
OncoVerity
We Seek a World Where Cancer Never Wins

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Acute Myeloid Leukemia (AML) requires a new, different approach for effective, sustained treatment outcomes

High Unmet Medical Need

- **Highly lethal cancer affecting ~20,000 people per year in the US**
- **Median overall survival of 14.7 months in elderly and unfit**
- **Heterogeneity underlies the poor prognosis**

Inherent Challenges of AML Drug Development

- **Limitations of pre-clinical models**
- **Emergence of drug resistance**
- **Identifying optimal treatment combinations**

Novel solutions

Require novel solutions to realize effective treatments

- Identify genetic subgroups that share similar characteristics
- Predictive modeling based on highly curated patient data
- Identify drivers of resistance using computational technologies
- Predict interactions and synergies between therapies and targets through computational technologies

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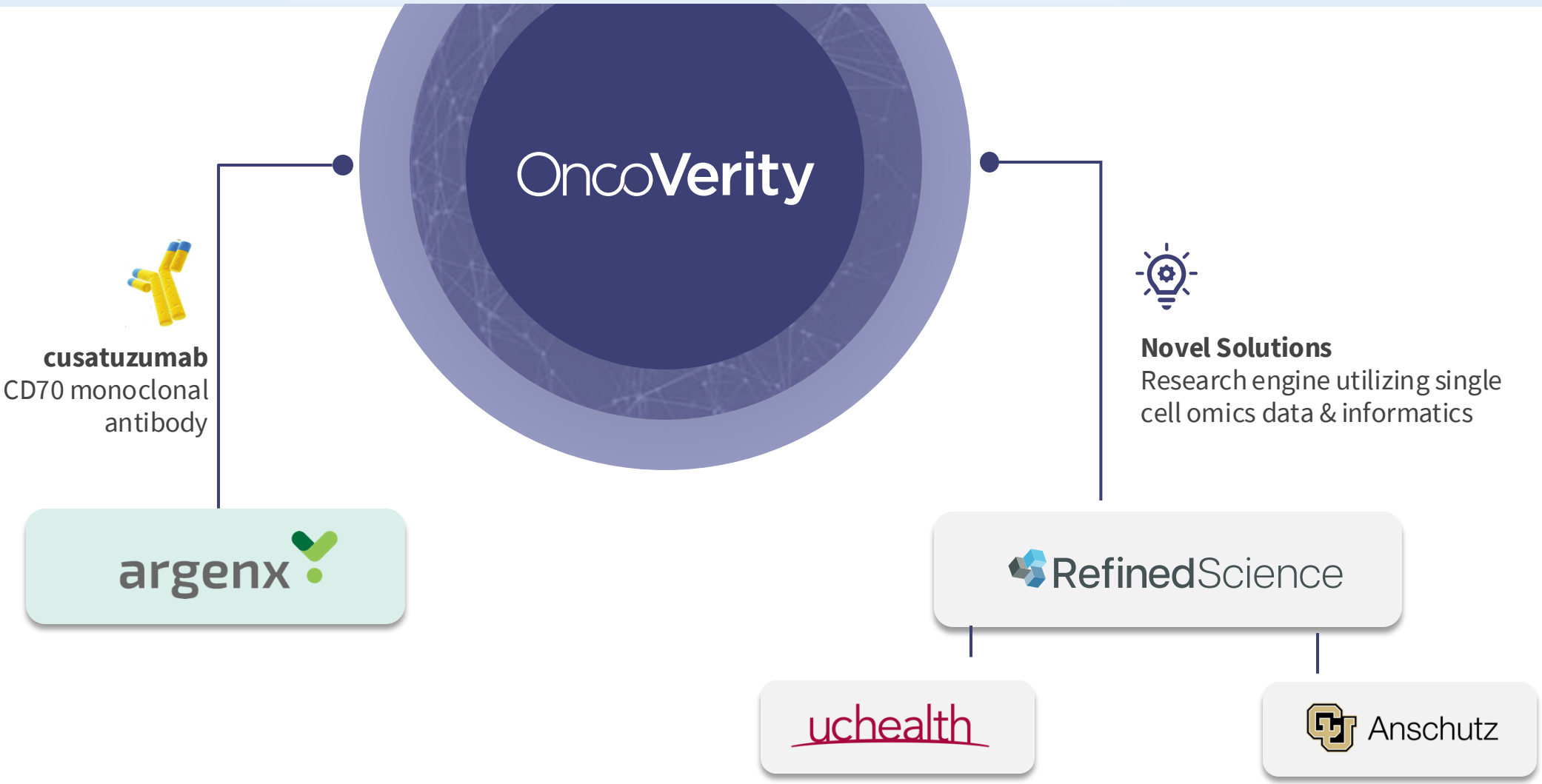
Built to accelerate development through state-of-the-art capabilities



