

**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 2, 2023

**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	<a href="#">GlycoMimetics, Inc. Corporate Presentation, March 2, 2023</a>
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 2, 2023

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

Glycobiology-based therapeutics  
**Transforming lives.**

NASDAQ: GLYC

March 2023

- 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,” “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; (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, and market adoption of our potential drug candidates by payors, physicians and patients; (vi) the likelihood and timing of regulatory filings, approvals or other anticipated interactions with regulatory authorities; (vii) our business and product development strategies, including our cash needs and expected cash runway; and (viii) 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, lower than expected enrollment rates in clinical trials, whether results of early clinical trials may 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 our Company’s Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 3, 2022, its Quarterly Report on Form 10-Q filed with the SEC on November 9, 2022, and 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.

### Uproleselan: Multiple Late-Stage Clinical Trials

- **Fully enrolled Phase 3 trial** in R/R AML (n=388), OS events trigger currently projected for **~1H-2024**
- **Fully enrolled Phase 2 trial** in front-line AML (n=267) ongoing, **NCI-sponsored**
- **Ongoing ISTs** in other AML populations. Preliminary data presented at ASH 2022
- **Novel MOA** → potential **broad utility** with **Breakthrough Therapy, Fast Track, and Orphan** designations

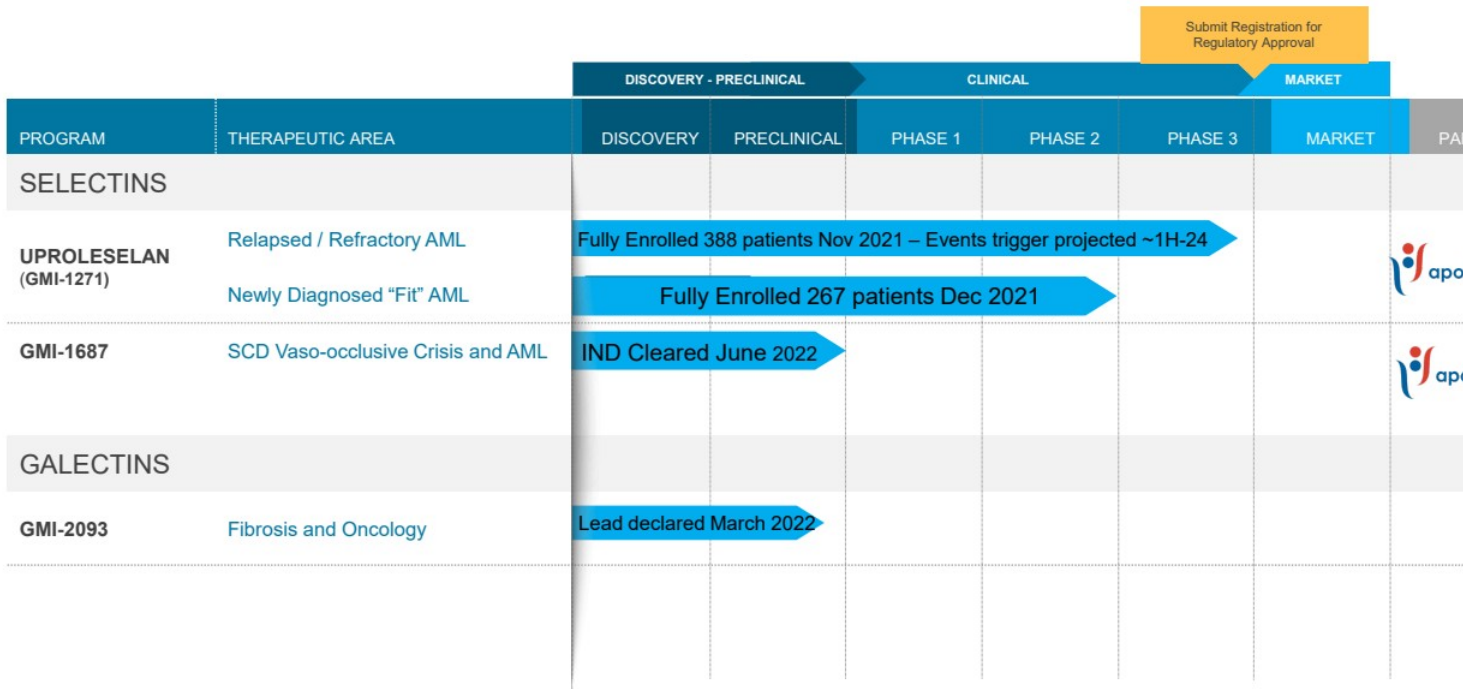
### Broad Early-Stage Pipeline

- Novel small molecules inhibit carbohydrate signaling
- **GMI-1687**
  - Targets sickle cell pain crises
  - Cleared FDA 30-day IND review
- **GMI-2093**
  - Targeting fibrotic diseases
  - First oral Galectin-3 antagonist

### Targeted Operational Execution

- **Recent Key Leadership Hires** → purpose-driven biotechnology team
- **Deep expertise** in regulatory, medical and commercialization across hem/onc therapies

# A Portfolio of Exciting Product Candidates



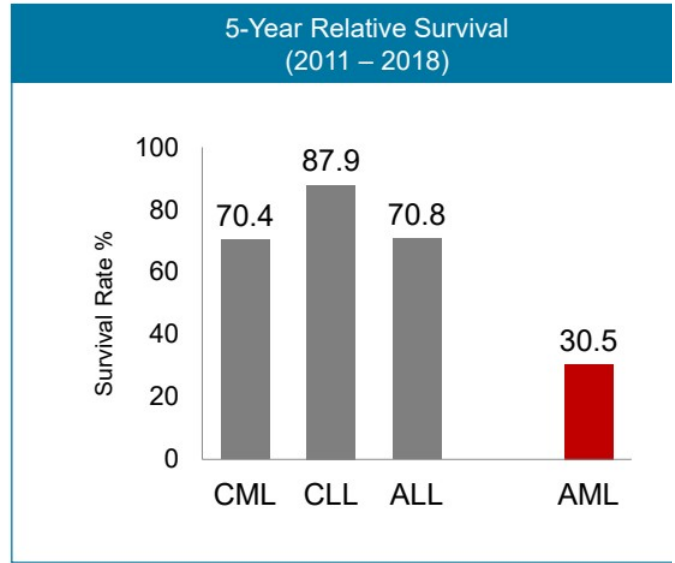
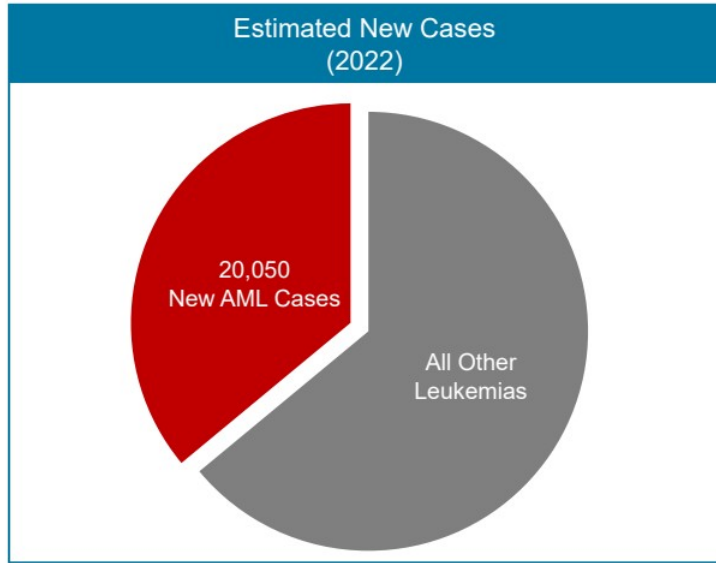


