GlycoMimetics Announces NCI-Sponsored Pivotal Trial of GMI-1271 in Older, Newly Diagnosed AML Patients Fit for Intensive Chemotherapy

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- *Third of three planned trials positions GlycoMimetics to address unmet needs across the AML spectrum*

ROCKVILLE, Md.--(BUSINESS WIRE)--May 30, 2018-- GlycoMimetics, Inc. (NASDAQ: GLYC), a biopharmaceutical company focused on discovering and developing novel small-molecule drug candidates to treat rare diseases, announced today it had signed a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI), part of the National Institutes of Health (NIH). Under the terms of the CRADA, GlycoMimetics will collaborate with both the NCI and the Alliance for Clinical Trials in Oncology to conduct a randomized, controlled clinical trial testing the addition of GMI-1271 to a standard cytarabine/daunorubicin regimen (7&3) in older adults with previously untreated acute myelogenous leukemia (AML) who are suitable for intensive chemotherapy. This Phase 3 trial will be led by Geoffrey Uy, M.D., Associate Professor of Medicine, Bone Marrow Transplantation and Leukemia, Washington University School of Medicine in St. Louis, and the primary endpoint will be overall survival, with a planned interim analysis based on event-free survival (EFS) after the first 250 patients have been enrolled in the study.

“The NCI’s support of this clinical development program in AML reflects a high-level of interest from the U.S.’s leading clinical investigators and oncology thought leaders,” noted Helen Thackray, M.D., FAAP, GlycoMimetics Senior Vice President, Clinical Development, and Chief Medical Officer. “Based on our Phase 2 data, we believe GMI-1271 has the ideal profile to become the possible foundation of treatment across the continuum of care in AML. This is an important collaboration for us as we seek to realize the full potential of this novel therapeutic.”

Under the terms of the CRADA, the NCI may also fund additional research, including clinical trials involving pediatric patients with AML as well as preclinical experiments and clinical trials evaluating alternative chemotherapy regimens. GlycoMimetics will supply GMI-1271 as well as provide financial support to augment data analysis and monitoring for the Phase 3 program.

In addition, GlycoMimetics announced that the generic name for GMI-1271 will be uproleselan, and the drug candidate will be referred to by this name going forward.

About GMI-1271 (Uproleselan)

GMI-1271 is designed to block E-selectin (an adhesion molecule on cells in the bone marrow) from binding with blood cancer cells as a targeted approach to disrupting well-established mechanisms of leukemic cell chemoresistance within the bone marrow microenvironment. In a Phase 1/2 clinical trial, GMI-1271 was evaluated in both newly diagnosed elderly and relapsed/refractory patients with acute myeloid leukemia (AML). In both populations, patients treated with GMI-1271 together with standard chemotherapy achieved better than expected remission rates and overall survival compared to historical controls, which have been derived from results from third party clinical trials evaluating standard chemotherapy, as well as lower than expected induction-related mortality rates. Treatment in these patient populations was generally well tolerated, with fewer than expected adverse effects. The FDA has granted GMI-1271 Breakthrough Therapy designation for the treatment of adult AML patients with relapsed/refractory disease.

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. 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 (uproleselan), an E-selectin antagonist, was evaluated in a Phase 1/2 clinical trial as a potential treatment for AML and is currently being evaluated in a Phase 1 clinical trial for the treatment of multiple myeloma. The FDA granted GMI-1271 Breakthrough Therapy designation for the treatment of adult AML patients with relapsed/refractory disease. GlycoMimetics is also conducting a Phase 1 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.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements regarding the clinical development of the company’s drug candidates, including the expected timing of completion of clinical trials and the presentation of clinical data. 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 filed with the U.S. Securities and Exchange Commission (SEC) on March 6, 2018, and other filings GlycoMimetics 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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