Cusatuzumab, a first-in-class CD70 antibody

→ Proven Activity in AML

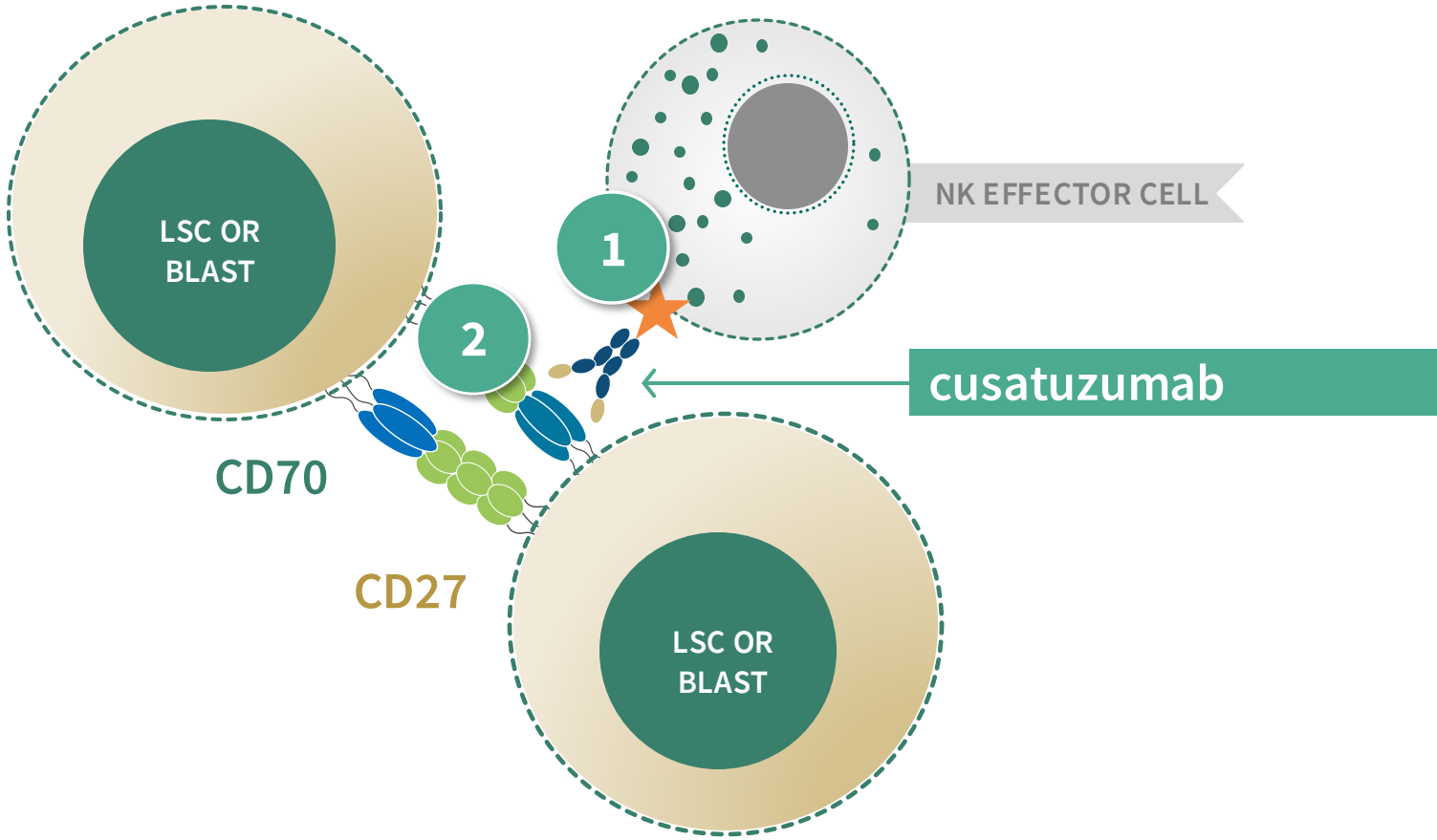
- CD70 expressed on AML blasts, selectively on LSCs, not HSC
- CD70 expression is increased after HMA and venetoclax treatment

