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GlycoMimetics Doses First Patient in Phase 2 Portion of Clinical Trial of GMI-1271 in Newly Diagnosed Acute Myeloid Leukemia

ROCKVILLE, Md.--(BUSINESS WIRE)-- GlycoMimetics, Inc. (NASDAQ: GLYC) today announced dosing of the first patient with newly diagnosed acute myeloid leukemia (AML) in the Phase 2 portion of its ongoing Phase 1/2 study evaluating its novel E-selectin antagonist, GMI-1271, combined with chemotherapy. Earlier this month, the company announced it had received Fast Track designation from the U.S. Food and Drug Administration (FDA) for GMI-1271 for treatment of adult patients with relapsed or refractory AML and elderly patients aged 60 years or older with AML. In addition, GlycoMimetics recently announced that the first patient with relapsed or refractory AML has been dosed in the other arm of the Phase 2 portion of this study.

For the study's Phase 2 portion, the optimal dose of GMI-1271 has been determined, and in this arm of the study clinical investigators will study the effects on newly diagnosed patients receiving the drug candidate to obtain additional safety and efficacy data. Study enrollment in this arm is limited to patients at least 60 years of age who have been newly diagnosed with AML and are eligible to receive treatment with the chemotherapy agents cytarabine and idarubicin ('7+3'). All patients must be eligible to receive this intensive chemotherapy regimen, and will be given GMI-1271 in addition to this combination chemotherapy. During the Phase 1 portion of the study, patients received a single cycle of treatment including GMI-1271. During this Phase 2 portion, certain patients will be eligible to receive additional cycles of treatment.

"The data from the first cohorts point to both the safety and potential efficacy of GMI-1271 as a treatment for AML," said Helen Thackray, M.D., Chief Medical Officer of GlycoMimetics. "We are now enrolling a new group of study participants to evaluate the effects of GMI-1271 on newly diagnosed patients who also are receiving chemotherapy. If the second half of the trial confirms our earlier preclinical and clinical findings, we believe that GMI-1271 could well address the unmet needs of AML patients, beyond what is currently possible with available therapies."

This clinical trial is a multinational open-label study evaluating endpoints for safety, pharmacokinetics (PK) and efficacy of GMI-1271 in combination with induction chemotherapy in patients with high-risk AML. This trial is being conducted at a number of academic medical institutions in the United States, Ireland, and Australia. While the primary objective is to assess safety, additional endpoints include overall response rate, biomarkers of activity, durability of response and overall survival. This Phase 2 portion of the study in newly diagnosed patients is expected to include approximately 25 participants.

GlycoMimetics announced on June 10, presentation of data in patients with relapsed/refractory acute AML from the Phase 1 portion of this ongoing study. Data were reported at the European Hematology Association 21st Congress in Copenhagen, Denmark in a poster entitled "Results of a Phase 1 study of GMI-1271, a potent E-selectin antagonist in combination with induction chemotherapy in relapsed/refractory AML: a novel, well-tolerated regimen with a high remission rate."

About GMI-1271

GMI-1271 is designed to block E-selectin (an adhesion molecule on cells in the bone marrow) from binding with AML cells as a targeted approach to disrupting well-established mechanisms of leukemic cell resistance within the bone marrow microenvironment. Preclinical research points to the drug's potential role in moving cancerous cells out of the protective environment of the bone marrow where they hide and escape the effects of chemotherapy. In preclinical studies using animal models of AML, the results of which were presented at meetings of the American Society of Hematology (ASH), GMI-1271 was also associated with a reduction of chemotherapy-induced neutropenia and chemotherapy-induced mucositis.

About GlycoMimetics, Inc.

GlycoMimetics is a clinical-stage biotechnology company focused on sickle cell disease and cancer. 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. GlycoMimetics expects to file an IND with the FDA for a third drug candidate, GMI-1359, a combined CXCR4 and E-selectin antagonist, in the third quarter of 2016. 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 February 29, 2016, 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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