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GlycoMimetics Announces Agreement with FDA on Special Protocol Assessment for Phase 3 Clinical Trial of Rivipansel (GMI-1070)

- Rivipansel is in clinical development as a potential therapy for treatment of vaso-occlusive crisis in patients with sickle cell disease -

GAITHERSBURG, Md.--(BUSINESS WIRE)-- GlycoMimetics, Inc. (NASDAQ:GLYC) announced today that Pfizer Inc., the company responsible for ongoing clinical development for rivipansel (GMI-1070), has reached agreement with the U.S. Food & Drug Administration (FDA) under a special protocol assessment (SPA) for a Phase 3 trial for rivipansel. A SPA is a written agreement between a trial's sponsor (in this case, Pfizer) and the FDA regarding the design, endpoints and statistical analysis approach of a Phase 3 clinical trial, results from which could potentially support approval of a New Drug Application (NDA). Rivipansel is being developed as a potential therapy for treatment of patients with sickle cell disease who are hospitalized for vaso-occlusive crisis (VOC).

Rivipansel has previously received both Orphan Drug and Fast Track status for the treatment of VOC from the FDA. Pfizer plans to begin the Phase 3 program before the end of 2014.

"There is an enormous need in the sickle cell community for new therapies to treat this debilitating disease," said Helen Thackray, M.D., Vice President of Clinical Development and Chief Medical Officer at GlycoMimetics. "We feel that the FDA reaching agreement with Pfizer on an SPA is extremely important because there are currently no approved medicines for this particular indication and, therefore, the regulatory path to potential approval has not been previously defined."

About Sickle Cell Disease

There are more than 80,000 people in the U.S. with sickle cell disease, and many of them have multiple, acute VOCs annually. These painful crises result in more than 75,000 hospitalizations per year in the U.S., with an average stay of approximately six days.

About Rivipansel

The compound is a synthetic glycomimetic molecule, which was rationally designed to inhibit all three selectin types (a pan-selectin inhibitor). Selectins are glycoprotein cell adhesion molecules implicated in inflammatory processes. To achieve adequate therapeutic activity in certain inflammatory disorders, inhibition of all three selectin types (E-selectin, L-selectin and P-selectin) may be required. GlycoMimetics has conducted a Phase 2 randomized, double-blinded study examining the efficacy, safety and pharmacokinetics of rivipansel in hospitalized sickle cell disease patients experiencing VOC. GlycoMimetics enrolled 76 patients ages 12 to 60 at 22 trial sites in the United States and Canada. The company reported topline data from the trial in April 2013 and presented full data from the clinical trial in two oral presentations and one poster presentation at the December 2013 meeting of the American Society of Hematology (ASH). One of the oral presentations was selected to be among "Best of ASH."

In the Phase 2 trial, patients treated with rivipansel experienced reductions in time to reach resolution of VOC, length of hospital stay and use of opioid analgesics for pain management, in each case as compared to patients receiving placebo. GlycoMimetics was responsible for this phase 2 study and Pfizer will be responsible for any future clinical development of rivipansel.

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 are molecules that mimic the structure of carbohydrates involved in important biological processes. Using its expertise in carbohydrate chemistry and knowledge of carbohydrate biology, GlycoMimetics is developing a pipeline of glycomimetic drug candidates that inhibit disease-related functions of carbohydrates, such as the roles they play in inflammation, cancer and infection.

This press release contains forward-looking statements regarding GlycoMimetics' planned activities with respect to the clinical development of GMI-1070 and other matters. 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 that was filed with the U.S. Securities and Exchange Commission on March 31, 2014, and other filings the company 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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