→ Significant Safety Advantage

- Strong safety profile: wide therapeutic window as CD70 is only transiently expressed on healthy cells (T, B, DC)

→ Dual Mechanism of Action

1. Kills blasts and LSCs selectively through NK-ADCC
2. Blocks CD70 proliferation and survival signal; inducing differentiation of LSC's



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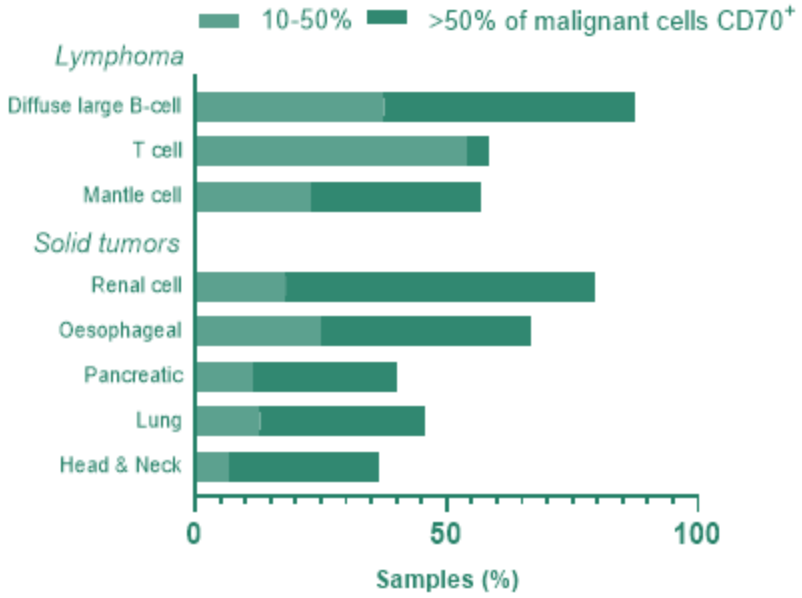
Abbreviations: LSC-Leukemic Stem Cells; HSC-Hematopoietic Stem Cells; HMA-Hypomethylating Agents; NK-Natural Killer Cells; ADCC-Antibody Dependent Cellular Cytotoxicity. References: Bertrand P et al, Genes, Chromosomes and Cancer 2013; Riether C et al, J Exp Med. 2017; Jacobs J et al Pharmacol Ther 2015; Bowman MR et al, J Immunol. Nolte MA et al, Immunol Rev. 2009; Riether C et al. Nat Med. 2020; Silence, K, et al. Landes Biosciences. 2013.

cusatuzumab has potential to treat a broad range of tumors with particularly strong rationale in AML

CD70 is broadly implicated in various cancers 1, 2…

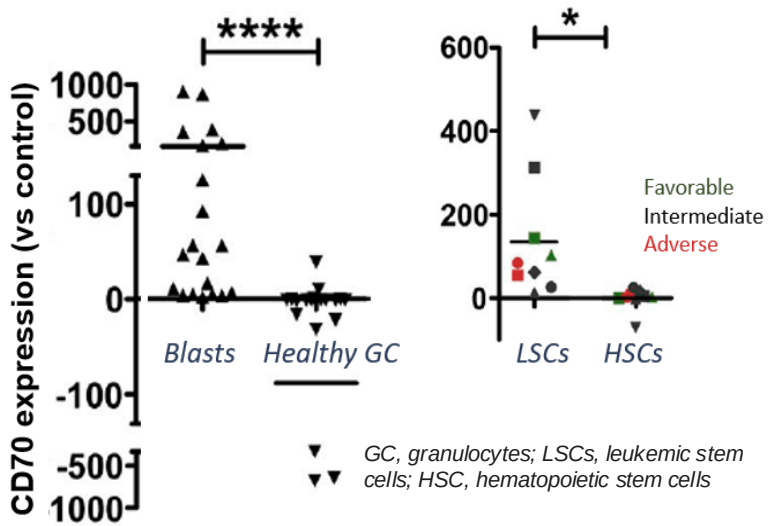
Expression on malignant cells



- CD70: interesting target for a broad range of malignancies
- Co-expression of CD70 & CD27 in lymphoma/ leukemia
- CD70 as a potential target for immunotherapy in solid tumors

