

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): March 1, 2024

GlycoMimetics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-36177
(Commission File Number)

06-1686563
(IRS Employer
Identification No.)

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

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

N/A
(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))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value	GLYC	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

A copy of a slide presentation that GlycoMimetics, Inc. (the "Company") plans to use for anticipated investor meetings is attached to this Current Report as Exhibit 99.1 and is incorporated herein solely for purposes of this Item 7.01 disclosure.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 7.01, including Exhibit 99.1 attached hereto, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as otherwise expressly stated in such filing.

Item 9.01. Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	GlycoMimetics, Inc. Corporate Presentation, March 1, 2024
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document)

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: March 1, 2024

By: /s/ Brian M. Hahn
Brian M. Hahn
Senior Vice President and Chief Financial Officer

Transforming Lives

Glycobiology-based Therapeutics

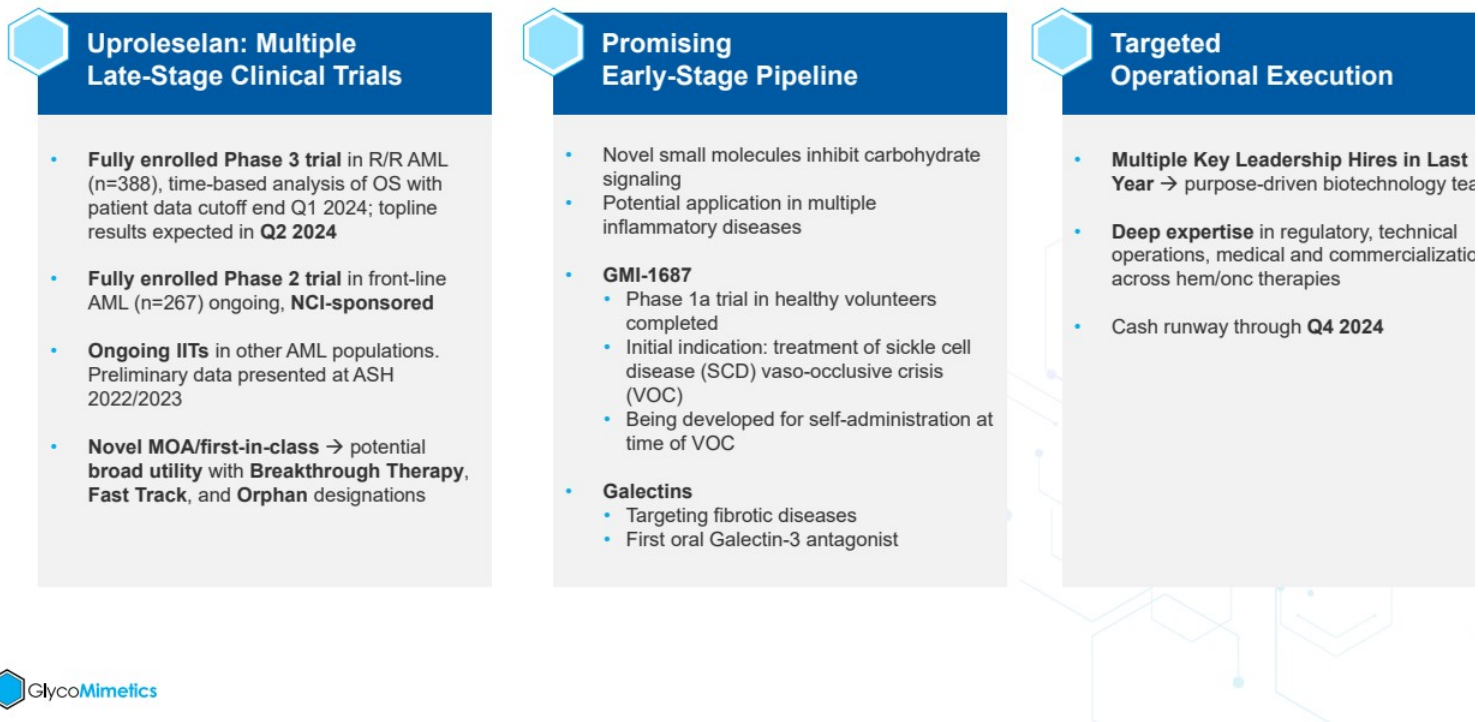
March 2024 | NASDAQ: GLYC



Forward-Looking Statements

- To the extent that statements contained in this presentation are not descriptions of historical facts, they are forward-looking statements reflecting the current beliefs and expectations of the management of GlycoMimetics, Inc. (“GlycoMimetics,” “we,” “us,” or “our”). Forward-looking statements contained in this presentation may include, but are not limited to: (i) the expected or projected timing of events and data readout from ongoing Phase 3 clinical trials of uproleselan; (ii) the planned or potential clinical development and potential indications, benefits and impact of our drug candidates, including uproleselan and GMI-1687; (iii) the timing of receipt of clinical data; (iv) the potential safety, efficacy or clinical utility of our drug candidates; (v) the size of patient populations targeted by drug candidates we or our collaborators develop; (vi) market adoption of our potential drug candidates by payors, physicians and patients, including potential market opportunity; (vii) the likelihood and timing of regulatory filings, approvals or other anticipated interactions with regulatory authorities; (viii) our business and product development strategies, including our cash needs and expected cash runway; and (ix) 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.
- Forward-looking statements are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry’s actual results, levels of activity, performance, or achievements to be materially different from those discussed, implied or otherwise anticipated by such statements. You are cautioned not to place undue reliance on such forward-looking statements, which are current only as of the date of this presentation. Examples of risks, uncertainties and factors that may cause differences between our expectations and actual results include unexpected safety or efficacy data, unexpected side effects observed during preclinical studies or in clinical trials, whether results of early clinical trials will be indicative of results from later clinical trials, changes in expected or existing competition or additional market research that may cause our expectations about market opportunity to change, changes in the regulatory environment for our drug candidates, failure of our collaborators to support or advance our collaborations or drug candidates, our need for future capital, the inability to adequately protect our intellectual property, and becoming a party to litigation or other disputes. 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 the Company’s Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 29, 2023, as well as other reports we file 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.

Near-Term Catalysts and Promising, Glycobiology-based Pipeline



A Portfolio of Promising Product Candidates

Program	Therapeutic Area	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Market
SELETINS							
UPROLESELAN (GMI-1271)*	Relapsed / Refractory AML	Time based data cutoff end Q1 2024, data in Q2 2024					
	Newly Diagnosed "Fit" AML	Fully enrolled 267 patients Dec 2021					
	Relapsed / Refractory Pediatric AML	Ph1 by NCI dosed 1 st patient					
GMI-1687*	SCD Vaso-occlusive Crisis and Inflammatory diseases	Ph1a completed					
GALECTINS							
GMI-2093	Fibrosis and Oncology	Lead declared March 2022					

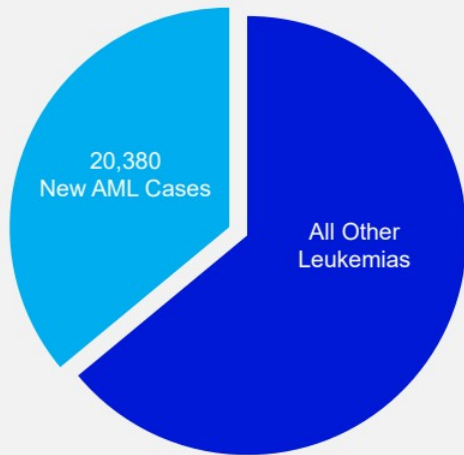
Breakthrough Therapy Designation in AML

Uproleselan (GMI-1271)