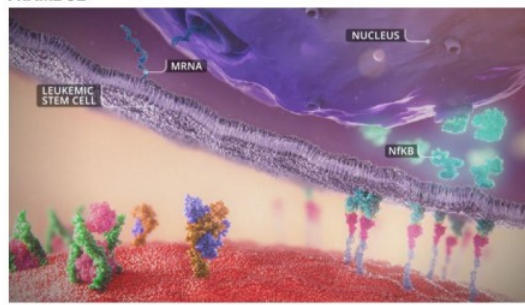
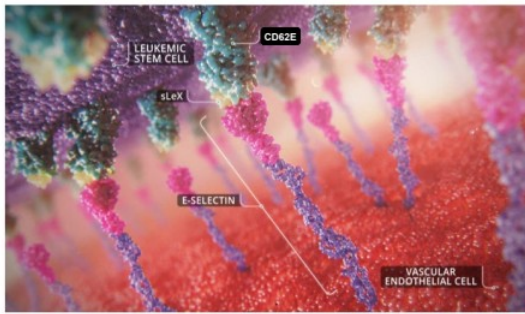
Uproleselan (GMI-1271)

Breakthrough Therapy Designation in AML









**E-selectin:**

- ✓ Adhesion molecule constitutively expressed in bone marrow microvasculature
- ✓ Up-regulated by Leukemic Stem Cells and AML blasts via secreted inflammatory mediators

**E-selectin/E-selectin Ligand Interaction:**

- ✓ Enables AML blast sequestration in bone marrow
- ✓ Activates pro-survival NF-κB pathways
- ✓ E-selectin ligand sLe<sup>x</sup> up-regulated on AML cells via multiple distinct drug resistance mechanisms

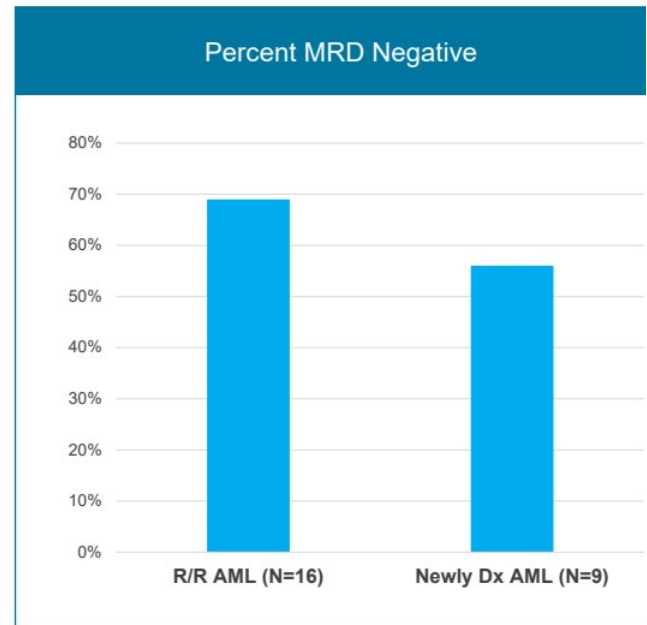
**Uproleselan, an E-Selectin Antagonist:**

- ✓ Releases AML blasts from vascular sequestration, agnostic to AML mutational status
- ✓ Disrupts NF-κB mediated chemoresistance pathways
- ✓ Potential broad utility across AML

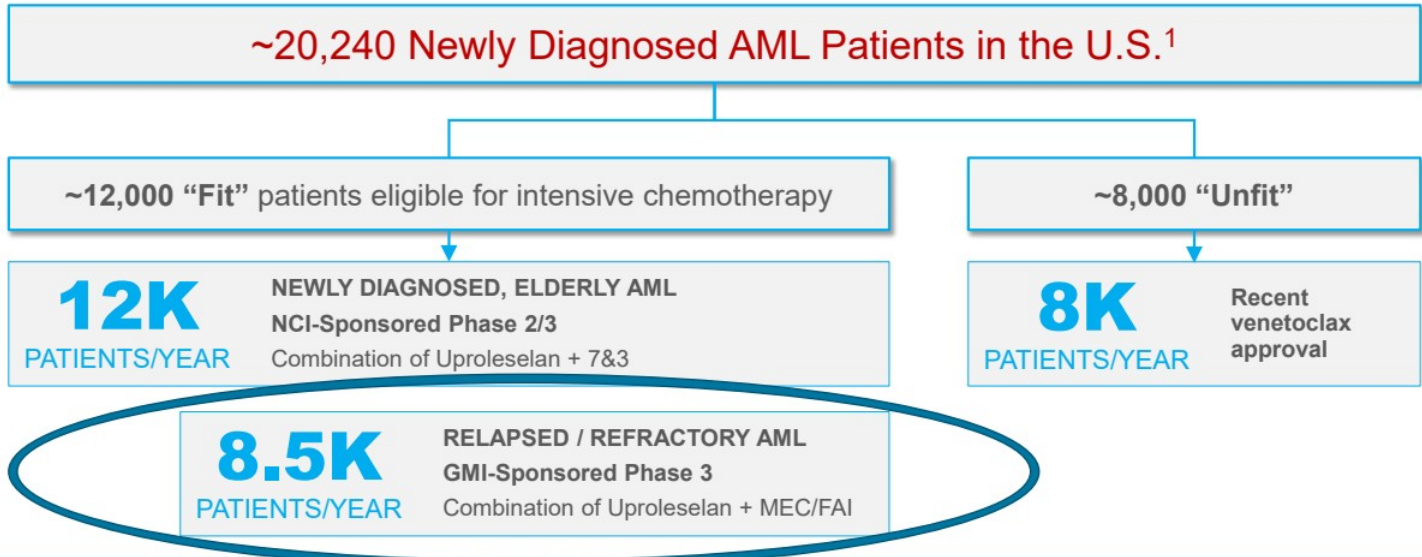
# UPROLESELAN in R/R and Newly Diagnosed AML Patients Phase 1/2 Results



