GlycoMimetics Reports Highlights and Financial Results for Third Quarter 2021

November 2, 2021

- *Significant progress achieved for lead investigational drug candidate uproleselan:*
  - *Robust enrollment momentum in the quarter indicates imminent completion of enrollment for Company-sponsored Phase 3 pivotal trial in patients with relapsed/refractory acute myeloid leukemia (AML); top line results anticipated after year-end 2022*
  - *Data showing high rate of Minimal Residual Disease (MRD) in evaluable relapsed/refractory AML patients were published in* BLOOD, as *part of a comprehensive review of the data set from the Company's Phase 1/2 trial evaluating uproleselan in both relapsed/refractory and newly diagnosed fit for chemo AML patient populations*
  - *Completed manufacturing of uproleselan drug product registration batches*
- *Transition of new CEO, Harout Semerjian, completed*
- *Hosting a conference call and webcast today at 8:30 a.m. ET*

ROCKVILLE, Md.--(BUSINESS WIRE)--Nov. 2, 2021-- GlycoMimetics, Inc. (Nasdaq: GLYC) today reported its financial results for the quarter ended September 30, 2021 and highlighted recent events. Cash and cash equivalents at September 30, 2021 were $101.9 million.

"I am excited about the strong momentum and opportunities we have in front of us. I am grateful for the dedication and perseverance of our employees and board of directors especially during my CEO transition period," commented Chief Executive Officer Harout Semerjian.

Operational Highlights

Uproleselan

- Enrollment of GlycoMimetics' pivotal Phase 3 trial in relapsed/refractory AML continued in the U.S., Canada, Australia and Europe at a robust pace throughout the third quarter of 2021. The Company anticipates imminent completion of enrollment with top line data anticipated after year-end 2022.
- The ongoing National Cancer Institute (NCI)-sponsored Phase 2/3 registration trial, designed to evaluate the use of uproleselan in newly diagnosed older adults with AML who are fit for chemotherapy is anticipated to complete enrollment of the Phase 2 portion by year-end, allowing for an interim Event-Free Survival analysis of 262 patients.
- Efficacy and safety data from a Phase 1/2 clinical study of uproleselan were published online September 16, 2021 in *BLOOD*. Investigators highlighted an analysis that reported an MRD negative rate of 69 percent in evaluable trial participants with relapsed/refractory AML, indicating an enhanced depth of response following addition of uproleselan to salvage therapy.
- The Company has had interactions with the U.S. Food and Drug Administration (FDA) under the Breakthrough Therapy Designation to align on key elements of the CMC program in advance of a new drug application (NDA) submission. Consistent with that guidance, uproleselan drug product registration batches have been completed.

GMI-1687

- The Company continued to advance GMI-1687 towards filing of an investigational new drug application (IND), anticipated in the first half of 2022. It has been shown in preclinical studies to be bioavailable via subcutaneous administration with potential clinical applications in vaso-occlusive crisis of sickle cell disease as well as a potential life-cycle extension opportunity for uproleselan.

Management

- The GlycoMimetics Board of Directors appointed Harout Semerjian as Chief Executive Officer and President, effective August 6, 2021, to succeed retiring founder Rachel King, who is continuing to serve on the Company's board. Mr. Semerjian, a seasoned executive with strong oncology commercialization experience, now leads the Company as it advances its registrational trials for uproleselan in AML, accelerates planning for potential commercialization, and continues to build out the Company's pipeline.

Third Quarter 2021 Financial Results

- Cash position: As of September 30, 2021, GlycoMimetics had cash and cash equivalents of $101.9 million as compared to $137.0 million as of December 31, 2020.

- R&D Expenses: Research and development expenses increased to $13.3 million for the quarter ended September 30, 2021 as compared to $10.7 million for the quarter ended September 30, 2020. This increase was primarily due to an increase in clinical trial costs in the ongoing global Phase 3 clinical trial of uproleselan in individuals with relapsed/refractory AML.
- G&A Expenses: General and administrative expenses were $4.1 million for the quarter ended September 30, 2021 and 2020.
- Shares Outstanding: Shares of common stock outstanding as of September 30, 2021 were 51,734,894.

The Company will host a conference call and webcast today at 8:30 a.m. ET. The dial-in number for the conference call is (844) 413-7154 for domestic participants and (216) 562-0466 for international participants, with participant code 2991493. Participants are encouraged to connect 15 minutes in advance of the call to ensure they are able to connect. A webcast replay will be available via the “Investors” tab on the GlycoMimetics website for 30 days following the call. A dial-in phone replay will be available for 24 hours after the close of the call by dialing (855) 859-2056 domestic participants and (404) 537-3406 for international participants, with participant code 2991493.

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 highly-targeted, highly-potent E-selectin antagonist that represents a potential life-cycle extension opportunity for uproleselan. It has been shown in preclinical studies to be bioavailable via subcutaneous administration, and could be a potentially self-administered drug to be used in treatment of AML. Additionally, data from recent oral presentations at major scientific conferences pointed to the potential for GMI-1687 as a self-administered drug to treat vaso-occlusive crisis of sickle cell disease.

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 located 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 include those relating to the planned or potential clinical development and commercialization of the Company’s product candidates, as well as the presentation of data from preclinical studies and clinical trials, 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 2, 2021, 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,	
	2021	2020	2021	2020
	(Unaudited)		(Unaudited)	

Revenue from collaboration and license agreements	$ 87	$ 1,000	$ 1,142	$ 10,000
Cost and expenses:				
Research and development expense	13,282	10,670	34,596	33,209
General and administrative expense	4,142	4,058	12,567	12,732
Total costs and expenses	17,424	14,728	47,163	45,941
Loss from operations	(17,337)	(13,728)	(46,021)	(35,941)
Other income	5	5	15	477
Net loss and comprehensive loss	$ (17,332)	$ (13,723)	$ (46,006)	$ (35,464)
Net loss per common share - basic and diluted	$ (0.34)	$ (0.29)	$ (0.90)	$ (0.79)
Weighted-average common shares outstanding - basic and diluted	51,564,674	47,511,818	51,266,955	44,962,886

GlycoMimetics, Inc.

Balance Sheet Data

(In thousands)

	September 30, 2021	December 31, 2020
	(unaudited)	
Cash and cash equivalents	$ 101,924	$ 137,035
Working capital	94,473	125,845
Total assets	107,945	142,832
Total liabilities	11,379	14,613
Stockholders' equity	96,566	128,219

View source version on businesswire.com: https://www.businesswire.com/news/home/20211102005466/en/

Investor Contact:
Shari Annes
Phone: 650-888-0902
Email: sannes@annesassociates.com

Media Contact:
Jamie Lacey-Moreira
Phone: 410-299-3310
Email: jamielacey@presscommpr.com

Source: GlycoMimetics, Inc.