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GlycoMimetics Reports Top-line Results From Pfizer's Phase 3 Clinical Trial Evaluating Rivipansel in Sickle Cell Disease

August 3, 2019

ROCKVILLE, Md.--(BUSINESS WIRE)--Aug. 2, 2019-- GlycoMimetics, Inc. (Nasdaq: GLYC) reported that Pfizer Inc. (NYSE: PFE) announced today that the Phase 3 Rivipansel (GMI-1070): Evaluating Safety, Efficacy and Time to Discharge (RESET) pivotal study did not meet its primary or key secondary efficacy endpoints. The objective of the trial was to evaluate the efficacy and safety of rivipansel in patients aged six and older with sickle cell disease (SCD) who were hospitalized for a vaso-occlusive crisis (VOC) and required treatment with intravenous (IV) opioids. The primary endpoint was time to readiness-for-discharge and the key secondary efficacy endpoints were time-to-discharge, cumulative IV opioid consumption, and time to discontinuation of IV opioids.

"We are both surprised and deeply disappointed by this outcome, as we had strongly hoped that rivipansel would have a positive benefit for people living with sickle cell disease," said Rachel King, Chief Executive Officer of GlycoMimetics. "We are grateful to the many people who supported and advanced this program over the years of clinical study, especially to sickle cell patients and their families."

About Rivipansel

Rivipansel is a glycomimetic drug candidate that acts as a pan-selectin antagonist, meaning it binds to all three members of the selectin family – E-, P- and L-selectin. Rivipansel is an investigational treatment for VOC in people with SCD and not approved for use. In 2011, GlycoMimetics and Pfizer Inc. entered into a worldwide license agreement for the development and, if approved by applicable regulatory authorities, commercialization of rivipansel. Since completion of the Phase 2 clinical trial, Pfizer has been responsible for clinical development of rivipansel, including the RESET clinical trial.

About SCD and VOC

SCD is the most common inherited blood disorder in the United States, impacting approximately 100,000 people. Worldwide, approximately 100 million people carry the SCD trait and an estimated five million live with the disease. While the majority of people with SCD are of African descent, the disease can affect all ethnic groups, especially those from areas where malaria is or was endemic, such as the Middle East, India and the Southern Mediterranean. Acute pain crises or VOCs are the most common clinical manifestation of SCD. A VOC occurs when sickled red blood cells irritate the lining of blood vessels and cause an inflammatory response leading to vascular occlusion, tissue ischemia and pain.

About GlycoMimetics, Inc.

GlycoMimetics is a clinical-stage biotechnology company focused on the discovery and development of novel glycomimetic drugs to address unmet medical needs resulting from diseases in which carbohydrate biology plays a key role. GlycoMimetics' most advanced drug candidate, rivipansel, a pan-selectin antagonist, is an investigational treatment for VOC being evaluated by Pfizer. GlycoMimetics' wholly owned drug candidate, uproleselan, an E-selectin antagonist, was evaluated in a Phase 1/2 clinical trial as a potential treatment for AML. It has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration and is being evaluated across a range of patient populations including a company-sponsored Phase 3 trial in relapsed/refractory AML. GlycoMimetics has also completed a Phase 1 clinical trial with a third 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 regarding the clinical development and potential benefits and impact of the Company's drug candidates. These forward-looking statements include those relating to the planned clinical development of the Company's wholly owned product candidates and the expected timing for receiving and reporting data from Pfizer's Phase 3 clinical trial of rivipansel. Actual results may differ materially from those 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 6, 2019, 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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Source: GlycoMimetics, Inc.

Investor: Shari Annes

Phone: 650-888-0902

Email: sannes@annesassociates.com

Media:

Jamie Lacey-Moreira Phone: 410-299-3310

Email: iamielacev@presscommpr.com