GlycoMimetics Reports Highlights and Financial Results for Fourth Quarter and Full Year 2023

March 27, 2024 at 7:00 AM EDT

- Topline results from pivotal Phase 3 study of uproleselan in relapsed/refractory (R/R) Acute Myeloid Leukemia (AML) to be reported in Q2 2024
- New Drug Application (NDA) for uproleselan to be submitted to the U.S. Food and Drug Administration (FDA) by end of 2024 if outcome of R/R AML pivotal study is positive
- Phase 1a study of GMI-1687, a highly potent E-selectin antagonist with an initial focus on sickle cell disease (SCD), met its primary and secondary endpoints
- The company has entered into a research collaboration for GMI-1687 with the ASH Research Collaborative (ASH RC), a non-profit organization established by the American Society of Hematology (ASH)
- Conference call and webcast to be hosted on March 27, 2024, at 8:30 a.m. ET.

ROCKVILLE, Md.--(BUSINESS WIRE)--Mar. 27, 2024-- 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 quarter and year ended December 31, 2023. Cash and cash equivalents as of December 31, 2023, were $41.8 million.

“With the time-based analysis imminent for our pivotal Phase 3 study of uproleselan in R/R AML, we are laser-focused on delivering the topline results in Q2 and excited about the possibility of submitting an NDA before year-end. This large, randomized, global trial now has a median follow-up of more than three years, which is remarkable in R/R AML, and could demonstrate the potential of uproleselan to become a new standard of care for a disease with limited treatment options and high unmet need,” said Harout Semerjian, Chief Executive Officer of GlycoMimetics. “We are also pleased to announce our agreement with the ASH RC for GMI-1687, further validating the potential of this highly potent E-selectin antagonist for the treatment of sickle cell disease. We remain deeply committed to bringing life-changing treatments to patients and look forward to sharing more important updates in the coming months.”

Operational Highlights

Uproleselan

- In June 2023, GlycoMimetics announced 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 adoption of the time-based analysis, the company expects to report topline results in Q2 2024.

- A total of 388 patients across 70 sites in nine countries were enrolled and randomized in the pivotal Phase 3 trial, which has a primary endpoint of overall survival. The time-based analysis dataset will reflect a median follow-up in patients remaining on study of more than three years, underscoring the potential utility of uproleselan in R/R AML.

- The National Cancer Institute (NCI) Alliance for Clinical Trials in Oncology will conduct an analysis of event-free survival in 267 patients enrolled and randomized in 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 2021. The company reiterates that when available, it will share these results.

GMI-1687

- In August 2023, GlycoMimetics initiated a Phase 1a single-center, double-blind, randomized, placebo-controlled, sequential, single ascending dose trial in healthy adult volunteers. The study enrolled 40 subjects. Eligible subjects received a single dose of GMI-1687 or placebo (6:2 ratio) via subcutaneous injection. In January 2024, the company announced that the study met its primary and secondary endpoints of safety/tolerability and pharmacokinetics. There were no dose-limiting toxicities or other safety signals. Potentially therapeutic plasma levels that may alleviate vaso-occlusive events (VOE) were achieved at multiple dose levels after a single injection. Full study results of this Phase 1a first-in-human trial of GMI-1687 will be presented at an upcoming medical meeting.

- GlycoMimetics announced today that it has entered into a research agreement with the ASH RC and its Sickle Cell Disease Research Network. This collaboration will obtain feedback on the GMI-1687 clinical development plan from people living with sickle cell disease and therapeutic area experts. ASH RC fosters partnerships to accelerate progress and improve outcomes for people living with SCD by expediting therapeutics development and generating high-quality evidence to support clinical decision-making.

Corporate Update

- GlycoMimetics strengthened its leadership team by appointing Shantha Tyavanagimatt, Ph.D., as Senior Vice President of Technical Operations.

Fourth Quarter and Full Year 2023 Financial Results

- Cash position: As of December 31, 2023, GlycoMimetics had cash and cash equivalents of $41.8 million, compared to $47.9 million as of December 31, 2022.
- R&D Expenses: The company's research and development expenses decreased to $5.3 million for the quarter ended December 31, 2023, compared to $5.9 million for the fourth quarter of 2022. Research and development expenses for the year ended December 31, 2023, decreased to $20.1 million, compared to $28.4 million in the prior year. These decreases were due to lower clinical development expenses for the global Phase 3 clinical trial of uproleselan in individuals with relapsed/refractory AML, and decreased manufacturing costs due to the completion of engineering and validation batches for uproleselan, partially offset by the Phase 1 clinical trial of GMI-1687.
- G&A Expenses: The company's general and administrative expenses decreased to $4.3 million for the quarter ended December 31, 2023, compared to $4.7 million for the fourth quarter of 2022. General and administrative expenses for the year ended December 31, 2023, increased slightly to $19.2 million, compared to $19.1 million in the prior year. The overall increase was due to higher personnel-related expenses, offset in part by a decrease in external consulting expenses.
- Shares Outstanding: Shares of common stock outstanding as of December 31, 2023, were 64,393,744.

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.

About Uproleselan

Discovered and developed by GlycoMimetics, uproleselan is an investigational, first-in-class E-selectin antagonist. Uproleselan (yoo' pro le'se lan) is currently being evaluated in a broad development program, including a late-stage Phase 3 trial in acute myeloid leukemia (AML), GlycoMimetics has received Breakthrough Therapy and Fast Track designations from the 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. 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 is believed to confer 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 is bioavailable after subcutaneous administration. This second-generation compound has potential application in inflammatory diseases, and the company's initial clinical development will focus on 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 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 data from clinical trials; planned or potential clinical development, regulatory interactions, or submissions; the company's collaborations with third parties; 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 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.

GlycoMimetics, Inc.
Condensed Statements of Operations

(In thousands, except share and per share data)

	Three months ended December 31,		Year ended December 31,	
	2023	2022	2023	2022
	(Unaudited)			
Revenue from collaboration and license agreements	$ 10	$ -	$ 10	$ 75
Costs and expenses:				
Research and development expense	5,289	5,891	20,072	28,391
General and administrative expense	4,312	4,732	19,213	19,087
Total costs and expenses	9,601	10,623	39,285	47,478
Loss from operations	(9,591)	(10,623)	(39,275)	(47,403)
Interest income	512	378	2,376	715
Net loss and net comprehensive loss	$ (9,079)	$ (10,245)	$ (36,899)	$ (46,688)
Net loss per common share – basic and diluted	$ (0.14)	$ (0.19)	$ (0.58)	$ (0.89)
Weighted-average common shares outstanding - basic and diluted	64,393,840	52,962,011	63,342,465	52,531,173

GlycoMimetics, Inc.
Balance Sheet Data
(In thousands)

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 41,793	$ 47,871
Working capital	36,956	41,834
Total assets	45,316	51,811

Total liabilities	6,902	8,881
Total stockholders' equity	38,414	42,930

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Investor Contact:
Argot Partners
Leo Vartorella
212-600-1902
Glycomimetics@argotpartners.com

Source: GlycoMimetics, Inc.