GlycoMimetics Announces New Uproleselan Clinical Data in Both Frontline Unfit and Treated Secondary Acute Myeloid Leukemia presented at ASH Annual Meeting

December 12, 2022

ROCKVILLE, Md.--(BUSINESS WIRE)--Dec. 12, 2022-- GlycoMimetics, Inc. (Nasdaq: GLYC), a late clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers and inflammatory diseases, today announced results from two investigator-sponsored trials studying uproleselan in patients with acute myeloid leukemia (AML). These results were presented at the 64th American Society of Hematology (ASH) Annual Meeting.

“We are excited to share initial results from these two investigator-sponsored trials of uproleselan. The studies describe safety and preliminary efficacy in frontline unfit and treated secondary AML populations not previously studied with this novel investigational agent,” said Edwin Rock, M.D., Ph.D., Chief Medical Officer. “These presentations provide the first uproleselan clinical data in AML generated outside of company-sponsored studies. We thank the investigators and patients for their efforts and consent, respectively, to show how adding uproleselan to existing therapies may benefit people with heterogeneous forms of AML.”

Uproleselan Added to Cladribine Plus Low Dose Cytarabine (LDAC) in Patients with Treated Secondary Acute Myeloid Leukemia (TS-AML)
Presenter: Emmanuel Almanza Huante, M.D., Department of Leukemia
The University of Texas MD Anderson Cancer Center, Houston, TX

This Phase Ib/II clinical trial evaluates safety, tolerability, and preliminary efficacy of uproleselan added to cladribine and low-dose cytarabine (LDAC) in patients with treated secondary AML. A majority of 15 patients enrolled were male (n=10) with ECOG status of less than 2 (ECOG 0=1; 1=10; 2=4). Median age was 71 years. Preliminary results from 12 evaluable patients at 3.3 months follow-up found cladribine and LDAC combined with uproleselan generated few treatment-related adverse events. The combination produced an overall response rate of 62% in a very high-risk population with expected median survival below 5 months. Disease responses were seen irrespective of previous hypomethylating agents and Venetoclax exposure. Enrollment in the study is ongoing.

Link to poster

A Phase I Study of Uproleselan Combined with Azacitidine and Venetoclax for the Treatment of Older or Unfit Patients with Treatment Naïve Acute Myeloid Leukemia
Presenter: Brian A. Jonas, M.D., Department of Internal Medicine, Division of Malignant Hematology, Cellular Therapy and Transplant, University of California Davis School of Medicine, Sacramento, CA

This Phase I study is evaluating the safety, tolerability, and preliminary efficacy of uproleselan in combination with azacitidine (Aza) and Venetoclax (Ven) in patients with untreated AML who were unfit for intensive chemotherapy. The majority of the 8 patients enrolled were female (n=6) with a median age of 78. Four patients had secondary AML, including 3 with therapy-related AML, and 75% had ELN adverse risk cytogenetics. Preliminary results showed that uproleselan with Aza/Ven did not lead to any dose-limited toxicities. The most common Grade 3-4 adverse events and serious adverse events were hematologic in nature. Dose modifications and/or cycle delays were common. In this study the combination produced promising preliminary results, with all 8 patients having a MLFS+ response. Five patients (63%) achieved CR and one patient achieved CRi, for a total CR/CRi rate of 75%, and two patients achieved MLFS. Four of the CR/CRi responses were MFC MRD-ve, for an overall MRD-ve CR/CRi rate of 50% and 67% among the CR/CRi responders. Enrollment is ongoing with current plans to add two additional sites to the study.

Link to Poster

About Uproleselan

Discovered and developed by GlycoMimetics, uproleselan is an investigational, first-in-class E-selectin antagonist. Uproleselan (yoo’ pro le’se lan), currently in a comprehensive Phase 3 development program in acute myeloid leukemia (AML), received Breakthrough Therapy designation from the U.S. FDA and from the Chinese National Medical Products Administration for treatment of adult AML patients with relapsed or refractory disease. Uproleselan is designed to block E-selectin binding and stimulation of myeloid cells. E-selectin is expressed on the surface of blood vessels, and its binding to myeloid cells confers a pro-survival effect via NF-kB signaling. Uproleselan is designed to provide a novel approach to disrupting established mechanisms of leukemic cell resistance.

About GlycoMimetics, Inc.

GlycoMimetics is a late clinical-stage biotechnology company discovering and developing glycobiology-based therapies for cancers, including AML, and for inflammatory diseases with high unmet needs. The company’s science is based on understanding the role that carbohydrates play in cell recognition and a specialized chemistry platform to discover small molecule drugs, known as glycomimetics, that alter carbohydrate-mediated recognition in diverse disease states, including cancer and inflammation. As a leader in this science, GlycoMimetics leverages this unique approach to advance its pipeline of wholly-owned drug candidates, with the goal of developing transformative therapies for diseases with high unmet need. GlycoMimetics is headquartered in Rockville, MD in the BioHealth Capital Region. Learn more at www.glycomimetics.com.

Forward-Looking Statements

To the extent that statements contained herein are not descriptions of historical facts, they are forward-looking statements reflecting the current beliefs

and expectations of the management of GlycoMimetics, Inc. Forward-looking statements include, but are not limited to, statements regarding the conduct of and data from clinical trials, planned or potential clinical development, the potential benefit and impact of uproleselan, and any other statement containing terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “intends,” or “continue,” or the negative of these terms or other comparable terminology. For a further description of the risks associated with forward-looking statements, as well as other risks facing GlycoMimetics, please see the risk factors described in GlycoMimetics’ Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (“SEC”) on March 3, 2022, Quarterly Report on Form 10-Q filed with the SEC on November 9, 2022, or other reports GlycoMimetics files with the U.S. Securities and Exchange Commission from time to time, including those factors discussed under the caption “Risk Factors” in such filings. Forward-looking statements speak only as of the date of this presentation, 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/20221212005234/en/

Investors:
Argot Partners
Leo Vartorella / Carrie McKim
212-600-1902
Glycomimetics@argotpartners.com

Source: GlycoMimetics, Inc.