GlycoMimetics Reports Highlights and Financial Results for Third Quarter 2020

November 6, 2020

- *Enrollment in the Company-sponsored pivotal Phase 3 trial evaluating uproleselan in patients with relapsed/refractory acute myeloid leukemia (AML) continues on track, and the Company reiterates its prior guidance that completion of enrollment for the Company-sponsored Phase 3 trial is expected in the second half of 2021*
- *Enrollment also continues in the National Cancer Institute (NCI)-sponsored Phase 3 trial to evaluate uproleselan for newly-diagnosed AML patients fit for chemotherapy*
- *Three oral presentations and two additional poster presentations at the upcoming American Society of Hematology (ASH) Annual Meeting will highlight the GlycoMimetics pipeline; multiple medical meetings in the second half of 2020 feature uproleselan and rivipansel*
- *U.S. Food and Drug Administration (FDA) grants Company a Rare Pediatric Disease designation for rivipansel for treatment of sickle cell disease*
- *Company hosting webcast and conference call this morning at 8:30 a.m. ET*

ROCKVILLE, Md.--(BUSINESS WIRE)--Nov. 6, 2020-- GlycoMimetics, Inc. (Nasdaq: GLYC) today reported its financial results for the third quarter ended September 30, 2020, and highlighted recent company events. Cash and cash equivalents at September 30, 2020 were $142.9 million.

“During the third quarter, both late-stage trials of uproleselan – the Company-sponsored Phase 3 trial in relapsed/refractory AML patients as well as the NCI’s study in newly-diagnosed AML patients fit for chemotherapy – progressed in the face of the COVID-19 pandemic, thanks in significant part to the dedicated efforts of clinicians, statisticians and sites. We continue to project completion of enrollment in our own Phase 3 trial in the second half of 2021,” said Rachel King, Chief Executive Officer. “In sickle cell disease, new *post hoc* analyses of the rivipansel Phase 3 study provide additional perspective on the potential of our targeted E-selectin product candidates in early vaso-occlusive crisis. We have presented findings at multiple sickle cell congresses, and at the upcoming ASH meeting, we plan to share key secondary endpoint, subgroup and subset data. We believe these data provide a foundation for our ongoing evaluation of potential opportunities in our pipeline for the treatment of acute vaso-occlusive crisis, or VOC.”

Operational Highlights

Uproleselan

- GlycoMimetics’ ongoing pivotal Phase 3 trial in relapsed/refractory AML continued to activate clinical sites and enroll patients in North America, Australia and Europe. While individual sites were affected earlier in the year by the COVID-19 pandemic, in this quarter patient enrollment returned to forecasted rates.
- GlycoMimetics reiterated its guidance that completion of enrollment for its trial was expected in the second half of 2021.
- New preclinical studies support the use of uproleselan with venetoclax and a hypomethylating agent (HMA) in AML:
  - At the upcoming ASH meeting in December 2020, GlycoMimetics will make an oral presentation of preclinical data from a study in an AML mouse model that shows the potential benefit of a combination therapy of uproleselan with venetoclax and HMA.
  - At the virtual meeting of the Society of Hematologic Oncology (SOHO) in September 2020, GlycoMimetics presented preclinical data showing a statistically significant prolongation of survival in a patient-derived xenograft (PDX) model.

Rivipansel

- At the Foundation for Sickle Cell Disease Research (FSCDR) virtual meeting held in September 2020, GlycoMimetics presented for the first time new efficacy and biomarker data from the *post hoc* analysis of the Phase 3 RESET trial that showed statistically significant improvements for patients treated early in crisis (within 26.4 hours of onset of pain) in the primary efficacy endpoint of time to readiness for discharge compared to placebo. This primary endpoint analysis demonstrated p=0.03, and median improvement of 56.3 hours compared to placebo.
- At the Annual Scientific Conference on Sickle Cell and Thalassaemia (ASCAT) in October 2020, a GlycoMimetics’ poster highlighted new pediatric and other key secondary endpoint subset/subgroup efficacy and biomarker data from the Phase 3 RESET trial.
- Accepted for oral presentation at the ASH meeting is an abstract also presenting pediatric and secondary endpoint data from the *post hoc* analysis of the Phase 3 RESET trial. These data as well as biomarker data show the potential benefits conferred when rivipansel is used to treat patients early in the VOC pain crisis.
- FDA granted GlycoMimetics a Rare Pediatric Disease designation for rivipansel for treatment of sickle cell disease.

