



GlycoMimetics, Inc.

Innovation Today, Healing Tomorrow.

## GlycoMimetics Reports Highlights and Financial Results for Second Quarter 2020

July 31, 2020

- Enrollment in the Company-sponsored pivotal Phase 3 trial evaluating uproleselan in patients with relapsed/refractory acute myeloid leukemia (AML) continued, and the company affirmed second half of 2021 as target for completion of enrollment
- A post hoc analysis of the Phase 3 RESET study evaluating the efficacy of rivipansel in acute vaso-occlusive crisis (VOC) in sickle cell disease (SCD) produced new efficacy data showing statistically significant improvements for patients treated early in crisis in the primary efficacy endpoint of time to readiness for discharge compared to placebo
- Pfizer completed the transfer to GlycoMimetics of all commercial and development rights and the Investigational New Drug Application (IND) for rivipansel

ROCKVILLE, Md.--(BUSINESS WIRE)--Jul. 31, 2020-- GlycoMimetics, Inc. (Nasdaq: GLYC) today reported its financial results for the second quarter ended June 30, 2020, and highlighted recent company events. Cash and cash equivalents at June 30, 2020 were \$149.8 million.

"The second quarter was quite productive as we noted strong enrollment in our company-sponsored pivotal trial of uproleselan in relapsed/refractory AML. Though we did see a slow down early in the COVID crisis, we were pleased to see enrollment pick back up later in the quarter. This was an important achievement in the face of the COVID-19 pandemic, and we are able to maintain prior guidance that we expect to complete enrollment in the second half of 2021. Also important were new data from a *post hoc* analysis of the rivipansel Phase 3 study that showed that patients treated with rivipansel within approximately 26 hours of the onset of pain in their crisis experienced statistically significant improvements in the primary efficacy endpoint of time to readiness for discharge compared to placebo. These data provide a foundation, we believe, for us to discuss with the U.S. Food and Drug Administration (FDA) whether there may be a path forward for rivipansel in acute VOC," commented Rachel King, Chief Executive Officer.

### 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 by COVID-19, overall clinicians continued to enroll patients well this quarter.
- At the [American Association for Cancer Research \(AACR\) Annual Meeting 2020](#), held June 22-24, preclinical research for both uproleselan and GMI-1359 was shared in a virtual format. Preclinical data supporting the potential use of uproleselan in the treatment of AML as well as in the setting of stem cell transplantation were presented. Additionally, new information demonstrated the ability of transcriptome profiling to identify those tumor types most likely to benefit from targeted E-selectin inhibition, a key mechanism of GlycoMimetics drug candidates.
- Important new preclinical data on the mechanism of action for uproleselan were published in the April 27, 2020, issue of *Nature Communications*. The paper outlined how uproleselan, a first-in-class, targeted inhibitor of E-selectin, can reduce chemoresistance in AML through the key mechanism of targeted E-selectin inhibition.

#### GMI-1687

- An abstract that was accepted for oral presentation at the Foundation for Sickle Cell Disease (FSCDR) meeting and published online in June, disclosed data from a preclinical model of the Company's E-selectin antagonist, GMI-1687, which is more potent than rivipansel and is being formulated for subcutaneous dosing. The data support development of GMI-1687 as a possible follow-on to rivipansel, which has the potential for subcutaneous self-administration as would be used in an outpatient setting.

#### Rivipansel

- The FSCDR also published online an abstract including data from a *post hoc* analysis of the Phase 3 RESET trial of 345 patients (ranging in age from six years to adults, with a mean age of 22 years) who were experiencing acute VOC requiring hospitalization for treatment. The organization selected the abstract for poster presentation at its September meeting. The analysis showed that patients treated with rivipansel early in their acute episode experienced a statistically significant improvement on the primary efficacy endpoint, time to readiness for discharge ( $p=0.03$ , median improvement at 56.3 hours compared to placebo).
- Based upon its review of the Phase 3 rivipansel data set, GlycoMimetics is committed to an assessment of what, if any, next steps to take, with a focus on determining if there is a potential path forward for this asset in sickle cell disease.
- GlycoMimetics completed in April a transfer back from Pfizer of the commercial and development rights and licenses for

rivipansel, the IND for the clinical development program, and the entire data set for the Phase 3 RESET trial.

#### **Executive Management Team**

- The Company announced that veteran regulatory expert Myra Rosario Herrle, PhD, RPh, RAC, joined the executive management team as Vice President, Regulatory Affairs.

