Trial Launches to Evaluate GlycoMimetics' Uproleselan Added to Cladribine Plus Low-Dose Cytarabine in AML Patients

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Trial to study uproleselan combination in patients with high-risk treated secondary AML

ROCKVILLE, Md.--(BUSINESS WIRE)--Jul. 22, 2021-- GlycoMimetics, Inc. (Nasdaq: GLYC) announced today that clinicians have treated the first patient in a Phase 1b/2 study evaluating the company's lead drug candidate, uproleselan, added to cladribine plus low dose cytarabine (LDAC) in patients with treated secondary AML (ts-AML). The investigator-sponsored trial is being led by Tapan Kadia, M.D., associate professor of Leukemia at The University of Texas MD Anderson Cancer Center.

According to Eric Feldman, M.D., GlycoMimetics' Chief Medical Officer, "Patients with treated secondary AML have an extremely poor prognosis. Despite new drug approvals in the field, subgroups of patients with limited options still exist, especially those whose disease has progressed following treatment with a hypomethylating agent. Our previous preclinical and clinical research supports the potential for these patients to benefit from the addition of uproleselan. If the new study demonstrates that targeting E-selectin with uproleselan could help to overcome resistance to other therapies, this would be a significant achievement that underscores the broad potential of our drug candidate."

About the Phase 1b/2 Clinical Trial

The Phase 1b/2 single-arm trial is enrolling patients 18 years or older, with a diagnosis of ts-AML who have not received therapy for their AML. Considered a distinct high-risk subset of AML with an adverse prognosis, ts-AML is defined as AML arising from a previously treated antecedent myeloid neoplasm (myelodysplastic syndrome or myeloproliferative neoplasm). Clinicians plan to enroll approximately 25 patients in the trial.

GlycoMimetics is providing uproleselan for the investigator-sponsored trial. The study is designed to evaluate both the safety and tolerability of the combination therapy, as well as to identify a recommended Phase 2 dose of the uproleselan triple combination approach in patients with ts-AML. Among the trial's secondary objectives are efficacy assessments including overall response rate, complete response, complete response without blood count recovery, and other measures. The rate of minimal residual disease negativity will also be evaluated by flow cytometry at response. Exploratory endpoints include examination of biomarkers of response and resistance and the correlation of the expression of E-selectin ligand-forming glycosylation genes of leukemic blasts with clinical outcome.

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 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.

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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