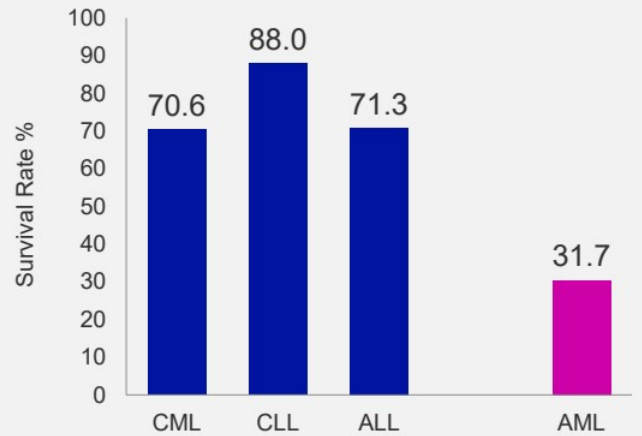


Significant Unmet Medical Need In AML¹

ESTIMATED NEW CASES (2023)

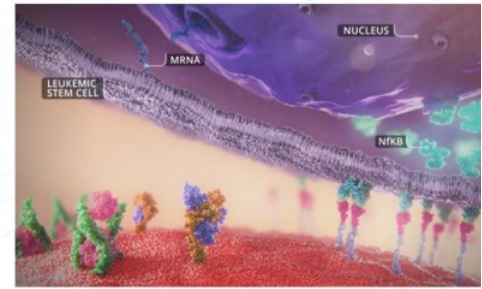
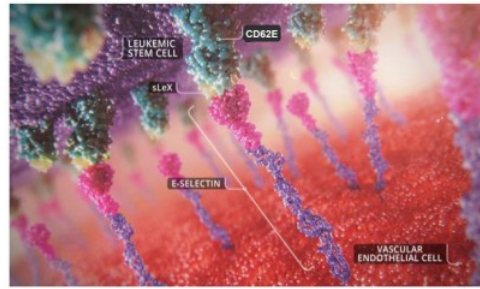


5-YEAR RELATIVE SURVIVAL (2013 – 2019)¹



American Cancer Society, Cancer Facts and Figures 2023. Atlanta: American Cancer Society; 2023. Accessed May 10, 2023. <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2023/2023-cancer-facts-and-figures.pdf>.

Uproleselan: First-in-Class E-Selectin Antagonist for AML



E-selectin:

- ✓ Leukocyte adhesion molecule constitutively expressed on marrow endothelial cells, also inducibly expressed throughout vasculature by innate inflammatory mediators
- ✓ Up-regulated by AML blasts via secreted inflammatory mediators, such as TNF-alpha and IL1-beta

E-selectin/E-selectin Ligand Interaction:

- ✓ Enables AML blast and leukemia stem cell sequestration in bone marrow
- ✓ Activates pro-survival NF-kB pathways
- ✓ E-selectin ligand sLex up-regulated on AML cells via multiple distinct drug resistance mechanisms

Uproleselan, a First-in-class E-Selectin Antagonist:

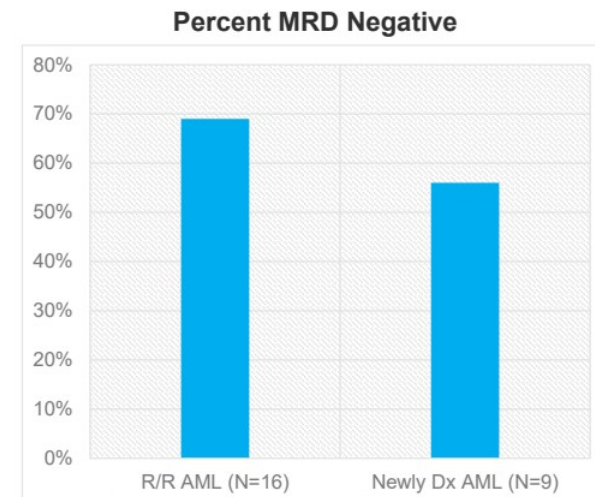
- ✓ Releases AML blasts and leukemic stem cells from vascular sequestration agnostic to AML mutational status
- ✓ Disrupts NF-kB mediated chemoresistance pathways
- ✓ Potential broad utility across AML

Phase 1/2 Results in R/R and Newly Diagnosed AML Patients

AML population	CR	CR/CRi	Median Outcome	MRD-negative
Relapsed / Refractory (n = 54)	35%	41%	8.8 mos OS	69%
Newly Diagnosed (n = 25)	52%	72%	9.2 mos EFS	55%

E-selectin ligand expression

- Detectable in every patient tested
- Higher levels in R/R patients achieving CR/CRi, MRD- and prolonged median OS



Potential Foundational Backbone Across Spectrum in AML

~20,380 Newly Diagnosed AML Patients in the U.S.¹

~12K "Fit" Patients eligible for intensive chemotherapy

~8K Unfit"

12K
PATIENTS/YEAR

NEWLY DIAGNOSED, ELDERLY AML
NCI-Sponsored Phase 2/3
Combination of Uproleselan + 7&3

8K
PATIENTS/YEAR

Recent venetoclax approval

8.5K
PATIENTS/YEAR

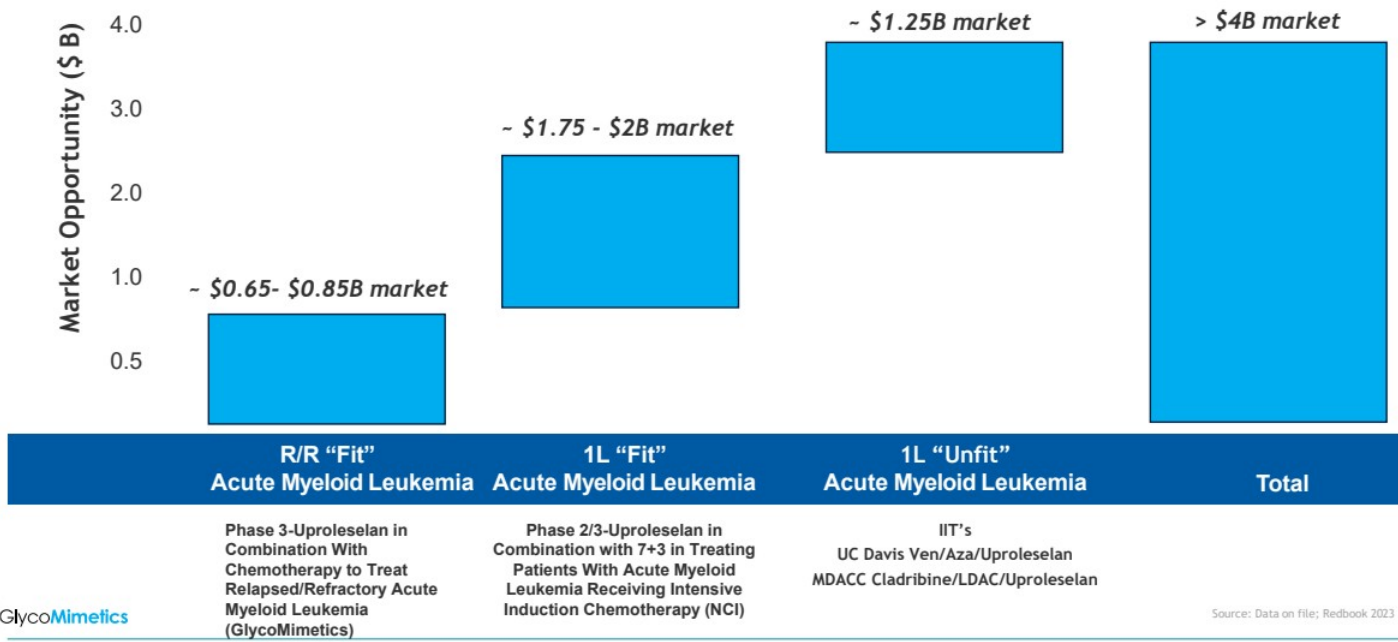
RELAPSED / REFRACTORY AML
GLYC-Sponsored Phase 3
Combination of Uproleselan + MEC/FAI

Uproleselan Value Proposition

- Improve achievement / depth of remission
- Extend overall survival
- Mitigate chemotherapy-related toxicity

