GlycoMimetics, Inc. Announces Enrollment Completed for Phase 3 Clinical Trial Evaluating Rivipansel in Sickle Cell Disease

May 6, 2019

ROCKVILLE, Md.--(BUSINESS WIRE)--May 6, 2019--GlycoMimetics, Inc. (Nasdaq: GLYC) today announced that patient enrollment has been completed in the Phase 3 RESET (Rivipansel: Evaluating Safety, Efficacy and Time to Discharge) clinical trial, which is evaluating the efficacy and safety of rivipansel for the acute treatment of vaso-occlusive crisis (VOC) in sickle cell disease (SCD). In 2011, GlycoMimetics and Pfizer Inc. (NYSE:PFE) 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.

“This is an important milestone for the development of rivipansel, bringing us one step closer to potentially addressing one of the most severe complications of sickle cell disease,” said GlycoMimetics Senior Vice President of Clinical Development and Chief Medical Officer Helen Thackray, M.D., FAAP. “We have great hope for the potential impact this treatment could have on individuals living with sickle cell and their families and look forward to seeing the top-line results.”

Rivipansel has received Orphan Drug and Fast Track status from the U.S. Food and Drug Administration (FDA). Rivipansel is an investigational pan-selectin inhibitor. The selectins have been shown to play a role in cell adhesion and inflammation. By inhibiting the selectins, rivipansel is believed to enhance blood flow through the microvasculature during VOC and reduce the pain and organ damage associated with VOC. Rivipansel is not a narcotic or a pain medication.

Under the Company’s license agreement, GlycoMimetics is eligible to receive payments of up to $80 million upon the achievement of specified development milestones, up to $70 million upon the achievement of specified regulatory milestones, and up to $135 million upon the achievement of specified levels of annual net sales of licensed products. GlycoMimetics is also eligible to receive tiered royalties, with percentages ranging from the low double digits to the low teens, based on net sales of rivipansel worldwide.

About SCD and VOC

SCD is the most common inherited blood disease impacting approximately 100,000 people in the United States, predominantly of African descent. One of the most severe complications of SCD is VOC, which is typically characterized by excruciating, debilitating pain that occurs periodically throughout the life of a person with SCD. Acute care encounters, including hospitalizations and rehospitalizations, due to VOC are frequent, particularly for 18 to 30-year old. Based on published rates of health care utilization by people with SCD, there are in excess of 100,000 hospitalizations due to VOC each year in the United States with an average hospital stay of six days. The current standard of care for VOC consists of supportive therapy, primarily in the form of hydration and pain management, typically requiring extended hospitalization.

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 currently being developed for the treatment of vaso-occlusive crisis in sickle cell disease in a Phase 3 trial being conducted by Pfizer Inc., the exclusive licensee of rivipansel for clinical development and worldwide commercialization. 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 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. 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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