- 41% CR/CRi; 8.8 mos. Median Overall Survival in Relapsed/Refractory AML
- 72% CR/CRi; 9.2 mos. Event Free Survival in Newly Diagnosed AML
- MRD-negativity in >50% of evaluable patients
  - Enhancing depth of response
- E-selectin ligand expression
  - Detectable in every patient tested
  - Higher levels in R/R patients achieving CR/CRi, MRD- and prolonged median OS



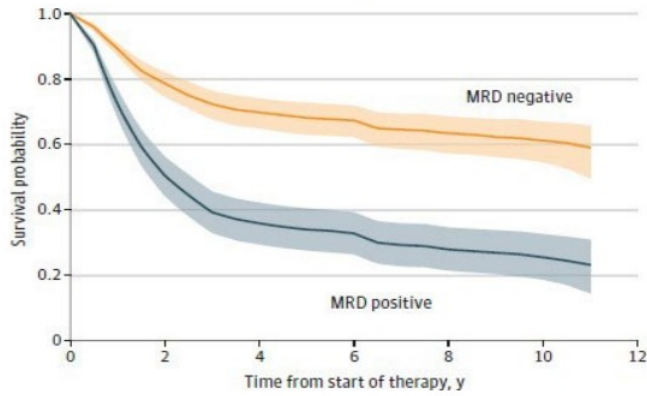
Results Published in *Blood* February '22



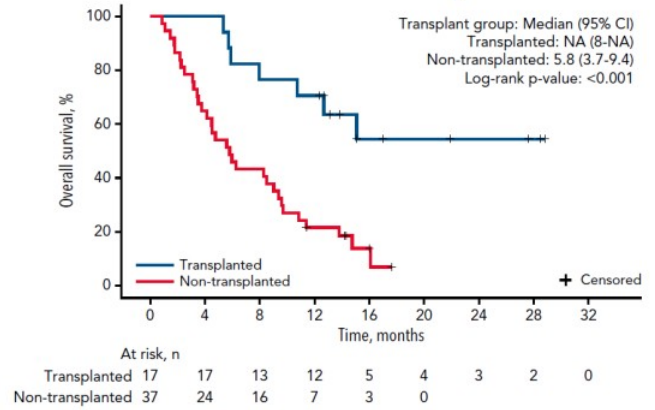
**UPROLESELAN VALUE PROPOSITION**

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

### Overall Survival by MRD status



### Overall Survival by HSCT

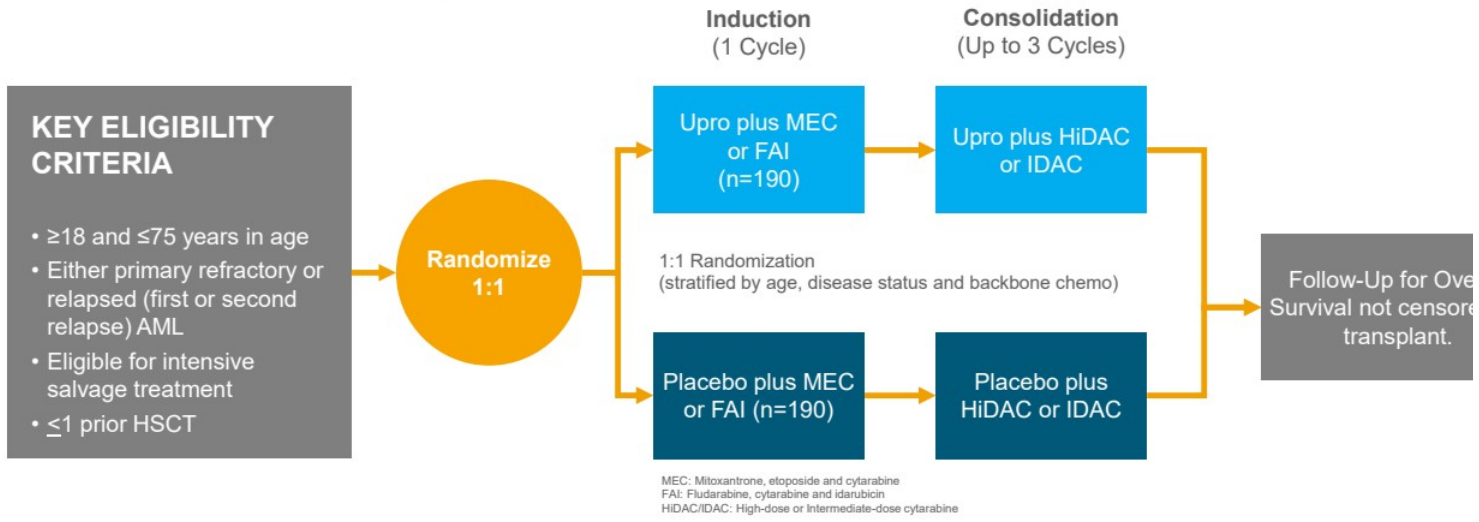


- Meta-analysis of 81 studies (N >11,000)
  - MRD negativity prognostic for superior OS
  - Average OS MRD HR 0.36,
  - Independent of age, subtype, timing, method