#### **Second Quarter 2020 Financial Results:**

- Cash position: As of June 30, 2020, GlycoMimetics had cash and cash equivalents of \$149.8 million as compared to \$158.2 million as of December 31, 2019. During the quarter, the Company sold common stock under its at-the-market facility with Cowen for aggregate net proceeds of \$9.6 million.
- R&D Expenses: The Company's research and development expenses decreased to \$9.9 million for the quarter ended June 30, 2020 as compared to \$13.1 million for the second quarter of 2019. The Company's research and development expenses decreased to \$22.5 million for the six months ended June 30, 2020 as compared to \$24.8 million for the same period in 2019. These decreases were due primarily to a decrease in manufacturing and formulation expenses resulting from lower raw material costs as the validation manufacturing batches were purchased in the prior year. The decreases were offset in part by higher clinical expenses as a result of 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. Contract research services, consulting and other costs were lower in 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 \$4.2 million for the second quarter ended June 30, 2020 as compared to \$3.8 million for the second quarter of 2019. General and administrative expenses for the six months ended June 30, 2020 increased to \$8.7 million as compared to \$7.1 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 both the three and six months ended June 30, 2020, as compared to the same periods in 2019, due to lower travel, meals and conference registration expenses as a result of the travel restrictions due to the COVID-19 pandemic.
- Shares Outstanding: Shares of common stock outstanding as of June 30, 2020 were 46,714,698.

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 or (216) 562-0466 for international participants, with participant code 1677593. 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 1677593.

#### **About Uproleselan (GMI-1271)**

Discovered and developed by GlycoMimetics, uproleselan and GMI-1687 are investigational, first-in-class, targeted inhibitors 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 GMI-1687**

GMI-1687 is a rationally designed, innovative antagonist of E-selectin that is potentially suitable for subcutaneous (SC) administration. When given by SC injection in preclinical models, GMI-1687 has been observed to have equivalent activity to uproleselan, but at an approximately 1,000-fold lower dose. GlycoMimetics believes that GMI-1687 could be developed as a potential life-cycle expansion to broaden the clinical usefulness of an E-selectin antagonist to conditions, such as sickle cell disease crisis, where outpatient treatment may be preferred or required. GMI-1687 is currently undergoing IND-enabling studies.

#### **About Rivipansel**

Rivipansel, a 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 in advance of a presentation to occur at the Foundation for Sickle Cell Disease Research Meeting in September 2020. GlycoMimetics is committed to exploring a path forward for the use of rivipansel in treating acute VOC in SCD.

## About GMI-1359

GMI-1359 is designed to simultaneously inhibit both E-selectin and CXCR4. E-selectin and CXCR4 are both adhesion molecules involved in tumor trafficking and metastatic spread. Preclinical studies indicate that targeting both E-selectin and CXCR4 with a single compound could improve efficacy in the treatment of cancers that involve the bone marrow such as AML and multiple myeloma or in solid tumors that metastasize to the bone, such as prostate cancer and breast cancer, as well as in osteosarcoma, a rare pediatric tumor. GMI-1359 has completed a Phase 1 clinical trial in healthy volunteers. The Duke University Phase 1b clinical study in breast cancer patients is designed to enable investigators to identify an effective dose of the drug candidate and to generate initial biomarker data around the drug's activity. GMI-1359 has received Orphan Drug Designation and Rare Pediatric Disease Designation from the FDA for the treatment of osteosarcoma, a rare cancer affecting about 900 adolescents a year in the United States.

## 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 as a potential treatment for acute VOC in SCD. 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](http://www.glycomimetics.com).

## Forward-Looking Statements

This press release contains forward-looking statements regarding the Company's strategy and the clinical development and potential utility, benefits and impact of its drug candidates. These forward-looking statements include those relating to the planned preclinical research and 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 potential impact of the ongoing global COVID-19 pandemic on the Company's operations, and the Company's plans for discussing data from the Phase 3 clinical trial of rivipansel with the FDA. Actual results may differ materially from those expressed in or implied by 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, the updated risk factors described in the Company's quarterly report on Form 10-Q filed with the SEC on July 31, 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 June 30, |          | Six months ended June 30, |          |
|------------------------------------|-----------------------------|----------|---------------------------|----------|
|                                    | 2020                        | 2019     | 2020                      | 2019     |
|                                    | (Unaudited)                 |          | (Unaudited)               |          |
| Revenue                            | \$ -                        | \$ -     | \$ 9,000                  | \$ -     |
| Cost and expenses:                 |                             |          |                           |          |
| Research and development expense   | 9,871                       | 13,065   | 22,539                    | 24,838   |
| General and administrative expense | 4,235                       | 3,751    | 8,675                     | 7,111    |
| Total costs and expenses           | 14,106                      | 16,816   | 31,214                    | 31,949   |
| Loss from operations               | (14,106)                    | (16,816) | (22,214)                  | (31,949) |
| Other income                       | 27                          | 986      | 472                       | 2,035    |

Net loss and comprehensive loss            \$ (14,079    ) \$ (15,830    ) \$ (21,742    ) \$ (29,914    )

Net loss per share - basic and diluted        \$ (0.32        ) \$ (0.37        ) \$ (0.50        ) \$ (0.69        )

Weighted average shares - basic and diluted    43,801,251    43,183,010    43,688,420    43,174,989

GlycoMimetics, Inc.

#### Balance Sheet Data

(In thousands)

June 30,    December 31,

2020        2019

(unaudited)

Cash and cash equivalents \$ 149,845    \$ 158,201

Working capital            143,657     151,577

Total assets                158,353     167,970

Total liabilities            12,600      13,769

Total stockholders' equity    145,752     154,201

View source version on [businesswire.com](https://www.businesswire.com/news/home/20200731005215/en/): <https://www.businesswire.com/news/home/20200731005215/en/>

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