

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **June 10, 2016**

GLYCOMIMETICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-36177
(Commission
File No.)

06-1686563
(IRS Employer
Identification No.)

9708 Medical Center Drive
Rockville, MD 20850
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(240) 243-1201**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01 Regulation FD Disclosure.

On June 10, 2016, members of management of GlycoMimetics, Inc. (the “*Company*”) will present at the European Hematology Association 21st Congress in Copenhagen, Denmark using a poster showing data from the Phase 1 portion of the Company’s Phase 1/2 clinical trial of its novel E-selectin antagonist, GMI-1271, combined with induction chemotherapy, in patients with relapsed/refractory acute myeloid leukemia. The Company also issued a press release regarding the data from the Phase 1/2 clinical trial and the presentation.

A copy of the poster to be used during the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and the press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K. The information contained in this Item 7.01 and in the presentation furnished as Exhibit 99.1 and the press release furnished as Exhibit 99.2 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), and is not incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Poster for the European Hematology Association 21 st Congress.
99.2	Press Release, dated June 10, 2016, “GlycoMimetics’ GMI-1271 yields high remission rates and favorable tolerability in Phase 1 Portion of Phase 1/2 clinical trial for AML.”

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GLYCOMIMETICS, INC.

Date: June 10, 2016

By: /s/ Brian M. Hahn
Brian M. Hahn
Chief Financial Officer

Exhibit Index

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Results of a Phase I 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



Daniel J. DeAngelo^{1*}, Michael E. O'Dwyer², Pamela S. Becker³, Jane L. Liesveld⁴, Dale L. Bixby⁵, John L. Magnani⁶, Helen M. Thakray⁶, Brian A. Jonas⁷



¹ Department of Medical Oncology, Dana-Farber Cancer Institute, Boston, United States; ² Department of Hematology, National University of Ireland, Galway, Ireland; ³ Department of Medicine, Division of Hematology, University of Washington, Seattle; ⁴ Department of Medicine, Hematology/Oncology, University of Rochester Medical Center, Rochester; ⁵ Department of Internal Medicine, Division of Hematology and Oncology, University of Michigan, Ann Arbor; ⁶ GlycoMimetics, Providence; ⁷ Department of Medicine, Division of Hematology and Oncology, UC-Love Comprehensive Cancer Center, Sacramento, United States

Background

The treatment of patients with relapsed or refractory acute myeloid leukemia (AML) remains a significant challenge with poor outcomes primarily due to low remission rates as well as short remission duration. Although cytotoxic chemotherapy remains the standard approach for the treatment of patients with relapsed or refractory (RR) AML, novel agents are urgently needed to improve clinical outcomes. The regimen consisting of mitoxantrone, etoposide, and cytarabine (MEC) is commonly used for patients with RR AML with remission rates of 25-30%.

E-selectin is an adhesion molecule expressed constitutively in the bone marrow endothelium which acts as a gatekeeper for cancer cells entering the bone marrow. Binding of leukemic blasts to E-selectin activates leukemic cell survival pathways, thereby contributing to chemotherapy resistance. Leukemic stem cells in the bone marrow can be resistant to cytotoxic treatment. Inhibition of E-selectin has been shown to riposte chemoresistance. Block cancer cells from entering the bone marrow and enhance mobilization of leukemic cells out of the bone marrow. GMI-1271 is a novel antagonist of E-selectin, and its addition in preclinical models breaks chemoresistance resulting in a 85% reduction of leukemic stem cells in the bone marrow over cytarabine alone. GMI-1271 significantly improves survival alone chemotherapy alone in multiple models of AML and other hematologic malignancies.

Treatment Schema

Safety and Tolerability

- No Dose Limiting Toxicities were seen in any subjects
- No deaths occurred during treatment phase (44 days)
- Adverse Events were typical for MEC induction chemotherapy.

