GlycoMimetics Announces Enrollment of First Patient in NCI-Sponsored Phase 3 Trial of Uproleselan in AML

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- *Evaluating previously untreated newly diagnosed adults with acute myeloid leukemia (AML) who are fit for intensive chemotherapy*
- *Second initiation among three late-stage uproleselan clinical trials*

ROCKVILLE, Md.--(BUSINESS WIRE)--Apr. 23, 2019-- GlycoMimetics, Inc. (NASDAQ: GLYC) announced today dosing of the first patient in a Phase 3 clinical trial being conducted under the auspices of a Cooperative Research and Development Agreement (CRADA) between GlycoMimetics and the National Cancer Institute (NCI), part of the National Institutes of Health. The second in a series of trials designed to evaluate uproleselan across the continuum of care in AML, this NCI-sponsored study is evaluating the addition of uproleselan to a standard cytarabine/daunorubicin regimen (7&3) in older adults with previously untreated AML who are suitable for intensive chemotherapy. A third trial, to be conducted by the European HOVON consortium, is expected to initiate later this year.

“The initiation of the NCI-sponsored trial is an important milestone for our uproleselan program, a drug candidate with the potential to address significant unmet treatment needs across the spectrum of AML,” noted Helen Thackray, M.D., FAAP, GlycoMimetics Senior Vice President, Clinical Development, and Chief Medical Officer. “Along with our global pivotal Phase 3 clinical trial testing the investigational drug in patients with relapsed/refractory acute myeloid leukemia, this trial will facilitate our growing understanding of how uproleselan may fit into the continuum of care for individuals living with AML.”

GlycoMimetics is collaborating with both the NCI and the Alliance for Clinical Trials in Oncology to conduct the trial, which is led by Geoffrey Uy, M.D., Associate Professor of Medicine, Bone Marrow Transplantation and Leukemia, Washington University School of Medicine in St. Louis. 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. More information on this clinical trial can be found at www.clinicaltrials.gov.

New data on uproleselan-treated high-risk patients with both relapsed/refractory and newly diagnosed AML were presented at an oral session during the 60th American Society of Hematology (ASH) Annual Meeting and Exposition in December 2018. An analysis of clinical outcomes from the Phase 1/2 clinical study showed that uproleselan (GMI-1271) resulted in the majority of evaluable patients achieving a stringent level of measurable residual disease (MRD) negativity, an effect which translated into extended survival relative to matched, historical controls.

About Uproleselan (GMI-1271)

uproleselan (yoo’ pro le’ sel an) 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 resistance within the bone marrow microenvironment. In a Phase 1/2 clinical trial, uproleselan was evaluated in both newly diagnosed elderly and relapsed/refractory patients with AML. In both populations, patients treated with uproleselan 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 U.S. Food and Drug Administration (FDA) has granted uproleselan Breakthrough Therapy Designation for the treatment of adult AML patients with relapsed/refractory (R/R) disease. GlycoMimetics is implementing a comprehensive development program across the clinical spectrum of AML.

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, uproleselan, an E-selectin antagonist, was evaluated in a Phase 1/2 clinical trial as a potential treatment for AML and is being evaluated across a range of patient populations including a company-sponsored Phase 3 trial in relapsed/refractory AML. GlycoMimetics has also completed 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.

Forward-Looking Statements

This press release contains forward-looking statements regarding the clinical development and regulatory pathway of the Company’s drug candidates, including the expected enrollment in and conduct of clinical trials, expected timelines related to the announcement of top-line rivipansel data, the potential for rivipansel and the Company’s other drug candidates to be attractive therapies if approved and the expected safety and efficacy of the Company’s drug candidates based on data from completed clinical trials. 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, 2019, 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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