GlycoMimetics Announces Results of Pivotal Phase 3 Study of Uproleselan in Relapsed/Refractory (R/R) Acute Myeloid Leukemia (AML)

May 6, 2024 at 6:00 AM EDT

- Study of uproleselan combined with chemotherapy did not meet its primary endpoint of overall survival in the intent to treat population
- Adverse events were consistent with known side effect profiles of chemotherapy used in the study
- Comprehensive data analysis with medical, statistical, and regulatory experts underway and will be shared as appropriate; company will submit results for presentation at an upcoming medical meeting
- National Cancer Institute (NCI) Phase 2/3 study in newly diagnosed AML patients remains ongoing
- Conference call and webcast to be hosted today, May 6, 2024, at 8:30 a.m. ET.

ROCKVILLE, Md.--(BUSINESS WIRE)--May 6, 2024-- GlycoMimetics, Inc. (Nasdaq: GLYC), a late clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers and inflammatory diseases, today announced topline results from its Phase 3 global pivotal study of uproleselan in 388 patients with R/R AML. In the study, uproleselan combined with chemotherapy did not achieve a statistically significant improvement in overall survival in the intent to treat population versus chemotherapy alone.

Patients treated with uproleselan had a median overall survival of 13 months, compared to 12.3 months in the placebo arm. Adverse events were consistent with known side effect profiles of chemotherapy used in the study.

“While the outcome of our Phase 3 study in R/R AML is not what we hoped, we wish to thank the investigators, the participating patients and their families for their dedication to this large, well-controlled randomized study,” said Harout Semerjian, Chief Executive Officer of GlycoMimetics. “We are thoroughly analyzing the data in collaboration with medical, statistical and regulatory experts and are committed to submitting a comprehensive data analysis for presentation at an upcoming medical meeting.”

The randomized, double-blind, placebo-controlled Phase 3 clinical study evaluated uproleselan in combination with MEC (mitoxantrone, etoposide and cytarabine) or FAI (fludarabine, cytarabine and idarubicin) in patients with R/R AML. Patients received either uproleselan or placebo for 8 days over 1 cycle of an induction and, if applicable, up to 3 cycles of consolidation. The primary endpoint of the study was overall survival without censoring for transplant. Secondary endpoints included incidence of severe oral mucositis, complete remission rate and remission rate. A total of 388 patients across 70 sites in nine countries were randomized 1:1 between treatment and placebo arms.

The 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. The 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. Results of the pre-planned Phase 2 event free survival interim analysis will be reported when available.

First Quarter 2024 Preliminary Financial Results

Today, the company also disclosed its preliminary financial results for the first quarter of 2024.

- Cash position: As of March 31, 2024, GlycoMimetics had cash and cash equivalents of $31.3 million, compared to $41.8 million as of December 31, 2023.
- R&D Expenses: The company’s research and development expenses increased to $6.0 million for the quarter ended March 31, 2024, as compared to $5.4 million for the same period in 2023. These increases were due to raw material acquisition costs for future manufacturing batches.
- G&A Expenses: The company’s general and administrative expenses decreased to $5.1 million for the quarter ended March 31, 2024, compared to $5.5 million for the same period in 2023. The decrease was due to lower personnel-related and external consulting expenses.
- Shares Outstanding: Shares of common stock outstanding as of March 31, 2024, were 64,450,835.

Conference Call Information

The company will host a conference call and webcast today at 8:30 a.m. ET. To access the call by phone, please go to this registration link and you will be provided with dial in details. Participants are encouraged to connect 15 minutes in advance of the scheduled start time.

A live webcast of the call will be available on the “Investors” tab on the GlycoMimetics website. A webcast replay will be available for 30 days following the call.

Please note this call will replace the previously announced First Quarter 2024 Financial Results call scheduled for May 9, 2024 at 8:30 a.m. ET.

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 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 is being deployed to discover small molecule drugs, known as glycomimetics, that alter carbohydrate-mediated recognition in diverse disease states, including cancers and inflammation. GlycoMimetics is leveraging its differentiated expertise with this scientific approach in order to advance its pipeline of wholly owned drug candidates. 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, and timing for analysis and presentation of data from, clinical trials; potential development and regulatory activities; and the potential benefits and impact of 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 March 27, 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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