GlycoMimetics Announces Strategic Review and Corporate Restructuring Plan

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- After meeting with the U.S. Food and Drug Administration (FDA), it has been determined that the regulatory path forward for uproleselan in relapsed and refractory (R/R) Acute Myeloid Leukemia (AML) would require an additional clinical trial
- The Company will conduct a strategic review of the business seeking to maximize shareholder value, including the evaluation of potential business development opportunities for uproleselan and GMI-1687 to ensure their continued advancement
- The Company is advancing discussions with the National Cancer Institute (NCI) and Alliance for Clinical Trials in Oncology for the ongoing Phase 2/3 study of uproleselan in newly diagnosed AML patients
- The Company will reduce its workforce by approximately 80%; cash and cash equivalents are expected to fund the company into the second quarter of 2025

ROCKVILLE, Md.--(BUSINESS WIRE)--Jul. 25, 2024-- GlycoMimetics, Inc. (Nasdaq: GLYC), a late clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers and inflammatory diseases, today announced the initiation of a strategic review and corporate restructuring plan. GlycoMimetics has engaged Lucid Capital Markets to act as a strategic advisor in the process.

“We are committed to acting in the best interests of patients, employees and shareholders. Given our organization’s cash resources, we plan to explore a range of potential strategic alternatives and seek to deliver value to our shareholders and find avenues that allow uproleselan and GMI-1687 to build upon their clinical promise, including in the ongoing NCI Phase 2/3 study of uproleselan in newly diagnosed AML patients,” said Harout Semerjian, Chief Executive Officer of GlycoMimetics. “We believe both drug candidates have the potential to address significant unmet needs in their respective therapeutic areas and we are focused on finding organizations to advance these programs. We are proud of our team’s dedication to improving the lives of patients and are thankful for their hard work progressing uproleselan and GMI-1687.”

The Company will evaluate strategic alternatives and no timetable has been set for the conclusion of the strategic review or the consummation of any such strategic transaction.

GlycoMimetics had cash and cash equivalents of approximately $31.3 million as of March 31, 2024. Based on the corporate restructuring and streamlining of operations, the Company expects to significantly reduce future operating expenses and extend its cash runway into the second quarter of 2025.

NCI Phase 2/3 Study of Uproleselan in Frontline AML

The National Cancer Institute (NCI) and the Alliance for Clinical Trials in Oncology are conducting an adaptive Phase 2/3 study of uproleselan in adults with newly diagnosed AML who are 60 years or older and fit for intensive chemotherapy. Their randomized, controlled study is evaluating the addition of uproleselan to a standard cytarabine / daunorubicin regimen (7+3) versus chemotherapy alone. The Phase 2 portion of the study completed enrollment of 267 patients in December 2021.

About AML

AML is the most common acute leukemia in adults. A cancer of the bone marrow, nearly 21,000 people in the United States are diagnosed with AML each year. Despite the availability of multiple treatments, disease prognosis is poor, and new treatment options are needed to improve outcomes. Newly diagnosed AML has the lowest 5-year survival rate of all leukemias at 31.7%. The five-year survival rate for people with relapsed/refractory disease is only 10%.

About Uproleselan

Discovered and developed by GlycoMimetics, uproleselan (yoo’ pro le’se lan) is an investigational, first-in-class E-selectin antagonist. GlycoMimetics has received Breakthrough Therapy and Fast Track designations from the U.S. Food and Drug Administration (FDA) and Breakthrough Therapy designation from the Chinese National Medical Products Administration for uproleselan as a potential treatment for adult AML patients with relapsed or refractory disease. E-selectin is a leukocyte adhesion molecule constitutively expressed on endothelial cells of the vasculature and bone marrow. In AML, there is evidence that E-selectin–ligand interaction between endothelial cells in the protective niche of the Bone Marrow microEnvironment (BME) and leukemic stem cells and blasts promotes leukemic cell survival and hides them from AML therapies. Uproleselan is designed to disrupt E-selectin binding and prevent leukemic myeloid cells using the protective niche of the BME.

About GMI-1687

Discovered and developed by GlycoMimetics, GMI-1687 is a highly potent E-selectin antagonist that is bioavailable after subcutaneous administration. This second-generation compound has potential application in oncology and inflammatory diseases, and the company’s initial clinical development has focused on sickle-cell disease (SCD). E-selectin is believed to play a major role in vaso-occlusive events (VOEs), a group of acute complications that are associated with SCD and include vaso-occlusive pain crises, acute chest syndrome (ACS), stroke, and splenic sequestration. Administration of GMI-1687 by subcutaneous injection, if successfully developed in the clinic, may enable this study drug to be approved as a patient-controlled, point-of-care treatment option.

About GlycoMimetics, Inc.

GlycoMimetics is a late clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers, including AML, and for inflammatory diseases. The company's scientific approach is based on an understanding of the role that carbohydrates play in cell recognition. Its specialized chemistry platform can be used to discover small molecule drugs, known as glycomimetics, that alter carbohydrate-mediated recognition in diverse disease states, including cancers and inflammation. The company's goal is to develop transformative therapies for diseases with high unmet medical need. GlycoMimetics is headquartered 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 may include, but are not limited to, statements regarding the conduct of a strategic review of its business, the implementation of a corporate restructuring plan, the extension of its cash resources, and the potential benefits and impact of its product 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 March 27, 2024, the company's Quarterly Report on Form 10-Q filed with the SEC on May 9, 2024, 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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Investor Contact:
Argot Partners
Leo Vartorella
212-600-1902
Glycomimetics@argotpartners.com

Source: GlycoMimetics, Inc.