

**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): October 4, 2022

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, October 4, 2022
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: October 4, 2022

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



Glycobiology-based therapeutics
Transforming lives.

NASDAQ: GLYC

October 2022 Corporate Presentation

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- 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 benefits and impact of our drug candidates, including uproleselan; (iii) the timing of receipt of clinical data for our drug candidates; (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 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 protect our intellectual property, and the risk that we become a party to unexpected 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 3, 2022, 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.

Uproleselan: Multiple Late-Stage Clinical Trials

- **Fully enrolled Phase 3 trial** in R/R AML (n=388), OS events trigger currently projected for **mid-2023**
- **Fully enrolled Phase 2 trial** in front-line AML (n=267) ongoing, NCI-sponsored
- **Ongoing ISTs** in other AML populations
- **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

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



Edwin Rock, MD, PhD – Chief Medical Officer

- Prior CMO at Partner Therapeutics, VP at MacroGenics, Clinical project leader for successful BLA of margetuximab. Ex- Astex, Otsuka, GSK
- Former FDA Medical Officer, serving as medical reviewer for >50 active INDs and 7 approved anticancer drugs
- Prior buyside analyst at Leerink Swann and Company, reporting to Jeffrey Leerink



Bruce Johnson – Chief Commercial Officer

- Former VP, Global Head Malignant Hematology, Novartis and Former VP and Head, Global Commercial Development, AbbVie
- >10 launches at the Global, US or regional level including Rydapt, Jakavi, Tassigna and Zometa
- Led lifecycle management and portfolio strategy for Venetoclax



Lisa DeLuca, PhD – Vice President, Regulatory Affairs and Quality Assurance

- Former VP, Regulatory Affairs at Celator Pharmaceuticals responsible for taking Vyxeos through clinical development, manufacturing optimization, NDA preparation, and the acquisition by Jazz Pharmaceuticals
- >27 years in Regulatory Affairs at both large pharma and small biotech companies working across multiple solid and liquid tumor types, including AML



Deepak Tiwari, PhD – Vice President, Technical Operations

- Former VP and Head of CMC Operations at Rafael Pharmaceutical working on development of devimistat in multiple indications including R/R AML
- >25 years experience in both large and small molecules, including pre-formulation, formulation development, analytical characterization, process development, scale-up, technology transfer and process validation.

AML is a **heterogeneous malignant disorder** of hemopoietic stem cells¹

Aggressive, rapidly progressive, and fatal if untreated

2022 Estimated AML Statistics for the US²

One of the most common types of leukemia



**20k new cases
>11k deaths / year**

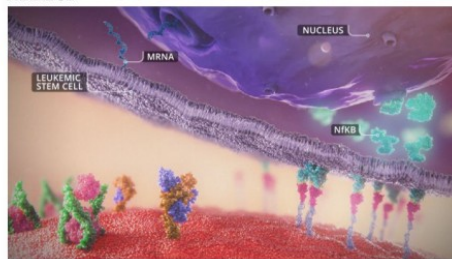
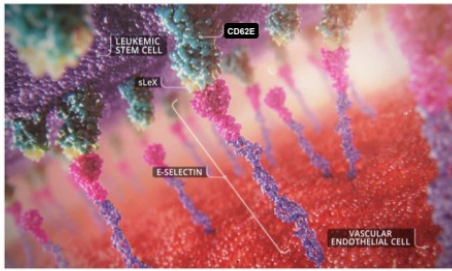
AML has lowest survival rate of all leukemias

Low 5-year survival rate: <30%
in US³ and Europe⁴ vs. >85% for CML/CLL⁵

Survival across all ages and risk groups is poor, particularly in R/R AML patients

