimetics, Inc. (NASDAQ: GLYC) announced today that the first patient has been dosed in a Phase 1/2 clinical study designed to evaluate the safety, pharmacokinetics (PK) and efficacy of GMI-1271, a novel and proprietary E-selectin antagonist in the company's pipeline, when used in combination with chemotherapy in patients with acute myeloid leukemia (AML). GlycoMimetics is initially exploring the clinical use of the drug candidate in hematologic malignancies following the successful completion of a Phase 1 healthy volunteer study late last year. The Company announced last week that the U.S. Food & Drug Administration (FDA) has granted Orphan Drug designation to GMI-1271 for treatment of AML.

"We have demonstrated a very attractive preclinical profile for GMI-1271, with research findings presented through four oral presentations and a poster at the 56th ASH Annual Meeting in December 2014. These data substantiate the focus on E-selectin as a potential target for blood-related malignancies and for solid tumors at risk of metastasis," said Helen Thackray, M.D., Vice President of Clinical Development and Chief Medical Officer at GlycoMimetics. "Based on our preclinical data and on a benign safety profile in Phase 1, we believe that GMI-1271 has the potential to be an important new therapy for people with certain blood cancers."

This Phase 1/2, open-label multicenter study is designed to determine safety, PK and efficacy of GMI-1271 in combination with chemotherapy in male and female adult patients with AML. Study sites are located in the United States, Australia and Ireland. While the primary objective is to analyze safety, additional endpoints include: mobilization of AML blasts, effect on neutropenia, time to and duration of remission, evaluation of event-free survival and evaluation of the overall survival probability at six- and 12-months. Approximately 77 subjects will be enrolled. The study will include a dose escalation phase followed by expansion of the study once the dose for the Phase 2 portion has been selected.

About AML

Adult acute myeloid leukemia (AML) is a cancer of the blood and bone marrow. AML is the most common type of acute leukemia in adults, and it is estimated that there will be over 18,000 new cases and over 10,000 deaths from the disease in 2014. 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 and as a result, impede normal blood cell production. While leukemic cells move into the blood, 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 are chemotherapy and stem cell transplantation, both of which can destroy cancer cells but do not reduce the related side effects.

About GlycoMimetics, Inc.

GlycoMimetics is a clinical stage biotechnology company focused on the discovery and development of novel glycomimetic drugs to address unmet medical needs resulting from diseases in which carbohydrate biology plays a key role. Pfizer is the company's development partner for rivipansel, a GlycoMimetics-discovered investigational therapy for pain crisis associated with sickle cell disease, and is preparing to conduct a Phase 3 clinical study. A GlycoMimetics wholly-owned candidate therapy (GMI-1271) for acute myeloid leukemia (AML) and other blood disorders is also in clinical trials. Glycomimetics are molecules that mimic the structure of carbohydrates involved in important biological processes. Using its expertise in carbohydrate chemistry and knowledge of carbohydrate biology, GlycoMimetics is developing a pipeline of glycomimetic drug candidates that inhibit disease-related functions of carbohydrates, such as the roles they play in inflammation, cancer and infection. Learn more at www.glycomimetics.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements regarding the clinical development of GMI-1271. Actual results may differ materially from those 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 that was filed with the U.S. Securities and Exchange Commission on March 16, 2015, and other filings the Company 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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GlycoMimetics, Inc.
Investor Contact:
Shari Annes
Phone: 650-888-0902
Email: sannes@annesassociates.com
or
Media Contact:
Jamie Lacey-Moreira
Phone: 410-299-3310
Email: jamielacey@presscommpr.com

Source: GlycoMimetics, Inc.