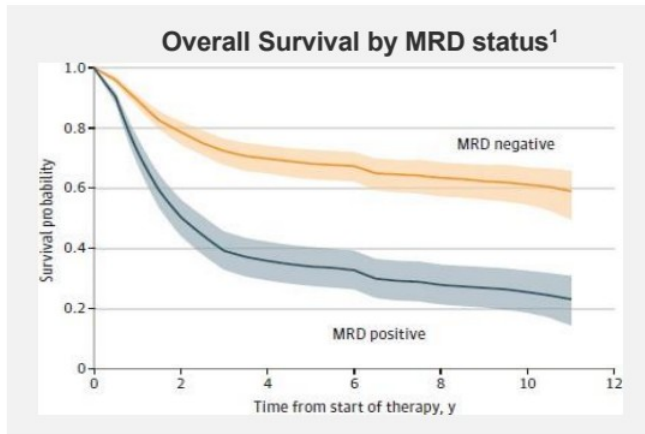
Full realization of uproleselan's potential across AML treatment continuum could provide access to >\$4B US market opportunity

Significant growth potential with indications in earlier lines of treatment



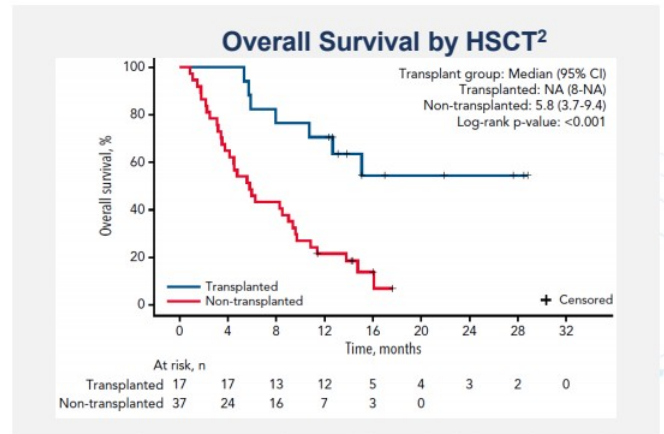
Source: Data on file; Redbook 2023

MRD Negativity and HSCT Both Favorably Prognostic



Meta-analysis of 81 studies (N >11,000)

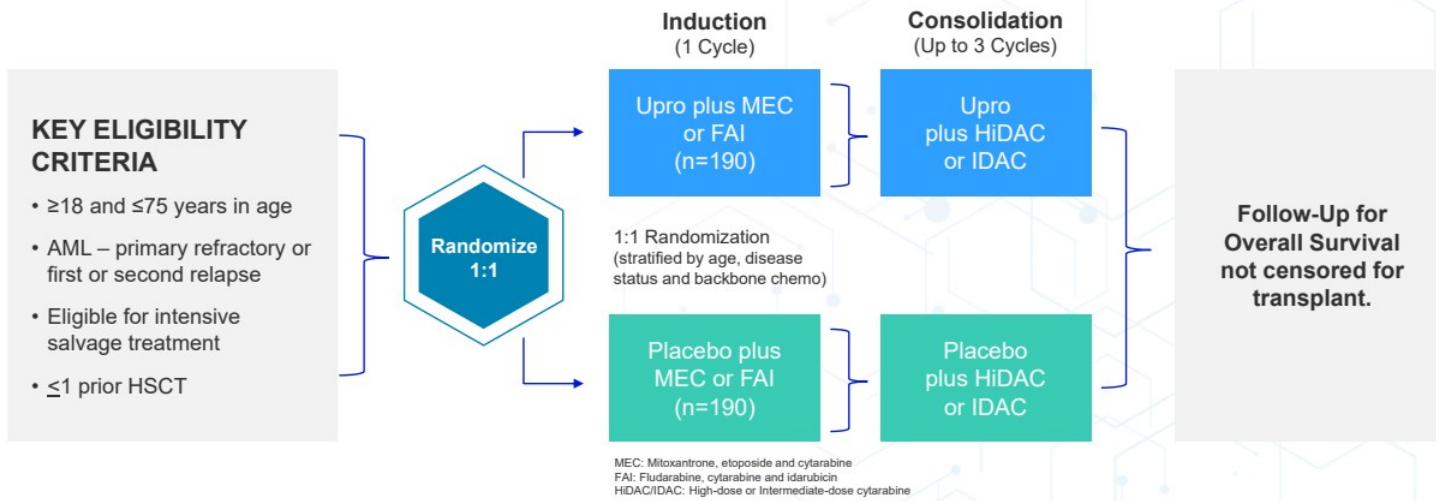
- MRD negativity favorably prognostic for survival
- Effect independent of age, subtype, timing, method



Uproleselan Phase 1/2 overall survival by HSCT

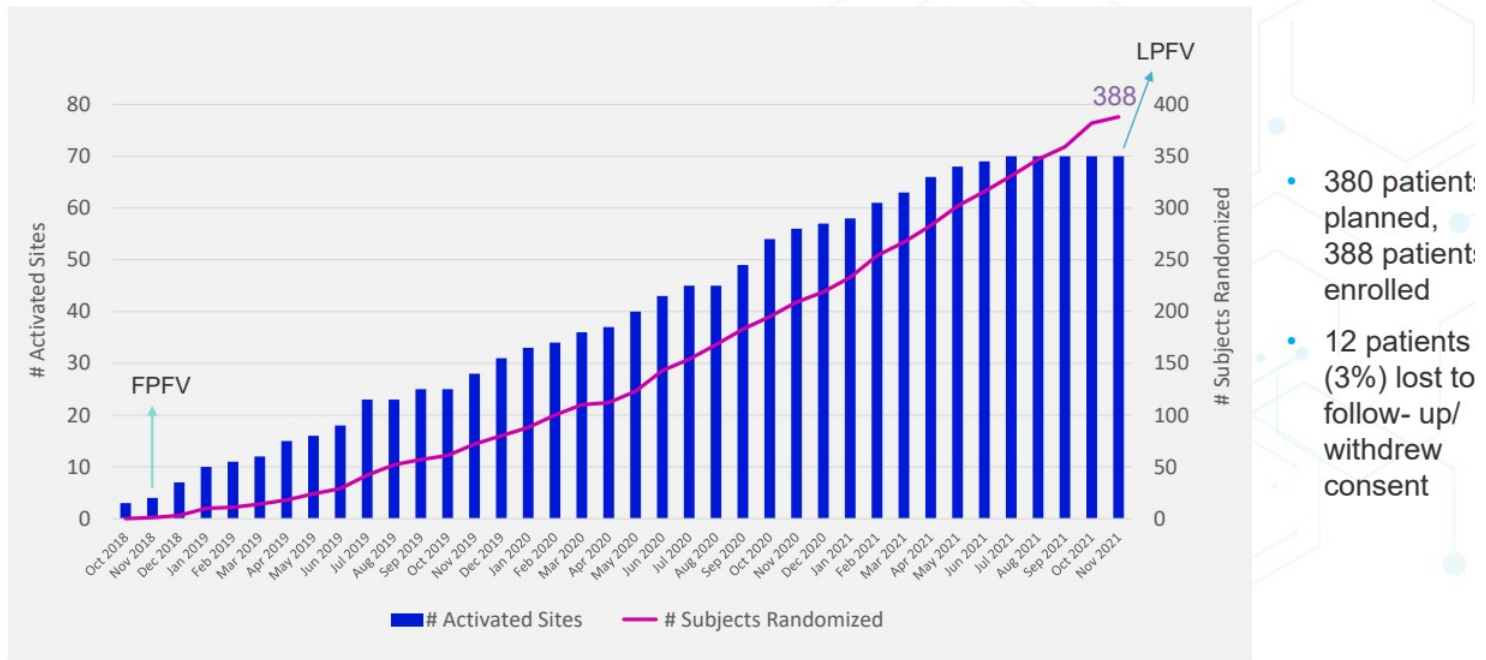
- N=54 R/R AML patients at 10 mg/kg RP2D
- Overall MRD-negative: 56% 1L, 69% R/R
- 10 longest survivors all MRD-negative

