GlycoMimetics Announces Initiation of Clinical Trial Evaluating Uproleselan in Combination With Venetoclax and Azacitidine

July 12, 2021

ROCKVILLE, Md.--(BUSINESS WIRE)--Jul. 12, 2021-- GlycoMimetics, Inc. (Nasdaq: GLYC) announced today that clinicians at University of California (UC) Davis Comprehensive Cancer Center initiated dosing of the first patient in a clinical study of uproleselan combined with venetoclax and azacitidine for the treatment of older or unfit patients with treatment-naïve acute myeloid leukemia (AML). Brian A. Jonas, MD, PhD, FACP, UC Davis Division of Hematology/Oncology, is the clinical trial's principal investigator.

According to Eric Feldman, MD, GlycoMimetics' Chief Medical Officer, "While the field has seen strong uptake on venetoclax paired with a hypomethylating agent (HMA) in the frontline unfit AML setting, the depth and durability of responses, particularly in patients with adverse risk biology, has been somewhat less than optimal. In this setting, there remains a significant unmet need, and we know that environment-mediated drug resistance (EMDR), driven by E-selectin, contributes to HMA/venetoclax resistance. If the study shows that E-selectin antagonism with uproleselan improves minimal residual disease (MRD) negative response rates, this would be an important step forward that underscores the foundational opportunities for uproleselan across the broad spectrum of patients treated for AML."

The UC Davis Comprehensive Cancer Center study is an investigator-sponsored trial (IST) for which GlycoMimetics is providing uproleselan. Designed to evaluate the safety and efficacy of the triple combination, the study is non-randomized, open label and multi-center. The goal of the two-part trial is first to determine a recommended Phase 2 dose, and then to explore efficacy in a dose expansion cohort. Up to 31 patients will be enrolled, and a preliminary/interim readout is expected in 2022.

At the 2020 annual meeting of the American Society of Hematology, a preclinical study of uproleselan in combination with venetoclax and the HMA azacitidine demonstrated the triple combination's potential in overcoming some of the limitations related to depth and durability of response with venetoclax/HMA alone. An oral presentation highlighted how antagonizing E-selectin with uproleselan can overcome microenvironment-mediated resistance to venetoclax/HMA therapy. In the study, the addition of uproleselan both prolonged survival of the murine model, and also promoted normal hematopeoic stem cell pro-survival signaling.

About Uproleselan

Discovered and developed by GlycoMimetics, uproleselan is an investigational, first-in-class, targeted antagonist of E-selectin. Uproleselan (yoo' pro le' sel an), currently in a comprehensive Phase 3 development program in AML, has received Breakthrough Therapy designation from the U.S. FDA and the Chinese Health authority for the treatment of adult AML patients with relapsed or refractory disease. Uproleselan is designed to block E-selectin (an adhesion molecule on cells in the bone marrow) from binding with blood cancer cells as a targeted approach to disrupting well-established mechanisms of leukemic cell resistance.

About GlycoMimetics, Inc.

GlycoMimetics is a clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers, including acute myeloid leukemia (AML), and for inflammatory diseases with high unmet need. The Company's science is based on an understanding of the role that carbohydrates play on the surface of every living cell and applying its specialized chemistry platform to discover small molecule drugs, known as glycomimetics, that alter these carbohydrate-mediated pathways in a variety of disease states, including signaling in cancer and inflammation. As a leader in this space, GlycoMimetics is leveraging this unique targeted approach to advance its pipeline of wholly owned drug candidates, with the goal of developing transformative therapies for serious diseases. The Company's lead drug candidate, uproleselan, has received Breakthrough Therapy Designation in the U.S. and China and is undergoing evaluation across a range of patient populations, including a Phase 3 trial in relapsed/refractory AML. 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. These forward-looking statements include those relating to the planned or potential clinical development, and the potential benefits and impact, of the Company's product candidate, uproleselan. Actual results may differ materially from those described 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 2, 2021, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210712005428/en/

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

Source: GlycoMimetics, Inc.