…with particularly strong biologic rationale in AML 3, 4

Expressed on 96-100% of AML blasts, selectively on LSCs, not HSCs



- Cusatuzumab targets across all AML risk categories 3, 4
- Higher CD70 expression in monocytic blasts makes it a target for difficult to treat monocytic AML cells - thought to be responsible for early relapse after SoC treatment. *(figure in slide 45)*
- Besides scientific rationale, safety profile allows combination with other key assets in AML / MDS paradigm

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[1] Jacobs J et al. Pharmacol Ther 2015; [2] Flieswasset T et al. Cancers 2019; [3] Riether C et al. J Exp Med 2017; [4] Riether C et al. Nat Med 2020.

Several cusatuzumab trials support future AML marketing approval

2016

Pre-Clinical Studies

Showed ability to eliminate leukemic stem cells & increase survival in animal models

Data showed that cusa could overcome ven/aza resistance

2017 Complete

Phase 1/2 | ARGX-1601

N=38
Open Label Study

Key Takeaway: No dose limiting toxicities

- Single agent activity demonstrated & showed that cusa + aza leads to strong responses in elderly AML patients

2019 On-Going

Phase 2 | CULMINATE

N=103
Randomized cusa (10mg/kg vs. 20mg/kg)

Key Takeaway: 20 mg/kg cohort (n=52) with strong safety & tolerability demonstrated

- Showed dose dependent and durable response in 20mg/kg cohort of cusa + aza in frail patients

2020 On-Going

Phase 1b ELEVATE

N=44
Open label, multi-center

Key Takeaway: Deep responses even among challenging patient population

- Includes new SOC ven/aza + cusa on-going trial
- Adds efficacy to ven/aza

Note: Standard of Care (SOC) in unfit AML evolved from azacitidine to ven/aza

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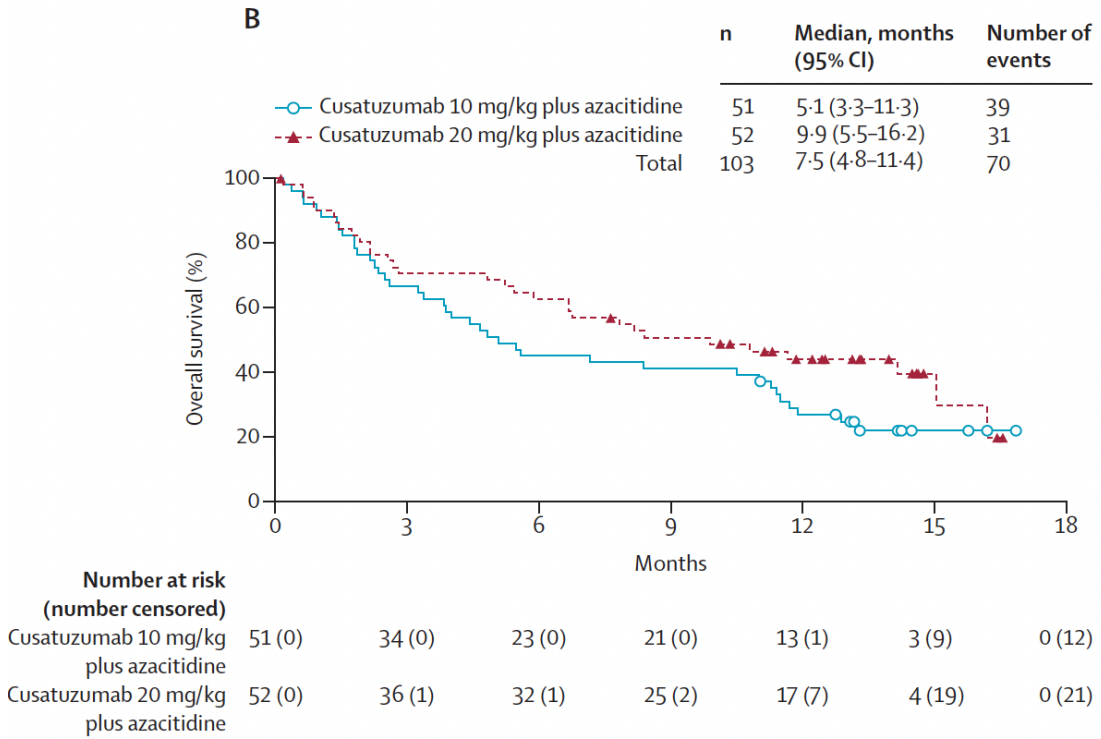
*References: Dombret H et al. Blood 2015 – Phase 3 Aza (ECOG 2: 23%), Dinardo C et al. NEJM 2020 – VIALE-A data (ECOG 2: 45%). **Pabst** et al 2023 Lancet (CULMINATE). **Pabst** T et al 2023 Haematologica (phase II 1601). **Reither** C et al. Nature Medicine (phase I 1601). **Reither** C et al. JEM (preclinical) ELEVATE: ASH abstract https://www.sciencedirect.com/science/article/pii/S000649712102365X*