Relapsed / Refractory AML Phase 3 Trial Design



Enrollment of 388 Patients Completed in November 2021; Data cutoff end Q1-2024, Topline Results to be Reported in Q2 2024

Trial GMI-1271-301 Enrollment



Phase 3 Patient Characteristics Broadly Similar to Phase 2

301 Study | N=388

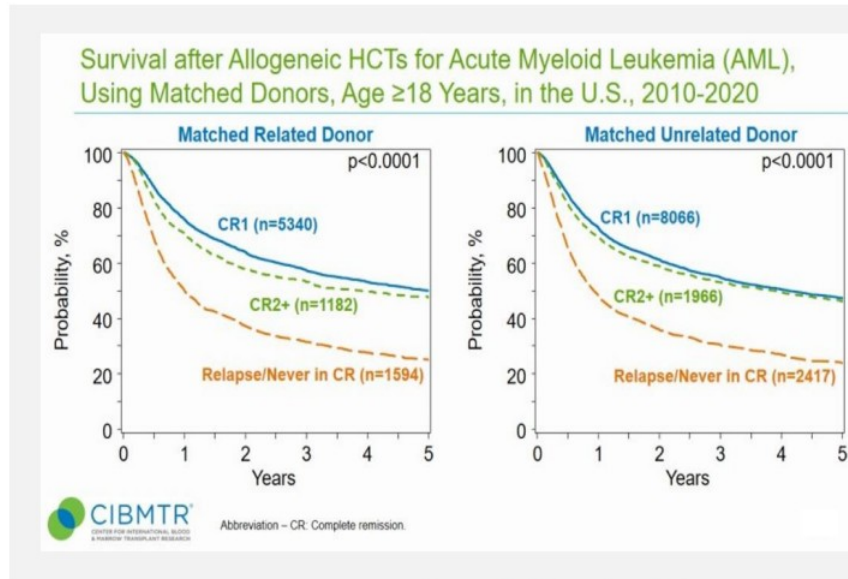
201 Study | N=66

Relapsed/Refractory Patient Demographics		
Age, median (range)	58 (20-75)	59 (26-84)
Refractory, n (%)	129 (33%)	22 (33%)
Relapsed, n (%)	259 (67%)	44 (67%)
Duration of prior remission ≤6 mos	56 (22%)	18 (41%)
Prior Therapies		
HSCT	70 (18%)	12 (18%)
≥2 Induction Regimens	63 (16%)	22 (33%)
ELN Risk Category		
Adverse	42%	50%
Intermediate	23%	17%
Favorable	21%	11%
Unknown	14%	22%

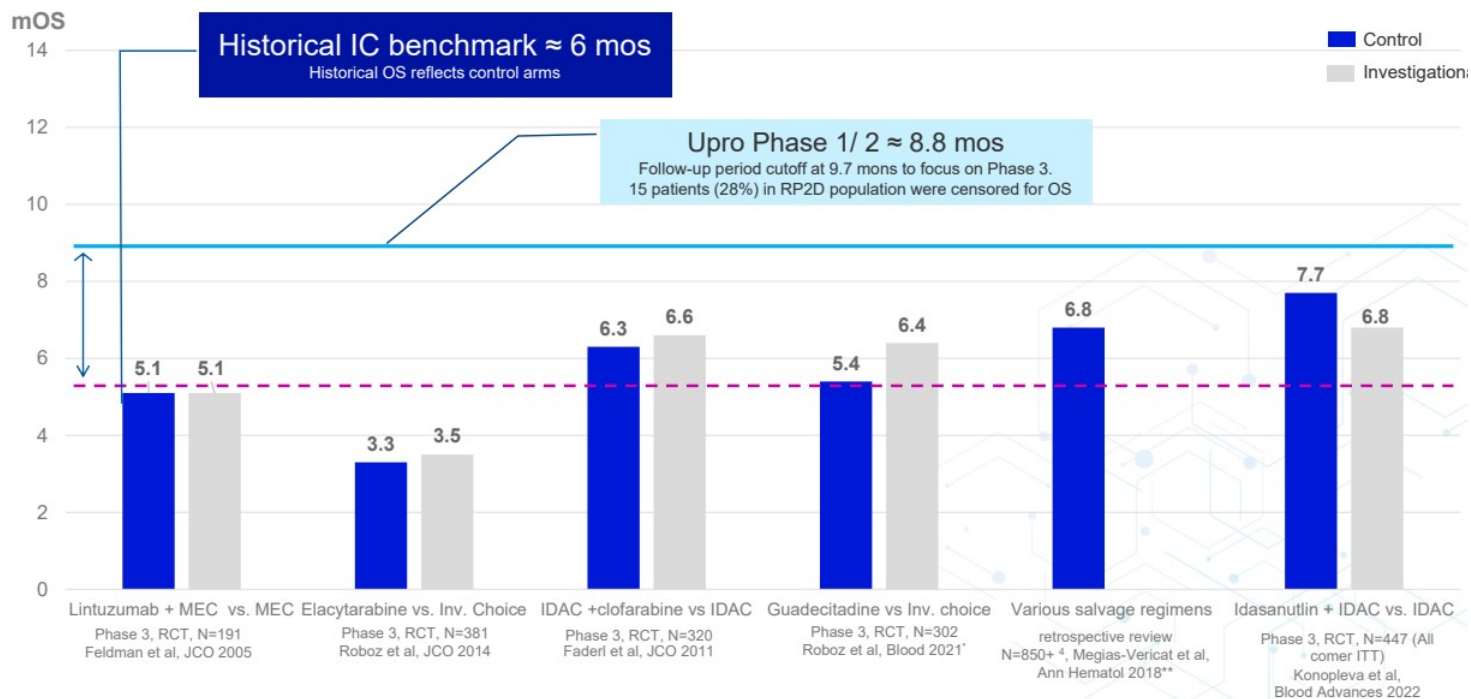


FDA Clears Time-Based Analysis to Phase 3 Trial Protocol

- June 2023 FDA clears Phase 3 time-based OS analysis after defined cutoff if 295 events not reached by that date
- Clinically mature data in Q2 2024 will reflect > 3 years median follow-up and > 2 years post-transplant follow-up for the substantial majority of remaining patients that received stem cell transplants
- After 2 years post-transplant, AML relapse becomes infrequent

