GlycoMimetics Reports Highlights and Financial Results for Second Quarter 2023

August 2, 2023 at 7:00 AM EDT

- Topline results from pivotal Phase 3 study of uproleselan in relapsed/refractory (R/R) Acute Myeloid Leukemia (AML) expected by end of Q2 2024 after addition of time-based analysis option
- U.S. Food and Drug Administration (FDA) agrees to initial Pediatric Study Plan (iPSP) for uproleselan, and National Cancer Institute (NCI) agrees to sponsor pediatric Phase 1/2 study in acute AML
- First pediatric patient dosed in separate investigator-initiated Phase 1/2 study of uproleselan combined with pre-stem cell transplant conditioning regimen for chemotherapy-resistant AML
- Clinical pipeline expanding with planned initiation of first-in-human Phase 1a study for GMI-1687 in Q3 2023
- Conference call and webcast today at 8:30 a.m. ET

ROCKVILLE, Md.--(BUSINESS WIRE)--Aug. 2, 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 second quarter ended June 30, 2023. Cash and cash equivalents as of June 30, 2023 were $58.0 million.

“With the addition of a time-based analysis option to our pivotal Phase 3 study, we look forward to reporting topline uproleselan results in R/R AML by the end of Q2 2024. This readout will draw from a clinically mature dataset with more than three years of median follow-up and can potentially bring us closer to delivering this therapy to patients in need of new treatment options,” said Harout Semerjian, Chief Executive Officer of GlycoMimetics. “We continue to execute our broad development strategy for uproleselan while we explore potential benefit in AML patients of all ages as evidenced by the FDA agreement on the pediatric study plan as well as the NCI sponsored, and investigator initiated pediatric studies. In addition to these advances, we are excited to expand our clinical pipeline and move GMI-1687, a novel, highly potent E-selectin antagonist into first-in-human studies. We look forward to initiating our Phase 1a study in the coming weeks.”

Operational Highlights

- 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 will allow conduct of 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 a time-based analysis, the company now expects to report topline results by the end of Q2 2024.

- The 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. When available, the company will share these results.

- In May 2023, FDA agreed to the initial Pediatric Study Plan (iPSP) submitted by GlycoMimetics. As part of the iPSP, NCI has agreed to sponsor a Phase 1/2 dose escalation study (NCI protocol PEPN2113) to explore safety and preliminary activity of uproleselan plus fludarabine and high dose cytarabine (FLA) in pediatric AML patients after 2 or more prior therapies. The Children’s Oncology Group will conduct this study. Enrollment in the Phase 1 portion is open and expected to be up to 18 patients.

- In June, the first pediatric patient was treated with uproleselan in an investigator-initiated single arm, multi-center Phase 1/2 study to assess safety and tolerability, as well as determine a recommended phase 2 dose (RP2D) of uproleselan plus myeloablative, busulfan-based, pre-transplant conditioning for treatment of AML. This study, led by John Horan, MD, MPH, of the Boston Children’s Hospital and Dana Farber Cancer Institute, will enroll up to 28 patients (Age ≥12 months and ≤ 30 years) and will also assess preliminary uproleselan efficacy at the RP2D.

- GlycoMimetics plans to initiate in Q3 2023 a Phase 1a study for GMI-1687 in healthy volunteers. GMI-1687 is a highly potent E-selectin antagonist that has potential application in inflammatory diseases with initial focus on sickle cell disease.

Second Quarter 2023 Financial Results:

- Cash position: As of June 30, 2023, GlycoMimetics had cash and cash equivalents of $58.0 million as compared to $47.9

million as of December 31, 2022.

- R&D Expenses: The Company's research and development expenses decreased to $4.1 million for the quarter ended June 30, 2023, as compared to $8.0 million for the same period in 2022. The decreased expenses were primarily due to lower clinical trial and development costs related to our global Phase 3 clinical trial of uproleselan in individuals with R/R AML, which completed enrollment November 2021.

- G&A Expenses: The Company's general and administrative expenses decreased to $4.9 million for the quarter ended June 30, 2023, as compared to $5.5 million for the same period in 2022, primarily due to lower outside consulting and professional expenses.

- Shares Outstanding: Shares of common stock outstanding as of June 30, 2023, were 64,313,333.

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 Phase 3 development program in acute myeloid leukemia (AML), has received Breakthrough Therapy and Fast Track designations from the U.S. 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. It is a second-generation compound that has potential application in inflammatory diseases with initial focus on 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. The administration of GMI-1687 via subcutaneous injection, if this treatment method is successfully developed in the clinic, may enable the drug to address certain 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, with the goal of developing 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 plans and submissions, 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 June 30,	Six months ended June 30,

	2023	2022	2023	2022
	(Unaudited)		(Unaudited)	
Revenue from collaboration and license agreements	$ -	$ 75	$ -	$ 75
Cost and expenses:				
Research and development expense	4,073	7,973	9,491	17,577
General and administrative expense	4,857	5,455	10,380	10,511
Total costs and expenses	8,930	13,428	19,871	28,088
Loss from operations	(8,930)	(13,353)	(19,871)	(28,013)
Other income	671	86	1,253	93
Net loss and comprehensive loss	$ (8,259)	$ (13,267)	$ (18,618)	$ (27,920)
Net loss per share - basic and diluted	$ (0.13)	$ (0.25)	$ (0.30)	$ (0.53)
Weighted-average common shares outstanding – basic and diluted	64,276,184	52,407,347	62,313,155	52,369,369

GlycoMimetics, Inc.

Balance Sheet Data

(In thousands)

	June 30, 2023 (unaudited)	December 31, 2022
Cash and cash equivalents	$ 58,037	$ 47,871
Working capital	53,797	41,834
Total assets	61,822	51,811
Total liabilities	7,021	8,881

Stockholders' equity	54,801	42,930

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