CULMINATE dose-optimization study demonstrated clinical activity, safety and tolerability

Totality of clinical evidence supports 20 mg/kg as optimal cusa dose

CULMINATE Randomized Phase 2 (ITT)	cusa 10 mg/kg+Aza N=51	cusa 20 mg/kg+Aza N=52
ORR (CR + CRh + CRi), n (%)	15 (29)	21 (40)
CR, n (%)	6 (12)	14 (27)
Median DoR, months (95% CI)	5.6 (0.7, NE)	13.6 (6.3, NE)
Median OS, months (95% CI)	5.1 (3.3, 11.3)	9.9 (5.5, 16.2)
Red blood cell/platelet transfusion independence, %	29/39	42/52



Pabst et al, Lancet Heme 2023

AE, adverse event; AML, acute myeloid leukemia; aza, azacitidine; cusa, cusatuzumab; DoR, duration of response; CR, Complete remission; CRh, complete remission with partial hematological recovery; CRi, complete remission with incomplete hematological recovery; ITT, intention-to-treat; NE, not estimable; ORR, overall response rate; OS, overall survival.

ELEVATE combined cusa with standard of care

Response rates suggest an additive effect of cusa to standard of care

ELEVATE Phase 1b ven/aza/cusa in newly diagnosed elderly unfit

	All Patients N=44	Response Evaluable N=42*
ORR (CR + CRh + CRi), n (%)	34 (77.3)	34 (81.0)
Best response, n (%)	-	
CR	21 (47.7)	21 (50)
CRi	13 (29.5)	13 (31)
CRh	9 (20.5)	9 (21.4)
MRD negativity after initial response	18 (52.9)	18 (52.9)
Red blood cell/platelet transfusion independence, %	66/80	69/84

* Two patients did not have post-baseline disease evaluation due to death

Key Notes/Insights

- **ORR of 81%, CR of 50%and MRD negativity of 53% compares favorably to historical controls**
  - **VIALE-A: CR 37%, CR/CRi 66%, 23% MRD negativity**
- **No obvious significant toxicities noted due to the addition of cusatuzumab**
  - **Mild IRRs (1 Grade 4)**

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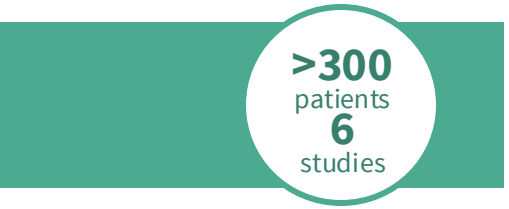
Note: Data cut-off 9 November 2021, with median follow-up of 43.1 weeks. Patients received cusatuzumab 20 mg/kg intravenously on days 3 and 17 with standard dose of azacitidine and venetoclax in 28-day cycles. AML, acute myeloid leukemia; CR, complete remission; CRh, complete remission with partial hematological recovery; CRi, complete remission with incomplete hematological recovery; IRR, infusion-related reaction; MRD, measurable residual disease; ORR, overall response rate.

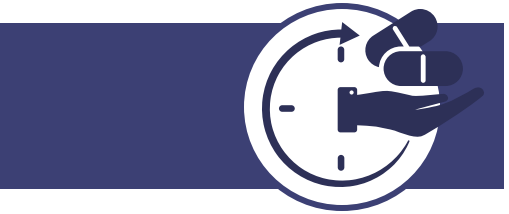
1. Roboz GJ, et al. Blood. 2021;138(suppl 1):369-372. 2. OncoVerity, data on file. 3. DiNardo CD, et al. N Engl J Med. 2020;383:617-629.

