GlycoMimetics Reports Highlights and Financial Results for Third Quarter 2023

November 3, 2023 at 7:00 AM EDT

- Topline results from pivotal Phase 3 study of uproleselan in relapsed/refractory (R/R) Acute Myeloid Leukemia (AML) on track to be reported by end of Q2 2024
- NDA filing for uproleselan anticipated by end of 2024 pending outcome of R/R AML pivotal study
- Initial results for GMI-1687 Phase 1a study expected by end of Q1 2024 with initial focus to develop highly potent E-selectin antagonist as point-of-care treatment in sickle cell disease
- Updated independent clinical data exploring potential of uproleselan in difficult to treat subtype of AML to be presented at the American Society of Hematology (ASH) meeting in December
- Conference call and webcast today at 8:30 a.m. ET

ROCKVILLE, Md.--(BUSINESS WIRE)--Nov. 3, 2023-- GlycoMimetics, Inc. (Nasdaq: GLYC), a late clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers and inflammatory diseases, today reported its financial results and highlights for the third quarter ended September 30, 2023. Cash and cash equivalents as of September 30, 2023 were $49.4 million.

“We look ahead to 2024 with anticipation and excitement. Topline results for our pivotal Phase 3 study of uproleselan in relapsed/refractory AML remain on track by the end of Q2 and together with our potential NDA filing before the end of 2024 represent a transformational opportunity for patients, clinicians, and our company,” said Harout Semerjian, Chief Executive Officer of GlycoMimetics. “Our progress toward these important milestones, along with the upcoming presentation of independent data on uproleselan at ASH and the expected initial results of our Phase 1a GMI-1687 study by end of Q1 2024, demonstrate our ability and ambition to deliver our development strategy and move closer to becoming a commercial stage company.”

Operational Highlights

Uproleselan

- In Q2, GlycoMimetics announced U.S. Food and Drug Administration (FDA) clearance of a protocol amendment to the company’s pivotal Phase 3 study of uproleselan for R/R AML. This amendment provides for a time-based analysis of the primary endpoint of overall survival after a defined cutoff date, if the 295 survival events of the originally planned event-driven analysis have not been observed by that date. With the addition of the time-based analysis, the company expects topline results by the end of Q2 2024.

- The National Cancer Institute (NCI) Alliance for Clinical Trials in Oncology will conduct a planned interim analysis of event-free survival in 267 patients randomized to its Phase 2/3 clinical trial (NCI protocol A041701) evaluating uproleselan in newly diagnosed older adults with AML who are fit for chemotherapy. Enrollment of the Phase 2 portion of the study was completed in December of 2021. The company reiterates that when available, it will share these results.

- The company agreed with the European Medicines Agency on a Pediatric Investigational Plan (PIP), which followed the prior agreement with the FDA in Q2 2023 on an initial Pediatric Study Plan (iPSP). The PIP and iPSP each include a deferral for study completion, and a waiver for children less than 28 days of age. As part of the pediatric plans, an NCI sponsored Phase 1/2 pediatric trial is currently being conducted by the Children’s Oncology Group Pediatric Early Phase Clinical Trials Network. The Phase 1/2 dose escalation study (NCI protocol PEPN2113) evaluates the safety and preliminary activity of uproleselan plus fludarabine and high dose cytarabine in pediatric AML patients after two or more prior therapies. The first patient in the Phase 1 portion of the study has been dosed with an expected enrollment of 18 patients.

- Updated clinical data from an investigator-initiated trial studying the use of uproleselan in combination with chemotherapy for patients with treated secondary AML has been accepted for poster presentation at the ASH Annual Meeting in December. Investigators at MD Anderson Cancer Center are conducting the Phase 1b/2 clinical trial to evaluate safety, tolerability, and preliminary efficacy of uproleselan added to cladribine and low dose cytarabine in patients with this difficult to treat subset of AML.