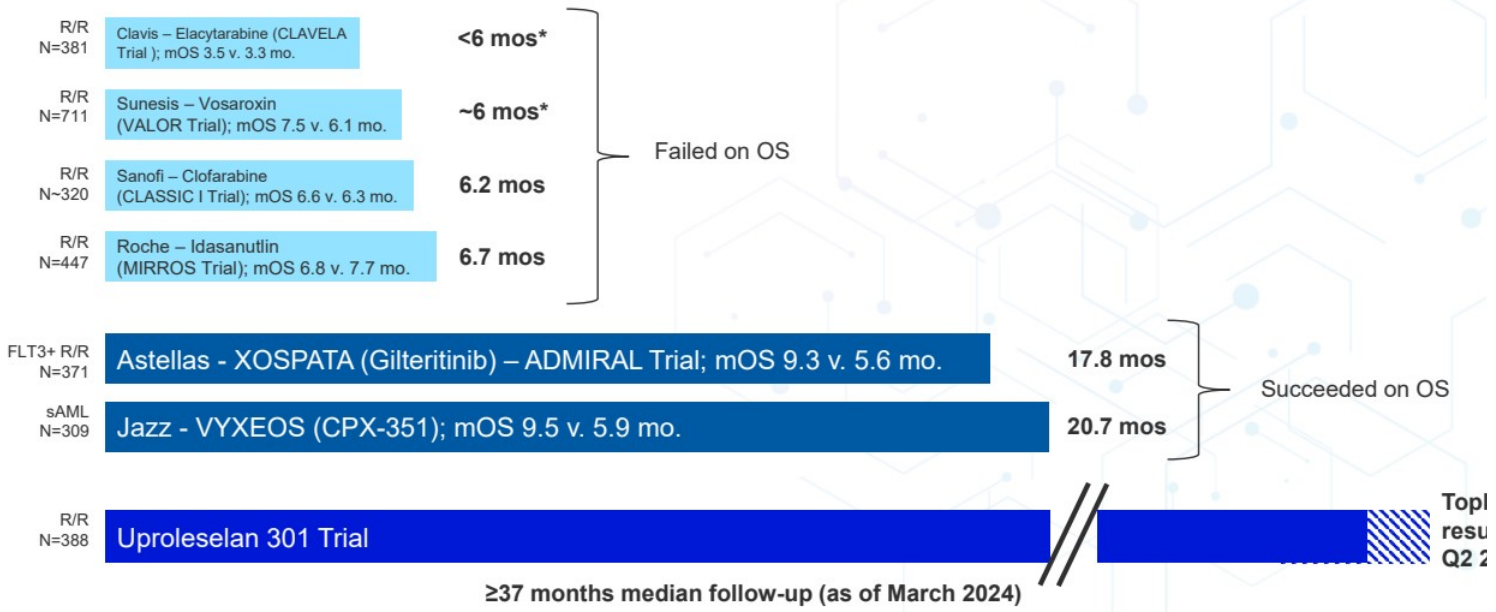


Historical Intensive Chemotherapy benchmarks for mOS are ~6 months



Note: patient outcomes for IC eligible populations often vary depending upon patient and disease characteristics
[†] Control group includes patients on MEC and FLAG-IDA
^{**} All patients in this analysis received MEC

Duration of Follow-Up and Outcomes in Key AML Trials



Follow-Up Versus Outcome in Select AML Trials

Trial	Median Survival (mos)	Median Follow-up (mos)	Enrolled (N)	Events	OS HR	P-value
CLAVELA	3.5 vs 3.3 mos	< 6*	381	302	0.97	0.96
VALOR	7.5 vs 6.1 mos	~ 6*	711	562	0.87	0.0610
CLASSIC I	6.6 vs 6.3 mos	6.2	320	258	1.00	1.00
MIRROS	6.8 vs 7.7 mos	6.7	436	296	1.09	0.52
VIALE-A	15 vs 10 mos	20.5	433	270	0.66	< 0.001
VYXEOS	9.6 vs 6.0 mos	20.7	309	236	0.69	0.003
ADMIRAL	9.3 vs 5.6 mos	17.8	371	258	0.64	< 0.001
Uproleselan	TBD	>37 (Mar '24)	388	295	TBD	TBD

Longer median follow-up at time of primary analysis correlates with trials being positive

Potential Foundational Backbone Across Spectrum in AML

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Recent venetoclax approval

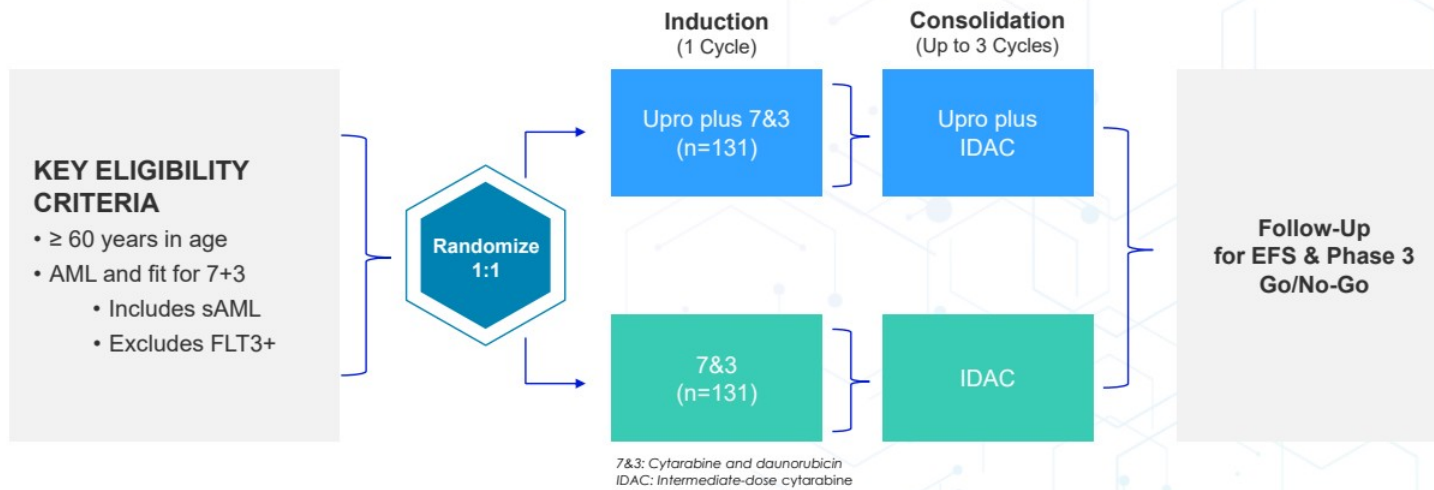
8.5K
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Uproleselan Value Proposition

- Improve achievement / depth of remission
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NCI / Alliance Frontline “Fit” AML Phase 2/3 Trial Design



Enrollment of 267 Patients in Phase 2 Portion Completed in December 2021

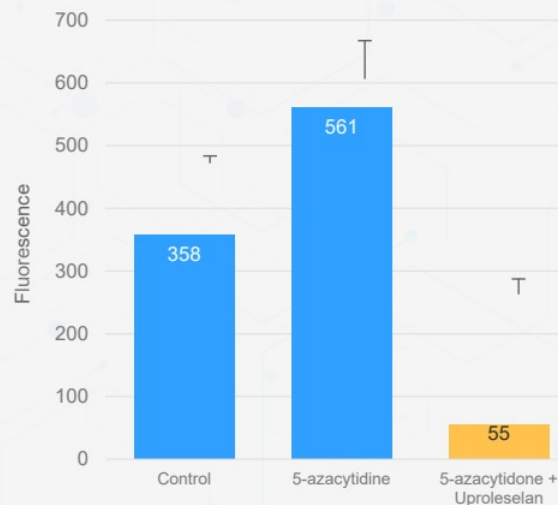
HMA Resistance is Driven by E-selectin, Broken by Uproleselan

UPROLESELAN INHIBITS BINDING OF BLASTS



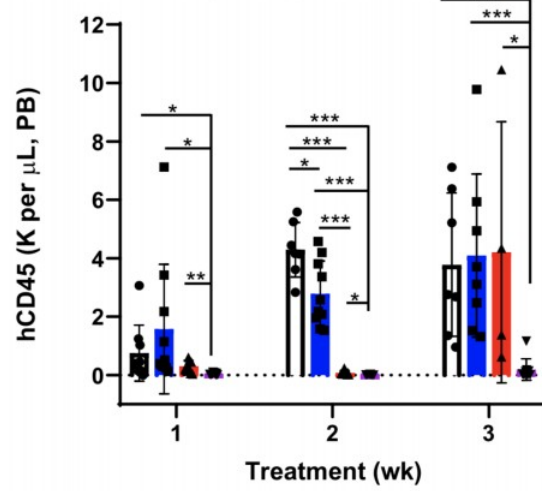
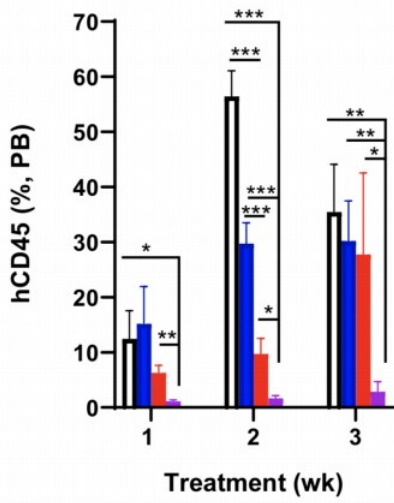
KG1 AML cells were incubated for 96 hours in the absence or presence of 100 nM 5-azacytidine, labeled with calcein and allowed to adhere to E-selectin coated plates (control and 5-azacytidine above). After 45 minutes of adhesion, Uproleselan was added to the wells and fluorescence determined after 30 minutes

(5-azacytidine → Uproleselan above).



