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University of Michigan to Study GlycoMimetics' GMI-1271 as Potential Treatment for Serious Blood-Clotting Disorder

- National Heart Lung and Blood Institute grant is funding University of Michigan Phase 1 trial

GAITHERSBURG, Md.--(BUSINESS WIRE)-- GlycoMimetics, Inc. (NASDAQ: GLYC) today announced that the University of Michigan (U-M) has dosed the first healthy volunteer in a Phase 1 clinical trial of GMI-1271, a novel and proprietary E-selectin antagonist. U-M researchers will study use of GMI-1271 in healthy volunteers to evaluate safety and pharmacokinetics (PK), as well as biomarkers of coagulation.

"We believe that GMI-1271 may have broad applications beyond acute myeloid leukemia and other blood cancers. The U-M study of our drug candidate as a potential treatment for a serious blood-clotting disorder is an important example of a potential additional indication," said Helen Thackray, M.D., Vice President of Clinical Development and Chief Medical Officer at GlycoMimetics. "Since thrombosis is also a problem in many cancer patients, this study will complement our evaluation of GMI-1271 in hematologic malignancies."

U-M announced last December that the National Institutes of Health's National Heart Lung and Blood Institute had awarded the University $1.7 million to collaborate with GlycoMimetics to study GMI-1271 as a potential new class of anticoagulant to help millions of Americans at risk for venous thromboembolic disease (VTE), a serious blood-clotting disorder. The goal of the grant is to evaluate potential therapies that could treat and prevent blood clots with reduced risk of bleeding. Suman Sood, M.D., a hematologist at the U-M Comprehensive Cancer Center, and Thomas Wakefield, M.D., head of vascular surgery at the U-M Frankel Cardiovascular Center, are the co-principal investigators of the study.

This first U-M study of GMI-1271 is a randomized, partially blinded, active placebo-controlled trial expected to last approximately 10 months. The primary objective of the study is to evaluate the safety and PK profile of GMI-1271 in a Phase 1 single ascending dose (SAD) study in healthy volunteers. The secondary objectives include: 1) to evaluate the incidence of bleeding and other adverse events, and 2) to evaluate the effects of GMI-1271 on biomarkers of coagulation, cell adhesion and leukocyte and platelet activation.

"VTE, which includes deep vein thrombosis (DVT) and pulmonary embolism (PE), may affect up to 900,000 patients per year, with over 300,000 deaths per year in the U.S., and an increasing incidence as our population ages," said Dr. Sood. "Given that current treatment options for VTE are far from perfect, this clinical study and further evaluation of GMI-1271 as a potential new treatment option are very important for both the medical community and the people who may face the threat of VTE."

In November 2014, GlycoMimetics announced that it had completed the first Phase 1 trial with GMI-1271 in healthy volunteers. The company is initially exploring clinical use of the drug candidate to treat AML following preclinical studies of GMI-1271 for blood cancers and other cancers that are associated with elevated risk of metastasis and thrombosis. The company's next planned study is a Phase 1/2 trial of GMI-1271 as an adjunct to standard chemotherapy in patients with AML.

Preclinical data for GMI-1271 will be presented in four oral presentations during the 2014 ASH Annual Meeting this month, including one presentation entitled "E-Selectin Inhibitor GMI-1271 Works in Combination with Low-Molecular Weight Heparin to Decrease Venous Thrombosis and Bleeding Risk in a Mouse Model."

About VTE

VTE, which can happen after a major operation, or severe illness such as heart attack, stroke and some cancers, refers to both pulmonary embolism and deep vein thrombosis (DVT), blood clots that form in large veins of the legs. The clots become dangerous when they break loose and affect blood flow to the heart and lungs. A mainstay of VTE prevention and treatment are anticoagulants that reduce blood clotting, but the medicines are associated with a significant risk of hemorrhage and for the most part do not decrease the inflammation that comes with VTE. Based upon preclinical study with data presented at the 2012 ASH Annual Meeting ("Novel E-Selectin Antagonist GMI-1271 Decreases Venous Thrombosis without Increased Bleeding Potential in a Mouse Model"), it appears that GMI-1271 may lead to reduced bleeding risk and reduction in inflammation. Studies have shown that inflammation and thrombosis are interrelated, and that inflammation contributes to the thrombotic process.

About GMI-1271

E-selectin antagonist GMI-1271 has the potential to be used in combination with chemotherapy to improve outcomes in cancer patients. It is being evaluated to determine if it can improve response rates and overall survival. It may also address both metastasis (cancer's spread) and thromboembolic complications (those occurring when a blood vessel is blocked by a blood clot dislodged from its site of origin). GlycoMimetics selected AML as the initial target disease indication for the compound and announced the completion of the first Phase 1 clinical study during November of 2014. GlycoMimetics has conducted preclinical studies to explore the compound's use in blood cancers and other cancers that are also associated with elevated risk of metastasis and thrombosis. Data supporting use of GMI-1271 was presented at the 2013 ASH Annual Meeting in an oral presentation entitled "Adhesion of Acute Myeloid Leukemia Blasts to E-Selectin in the Vascular Niche Enhances Their Survival By Mechanisms Such as Wnt Activation" and in a poster entitled "Administration of E-selectin Antagonist GMI-1271 Improves Survival to High-Dose Chemotherapy by Alleviating Mucositis and Accelerating Neutrophil Recovery."

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 on Forward-Looking Statements

The statements in this press release that are not historical facts constitute "forward-looking statements" that involve risks and uncertainties and are made pursuant to the Private Securities Litigation Reform Act of 1995. These forward-looking statements may be identified by their use of terms and phrases such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, or the negative of such terms, and include, but are not limited to, GlycoMimetics' expectations regarding potential payments under its collaboration with Pfizer and its planned activities with respect to the clinical development of GMI-1271. Actual results may differ materially from those expressed or implied by these forward-looking statements as a result of a number of 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" sections of the company's quarterly Report on Form 10-Q that was filed with the U.S. Securities and Exchange Commission (SEC) on October 31, 2014, and in other filings GlycoMimetics makes with the SEC from time to time. The forward-looking statements included in this press release represent GlycoMimetics' views as of the date of this release and should not be relied upon as representing the company's views as of any date subsequent to 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, it undertakes no obligation to update or revise these statements, except as may be required by law.

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