GlycoMimetics Reports Highlights and Financial Results for Fourth Quarter and Year-end 2022

March 29, 2023

- Significant progress in strengthening leadership, raising capital, and preparing for final results of the uproleselan Phase 3 study in relapsed/refractory (R/R) acute myeloid leukemia (AML)
- Interim utility analysis used high statistical threshold and resulted in independent Data Monitoring Committee (DMC) recommending trial continue to final survival events, projected to occur in the first half of 2024; DMC also expressed no safety concerns about the trial
- Cash and cash equivalents expected to fund current operations to year end 2024
- Conference call and webcast today at 8:30 a.m. ET

ROCKVILLE, Md.--(BUSINESS WIRE)--Mar. 29, 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 quarter and year ended December 31, 2022. Cash and cash equivalents as of December 31, 2022 were $47.9 million. After year-end, the company raised an additional $28.7 million in net proceeds from its “at-the-market” (ATM) sales facility.

“In 2022, we made great strides in our continued organizational evolution, strengthening our leadership team and financial position as we aspire to become a commercial-stage company capable of delivering uproleselan to R/R AML patients in need of innovative new treatment options,” said Harout Semerjian, Chief Executive Officer of GlycoMimetics. “Patients continue to live longer in our pivotal Phase 3 study of uproleselan, with duration of median follow-up for the blinded, pooled patient population now at a remarkable 25 months. Our Phase 3 AML trial projects to have the longest duration of median follow-up at time of primary analysis of any study, to our knowledge, previously conducted in this disease area. We remain optimistic and excited about the potential of uproleselan to improve overall survival in R/R AML.”

Operational Highlights

Uproleselan

- In February 2023, GlycoMimetics announced the DMC conducted an interim utility analysis (IA) and recommended the uproleselan Phase 3 study should continue to the originally planned final overall survival events. A statistical plan to add an IA to the Phase 3 study was cleared with the US Food and Drug Administration in the fourth quarter of 2022, which enabled the DMC to review efficacy and safety data from that study at around 80% of planned survival events. The IA utilized a very high statistical threshold to preserve the statistical integrity of the originally planned final overall survival analysis. Per previous guidance, the overall survival events trigger is now expected to occur in the first half of 2024.

- Initial clinical data from two investigator-sponsored studies exploring the use of uproleselan in combination with other treatments in patients with different forms of AML were presented at the 64th American Society of Hematology (ASH) Annual Meeting in December 2022. These studies provided the first uproleselan clinical data in AML generated outside of company-sponsored studies. Early findings showed promising safety and potential efficacy of uproleselan to benefit patients across a broader AML spectrum, including older, unfit, treatment-naïve patients and those with treated secondary AML. Patient enrollment is ongoing in these studies and further data are expected at future medical meetings.

- 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 evaluating uproleselan in newly diagnosed older adults with AML who are fit for chemotherapy. When available, the company will share these interim analysis results.

GMI-1687

- In June 2022, GlycoMimetics received FDA clearance of an IND application for clinical development of GMI-1687 in sickle cell disease (SCD). GMI-1687 is a highly potent E-selectin antagonist initially targeted for development to treat acute vaso-occlusive crises (VOCs) in SCD with potential to address a high unmet medical need.

Corporate Update

- GlycoMimetics strengthened its clinical and commercial leadership team in 2022 and early 2023 with the appointments of Edwin Rock, MD, Ph.D. as Chief Medical Officer, Deepak Tiwari as Vice President of Technical Operations, Bruce Johnson as Chief Commercial Officer, and most recently, Chinmaya Rath as Chief Business Officer.

Fourth Quarter and Year-end 2022 Financial Results:

- Completion of some early-commercial and manufacturing activities for uproleselan now enable the company to project its cash runway to the end of 2024. The company's allocation of its capital resources will continue to prioritize the advancement of the uproleselan program, including key regulatory and pre-commercial activities.

- Cash position: As of December 31, 2022, GlycoMimetics had cash and cash equivalents of $47.9 million as compared to $90.3 million as of December 31, 2021. In the first quarter of 2023, GlycoMimetics raised a total of $28.7 million from sales of shares of common stock under its existing ATM facility.

- Revenue: There was minimal revenue recognized during the year ended December 31, 2022, compared to $1.2 million for the year ended December 31, 2021, all of which was the result of payments received under the company's license and collaboration agreement with Apollomics for the development and commercialization of uproleselan and GMI-1687 in Greater China.

- R&D Expenses: The company's research and development expenses decreased to $5.9 million for the quarter ended December 31, 2022, as compared to $12.9 million for the fourth quarter of 2021 due to lower development expenses related to manufacturing costs and lower clinical trial costs from the company's global Phase 3 uproleselan trial.

Research and development expenses for the year ended December 31, 2022, decreased to $28.4 million as compared to $47.5 million in the prior year. The decrease in expenses was due to lower clinical development expenses related to the company's ongoing global Phase 3 clinical trial of uproleselan, decreased manufacturing costs and decreased IND enabling activities related to GMI-1687.

- G&A Expenses: The company's general and administrative expenses increased to $4.7 million for the quarter ended December 31, 2022, as compared to $4.5 million for the fourth quarter of 2021. General and administrative expenses for the year ended December 31, 2022 increased to $19.1 million as compared to $17.1 million in the prior year. These increases were due to higher pre-commercial expenses for uproleselan in 2022 offset by lower grant date fair market values for equity awards issued in 2022.

- Stock Sales: In the fourth quarter of 2022 and first quarter of 2023, GlycoMimetics sold a total of 11,776,784 shares of common stock under its existing ATM facility, raising a total of $32.9 million in net proceeds. Of these proceeds, $4.2 million were received in the fourth quarter of 2022 and $28.7 million in the first quarter of 2023.

- Shares Outstanding: Shares of common stock outstanding as of December 31, 2022, were 54,377,798. Shares outstanding as of March 27, 2023, were 64,245,224.

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 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.

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 atwww.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 submissions and commercialization activities, 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 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 December 31,		Year ended December 31,	
	2022	**2021**	**2022**	**2021**
	(Unaudited)			
Revenue from collaboration and license agreements	$ —	$ 18	$ 75	$ 1,160
Costs and expenses:				
Research and development expense	5,891	12,896	28,391	47,492
General and administrative expense	4,732	4,548	19,087	17,115
Total costs and expenses	10,623	17,444	47,478	64,607
Loss from operations	(10,623)	(17,426)	(47,403)	(63,447)
Interest income	378	4	715	20
Net loss and comprehensive loss	$ (10,245)	$ (17,422)	$ (46,688)	$ (63,427)
Net loss per common share – basic and diluted	$ (0.19)	$ (0.33)	$ (0.89)	$ (1.23)
Weighted-average common shares outstanding – basic and diluted	52,962,011	52,011,950	52,531,173	51,453,204

GlycoMimetics, Inc.

Balance Sheet Data

(In thousands)

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 47,871	$ 90,255
Working capital	41,834	78,964
Total assets	51,811	94,347
Total liabilities	8,881	12,743
Total stockholders' equity	42,930	81,604

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