Positive Findings From Phase 1b Trial of GlycoMimetics' GMI-1359 To Be Presented at AACR 2021 Meeting

April 10, 2021

- Preclinical research included in poster supports clinical findings and demonstrates enhanced immune response in metastatic breast carcinoma model

ROCKVILLE, Md.--(BUSINESS WIRE)--Apr. 10, 2021-- GlycoMimetics, Inc. (Nasdaq: GLYC) today announces that a Phase 1b trial of GMI-1359, being conducted at Duke University Cancer Center, showed evidence of on-target effects, immune-activation and cell mobilization in the initial two patients treated with the Company's dual antagonist of E-selectin and CXCR4. Dorothy Sipkins, MD, PhD, Associate Research Professor in Pharmacology and Cancer Biology at Duke University School of Medicine, will present results from the proof-of-concept clinical study as well as a separate preclinical study supporting the positive biologic findings of the Phase 1b study. The presentation will be made at the American Association of Cancer Research (AACR) 2021 Annual Meeting, which is being held virtually on April 10-15 and May 17-21. GMI-1359 is GlycoMimetics' novel small molecule drug candidate, a dual antagonist of E-selectin and CXCR4, designed to target tumor-microenvironment resistance to chemotherapy in cancers with bone metastases.

The initial data from the study confirmed the dual CXCR4 and E-selectin antagonist's on-target effects. In the two patients who completed treatment, evaluations of peripheral blood showed a consistent mobilization of CD34+ hematopoietic stem and progenitor cells at doses beginning at 5 mg/kg and a reduction of plasma levels of soluble E-selectin. Furthermore, in one individual, following the administration of 7.0 mg/kg of GMI-1359, an immunophenotyping assessment of peripheral blood showed a redistribution of myeloid derived suppressor cells (MDSCs) as evidenced by increased percentages of both the monocytic and granulocytic MDSCs. In this same individual following administration of 7.0 mg/kg GMI-1359, the incidence of M1 proinflammatory macrophages increased while the M2 anti-inflammatory macrophages, often associated with tumor progression, decreased. The clinical poster concludes that GMI-1359 demonstrated an acceptable safety and tolerability profile in the patients treated to date. No dose limiting toxicities were observed following multiple dose administration up to 7 mg/kg.

Dr. Sipkins noted, "Despite the fact that our patient numbers are very small due to COVID's impact on recruitment, we are seeing the on-target effects of antagonizing both CXCR4 and E-selectin with use of GMI-1359, and that the drug is well-tolerated at all dose levels. Our pilot immune profile analysis also suggests that the drug could have favorable effects on the tumor immune microenvironment, echoing results seen in our preclinical work."

Dr. Sipkins will disclose preclinical evidence that it may be possible for GMI-1359 to augment immune recognition of the tumor. The data in the poster from a mouse metastatic breast carcinoma model demonstrated a reduction in the immune suppressive monocytic MDSCs at the primary tumor site and a significant increase in the CD8/Treg ratio in both the primary tumor and at the bone metastatic sites. These findings on immune cell redistributions strongly suggest the induction of a more favorable anti-tumor environment following GMI-1359 administration.

According to Dr. Eric J. Feldman, GlycoMimetics Senior Vice President and Chief Medical Officer, "The information shared in this AACR poster provides us with important understandings upon which we expect to identify a potential indication for advancing GMI-1359 in the clinic. It suggests that this small molecule drug candidate could improve responses to therapies and potentially reduce the burden of metastatic breast cancer disease."

In prior preclinical research supported by GlycoMimetics, Dr. Sipkins' laboratory demonstrated that E-selectin and CXCR4/SDF-1 interactions were critical for breast carcinoma cells (BCCs) invasion and retention, respectively, into bone. Moreover, they found that dormant and proliferating BCCs occupy distinct regions of the bone microenvironment, with dormant BCCs predominantly found in SDF-1 and E-selectin rich regions. These dormant BCCs are expected to be highly susceptible to GMI-1359 mobilization, suggesting a new intervention to break the foothold of dormant BC micrometastases in bone.

Details on the GMI-1359 e-presentation at the AACR Meeting are as follows:

Title: Development of GMI-1359, a novel agent targeting tumor-microenvironment cross-talk in bone metastatic cancer
Presenter: Dorothy Sipkins, MD, PhD, Associate Research Professor in Pharmacology and Cancer Biology at Duke University School of Medicine
Session: e-Presentation
Date and Time: Saturday, April 10, 2021 (available online through Monday, June 21)

About GMI-1359

GMI-1359 is designed to simultaneously inhibit both E-selectin and CXCR4, which are 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 affecting about 900 adolescents a year in the United States. GMI-1359 completed a Phase 1 clinical trial in healthy volunteers, and a Phase 1b clinical study is underway in breast cancer patients and is designed to enable investigators to identify study dose ranging and to generate initial biomarker data around the drug's activity. In the first two patients evaluated, the study showed evidence of on-target effects, immune-activation and cell mobilization. GMI-1359 has received Orphan Drug designation and Rare Pediatric Disease designation from the FDA for the treatment of osteosarcoma.

About GlycoMimetics, Inc.

GlycoMimetics is a biotechnology company with a focus in hematology-oncology 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 in a Company-sponsored Phase 3 trial in relapsed/refractory AML. GlycoMimetics has an ongoing Phase 1b clinical trial evaluating its 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 clinical development 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.

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