- Based upon its review of the emerging Phase 3 rivipansel data set, GlycoMimetics is engaging with the FDA to identify what, if any, next steps to take, with a focus on determining if there is a potential streamlined path forward for this product candidate in sickle cell disease.

GMI-1687

- Building on clinical data for rivipansel disclosed at the FSCDR meeting in September and at ASCAT in October, GlycoMimetics also gave oral presentations at the FSCDR and ASCAT meetings reporting on preclinical data highlighting GMI-1687 in animal models of VOC. The data demonstrated its potential efficacy as a subcutaneously administered treatment for VOC to prevent sickle red blood cell adherence to inflamed vasculature, inhibit vessel occlusion and restore normal blood flow.
- An abstract was accepted for oral presentation at the ASH meeting in December 2020 on the product candidate's potential for intravenous and subcutaneous administration to restore blood flow. A mouse model of VOC sickle cell disease will be highlighted.

Third Quarter 2020 Financial Results:

- Cash position: As of September 30, 2020, GlycoMimetics had cash and cash equivalents of $142.9 million as compared to $158.2 million as of December 31, 2019. During the quarter, the Company received a $1 million clinical development milestone from Apollomics pursuant to the Company's collaboration and license agreement for the development and commercialization of uproleselan and GMI-1687 in Mainland China, Hong Kong, Macau and Taiwan.

- R&D Expenses: The Company's research and development expenses were $10.7 million for each of the quarters ended September 30, 2020 and 2019. The Company's research and development expenses decreased to $33.2 million for the nine months ended September 30, 2020 as compared to $35.6 million for the same period in 2019. Manufacturing and formulation expenses decreased in the three and nine months ended September 30, 2020 as compared to the same periods in 2019 as a result of lower raw material costs purchased in 2020. These decreases were offset by higher clinical expenses due to the increased enrollment in the ongoing global Phase 3 clinical trial of uproleselan in individuals with relapsed/refractory AML and the Phase 2/3 clinical trial being conducted by the National Cancer Institute in 2020 as compared to 2019. Contract research services, consulting and other costs were lower in the three and nine months ended September 30, 2020 as research activities were affected at outside universities and travel by research and development personnel was largely eliminated due to the COVID-19 pandemic.

- G&A Expenses: The Company's general and administrative expenses increased to $4.1 million for the third quarter ended September 30, 2020 as compared to $3.4 million for the third quarter of 2019. General and administrative expenses for the nine months ended September 30, 2020 increased to $12.7 million as compared to $10.5 million in the same period in 2019. Personnel-related expenses increased due to additional general and administrative headcount, annual salary adjustments awarded in the first quarter of 2020 and retention bonuses. Patent, legal fees, consulting and other professional expenses, including director and officer's insurance premiums, increased as compared to 2019. Other general and administrative expenses decreased for the three and nine months ended September 30, 2020, as compared to the same periods in 2019, due to lower travel, meals and conference registration expenses as a result of travel restrictions imposed during the COVID-19 pandemic.

- Shares Outstanding: Shares of common stock outstanding as of September 30, 2020 were 47,828,831

The Company will host a conference call and webcast today at 8:30 a.m. ET. The conference call will be broadcast live in listen-only mode on the "Investors" tab of the Company's website at https://ir.glycomimetics.com/investor-relations. For those who wish to ask questions, the dial in number for the conference call is (844) 413-7154 for domestic participants or (216) 562-0466 for international participants, with participant code 3073766. Participants are encouraged to connect 15 minutes in advance of the call to ensure that all callers 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 for domestic participants and (404) 537-3406 for international participants, participant code 3073766.