All subjects completed full course of GMI-1271 and MEC chemotherapy and tolerated combined regimen well. Mucositis developed in 5 subjects (4 in Cohort 1, 1 in Cohort 2), of whom 2 required IV nutrition (both in Cohort 1). No subjects in Cohort 3 had AEs of mucositis or required IV nutrition. In total, 14 subjects did not develop mucositis during MEC induction chemotherapy.

Serious Adverse Events (SAEs) reported in 9/19 subjects (25%)

- 3 in Cohort 1
- 6 in Cohort 2
- 2 in Cohort 3

All SAEs resolved during treatment phase; none resulted in discontinuation of GMI-1271 or chemotherapy. Individual SAEs included sepsis (2), pneumonia (1), de novo infection (1), enterocolitis (1), hypotension (1) and adjustment disorder (1).

Results

Efficiency

Outcome	Response Rate N=18	AML Subgroup	CR/CRi Rate n (%)
BONE MARROW RESPONSE, n (%)		Primary Refractory, N=6	3 (50)
Complete Remission (CR)	8 (42)	Relapsed, N=13	6 (45)
CR with incomplete recovery (CRi)	1 (5)	Relapsed < 2 months, N=12	5 (30)
ORR = CR + CRi	9 (47)	Relapsed > 2 months, N=9	2 (22)
	30% CI 27-33%		
Myelophagocytosis-Free State	1 (5)	Age < 60 years, N=14	7 (60)
Perks n/Disose	9 (47)	Age ≥ 60 years, N=6	2 (40)
Proceeded to HSCT n (%)	8 (28)		
Mortality 30 days, n (%)	0 (0)	Intermediate risk, N=6	5 (55)
Mortality 60 days, n (%)	2 (11)	Unfavorable risk, N=10	4 (40)
TIME TO COUNT RECOVERY, Median Days		FLT3-ITD mutated, N=2	1 (50)
ANC < 500	33		
ANC > 1000	37		
Platelets > 100K	35		

Methods

A multi-center open-label phase 1/2 trial enrolled adults with RR AML receiving MEC induction chemotherapy. The primary objective was to assess safety of escalating doses of GMI-1271 when combined with MEC; secondary objectives were to characterize pharmacokinetics (PK) and pharmacodynamics (PD) and to observe anti-leukemic activity. Eligible patients (ECOG 0-2) must have received ≥ 2 prior induction regimens, have no active CNS disease, have adequate renal and hepatic function, absolute blast count ≥ 500/μL, and no more than one prior HSCT. Adjunctive treatment with GMI-1271 at increasing doses was administered concurrent with chemotherapy (24 hours prior, throughout, and 48 hours post MEC). MEC consisted of mitoxantrone 10 mg/m², etoposide 100 mg/m², and cytarabine 100 mg/m² for 5 days and supportive care was given as per institutional guidelines. Dose limiting toxicity (DLT) was assessed at count recovery or Day 44 whichever came first. DLT was defined as either persistent neutropenia and/or thrombocytopenia beyond day 44 in the absence of disease OR any grade 3 non-hematologic toxicity that did not resolve to Grade 2 by day 44. At End of Treatment (Day 44 or count recovery if earlier), bone marrow was assessed for remission of leukemia. No formal hypothesis testing was done; comparison to historical control overall remission rate of 25% was done using one-sided exact binomial analysis and the Clopper and Pearson method for 95% CI.

Samples were obtained for PK, sparse sampling and population PK analysis methods were applied. Plasma was also assayed by ELISA for E-selectin levels. Whole blood was collected for flow cytometry; peripheral CD34+ counts were established by validated flow assay at Laboratory.