GMI-1687

- In August, GlycoMimetics initiated a Phase 1a double-blind, single-center, randomized, placebo-controlled, sequential, single ascending dose trial in healthy adult volunteers. It is expected to enroll approximately 40 subjects. Eligible subjects will receive a single dose of GMI-1687 or placebo (6:2 ratio) via subcutaneous injection. Safety, tolerability, and

pharmacokinetics of up to five dose levels (3.3, 10, 20, 40, and 80 mg) will be evaluated. GMI-1687 is a highly potent E-selectin antagonist that has potential application in inflammatory diseases with initial focus on sickle cell disease. Initial results are expected by the end of Q1 2024.

Third Quarter 2023 Financial Results:

- Cash position: As of September 30, 2023, GlycoMimetics had cash and cash equivalents of $49.4 million as compared to $47.9 million as of December 31, 2022.
- R&D Expenses: The company's research and development expenses increased to $5.3 million for the quarter ended September 30, 2023, as compared to $4.9 million for the same period in 2022. The increased expenses were primarily due to the clinical development costs related to the Phase 1a trial of GMI-1687 in healthy adult volunteers, which was initiated in August 2023; the increase was partially offset by decreased personnel-related and stock-based compensation costs due to a lower number of personnel than in the prior year.
- G&A Expenses: The company's general and administrative expenses increased to $4.5 million for the quarter ended September 30, 2023, as compared to $3.8 million for the same period in 2022. The increased expenses were primarily due to higher personnel-related expenses and higher professional fees as the company advances uproleselan and prepares for potential regulatory filing and commercialization.
- Shares Outstanding: Shares of common stock outstanding as of September 30, 2023 were 64,368,843.

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.

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 broad development program including a late-stage Phase 3 trial in acute myeloid leukemia (AML), has received Breakthrough Therapy and Fast Track designations from the FDA and Breakthrough Therapy designation 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. Uproleselan is intended to enable a novel approach to disrupting established mechanisms of leukemic cell resistance.

About GMI-1687

Discovered and developed by GlycoMimetics, GMI-1687 is a highly potent E-selectin antagonist that has been shown in animal models to be fully bioavailable following subcutaneous administration. This second-generation compound is currently being studied in a Phase 1a double-blind, single-center, randomized, placebo-controlled, sequential, single ascending dose trial in healthy adult volunteers. GMI-1687 is believed to have potential application in inflammatory diseases, and the company's initial development focus is treatment of sickle cell disease (SCD). E-selectin is believed to play a major role in vaso-occlusive crisis (VOC), the vascular clots and blockages that cause pain crises in people living with SCD. Administration of GMI-1687 via subcutaneous injection, if successfully developed in the clinic, may enable the drug to address current challenges of IV therapies for SCD as well as offer a potential point-of-care treatment option at the onset of VOC.

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 science 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. As a leader in this science, GlycoMimetics leverages this unique approach 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 data from clinical trials; planned or potential clinical development, regulatory interactions or submissions, and pre-commercialization activities; 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 March 29, 2023, 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.

GlycoMimetics, Inc.

Condensed Statements of Operations

(In thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
	(Unaudited)		(Unaudited)	
Revenue from collaboration and license agreements	$ -	$ -	$ -	$ 75
Cost and expenses:				
Research and development expense	5,292	4,923	14,783	22,500
General and administrative expense	4,522	3,845	14,901	14,356
Total costs and expenses	9,814	8,768	29,684	36,856
Loss from operations	(9,814)	(8,768)	(29,684)	(36,781)
Other income	611	244	1,864	336
Net loss and comprehensive loss	$ (9,203)	$ (8,524)	$ (27,820)	$ (36,445)
Net loss per share - basic and diluted	$ (0.14)	$ (0.16)	$ (0.44)	$ (0.70)
Weighted-average common shares outstanding – basic and diluted	64,349,709	52,423,944	62,992,006	52,387,561

GlycoMimetics, Inc.

Balance Sheet Data

(In thousands)

	September 30, 2023	December 31, 2022
	(unaudited)	
Cash and cash equivalents	$ 49,408	$ 47,871
Working capital	45,619	41,834
Total assets	53,201	51,811

Total liabilities	6,653	8,881
Stockholders' equity	46,548	42,930

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