NCI-Sponsored Trial of Uproleselan in Older, Newly Diagnosed AML Patients Fit for Intensive Chemotherapy Completes Enrollment of Phase 2 Portion Ahead of Schedule

December 6, 2021

Completion of enrollment sets the stage for planned interim analysis evaluating event-free survival and potential for regulatory filings, if positive

ROCKVILLE, Md.--(BUSINESS WIRE)--Dec. 6, 2021-- GlycoMimetics, Inc. (Nasdaq: GLYC), a clinical-stage biotechnology company, announced today that the National Cancer Institute (NCI), part of the National Institutes of Health (NIH), and the Alliance for Clinical Trials in Oncology, have completed enrollment of 267 patients in the Phase 2 portion of the adaptive Phase 2/3 trial evaluating whether uproleselan improves overall survival in newly diagnosed patients 60 years or older with acute myeloid leukemia (AML). The randomized, controlled trial is evaluating the addition of uproleselan, GlycoMimetics' investigational, first-in-class, targeted antagonist of E-selectin, to a standard cytarabine/daunorubicin regimen (7&3) in older adults with previously untreated AML who are suitable for intensive chemotherapy. Completion of enrollment now sets the stage for a planned evaluation of the Phase 2 portion of the trial to determine whether the prespecified threshold for continuing to Phase 3 has been met based on event-free survival (EFS). Geoffrey Uy, M.D., Professor of Medicine, Washington University School of Medicine in St. Louis, is the trial's Principal Investigator. GlycoMimetics and NCI are collaborating on the development of uproleselan under a Cooperative Research and Development Agreement.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20211206005485/en/

"I would like to thank the Alliance for completing the enrollment of the Phase 2 portion despite all of the logistical challenges associated with the pandemic. If the EFS analysis meets the preplanned metric, the data will be transferred confidentially to GlycoMimetics to support regulatory filings for uproleselan in AML, and enrollment will continue in the Phase 3 portion of the trial," said Harout Semerjian, GlycoMimetics Chief Executive Officer. "Together, the GlycoMimetics- and NCI-sponsored programs will constitute a large dataset of 650 patients with AML. We would anticipate filing with regulatory agencies for approval for treatment of patients in both the frontline and relapsed/refractory AML settings should both trials achieve positive readouts."

About Uproleselan

Discovered and developed by GlycoMimetics, uproleselan is an investigational, first-in-class, targeted antagonist of E-selectin. Uproleselan (yoo' pro le' sel an), currently in a comprehensive Phase 3 development program in AML, has received Breakthrough Therapy designation from the U.S. Food and Drug Administration and the Chinese Health authority for the treatment of adult patients with AML who have relapsed or refractory disease. Uproleselan 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.

About GlycoMimetics, Inc.

GlycoMimetics is a clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers, including acute myeloid leukemia (AML), and for inflammatory diseases with high unmet need. The Company's science is based on an understanding of the role that carbohydrates play on the surface of every living cell and applying its specialized chemistry platform to discover small molecule drugs, known as glycomimetics, that alter these carbohydrate-mediated pathways in a variety of disease states, including signaling in cancer and inflammation. As a leader in this space, GlycoMimetics is leveraging this unique targeted approach to advance its pipeline of wholly owned drug candidates, with the goal of developing transformative therapies for serious diseases. The Company's leading drug candidate, uproleselan, has received Breakthrough Therapy Designation in the U.S. and China and is undergoing evaluation across a range of patient populations, including a phase 3 trial in relapsed/refractory AML. GlycoMimetics is located in Rockville, MD in the BioHealth Capital Region. Learn more at www.glycomimetics.com.

About Alliance for Clinical Trials in Oncology

The Alliance for Clinical Trials in Oncology comprises nearly 10,000 cancer specialists at hospitals, medical centers and community clinics across the United States and Canada. Through collaboration with the NCI National Clinical Trials Network (NCTN), the Alliance develops and conducts clinical trials with promising new cancer therapies, and utilizes the best science to develop optimal treatment and prevention strategies for cancer, as well as research methods to alleviate side effects of cancer and cancer treatments. To learn more about the Alliance, visit http://www.AllianceforClinicalTrialsinOncology.org.

Forward-Looking Statements

This press release contains forward-looking statements. These forward-looking statements include those relating to the planned or potential clinical development and potential benefits and impact of the Company's drug candidate, uproleselan. Actual results may differ materially from those described 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 February 28, 2021, 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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