Short, et al. JAMA Oncology 2020 6(12): 1890-1899

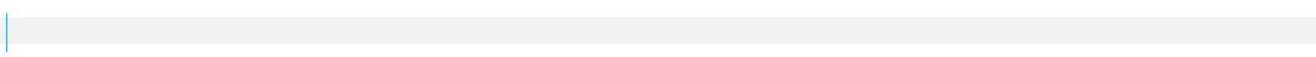
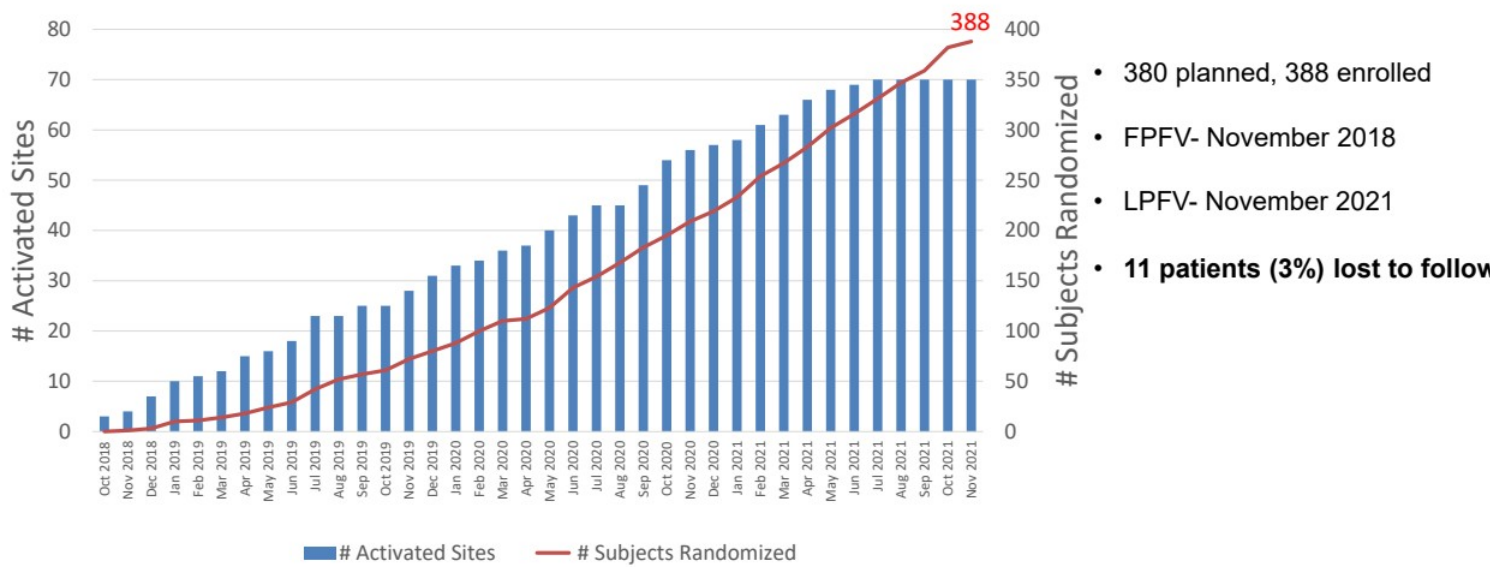
- Uproleselan Phase 1/2 overall survival by HSCT
  - N=54 R/R AML patients at 10 mg/kg RP2D
  - 10 longest survivors all MRD-negative
  - Overall MRD-negative: 56% 1L, 69% R/R

DeAngelo et al, Blood 2022 139(8):1135-1146.



Enrollment of 388 Completed in November 2021

# Study GMI-1271-301 Enrollment



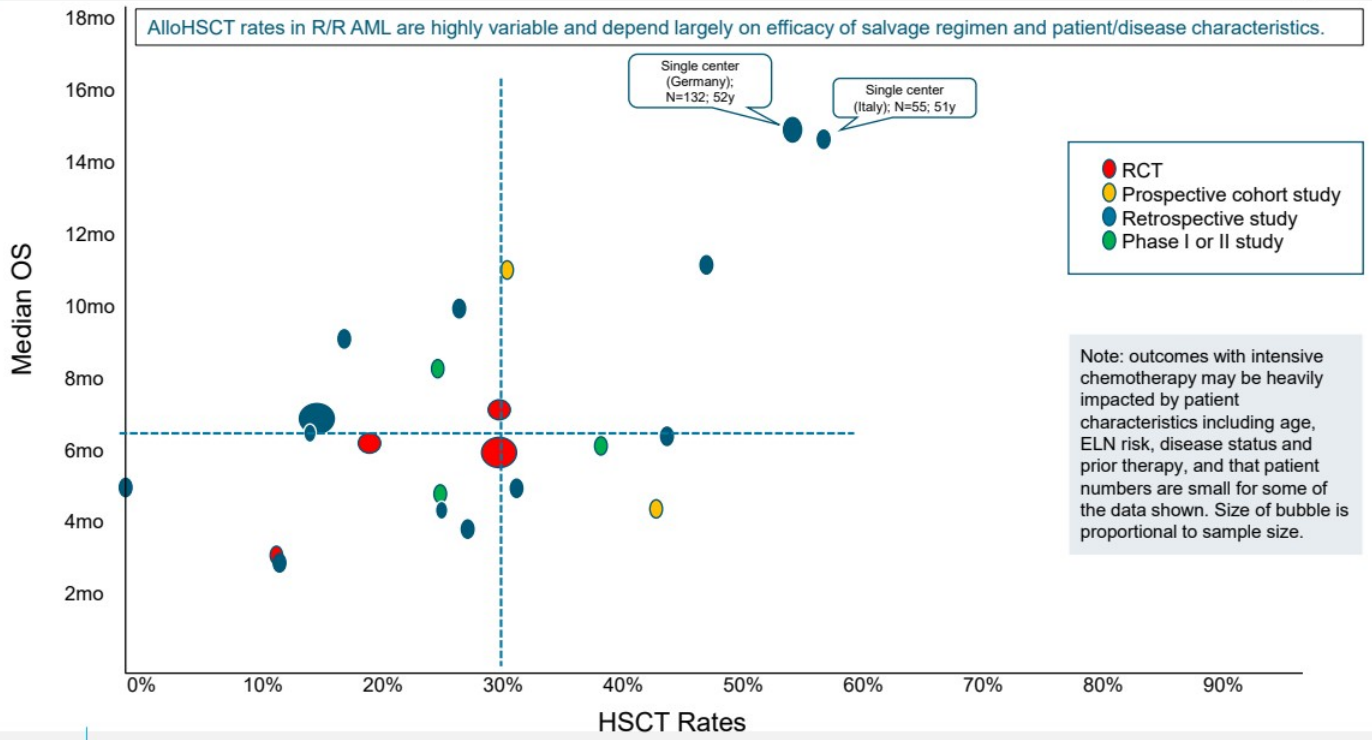
**Relapsed/Refractory Patient Demographics**

	<b>301 Study N=388</b>	<b>201 Study N=66</b>
<b>Age, median (range)</b>	<b>58 (20-75)</b>	<b>59 (26-84)</b>
<b>Refractory, n (%)</b>	<b>129 (33%)</b>	<b>22 (33%)</b>
<b>Relapsed, n (%)</b>	<b>259 (67%)</b>	<b>44 (67%)</b>
Duration of prior remission ≤6 mos	<b>49 (19%)</b>	<b>18 (41%)</b>
<b>Prior Therapies</b>		
HSCT	<b>70 (18%)</b>	<b>12 (18%)</b>
≥2 Induction Regimens	<b>63 (16%)</b>	<b>22 (33%)</b>
<b>ELN Risk Category</b>		
Adverse	<b>42%</b>	<b>50%</b>
Intermediate	<b>23%</b>	<b>17%</b>
Favorable	<b>21%</b>	<b>11%</b>
Unknown	<b>14%</b>	<b>22%</b>

