GlycoMimetics Reports Highlights and Financial Results for Second Quarter 2022

August 3, 2022

- U.S. Food and Drug Administration (FDA) Clearance of Investigational New Drug (IND) application to study GMI-1687 in Sickle Cell Disease (SCD) received in June
- The Company previously disclosed and will continue to update its projection of mid-year 2023 for the survival events trigger for its pivotal Phase 3 trial evaluating uproleselan in patients with relapsed/refractory acute myeloid leukemia (AML)
- Progress in data collection now enables the Company to share a comparison of the demographics of the pivotal Phase 3 study to those of the completed Phase 2 study
- Conference call and webcast today at 8:30 a.m. ET including discussion of AML landscape and uproleselan opportunity by Chief Commercial Officer Bruce Johnson

ROCKVILLE, Md.--(BUSINESS WIRE)--Aug. 3, 2022-- GlycoMimetics, Inc. (Nasdaq: GLYC) today reported its financial results and highlights for the second quarter ended June 30, 2022. Cash and cash equivalents as of the end of the quarter were $60.2 million.

“During second quarter, we made strides in advancing our transformation from a research company to a commercially focused organization and are encouraged by the continued progress of our pivotal Phase 3 trial of uproleselan in relapsed/refractory AML,” said Harout Semerjian, Chief Executive Officer. “Clearance by the FDA of the IND for GMI-1687 demonstrates our ability to create and advance innovative drug candidates for clinical development. GMI-1687 is now ideally suited for partnership and we are actively pursuing a licensing agreement for continued development of this novel molecule in sickle cell disease.”

Operational Highlights

Uproleselan

- GlycoMimetics continued efforts to clean the data received from the 70 sites in the U.S., Europe, Canada, and Australia that enrolled a total of 388 patients in the Company’s pivotal Phase 3 trial in relapsed/refractory AML. Progress to date now enables the Company to share a comparison of the demographics of those 388 patients against the patient demographics from the Company’s completed phase 2 study with respect to age, severity of AML, prior stem cell transplantation rate, and distribution of relapsed and refractory patients (Table 1). The Company has previously disclosed and will continue to update its projection of mid-year 2023 for the overall survival events trigger, with disclosure of top-line data results shortly thereafter.
- The National Cancer Institute (NCI) continues to prepare for its planned interim analysis of event free survival of the 267 patients in its Phase 2/3 clinical trial evaluating uproleselan in newly diagnosed older adults with AML who are fit for chemotherapy. The Company intends to publicly share the outcome of the NCI’s analysis of the Phase 2 data.
- Investigator-sponsored clinical trials to evaluate expanded indications for uproleselan continue to progress at the University of California-Davis, Washington University at St. Louis, MD Anderson Cancer Center, and the University of Michigan.

GMI-1687

- In June, GlycoMimetics received clearance from the FDA of an IND application for clinical development of GMI-1687 in 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.
- E-selectin is believed to play a major role in the cascade of events leading to clots and blockages that cause patients’ VOCs. The administration of GMI-1687 via subcutaneous injection may have the potential to offer a treatment option at the onset of pain crisis.
- The Company is actively seeking a licensing partner to continue clinical development of this drug candidate.

Second Quarter 2022 Financial Results:

Cash position: As of June 30, 2022, GlycoMimetics had cash and cash equivalents of $60.2 million as compared to $90.3 million as of December 31, 2021.

Revenue: There was minimal revenue recognized during the three months ended June 30, 2022 and 2021.

R&D Expenses: The Company’s research and development expenses decreased to $8.0 million for the quarter ended June 30, 2022, as compared to $10.2 million for the same period in 2021. The decreased expenses were primarily due to lower clinical trial and development costs related to our ongoing global Phase 3 clinical trial of uproleselan in individuals with relapsed/refractory AML as patient enrollment ended in November 2021.

G&A Expenses: The Company's general and administrative expenses increased to $5.5 million for the quarter ended June 30, 2022, as compared to $4.2 million for the first quarter of 2021 primarily due to commercial start-up expenses for uproleselan.

Shares Outstanding: Shares of common stock outstanding as of June 30, 2022, were 52,423,944.

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, targeted inhibitor of E-selectin. Uproleselan (yoo' pro le'sel an), currently in a comprehensive Phase 3 development program in 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 (an adhesion molecule on cells in the bone marrow) from binding with blood cancer cells as a targeted approach to disrupting well-established mechanisms of leukemic cell resistance within the bone marrow microenvironment.

About GMI-1687

Discovered and developed by GlycoMimetics, GMI-1687 is a 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 may be able to be developed to address certain challenges of IV therapies for SCD. E-selectin is believed to play a major role in the cascade of events leading to clots and blockages that cause pain crises in people living with SCD. The administration of GMI-1687 via subcutaneous injection may have the potential to offer a treatment option at the onset of pain crisis.

About GlycoMimetics, Inc.

GlycoMimetics is a clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers, including acute myeloid leukemia (AML), and for inflammatory diseases with high unmet need. The Company's science is based on an understanding of the role that carbohydrates play on the surface of every living cell and applying its specialized chemistry platform to discover small molecule drugs, known as glycomimetics, which alter these carbohydrate-mediated pathways in a variety of disease states, including signaling in cancer and inflammation. As a leader in this space, GlycoMimetics is leveraging this unique targeted approach to advance its pipeline of wholly owned drug candidates, with the goal of developing transformative therapies for serious diseases. GlycoMimetics is 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, and the commercialization and 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 3, 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.

GlycoMimetics, Inc.

Condensed Statements of Operations

(In thousands, except share and per share data)

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	
Revenue from collaboration and license agreements	$ 75	$ -	$ 75	$ 1,056
Cost and expenses:				
Research and development expense	7,973	10,167	17,577	21,315

General and administrative expense	5,455	4,237	10,511	8,425
Total costs and expenses	13,428	14,404	28,088	29,740
Loss from operations	(13,353)	(14,404)	(28,013)	(28,684)
Other income	86	5	93	11
Net loss and comprehensive loss	$ (13,267)	$ (14,399)	$ (27,920)	$ (28,673)
Net loss per share - basic and diluted	$ 0.25	$ (0.28)	$ (0.53)	$ (0.56)
Weighted-average common shares outstanding – basic and diluted	52,407,347	51,539,010	52,369,369	51,118,096

GlycoMimetics, Inc.

Balance Sheet Data

(In thousands)

	June 30, 2022 (unaudited)	December 31, 2021
Cash and cash equivalents	$ 60,244	$ 90,255
Working capital	52,326	78,964
Total assets	65,044	94,347
Total liabilities	9,317	12,743
Stockholders' equity	55,727	81,604

Table 1
Demographics- Relapsed/Refractory Patients

	301 Study N=388	**201 Study N=66**
Age, median (range)	**58 (20-75)**	**59 (26-84)**

Refractory, n (%)	**130 (33.5%)**	**22 (33%)**
Relapsed, n (%)	**258 (66.5%)**	**44 (67%)**
Duration of prior remission ≤6 mos	**49 (19%)**	**18 (41%)**
Prior Therapies		
HSCT	**70 (18%)**	**12 (18%)**
≥2 Induction Regimens	**63 (16%)**	**22 (33%)**
ELN Risk Category		
Adverse	**40%**	**50%**
Intermediate	**21%**	**17%**
Favorable	**22%**	**11%**
Unknown	**17%**	**22%**

Data as of August 2022

View source version on businesswire.com: https://www.businesswire.com/news/home/20220803005327/en/

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