GlycoMimetics Announces Continuation of Phase 3 Study of E-selectin Antagonist Uproleselan in Relapsed/Refractory AML to Originally Planned Final Analysis Following Interim Analysis by Independent Data Monitoring Committee

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- Independent Data Monitoring Committee recommended pivotal Phase 3 study continue to the originally planned final overall survival events trigger and expressed no concerns about safety
- Interim utility analysis was conducted using a very high statistical threshold to preserve the integrity of the originally planned final analysis
- Review of blinded pooled data shows patients continue to live longer than historical benchmarks; final survival event trigger now expected within first half of 2024
- Company raised $32.9 million net proceeds via ATM facility, extending cash runway into Q4 2024

ROCKVILLE, Md.--(BUSINESS WIRE)--Feb. 15, 2023-- GlycoMimetics, Inc. (Nasdaq: GLYC) today announced the independent Data Monitoring Committee (DMC) reviewed the interim utility analysis of its Phase 3 study of uproleselan in relapsed/refractory (R/R) acute myeloid leukemia (AML) and recommended the study should continue to the originally planned final overall survival event trigger.

“We thank the independent DMC for its recommendation and are strongly encouraged as the blinded pooled survival data continues to show patients living longer than historical benchmarks. Going forward, survival duration for new events in the study will be greater than 14 months since the last patient was randomized, giving us confidence in the potential for uproleselan to improve outcomes for people living with R/R AML,” said Harout Semerjian, Chief Executive Officer of GlycoMimetics. “We are proud to be advancing a novel treatment with significant potential to address the urgent unmet medical need in this acute leukemia, and we look forward to continuing the study to the originally planned final overall survival analysis, now expected within the first half of 2024.”

The interim utility analysis was added to the study in the fall of 2022 as blinded pooled survival data showed patients living longer than expected based on the historical benchmarks used to design the study. The plan for the independent DMC to review efficacy and safety data at approximately 80% of planned survival events was cleared with the U.S. Food and Drug Administration.

When designing the interim analysis, the company amended the protocol to create the opportunity to achieve unblinding at around 80% of survival events while maintaining the integrity of the final analysis should the DMC recommend the study continue to the final overall events trigger. The interim analysis plan required a high statistical threshold to be met for the independent DMC to recommend unblinding, reserving approximately 95% of the study’s statistical power for the final analysis.

Recent Sales under ATM Facility

Since the start of the fourth quarter of 2022, GlycoMimetics sold 11,776,784 shares of common stock under its existing “at-the-market” (ATM) sales facility, raising a total of $32.9 million in net proceeds. These additional proceeds are expected to extend the company’s cash runway into the fourth quarter of 2024. The company intends to use its capital resources to advance the clinical development of and prepare regulatory filings for marketing approval of uproleselan, and to plan for uproleselan’s potential commercialization to continue the evolution of GlycoMimetics into a commercial-stage company.

About Uproleselan

Discovered and developed by GlycoMimetics, uproleselan is an investigational first-in-class, E-selectin antagonist. Uproleselan (yoo’ pro le’se lan), currently in a comprehensive Phase 3 development program in acute myeloid leukemia (AML), has received Breakthrough Therapy designation from the U.S. FDA and from the Chinese National Medical Products Administration for the treatment of adult AML patients with relapsed or refractory disease. Uproleselan is designed to block E-selectin binding and stimulation of myeloid cells. E-selectin is expressed on the surface of blood vessels, and its binding to myeloid cells confers a pro-survival effect via NF-kB signaling. Uproleselan intends to provide a novel approach to disrupting established mechanisms of leukemic cell resistance.

The pivotal Phase 3 trial evaluating uproleselan in addition to a cytarabine-based chemotherapy regimen in patients with relapsed/refractory AML completed enrollment in November of 2021. A total of 388 patients across 70 sites in nine countries were randomized in the clinical trial, which has a primary endpoint of overall survival.

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 with high unmet needs. The company’s science is based on an understanding of the role that carbohydrates play in cell recognition and its specialized chemistry platform to discover small molecule drugs, known as glycomimetics, which alter carbohydrate-mediated recognition in diverse disease states, including cancer and inflammation. As a leader in this science, GlycoMimetics leverages this unique approach to advance its pipeline of wholly-owned drug candidates, with the goal of developing transformative therapies for diseases with high unmet 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 data from clinical trials, planned or potential clinical development, regulatory interactions and submissions, the commercialization and potential benefits and impact of the Company's drug candidates, and the Company's expected cash runway. 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 3, 2022, its Quarterly Report on Form 10-Q filed with the SEC on November 9, 2022, 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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