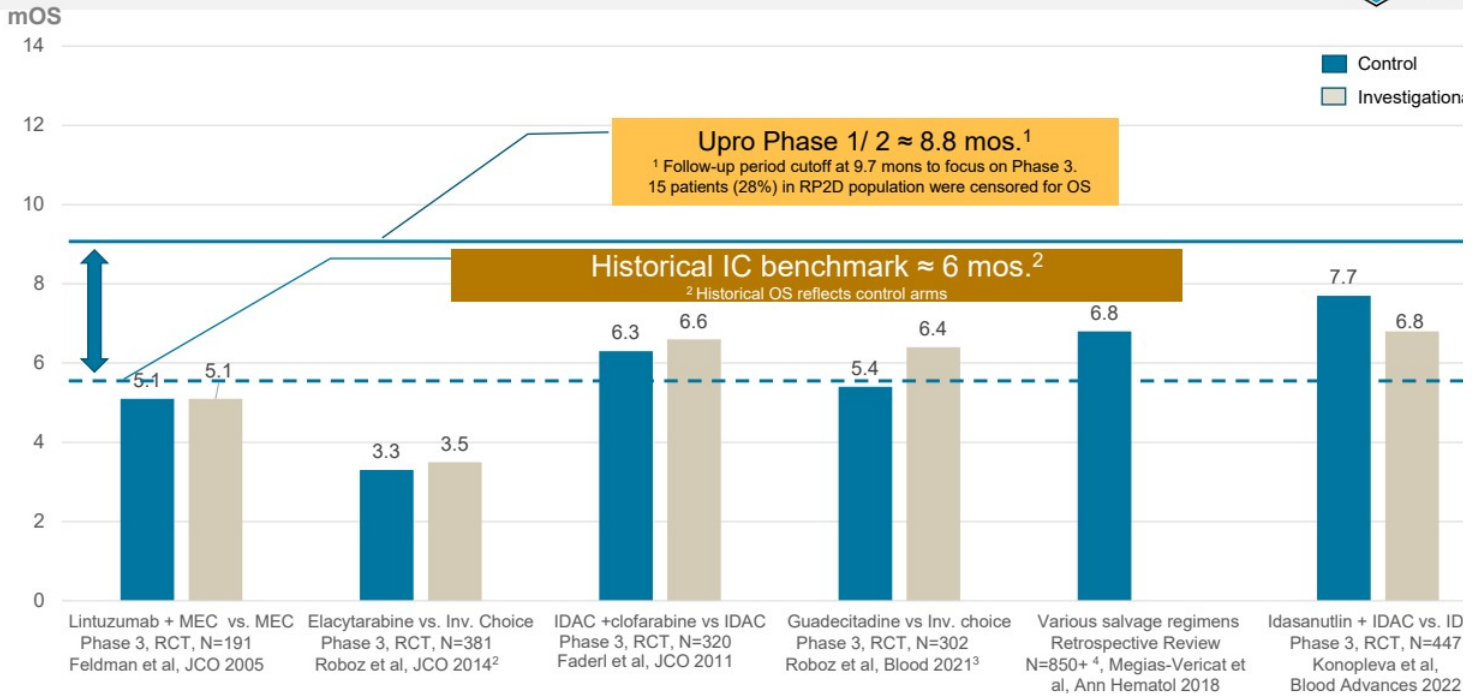


# Intensive Chemotherapy (IC) in R/R AML

## Typical ~6-7 months mOS and HSCT rates ~25-30%



# Historical Intensive Chemotherapy benchmarks for mOS are ~6 months

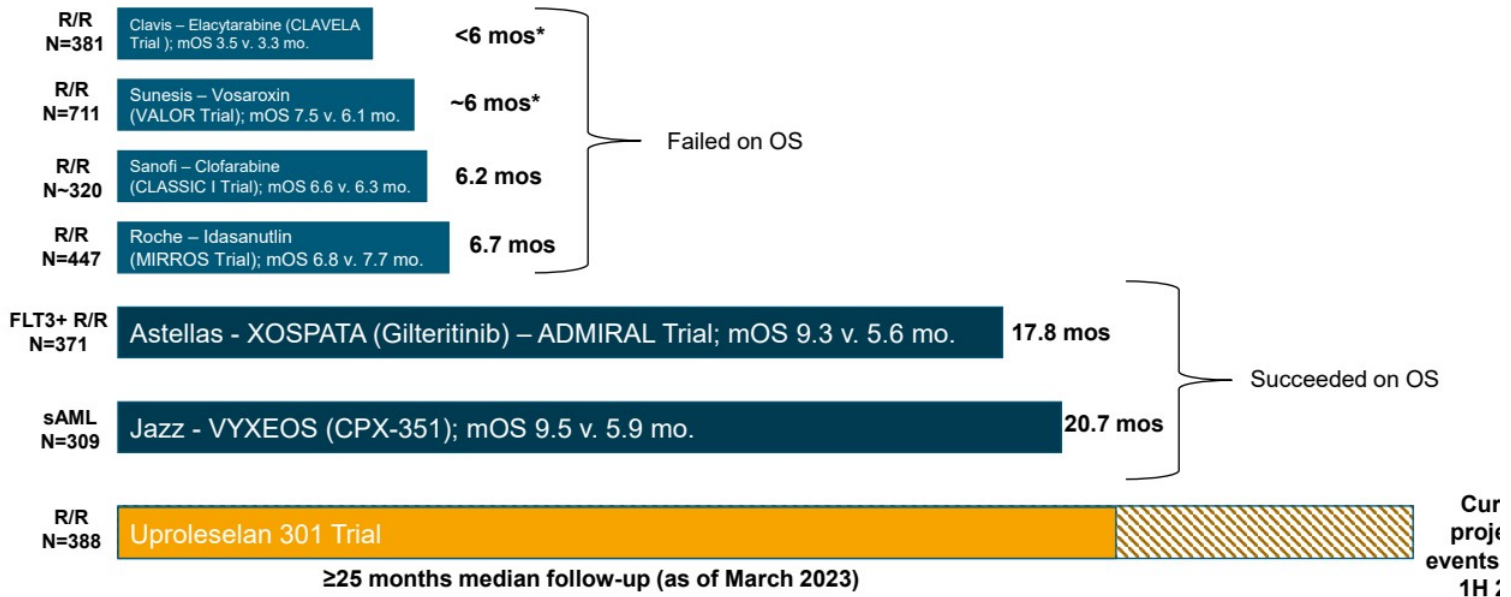


Note: patient outcomes for IC eligible populations often vary depending upon patient and disease characteristics