Overall survival in R/R AML measured in months⁶

1. Short, Rytting, and Cortes. *Lancet* 2018; 392: 593-606;
2. American Cancer Society, AML Key Statistics (accessed April 2022);
3. American Cancer Society Cancer Facts & Figures 2022, 5-year age-adjusted relative survival rates
4. Gatta et al., Burden and centralised treatment in Europe of rare tumours: results of RARECAREnet – a population-based study. *Lancet Oncol.* 2017, doi: 10.1016/S1470-2045(17)30445-X.
5. Blood cancer UK, Facts and information about blood cancer, August 2019 (accessed April 2022)
6. Megias-Venicat JE et al. Salvage regimens using conventional chemotherapy agents for relapsed/refractory adult AML patients: a systematic literature review, *Ann Hematol.* 2018;



E-selectin:

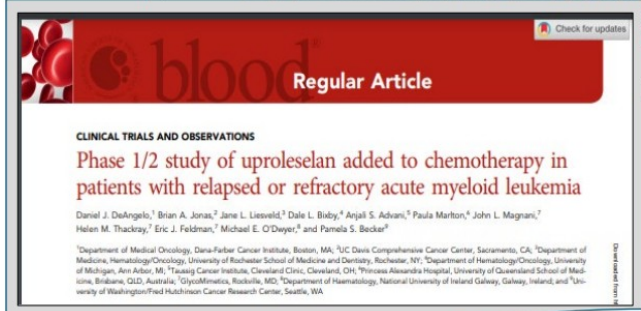
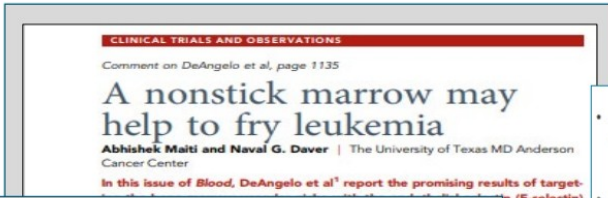
- ✓ Adhesion molecule constitutively expressed in bone marrow microvasculature
- ✓ Up-regulated by Leukemic Stem Cells and AML blasts via secreted inflammatory mediators

E-selectin/E-selectin Ligand Interaction:

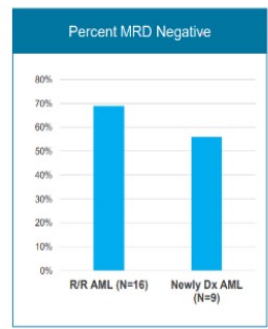
- ✓ Enables AML blast sequestration in bone marrow
- ✓ Activates pro-survival NF-kB pathways
- ✓ E-selectin ligand sLe^x up-regulated on AML cells via multiple distinct drug resistance mechanisms

Uproleselan, an E-Selectin Antagonist:

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

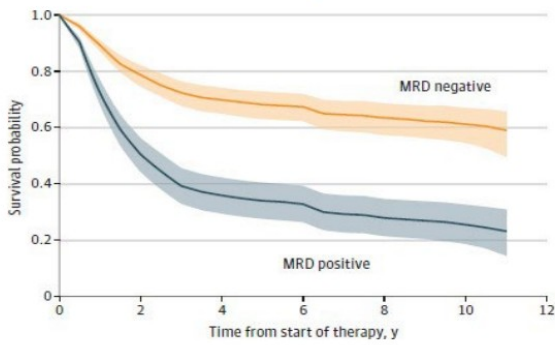


- 41% CR/CRi; 8.8 mos. Median Overall Survival in Relapsed/Refractory AML
- 72% CR/CRi; 9.2 mos. Event Free Survival in Newly Diagnosed AML
- MRD-negativity in >50% of evaluable patients
 - Enhancing depth of response
- E-selectin ligand expression
 - Detectable in every patient tested
 - Higher levels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