Uproleselan/ Venetoclax/ HMA Combination Significantly Reduces Leukemia Burden, Compared to Ven+5Aza Alone¹

AML-PDX FROM A VENETOCLAX / HMA RESISTANT PATIENT



*p < 0.05; **p < 0.01; ***p < 0.001, Student's t-test for experiments that compare two groups.

ASH 2022/2023: First Clinical Uproleselan Data Generated Outside of GLYC-Sponsored Trials

Uproleselan data from two investigator-initiated trials presented at ASH in December 2022/2023

A Phase I Study of Uproleselan Combined with Azacitidine and Venetoclax for the Treatment of Older or Unfit Patients

with Treatment Naïve Myeloid Leukemia B.A. Jonas, J.L. Welborn, N.S. Esteghamat, R.T. Hoeg, A.S. Rosenberg, L. Molnar, A. Linh Dang-Chu, S.L. Steward, and J.M. Tuscano, 2022

Publication Number: 2764

Encouraging safety and evidence of disease activity

- **8 evaluable patients with poor prognosis**
 - 6/8 (75%) were ELN 2017 adverse risk disease
 - 3/8 (38%) had complex cytogenetics
- **Data outcomes**
 - 6/8 (75%) CR/CRi
 - 5/8 (63%) full CR
 - 1/8 (13%) CRi
 - 5/8 (63%) CR/CRi responses occurred with cycle 1
 - 4 CR/CRi MFC MRD negative
 - 50% overall MRD negative rate
 - 67% among CR/CRi responders

Uproleselan added to Cladribine Plus Low Dose Cytarabine (LDAC) in Patients with Treated Secondary Myeloid Leukemia (TS-AML)

E.A. Huante, H. Kantarjian, K.S. Chien, C.D. DiNardo, N. Short, A. Maiti, G. Montalban, N. Daver, J.D. Kawedia, K. Bowie, S.A. Pierce, F. Ravandi, M. Konopleva, G. Garcia Manero, and T. M. Kadia, 2023

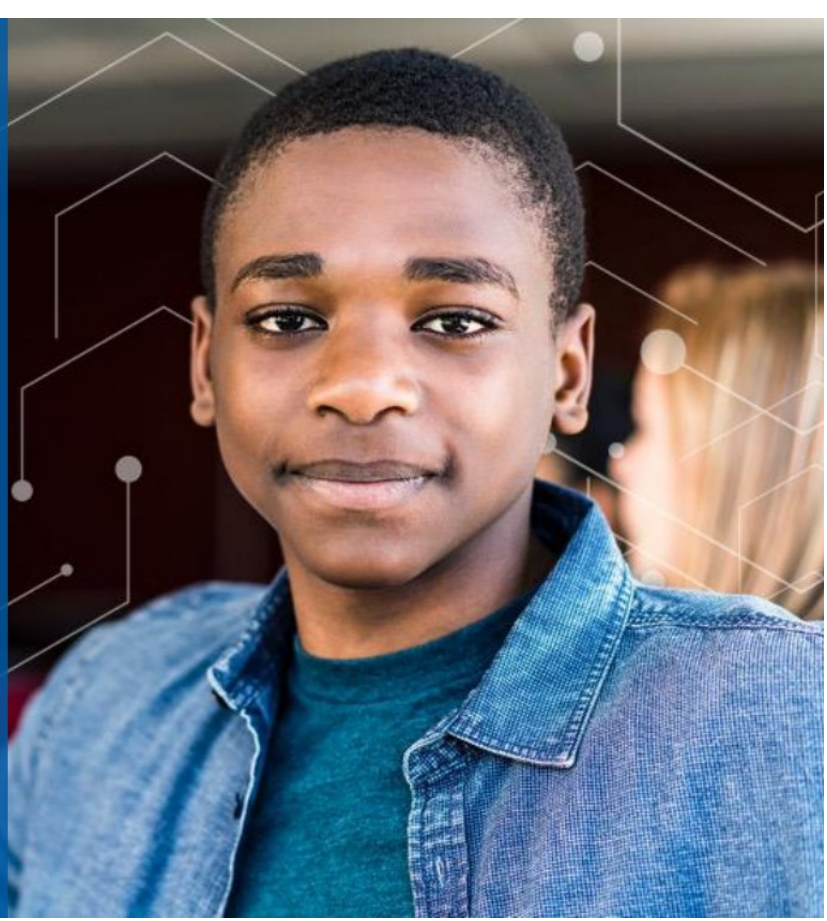
Publication Number: 2992

39% ORR in very high-risk patient population

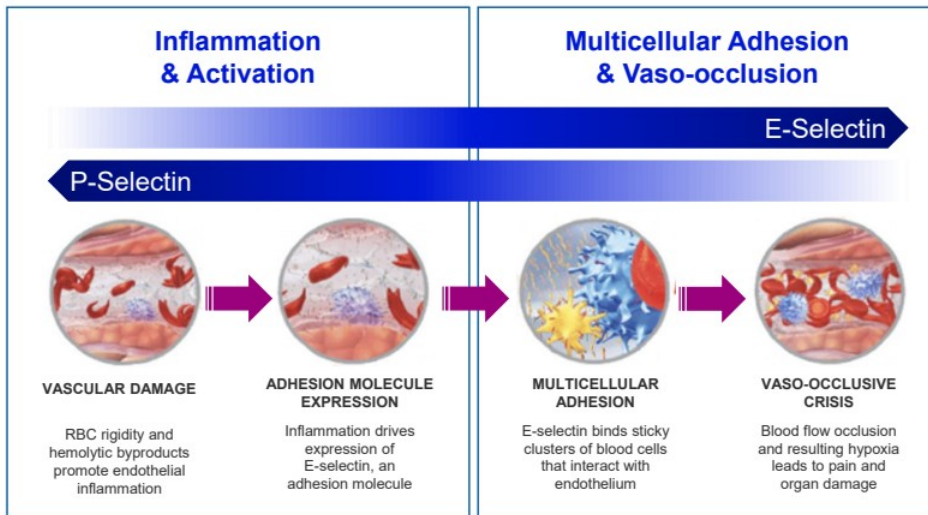
- **18 evaluable patients**
 - All patients had unfavorable cytogenetics and had previously received treatment with a hypomethylating agent.
 - 11 patients (55%) had received prior treatment with venetoclax, and five (25%) had undergone stem cell transplantation.
- **Data outcomes**
 - Combination of Cladribine + LDAC with uproleselan overall well tolerated with few treatment-related AEs
 - Combination reduced bone marrow blasts in 13 (72%) patients
 - Three patients went on to receive a potentially curative hematopoietic cell transplantation (HCT)
 - Study investigators concluded data support this low-risk approach to marrow blast reduction and disease control in preparation for HCT