<sup>3</sup> Control group includes patients on MEC and FLAG-IDA

<sup>4</sup> All patients in this analysis received MEC

# Duration of Follow-Up and Outcomes in Key AML Trials



16 \* Median follow-up stated at time of event trigger and derived from protocol and/ or final results as it was not included in the publication

# Follow-Up Versus Outcome in Select AML Trials

Trial	Median Survival (mos)	Enrollment (mos)	Median Follow-up (mos)	Enrolled (N)	Events	OS HR	P-value
<b>CLAVELA</b>	3.5 vs 3.3 mos	28	< 6	381	302	0.97	0.96
<b>VALOR</b>	7.5 vs 6.1 mos	33	~ 6	711	562	0.87	0.0610
<b>CLASSIC I</b>	6.6 vs 6.3 mos	38	6.2	320	258	1.00	1.00
<b>MIRROS</b>	6.8 vs 7.7 mos	48.5	6.7	436	296	1.09	0.52
<b>VIALE-A</b>	15 vs 10 mos	27	20.5	433	270	0.66	< 0.001
<b>VYXEOS</b>	9.6 vs 6.0 mos	~24	20.7	309	236	0.69	0.003
<b>ADMIRAL</b>	9.3 vs 5.6 mos	28	17.8	371	258	0.64	< 0.001
<b>Uproleselan</b>	TBD	36	>25 (Mar 23)	388	295	TBD	TBD

~20,240 Newly Diagnosed AML Patients in the U.S.<sup>1</sup>

~12,000 "Fit" patients eligible for intensive chemotherapy

~8,000 "Unfit"

**12K**

PATIENTS/YEAR

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

**8K**

PATIENTS/YEAR

Recent  
Venetoclax  
approval

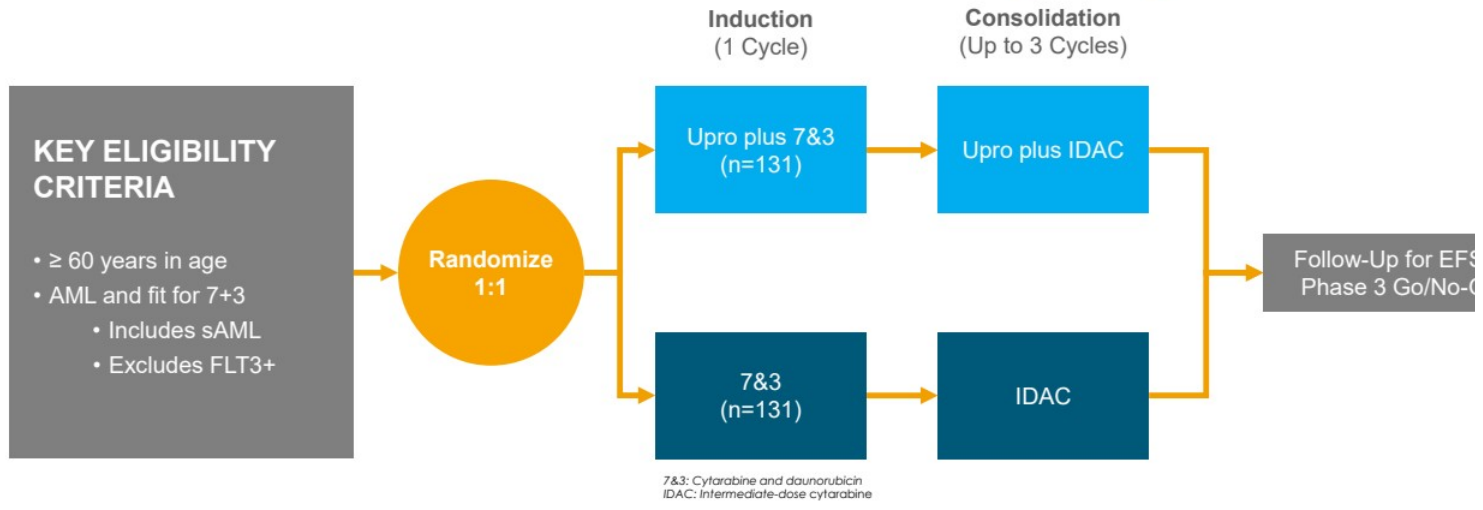
**8.5K**

PATIENTS/YEAR

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

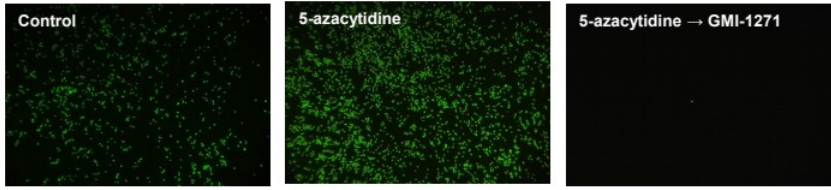
**UPROLESELAN VALUE PROPOSITION**

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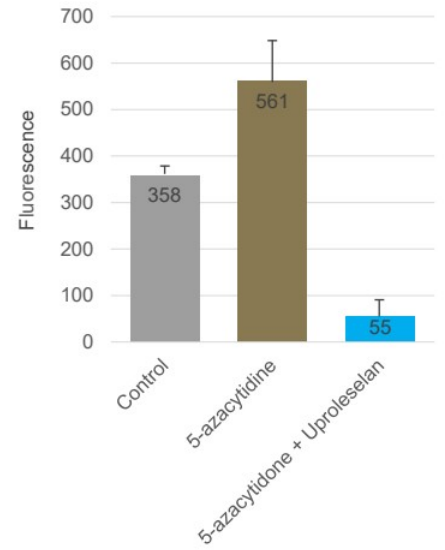


Phase 2 portion fully enrolled in December 2021

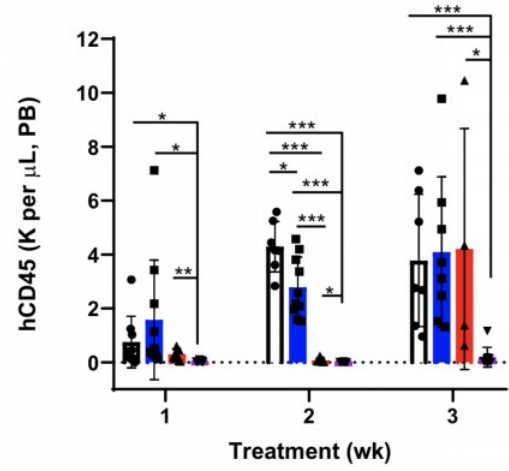
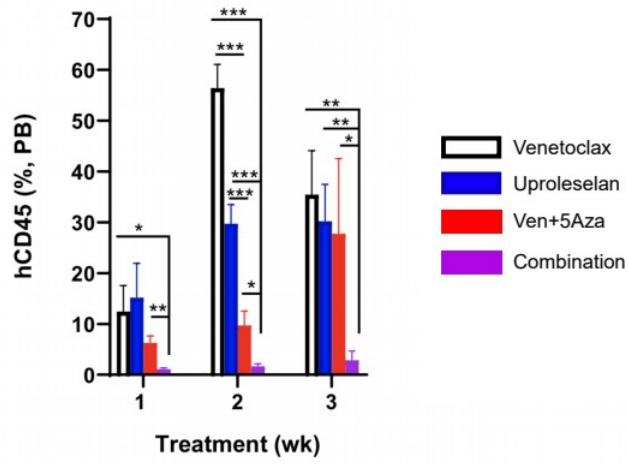
UPROLESELAN INHIBITS BINDING OF BLASTS



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).