Demographics

Characteristic	n (%)
Total enrolled	19
Age, median (range)	59 (29-71)
Male, n (%)	13 (68)
Relapsers, n (%)	6 (32)
Relapsed, AEs, n (%)	13 (68)
Relapsed < 2 months	9 (47)
Relapsed > 2 months	4 (21)
Prior Therapies, n (%)	
HSCT	4 (21)
1 Induction Regimen	14 (74)
2 Induction Regimens	5 (26)
Risk Category (SWOG), n (%)	
Intermediate	9 (47)
Unfavorable	10 (53)
ECOG Performance Status	
0	6 (32)
1	7 (37)
2	6 (32)

Pharmacokinetics

Pharmacokinetic profile and dose-proportionality were consistent with previous healthy volunteer studies, with the exception that clearance was 28% lower in patients with AML. In this study, clearance of GMI-1271 in a typical 60-year old subject was 1.28 L/hour. Overall, clearance of GMI-1271 decreased about 2% per year with age, possibly as a function of changes in creatinine clearance. C_{max} and Area Under the Curve (AUC) at steady state are shown as a function of age and dose.

Pharmacodynamics

Plasma soluble E-selectin levels decreased over the treatment period in all dose groups. This response is seen both in mean levels and Area Under the Curve (AUC). A dose-related difference was not seen, suggesting all dose levels may be above a plateau for on-target activity.

Peripheral CD34+ cells, including both hematopoietic stem cells and leukemic blasts, were not observed to increase in the 24 hours after treatment with a seasonal dose of GMI-1271. Total peripheral CD34+ counts varied widely and were noted to be higher in subjects with high WBC and absolute blast counts, but did not change after GMI-1271 administration.

Safety and Tolerability (Table)

Adverse Event, Grade 2 or above	Cohort 1 (N=6)	Cohort 2 (N=7)	Cohort 3 (N=6)	Total (N=19)
Infections				
Sepsis	1 (17)	1 (14)	3 (50)	5 (26)
Pneumonia	1 (17)	2 (28)	1 (17)	4 (21)
De novo viral infection	2 (33)	0 (0)	0 (0)	2 (11)
Bacteremia + fungemia	0 (0)	2 (29)	0 (0)	2 (11)
Sinusitis	0 (0)	0 (0)	1 (17)	1 (5)
Blood system disorders				
Thrombocytopenia	3 (50)	2 (29)	4 (67)	9 (47)
Anemia	3 (50)	3 (43)	3 (50)	9 (47)
Neutropenia	5 (83)	1 (14)	3 (50)	9 (47)
Metabolism and nutrition disorders				
ENRTP/ENRTPs	2 (33)	0 (0)	2 (33)	4 (21)
Diplopia	2 (33)	0 (0)	0 (0)	2 (11)
Respiratory and cardiovascular disorders				
Hypoxia	2 (33)	1 (14)	1 (17)	4 (21)
Acute respiratory distress syndrome	0 (0)	0 (0)	1 (17)	1 (5)
Cardiac disorders	1 (17)	0 (0)	0 (0)	1 (5)
Gastrointestinal disorders				
Colitis	2 (33)	1 (14)	0 (0)	3 (16)
General disorders				
Fatigue	0 (0)	1 (14)	0 (0)	1 (5)
Headache	0 (0)	1 (14)	0 (0)	1 (5)
Arthralgia	1 (17)	0 (0)	0 (0)	1 (5)

Current Study Status

Confirmatory Phase 2 expansion at 10 mg/m² in two patient populations

- Arm A: GMI-1271 + MEC in patients with relapsed/refractory AML
- Arm B: GMI-1271 + 7+3 in elderly patients with de novo AML (age ≥ 60 years)

Conclusions

We report the Phase I clinical assessment of novel E-selectin antagonist GMI-1271, in combination with one cycle of induction chemotherapy (MEC), in heavily pretreated, high-risk patients with relapsed/refractory AML.