Treatment of
Vaso-occlusive Crisis
(VOC) in Patients with
Sickle Cell Disease

GMI-1687



E-Selectin Mediates Multicellular Adhesion and Vaso-Occlusion



Data Supporting E-Selectin Role in Cellular Adhesion and Clotting

Preclinical

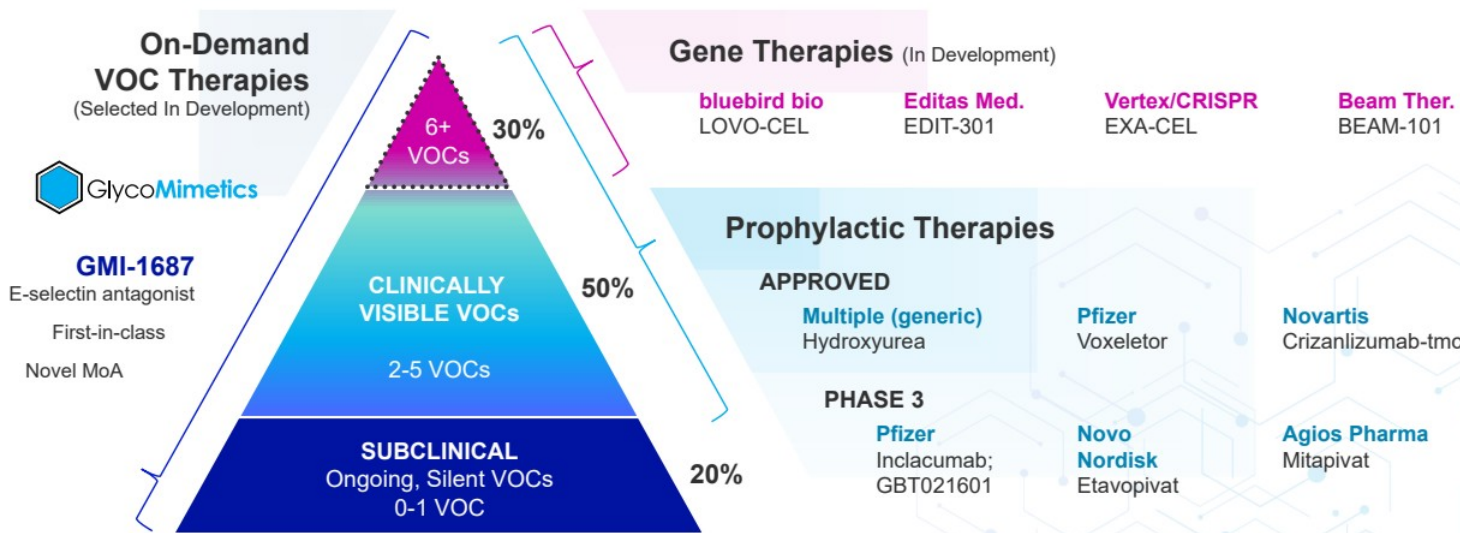
- E-selectin leads to rolling and cell arrest
- Blocking E-selectin inhibits leukocyte adhesion
- Blocking E-selectin restores blood flow in animal models of vessel occlusion in sickle cell disease

Clinical

- sE-selectin correlates with frequency of VOC
- sE-selectin correlates with poor survival
- Reduced sE-selectin correlated with clinical benefit in RESET trial (time to discharge)

E-selectin Antagonism Provides a Unique Therapeutic Target to Interrupt VOC in SCD patients

Even with Prophylactic and Gene Therapy Approaches, VOC Will Remain A Significant Unmet Medical Need



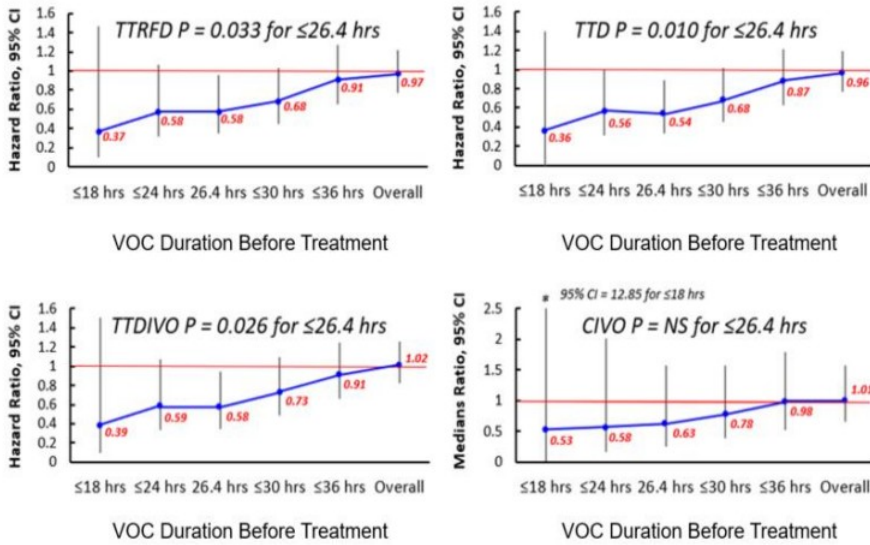
220,000 – 450,000 VOCs/year (in the era of prophylactic therapies)



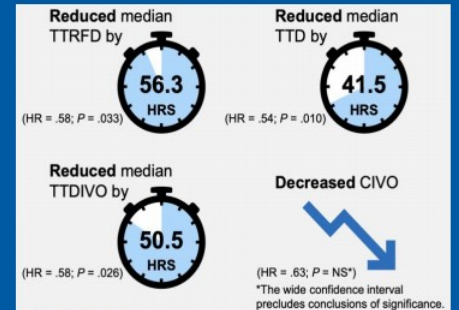
*Authorization revoked in EU

Dampier et al. 2017 American Society of Hematology Annual Meeting, Abstract# 4660.
N Engl J Med 2019; 381:509-51; N Engl J Med 2017; 376:429-439

Early Treatment Resulted in Clinical Benefit



For patients treated within first quartile of treatment (≤26.4hrs), a meaningful, statistically significant benefit was seen across study endpoints



TTRFD = time to readiness for discharge; TTD = time to discharge;
 TTDIVO = time to discontinuation of IV opioids; CIVO = cumulative IV opioid use
 Dampier et al, Blood 2023

GMI-1687 Seeks to Empower Patients to Take Control

Potentially revolutionizing the treatment paradigm to on-demand disease modifying therapy



Lessons Learned	GMI-1687
E-selectin drives VOC¹	<ul style="list-style-type: none">• Fast-acting, small molecule E-selectin antagonist to eliminate vaso-occlusion
Early treatment in VOC is critical	<ul style="list-style-type: none">• Potential self-administration of GMI-1687 after patient recognizes VOC episode<ul style="list-style-type: none">• 100% bioavailable in preclinical models following subcutaneous administration
Deliver full dose to stop VOC	<ul style="list-style-type: none">• Optimize dose and regimen based on reductions in sE-selectin<ul style="list-style-type: none">• Agreed to as part of FDA Pre-IND Meeting



Phase 1a Study Completed

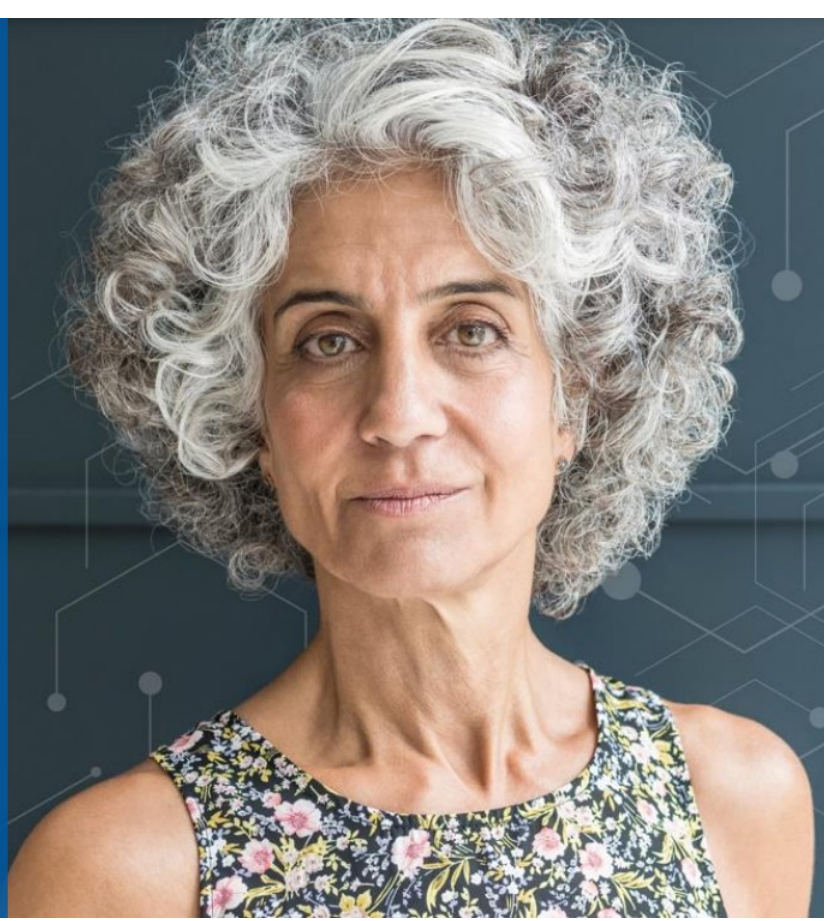


GlycoMimetics

1 Morikis et al, Frontiers in Immunology, April 2021, Vol. 12, Article 663886

Potential Treatments in Oncology, Inflammation and Fibrosis

GALECTIN-3 INHIBITORS



The Promise of Targeting Galectins



Potential to modulate the immune and inflammatory response to cancer and fibrosis