Safety: cusa tolerability established in >300 patients



Well tolerated with no MTD identified across 6 studies involving 316 patients[1-7]

Combined with ven/aza had a safety profile consistent with that previously reported for ven/aza, with the exception of infusion-related reactions (IRRs)[1]



IRRs are typically low grade and manageable, and can be reduced with premedication[1-3,a]

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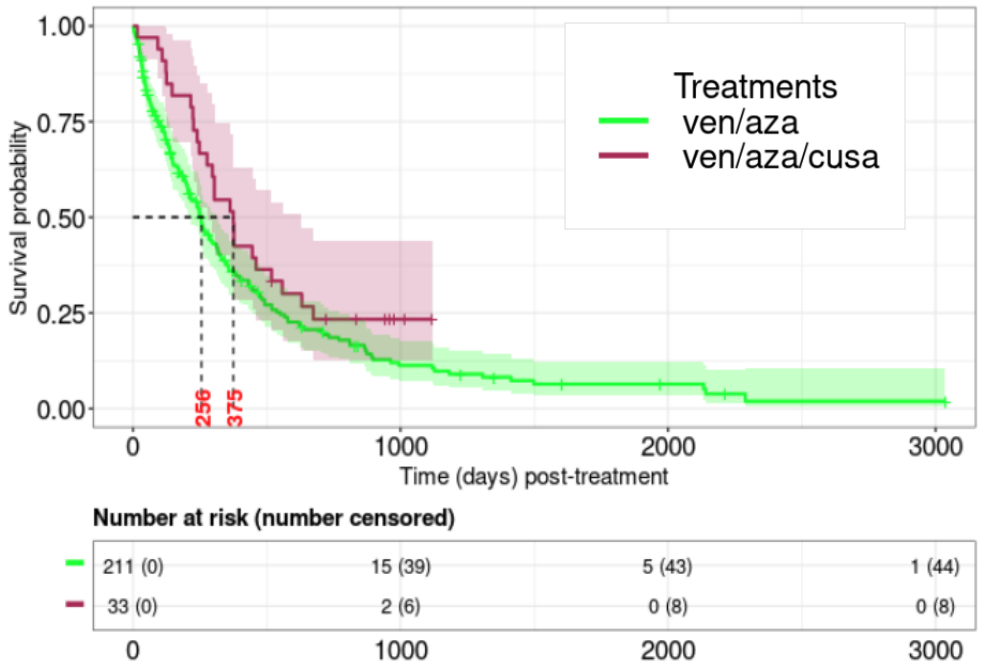
1. Roboz GJ, et al. Blood. 2021;138(suppl 1):369-372. 2. Pabst T, et al. Haematologica. 2023:108:1793-1802. 3. Pabst T, et al. Lancet Haematol. 2023;10;e902-912. 4. Riether C, et al. Nature Medicine. 2020;26:1459-1467. 5. De Meulenaere A, et al. Clin Transl.Sci. 2021;14:2300-2313. 6. Leupin N, et al. Cancer. 2022;128:1004-1014. 7. Aftimos P, et al. Clin Cancer Res. 2017;23:6411-6420. [a]Premedication consists of acetaminophen, diphenhydramine, and corticosteroids. MTD, maximum tolerated dose.

Compelling comparative data support development of cusa in triplet combination

More favorable outcomes in AML patients treated with cusa/ven/aza in ELEVATE

(n=33) vs retrospective single center control cohort treated with ven/aza (n=211)

Kaplan-Meier analysis of overall survival (OS)



- Patients receiving ven/aza were ~1.3x more likely to die than those receiving cusa/ven/aza (aHR: 0.78; 95% CI: 0.41-0.88)
- Longer OS benefit with triplet over time (log-rank [proportional)] based p-value: 0.0859
- Diverging survival noted with a stable plateau for triplet starting at ~700 days post-treatment
- No substantial differences in toxicity