Safety

- The combination of GMI-1271 with MEC chemotherapy is well tolerated
- No Dose Limiting Toxicities (DLTs) have been observed in all 3 cohorts evaluated
- Periportal counts, including neutrophils and platelets, recovered by Day 44 in patients achieving remission

PD/AD

- Reduction in E-selectin plasma levels confirmed on-target activity for all dose levels
- GMI-1271 plasma levels were above levels associated with anti-leukemic activity in animal models of AML

Clinical Outcomes

- An Overall Remission Rate (ORR) of 47% was observed; Complete Remission Rate was 42%
- This is higher than expected given the high risk cytogenetic and disease features in this group
- Remission duration was sufficient to allow patients to proceed to salvage stem cell transplant (N=6)

Conflict of Interest Disclosures: D.J.D., J.L.L., D.L.B., and B.A.J. have no conflicts to report. MEC and PBS receive research funding from GlycoMimetics, Inc. J.L.M. and H.M.T. are employees of and have equity ownership in GlycoMimetics, Inc. Funding for this trial: GlycoMimetics, Inc. ClinicalTrials.gov Identifier: NCT02368291

Background: DeAngelis DJ, et al. Clin Oncol (2016) 28:1078-1088. | Rahbari et al. J Clin Oncol (2016) 34:4103-4110. | Walker et al. Blood (2014) 114:309-318. For further information please contact: hthakray@glycomimetics.com. More information on this and related GlycoMimetics projects can be obtained at glycomimetics.com



GLYCOMIMETICS' GMI-1271 yields high remission rates and favorable tolerability in Phase 1 PORTION OF PHASE 1/2 clinical trial FOR AML

Data presented via poster at European Hematology Association 21st Congress

ROCKVILLE, MD, JUNE 10, 2016 – GlycoMimetics, Inc. (NASDAQ: GLYC) today announced data from the Phase 1 portion of its Phase 1/2 clinical trial of its novel E-selectin antagonist, GMI-1271, combined with induction chemotherapy, in patients with relapsed/refractory acute myeloid leukemia (AML). Dose escalation is complete and a GMI-1271 dose was identified for Phase 2 testing.

The results, presented at the European Hematology Association 21st Congress in Copenhagen, Denmark, showed an overall response rate (combined complete remission (CR) and remission with incomplete recovery (CRI)) of 47 percent among 19 patients, including those who were older than 60 years of age, with primary refractory or relapsed disease, poor cytogenetic risk factors including FLT-3 ITDs, and/or extramedullary disease. Eight of the 19 patients achieved a best clinical response of CR, one patient achieved CRI, and one patient achieved morphologic leukemia-free state (MLFS). Five of the 19 patients went on to receive a hematopoietic stem cell transplant. There was no mortality reported during the treatment phase of 44 days, and no dose-limiting toxic reactions were observed among participants. Pharmacokinetic (PK) data showed a dose-dependent increase in plasma concentrations of GMI-1271, above levels associated with anti-leukemic activity in animal models of AML. In addition, biomarker analysis confirmed on-target activity for GMI-1271 at all dose levels. During dose escalation, patients received only one cycle of treatment with GMI-1271. As part of the Phase 2 expansion, certain patients will be eligible to receive more than one cycle of treatment.

“The data from the Phase 1 portion of this Phase1/2 trial are very encouraging, demonstrating a high remission rate; and the combination of GMI-1271 and chemotherapy seems to be extremely well tolerated,” said Daniel J. DeAngelo, M.D., Ph.D., Director of Clinical and Translational Research, Adult Leukemia, Department of Medical Oncology, Dana-Farber Cancer Institute, and Associate Professor of Medicine, Harvard Medical School. “We believe GMI-1271 when combined with chemotherapy has the potential to address the unmet therapeutic needs of AML patients, and we look forward to gathering data from study of additional patients.”

The poster (P191), 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,” is available here and will be displayed as part of a poster session scheduled for 5:15 p.m. CET today.

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 soft tissues. 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 relapsed/refractory AML have low remission rates, typically between 25 and 30 percent.

GlycoMimetics recently announced that the first patient with relapsed or refractory AML has been dosed in the Phase 2 portion of the ongoing clinical trial of GMI-1271. This clinical trial is a multinational open-label study evaluating endpoints for safety, 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 trial is expected to include approximately 25 participants over 18 years of age with relapsed or refractory AML and approximately 25 participants over 60 years of age 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 investigational new drug application (IND) with the U.S. Food and Drug Administration (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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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