Target
Galectin-3 carbohydrate-binding protein



Chemistry
Rationally designed with proprietary platform



Differentiation
Compounds have high binding affinity and specificity for Galectin-3



Relevance

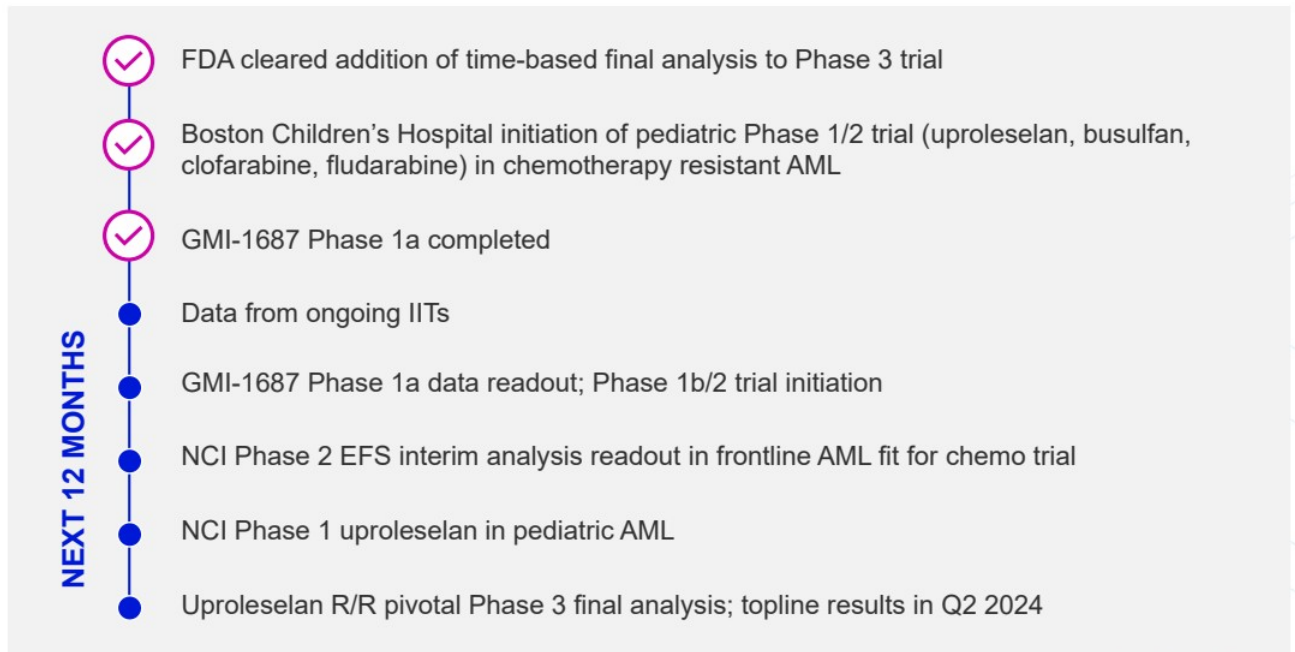
Central role in fibrosis and cancer

- Inflammation, aberrant cell activation/proliferation, fibrogenesis
- Blockade may prevent/reverse fibrosis following organ damage
- Antifibrotic/antitumor activity in various disease models

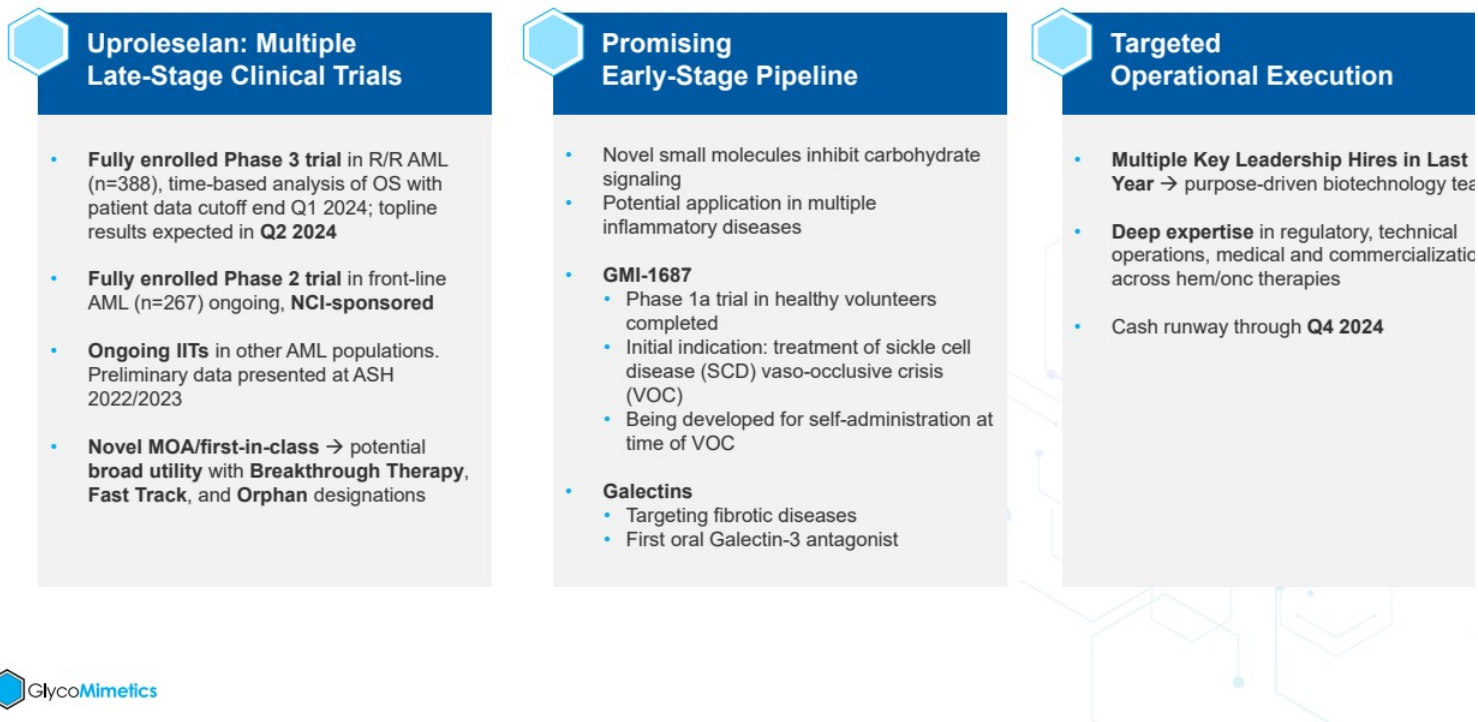


Orally Bioavailable

Recent Accomplishments and Expected News Flow*



Near-Term Catalysts and Promising, Glycobiology-based Pipeline





Thank You

www.glycomimetics.com | NASDAQ: GLYC