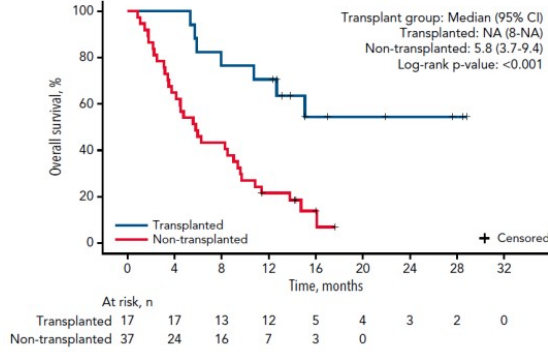


February 2022 Blood data with corresponding commentary by MD Anderson experts highlight uproleselan early clinical activity

Overall Survival by MRD status



Overall Survival by HSCT

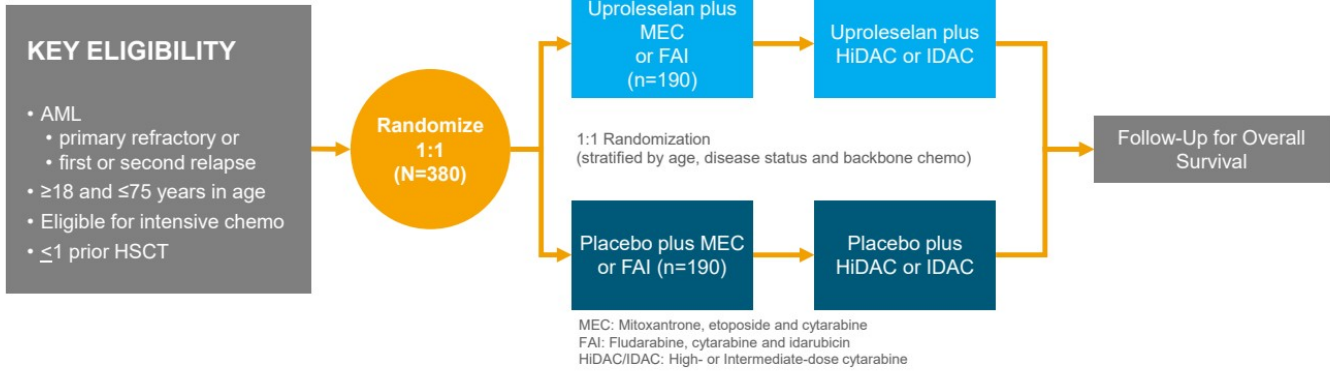


- Meta-analysis of 81 studies (N >11,000)
 - MRD negativity prognostic for superior OS
 - Average OS MRD HR 0.36
 - Independent of age, subtype, timing, method

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.



PRIMARY ENDPOINT | Overall survival **not censored** for transplant

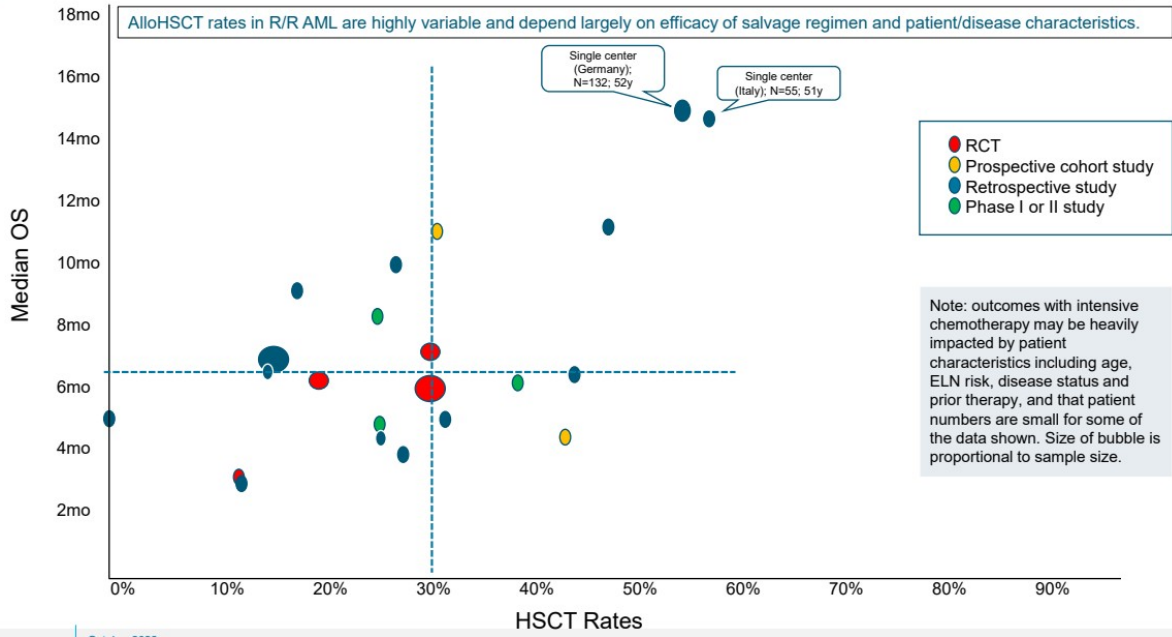
- 90% power to detect Hazard ratio of 0.68 with one-sided 0.025 Type I error rate
- Total of 388 patients were enrolled in the trial as of November 2021