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.



Uproleselan data from two investigator-sponsored trials presented at ASH in December 2022

## *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*

Brian Jonas, M.D., Ph.D., of the University of California, Davis  
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 Acute Myeloid Leukemia (TS-AML)*

Emmanuel Almanza-Huante, M.D.  
Publication Number: 1448

### **62% ORR in very high-risk patient population**

- 9 evaluable patients
  - All patients had unfavorable features by ELN 2017
- Data outcomes
  - Combination of Cladribine + LDAC with uproleselan overall well tolerated with few treatment-related AEs
  - No dose-limiting toxicities observed on dose levels -1 or 1

A young boy with short dark hair, wearing a blue and white plaid shirt, is smiling and looking towards the camera. He is in a classroom setting with other people blurred in the background.

GMI-1687

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



## Prevalence

**~100K**

SCD patients in the US

**~1 in 365**

Black Americans affected at birth

**25-30yr**

Reduction in average life expectancy

## Symptoms

Vaso-occlusive crises (VOCs), also referred to as pain crises, are the clinical hallmark of SCD

**>90%**

of hospitalizations due to VOC

**↑Risk of**

Stroke  
Acute Chest Syndrome  
Renal failure

## Current Treatments

**Voxelator**

**<1**

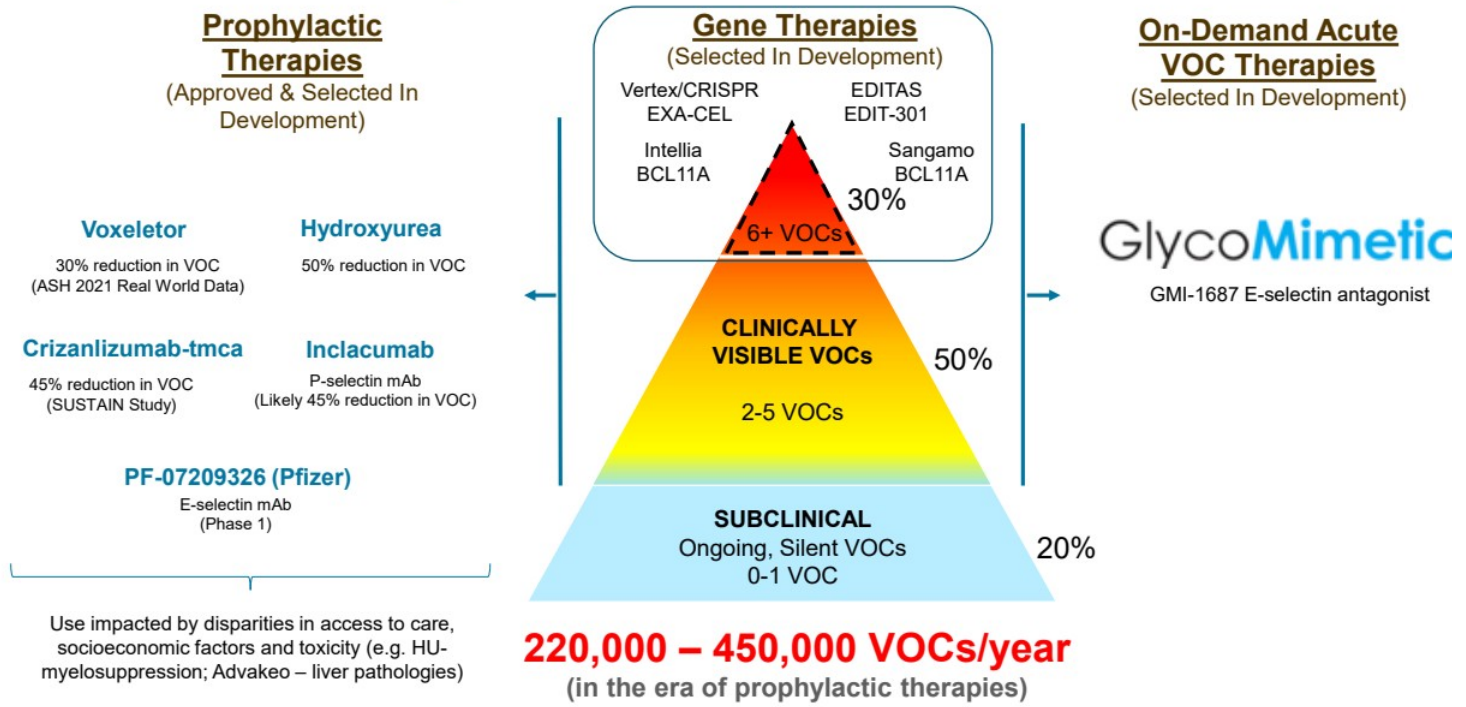
VOC improvement per yr (From 3.19 to 2.77 VOCs/yr)

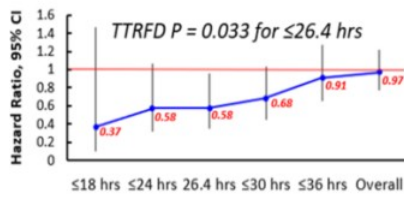
**Crizanlizumab-tmca**

**~1**

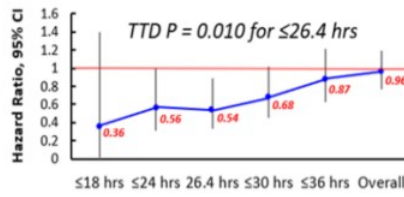
VOC improvement per yr (From to 1.6 VOCs/yr)

