Pfizer Logo

GLYCOMIMETICS, INC. ANNOUNCES INITIATION OF FIRST CLINICAL TRIAL EVALUATING SUBCUTANEOUS ADMINISTRATION OF RIVIPANSEL

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ROCKVILLE, MD, October 29, 2015 – GlycoMimetics, Inc. (NASDAQ: GLYC) announced today that the first healthy participant has been dosed with a subcutaneous (SC) formulation of rivipansel in a Phase 1, single ascending-dose clinical study to evaluate its safety, tolerability and pharmacokinetics. Rivipansel (GMI-1070) is an investigational compound being studied as a potential therapy for the treatment of vaso-occlusive crisis (VOC) in sickle cell disease and is being developed by Pfizer Inc. under a worldwide licensing agreement the two companies entered into in 2011.

The SC formulation of rivipansel utilizes Enhanze™ Technology, licensed by Pfizer from Halozyme Therapeutics, Inc. This technology is based on a proprietary recombinant human hyaluronidase enzyme (rHuPH20) that temporarily modifies components of the extracellular matrix in order to aid in the dispersion and absorption of other SC injected therapeutic drugs.

“We believe that having two potential formulations may provide opportunities for treatment in different settings depending on the severity of the VOC,” said Helen Thackray, M.D., Vice President of Clinical Development and Chief Medical Officer, GlycoMimetics.

The Phase 1 study will recruit approximately 27 healthy participants and will be conducted at one center in Belgium.

Rivipansel, an investigational compound that has both Orphan Drug and Fast Track status for VOC from the U.S. Food & Drug Administration, is also being studied with intravenous dosing. In June 2015, GlycoMimetics announced that Pfizer had dosed the first patient in the RESET (Rivipansel: Evaluating Safety, Efficacy and Time to Discharge) trial, a Phase 3 clinical trial assessing the efficacy and safety of rivipansel for the treatment of vaso-occlusive crisis (VOC) in patients hospitalized with sickle cell disease who are at least six years old.

GlycoMimetics has previously conducted a Phase 2 randomized, double-blinded study examining the efficacy, safety and pharmacokinetics of rivipansel administered intravenously in hospitalized sickle cell disease patients experiencing VOC. 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 a “Best of ASH.”

In the Phase 2 trial, patients treated with intravenous 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. In addition, the safety profile was benign.

About Sickle Cell Disease and VOC

Sickle cell disease is a genetic disease affecting 90,000 to 100,000 people in the United States, predominantly of African descent. One of the most severe complications of sickle cell disease is vasoocclusive crisis (VOC). VOC is typically characterized by excruciating, debilitating pain that occurs periodically throughout the life of a person with sickle cell disease. VOC is responsible for more than 73,000 hospitalizations per year in the United States with an average hospital stay of approximately 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 entered into an exclusive license agreement with Pfizer for rivipansel in October 2011. Under the license agreement, Pfizer is responsible for the clinical development, regulatory approval and potential commercialization of rivipansel.

GlycoMimetics's wholly-owned drug candidate (GMI-1271) for AML and other blood disorders is also in clinical trials. 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. Learn more at www.glycomimetics.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements regarding the clinical development of the company's drug candidates and the presentation of data. 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 16, 2015, and other filings the company makes with the SEC from time to time. Forwardlooking 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

Investor Contact:
Shari Annes
Phone: 650-888-0902
Email: sannes@annesassociates.com

Media Contact:
Jamie Lacey-Moreira
Phone: 410-299-3310
Email: jamielacey@presscommpr.com