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GlycoMimetics' GMI-1271 Receives FDA Fast Track Designation for Treatment of Acute Myeloid Leukemia

ROCKVILLE, Md.--(BUSINESS WIRE)-- GlycoMimetics, Inc. (NASDAQ:GLYC) today announced that it received Fast Track designation from the U.S. Food and Drug Administration (FDA) for its novel E-selectin antagonist GMI-1271 for treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) and elderly patients aged 60 years or older with AML.

"We believe GMI-1271 has the potential to address important unmet needs for individuals with relapsed or refractory AML, as well as for older AML patients, for whom the standard of care often fails to provide outcomes as positive as those seen in other patient groups," said Helen Thackray, M.D., Chief Medical Officer of GlycoMimetics. "The FDA's granting of a Fast Track designation for GMI-1271 to treat AML is an important step in advancing this drug candidate through the regulatory process, and if successful, in bringing a novel drug to patients in an expedited time frame."

The Fast Track Designation is designed to facilitate development and expedite review of experimental therapies that address the unmet medical needs of patients with serious conditions.

AML is a cancer of immature white blood cells that starts in the bone marrow but can quickly spread into the blood, lymph nodes, liver, spleen, central nervous system, and testicles. Each year in the United States, about 19,900 people (usually older than 45 years of age) are diagnosed, and about 10,400 people die from all forms of the disease, according to the American Cancer Society. Chemotherapeutic methods among patients with refractory and relapsed AML have low remission rates, between 25 and 30 percent.

GlycoMimetics announced on Friday, June 10, presentation of data from the Phase 1 portion of its on-going Phase 1/ 2 clinical trial testing GMI-1271 combined with induction chemotherapy, in patients with relapsed/refractory acute myeloid leukemia (AML). Data was reported at the European Hematology Association 21st Congress in Copenhagen, Denmark in a poster entitled "Results of a Phase 1 study of GMI-1271, a potent E-selectin antagonist in combination with induction chemotherapy in relapsed/refractory AML: a novel, well-tolerated regimen with a high remission rate."

In addition, GlycoMimetics recently announced that the first patient with relapsed or refractory AML has been dosed in the company's Phase 2 portion of the ongoing Phase 1/2 clinical trial of GMI-1271. This clinical trial is a multinational open-label study evaluating endpoints for safety, pharmacokinetics (PK) and efficacy of GMI-1271 in combination with induction chemotherapy in patients with high-risk AML. This trial is being conducted at a number of academic medical institutions in the United States, Ireland, and Australia. While the primary objective is to assess safety, additional endpoints include overall response rate, biomarkers of activity, durability of response and overall survival. The Phase 2 portion of the study is expected to include approximately 25 participants with relapsed or refractory AML and approximately 25 participants who are newly diagnosed.

About GMI-1271

GMI-1271 is designed to block E-selectin (an adhesion molecule on cells in the bone marrow) from binding with AML cells as a targeted approach to disrupting well-established mechanisms of leukemic cell resistance within the bone marrow microenvironment. Preclinical research points to the drug's potential role in moving cancerous cells out of the protective environment of the bone marrow where they hide and escape the effects of chemotherapy. In preclinical studies using animal models of AML, the results of which were presented at meetings of the American Society of Hematology (ASH), GMI-1271 was also associated with a reduction of chemotherapy-induced neutropenia and chemotherapy-induced mucositis.

About GlycoMimetics, Inc.

GlycoMimetics is a clinical-stage biotechnology company focused on sickle cell disease and cancer. GlycoMimetics' most advanced drug candidate, rivipansel, a pan-selectin antagonist, is being developed for the treatment of vaso-occlusive crisis in sickle cell disease and is being evaluated in a Phase 3 clinical trial being conducted by its strategic collaborator, Pfizer. GlycoMimetics' wholly-owned drug candidate, GMI-1271, an E-selectin antagonist, is being evaluated in an ongoing Phase 1/ 2 clinical trial as a potential treatment for AML. GlycoMimetics expects to file an IND with the FDA for a third drug candidate, GMI-1359, a combined CXCR4 and E-selectin antagonist, in the third quarter of 2016. GlycoMimetics is located in Rockville, MD in the BioHealth Capital Region. Learn more at www.glycomimetics.com.

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For GlycoMimetics:
Investor:
Shari Annes, 650-888-0902
sannes@annesassociates.com
or
Media:
Jamie Lacey-Moreira, 410-299-3310
jamielacey@presscommpr.com

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