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

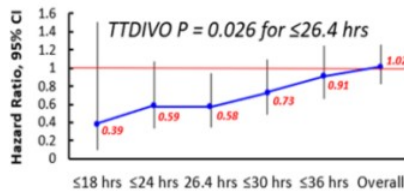




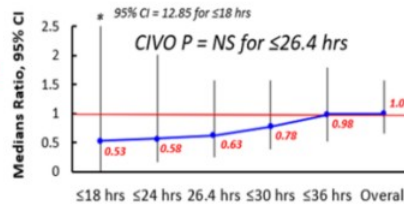
VOC Duration Before Treatment



VOC Duration Before Treatment



VOC Duration Before Treatment



VOC Duration Before Treatment

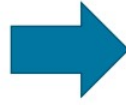
TTRD = time to readiness for discharge; TTD = time to discharge;  
 TTDIVO = time to discontinuation of IV opioids; CIVO = cumulative IV opioid use

For patients treated with first quartile of treatment timeliness ( $\leq 26.4$  hrs), meaningful, statistically significant benefit was seen across study endpoints

<p>Reduced median TTRFD by</p> <p>56.3 HRS (HR = .58; P = .033)</p>	<p>Reduced median TTD by</p> <p>41.5 HRS (HR = .54; P = .010)</p>
<p>Reduced median TTDIVO by</p> <p>50.5 HRS (HR = .58; P = .026)</p>	<p>Decreased CIV</p> <p>(HR = .63; P = NS*) *The wide confidence interval precludes conclusions of s</p>

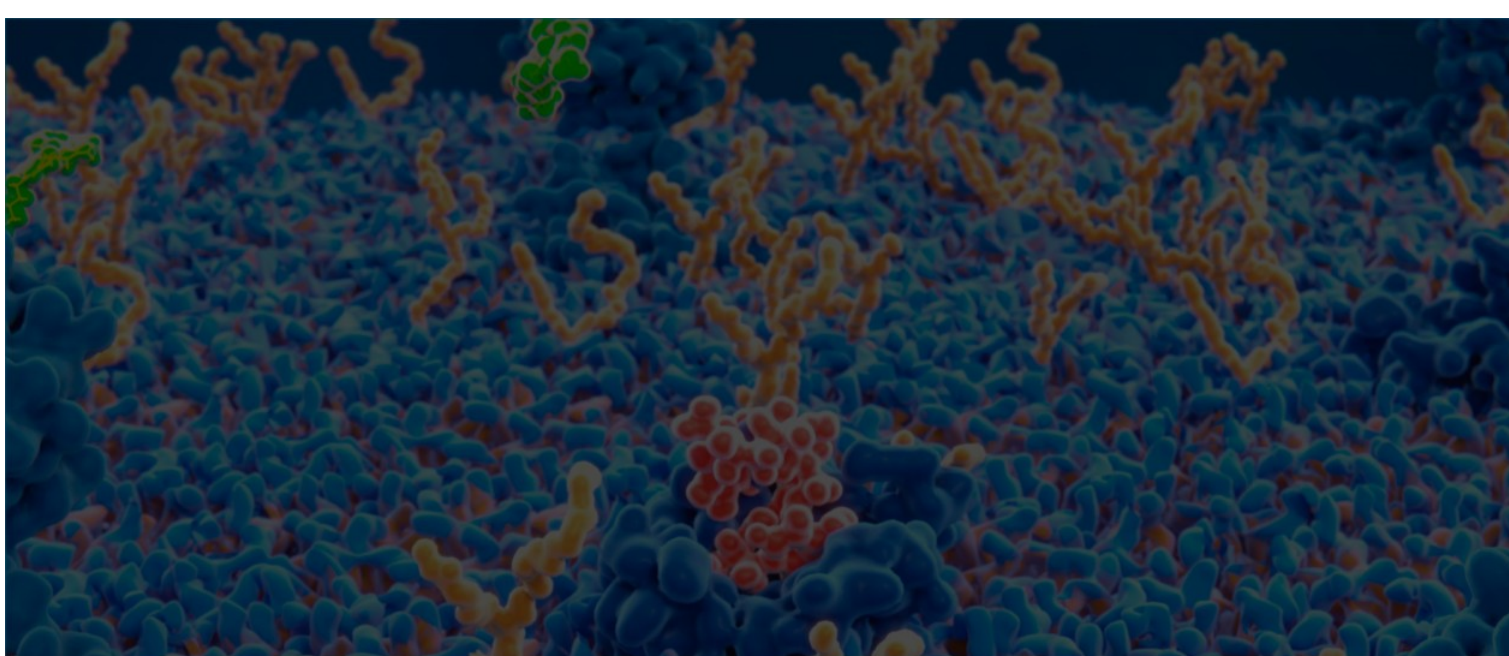


Potentially changing the treatment paradigm to convenient, early, on-demand disease modifying therapy



Lessons Learned	GMI-1687
E-selectin drives acute VOC <sup>1</sup>	<ul style="list-style-type: none"> <li>• <b>Fast-acting</b>, small molecule inhibitor against E-selectin to block endothelial activation and multicellular adhesion that are the foundation of acute VOC                             <ul style="list-style-type: none"> <li>• <math>\geq 500</math>-fold more potent than rivipansel</li> </ul> </li> </ul>
Treatment early during VOC is critical	<ul style="list-style-type: none"> <li>• Patients (or caregiver) can potentially <b>self-administer</b> GMI-1687 via an autoinjector upon recognition of an acute VOC episode                             <ul style="list-style-type: none"> <li>• 100% bioavailable following subcutaneous administration</li> </ul> </li> </ul>
Too little, too late - must give full doses	<ul style="list-style-type: none"> <li>• <b>Optimize dose and regimen</b> based on reductions in sE-selectin – <u>drive and sustain</u> <ul style="list-style-type: none"> <li>• Agreed to as part of FDA Pre-IND Meeting</li> </ul> </li> </ul>

**FDA “Safe to Proceed” Clearance for IND in June 2022**



## GALECTIN-3 INHIBITORS

Potential Treatments in Oncology, Inflammation and Fibrosis



- Target: Galectin-3 carbohydrate-binding protein
  - GMI-2093 development candidate
- 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
- Chemistry: Rationally designed with proprietary platform
- Differentiation: Compounds have high binding affinity and specificity for Galectin-3
- Orally bioavailable

The Promise of Targeting  
The Galectins:

Modulating The Immune  
And Inflammatory  
Response to Cancer and  
Fibrosis



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- **GMI-2093**
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  - First oral Galectin-3 antagonist

### Targeted Operational Execution

- **Recent Key Leadership Hires** → purpose-driven biotechnology team
- **Deep expertise** in regulatory, medical and commercialization across hem/onc therapies



**THANK YOU!**

NASDAQ: GLYC

[www.glycomimetics.com](http://www.glycomimetics.com)