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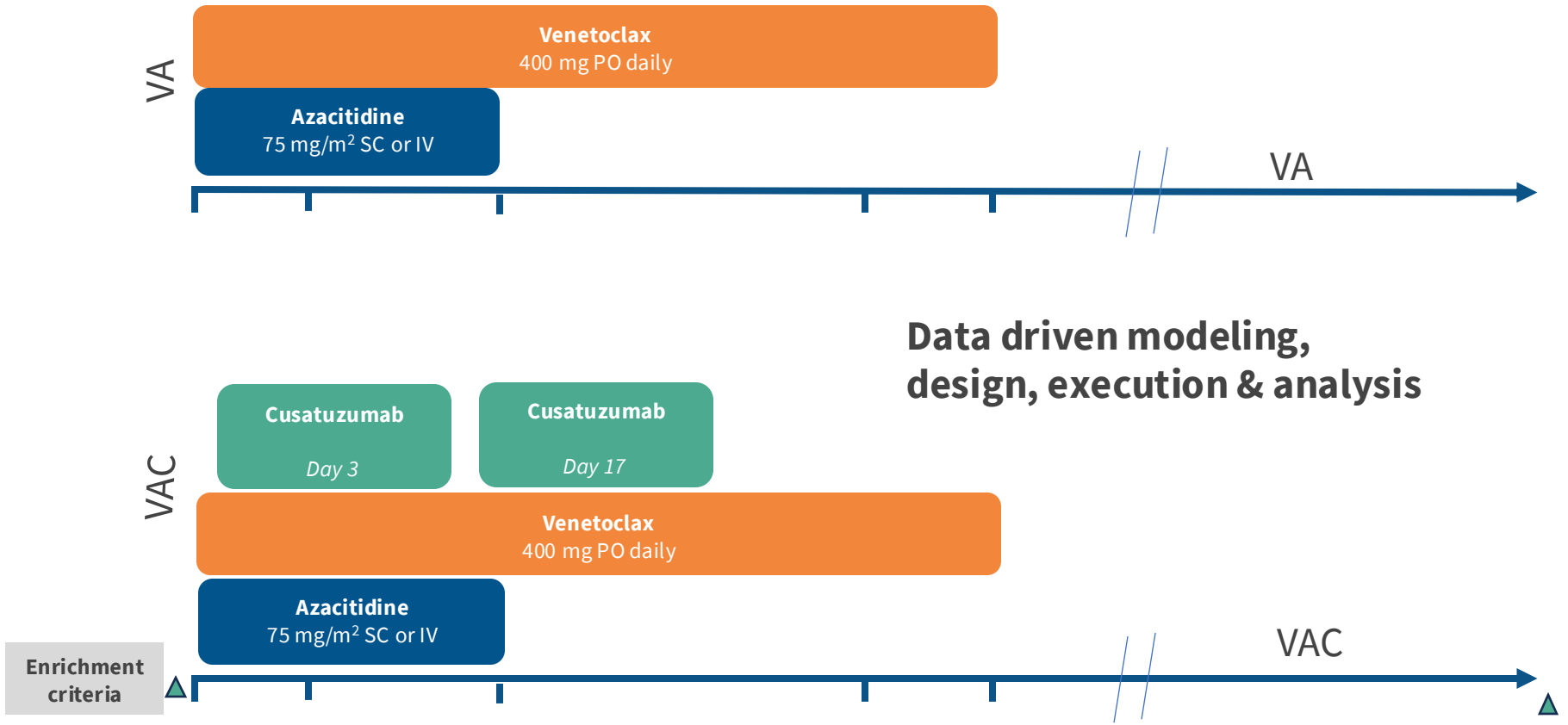
Note: Patients receiving potentially curative hematopoietic stem cell transplant were excluded from the ELEVATE and retrospective control cohort analysis. AML, acute myeloid leukemia; aza, azacitidine; CR, complete remission; CRi, complete remission with incomplete hematological recovery; cusa, cusatuzumab; OS, overall survival; ven, venetoclax. OncoVerity, data on file.

OV- AML 1231: Randomized phase II trial of ven/aza/cusa vs ven/aza in elderly/unfit AML

- Scientific Rationale
- #Patients
- Inclusion/ exclusion
- Patient enrichment
- Drug dosing and timing
- Management of AEs
- Statistical analyses
- Biologic analyses
- Regulatory
- Trial sites
- Other