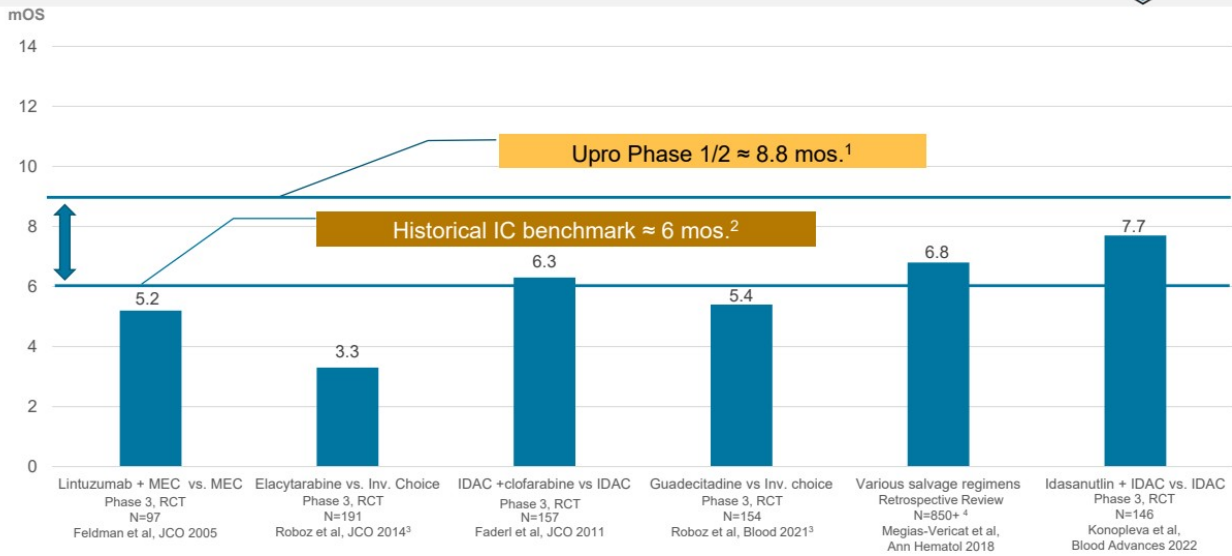
Relapsed/Refractory Patient Demographics

	301 Study N=388	201 Study N=66
Age, median (range)	58 (20-75)	59 (26-84)
Refractory, n (%)	130 (33.5%)	22 (33%)
Relapsed, n (%)	258 (66.5%)	44 (67%)
Duration of prior remission ≤6 mos	49 (19%)	18 (41%)
Prior Therapies		
HSCT	70 (18%)	12 (18%)
≥2 Induction Regimens	63 (16%)	22 (33%)
ELN Risk Category		
Adverse	40%	50%
Intermediate	21%	17%
Favorable	22%	11%
Unknown	17%	22%

