GlycoMimetics Announces Investigator-Sponsored Phase 2 Clinical Trial Evaluating Uproleselan for Prevention of Gastro-Intestinal Toxicity in Autologous Hematopoietic Cell Transplantation

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Clinicians at Washington University in St. Louis Enroll Trial's First Patient at Siteman Cancer Center

ROCKVILLE, Md.--(BUSINESS WIRE)--May 26, 2021-- GlycoMimetics, Inc. (Nasdaq: GLYC) announced today that clinicians at Washington University School of Medicine in St. Louis have dosed the first patient in an investigator-sponsored trial (IST) evaluating uproleselan as a prophylactic agent to reduce gastrointestinal (GI) toxicities associated with high-dose melphalan in autologous hematopoietic cell transplantation (auto-HCT) for multiple myeloma (MM). Dr. Keith Stockerl-Goldstein, M.D., Professor of Medicine, Division of Oncology, Section of Bone Marrow Transplantation, Washington University School of Medicine, is the clinical trial's principal investigator.

"GI side effects are the dose-limiting toxicities of high-dose melphalan in autologous hematopoietic stem-cell transplantation. Preclinical data have demonstrated a protective effect of uproleselan against mucosal damage and, in the GlycoMimetics Phase 2 trial reported at the American Society of Hematology (ASH) meeting in 2018, uproleselan demonstrated the potential to mitigate severe mucositis in relapsed and refractory acute myeloid leukemia (AML) patients undergoing intensive chemotherapy," said Eric J. Feldman, M.D., GlycoMimetics' Chief Medical Officer. "With this background, Washington University clinicians at Siteman Cancer Center will be the first to look closely at the potential of uproleselan to attenuate GI toxicities in multiple myeloma patients undergoing transplant. If this placebo-controlled study demonstrates positive improvements, we believe it will underscore the unique properties of our compound and the potential safety benefits of adding uproleselan to a range of other standard blood cancer therapies where toxicity and durability of response are concerns."

About the Phase 2 Study

The study led by Washington University is a Phase 2, single-center, randomized, double-blind, and placebo-controlled IST designed to evaluate whether prophylactic uproleselan plus standard of care (SOC) compared to placebo plus SOC can reduce diarrhea severity in patients receiving high-dose melphalan conditioning in preparation for auto-HCT in MM. Clinicians will observe for oral mucositis severity and other GI toxicities as secondary endpoints. Exploratory endpoints will also assess minimal residual disease at 100 days post-HCT; soluble E-selectin levels at pre-dose and post-conditioning time points; progression free survival; and overall survival.

Eligible patients undergoing first auto-HCT with melphalan conditioning (200mg/m^2) for MM will be randomized in a 1:1 allocation to receive either prophylactic uproleselan plus SOC or placebo plus SOC. Randomization will be stratified by age ≥65 years and <65 years, due to increased frequency of GI toxicity in elderly populations. GlycoMimetics anticipates a data readout from the trial in mid-2022.

Siteman Cancer Center, based at Barnes-Jewish Hospital and Washington University School of Medicine, is a top-ranked National Cancer Institute (NCI)-designated Comprehensive Cancer Center and recently received the NCI's highest possible rating of "Exceptional" for its research programs.

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 AML patients with 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 breast cancer, and inflammatory diseases with high unmet need. Our science is based on an understanding of the role that carbohydrates play on the surface of every living cell and applying our 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, we are leveraging this unique targeted approach to advance our pipeline of wholly owned drug candidates, with the goal of developing transformative therapies for serious diseases. Our 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.

Forward-Looking Statements

This press release contains forward-looking statements. These forward-looking statements include those relating to the planned or potential clinical development of the Company's product candidates, as well as the presentation of data from preclinical studies and clinical trials and the potential benefits and impact of the Company's drug candidates. 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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