About Uproleselan (GMI-1271)

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 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. In a Phase 1/2 clinical trial, uproleselan was evaluated in both newly diagnosed elderly and relapsed or refractory patients with AML. In both populations, patients treated with uproleselan together with standard chemotherapy achieved better-than-expected remission rates and overall survival compared to historical controls, which have been derived from results from third-party clinical trials evaluating standard chemotherapy, as well as lower-than-expected induction-related mortality rates. Treatment in these patient populations was generally well-tolerated, with fewer than expected adverse effects.

About Rivipansel

Rivipansel, the Company's wholly-owned glycomimetic drug candidate that binds to all three members of the selectin family (E-, P- and L-selectin), was GlycoMimetics' first drug candidate to enter clinical development. After the Phase 3 RESET trial conducted by Pfizer, GlycoMimetics' former collaborator, did not meet its primary or key secondary efficacy endpoints in 2019, new efficacy data from a *post hoc* analysis of rivipansel were published in June 2020 and subsequently presented at the Foundation for Sickle Cell Disease Research Meeting in September 2020. GlycoMimetics is engaging with the FDA to identify what, if any, next steps to take, with a focus on determining if there is a potential streamlined path forward for this asset in sickle cell disease.

About GMI-1687

Discovered and developed by GlycoMimetics, GMI-1687 is a highly-targeted, highly-potent E-selectin antagonist. It has been shown in preclinical studies to be bioavailable via subcutaneous administration. At the 2018 Annual Meeting of the American Society of Hematology, data presented in a poster about GMI-1687 pointed to the potential for a life-cycle extension for GlycoMimetics' uproleselan. The investigational drug has also been shown to represent a more highly-potent and subcutaneously bioavailable potential life-cycle extension for rivipansel.

About GlycoMimetics, Inc.

GlycoMimetics is a biotechnology company with two late-stage clinical development programs and a pipeline of novel glycomimetic drugs, all designed to address unmet medical needs resulting from diseases in which carbohydrate biology plays a key role. GlycoMimetics' drug candidate, uproleselan, an E-selectin antagonist, was evaluated in a Phase 1/2 clinical trial as a potential treatment for AML and is being evaluated across a range of patient populations including a Company-sponsored Phase 3 trial in relapsed/refractory AML under Breakthrough Therapy designation. Rivipansel, a pan-selectin antagonist, is being explored for use in treatment of acute VOC in sickle cell disease. GlycoMimetics has also completed a Phase 1 clinical trial with another wholly-owned drug candidate, GMI-1359, a combined CXCR4 and E-selectin antagonist. 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 of the Company's product candidates, including expectations with regard to the enrollment of patients in its ongoing Phase 3 clinical trial of uproleselan and the Company's engagement with regulatory authorities, 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 February 28, 2020, 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,	
	2020	2019	2020	2019
	(Unaudited)		(Unaudited)	
Revenue	$ 1,000	$ -	$ 10,000	$ -
Cost and expenses:				
Research and development expense	10,670	10,724	33,209	35,562
General and administrative expense	4,058	3,381	12,732	10,492
Total costs and expenses	14,728	14,105	45,941	46,054
Loss from operations	(13,728)	(14,105)	(35,941)	(46,054)

Other income	5	853	477	2,888
Net loss and comprehensive loss	$ (13,723)	$ (13,252)	$ (35,464)	$ (43,166)
Net loss per share - basic and diluted	$ (0.29)	$ (0.31)	$ (0.79)	$ (1.00)
Weighted average shares - basic and diluted	47,511,818	43,295,397	44,962,886	43,215,125

GlycoMimetics, Inc.

Balance Sheet Data

(In thousands)

	September 30, 2020 (unaudited)	December 31, 2019
Cash and cash equivalents	$ 142,870	$ 158,201
Working capital	135,825	151,577
Total assets	150,419	167,970
Total liabilities	12,153	13,769
Total stockholders' equity	138,266	154,201

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