Intensive Chemotherapy (IC) in R/R AML

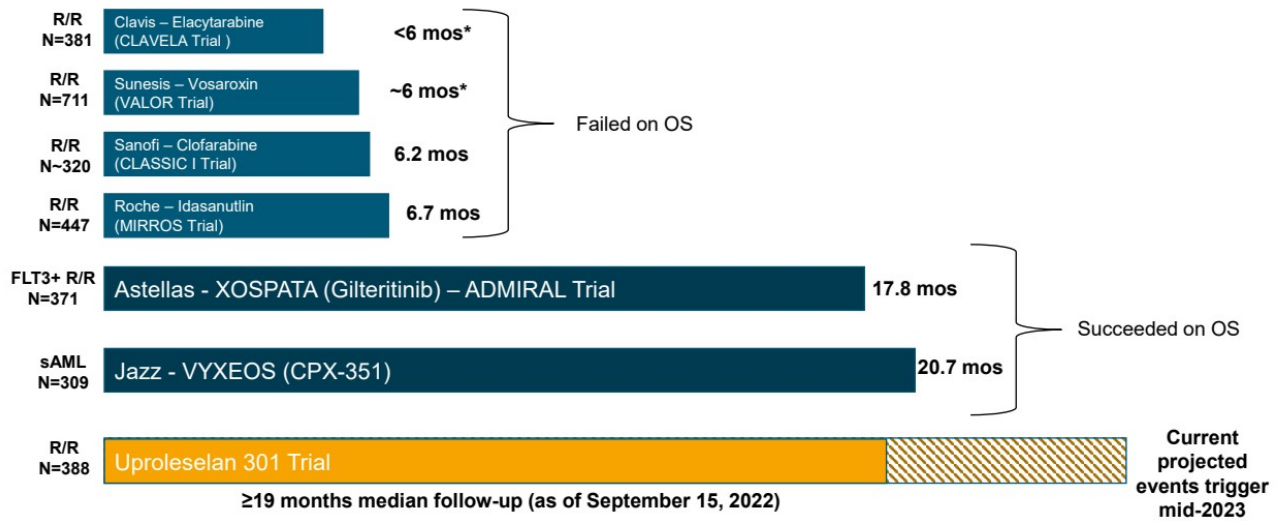
Typical ~6-7 months mOS and HSCT rates ~25-30%





Note: patient outcomes for IC eligible populations often vary depending upon patient and disease characteristics
¹ Follow-up period cutoff at 9.7 mos to focus on Phase 3. 15 patients (28%) in RP2D population were censored for OS
² Historical OS reflects control arms
³ Control group includes patients on MEC and FLAG-IDA
⁴ All patients in this analysis received MEC

