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GlycoMimetics Doses First Patient in Phase 2 Portion of GMI-1271 Clinical Trial in Relapsed/Refractory Acute Myeloid Leukemia

ROCKVILLE, Md.--(BUSINESS WIRE)-- GlycoMimetics, Inc. (NASDAQ:GLYC) today announced dosing of the first patient with relapsed/refractory acute myeloid leukemia in the Phase 2 portion of its ongoing Phase 1/2 clinical trial evaluating its novel E-selectin antagonist, GMI-1271, combined with induction chemotherapy.

For the study's Phase 2 portion, the optimal dose has been determined, and clinical investigators will expand the number of patients receiving GMI-1271 to obtain additional safety and efficacy data. Study enrollment is limited to patients at least 18 years old with relapsed or refractory AML and who would be treated with mitoxantrone, etoposide, and cytarabine ('MEC'). All patients must be eligible to receive this 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 an additional cycle 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. "In the second half of this trial, we will further assess if patients with relapsed or refractory AML respond well to this combination approach while also including those who have been newly diagnosed with the disease in a separate arm of the study. If the second half confirms our earlier preclinical and clinical findings, we believe that GMI-1271 could well address the unmet needs of AML patients, beyond what can be done with currently 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 is expected to include approximately 25 participants.

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.

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