Duration of Follow-Up and Outcomes in Key AML Trials





GMI-1687

Potential on-demand treatment for SCD Acute VOC



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

Treatments

Voxelator

<1

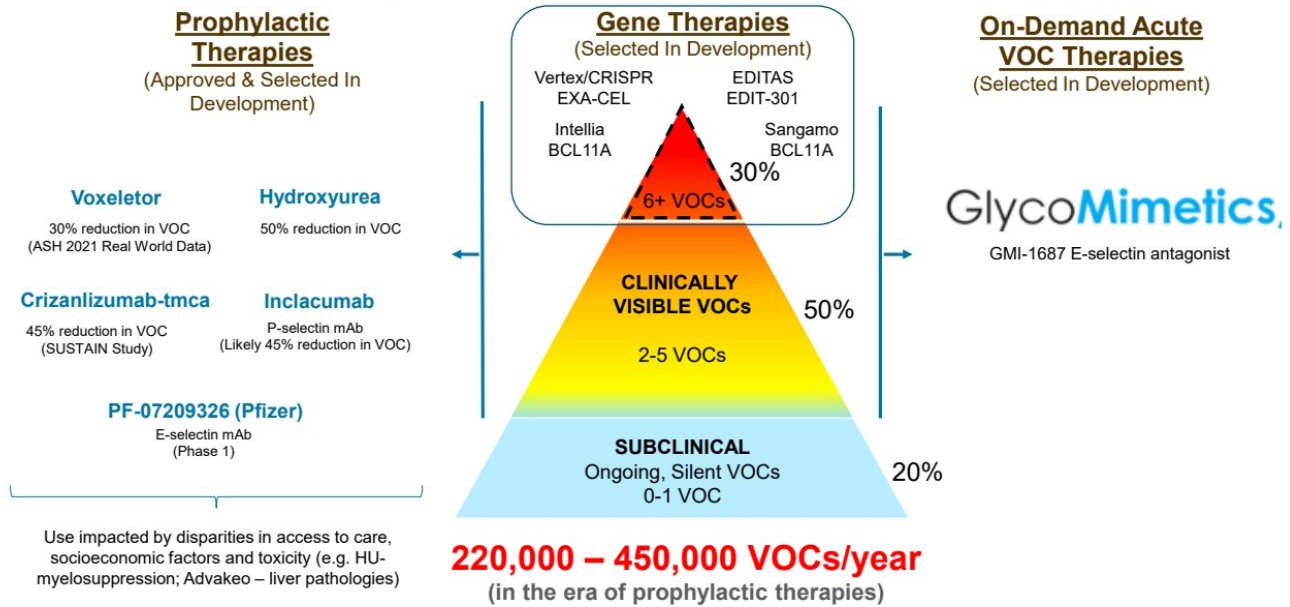
VOC improvement per yr (From 3.19 to 2.77 VOCs/yr)

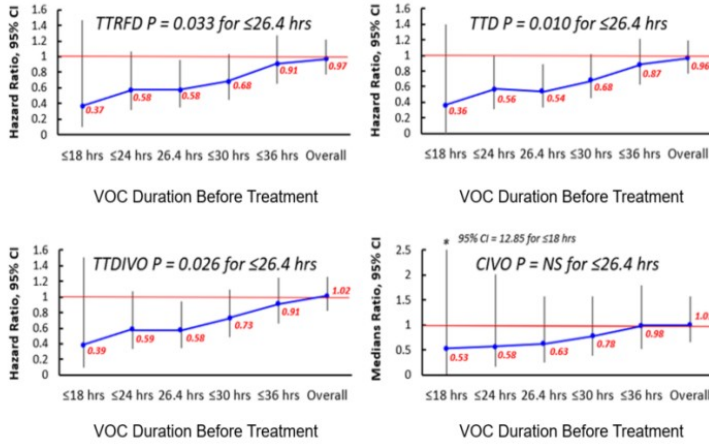
Crizanlizumab-tmca

~1

VOC improvement per yr (From 3 to 1.6 VOCs/yr)

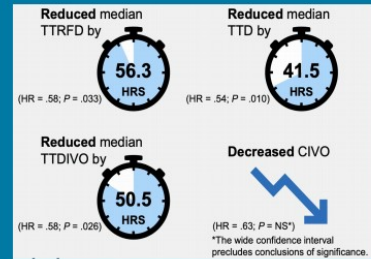
Even with Prophylactic and Gene Therapy Approaches, Acute VOC Will Remain A Significant Unmet Medical Need





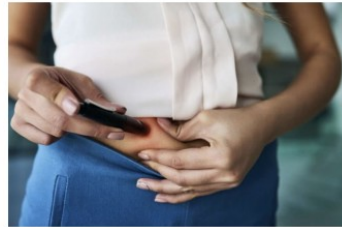
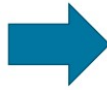
TTRD = time to readiness for discharge; TTD = time to discharge;
 TTDIVO = time to discontinuation of IV opioids; CIVO = cumulative IV opioid use

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





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



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

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