Endpoints

Statistical Endpoints

- OS
- CR/CRi/CRh
- MRD
- Subsets

Biologic Endpoints

- LSCs
- Sensitive MRD

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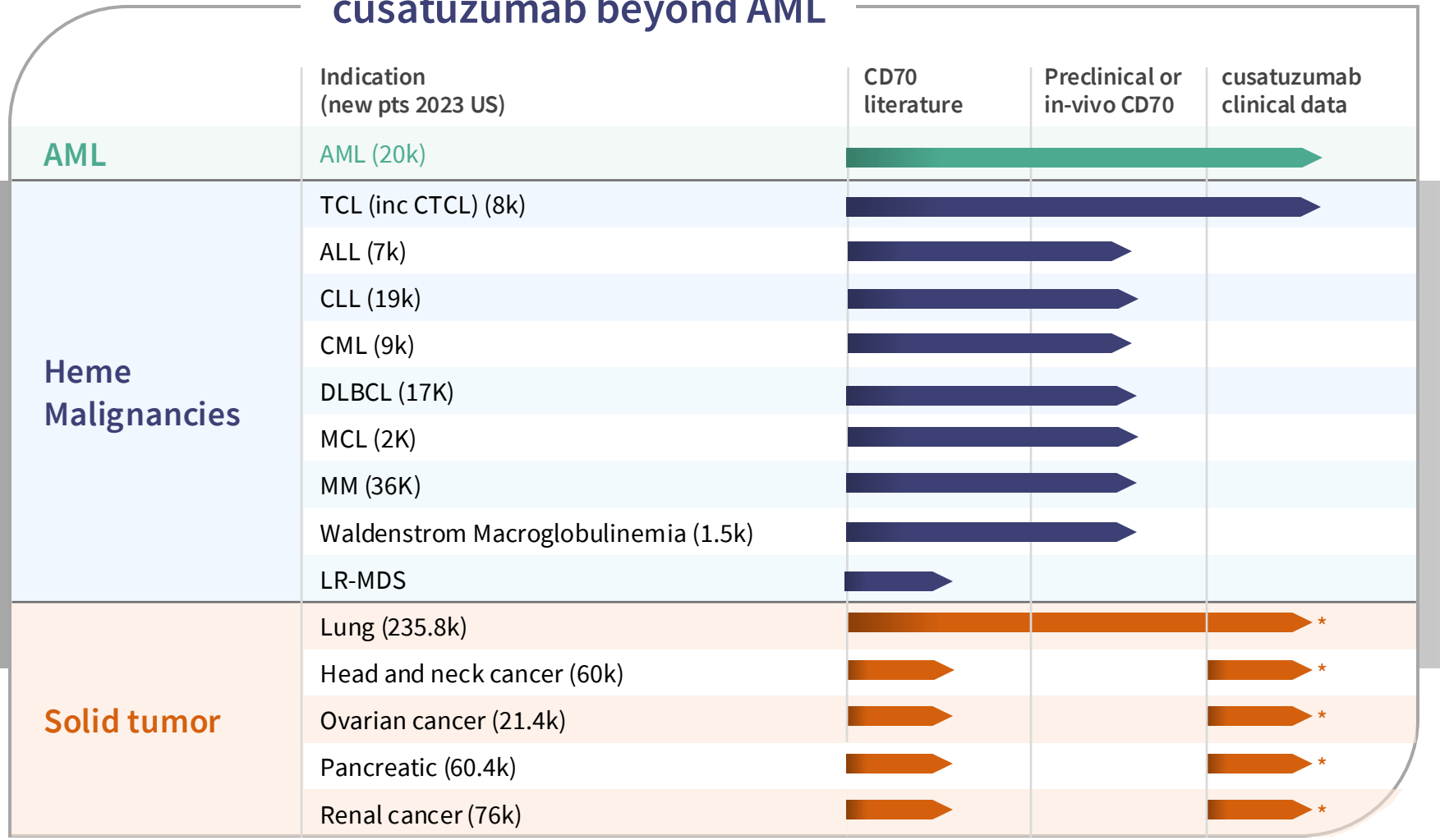
Potential additional indications beyond AML

cusatuzumab beyond AML



Pipeline Expansion

- Collaboration with argenx on novel targets
- Partnerships to propel pipeline

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** Part of phase 1 dose escalation trial for CD70 allcomers Source: SEER, cancer.org, Mourad 2017. Flieswasser T J Exp Clin Cancer Res 2022. Jacobs J 2015*

Summary: Transforming hope to reality for cancer patients

Pioneer in applying computational tools to clinical and biological data advance therapies

- Phase 2 clinical stage oncology company
- Transforming care in ongoing AML trials
  Cusatuzumab: dual mode of action, robust and durable response, safety established in >300 patients
- Revolutionizing Drug Development
  Applying computational tools to accelerate and de-risk oncology drug development
- Addressing significant AML unmet need in first line patients
- $72M in Series A: Strong existing investor support
- Market opportunity in AML is expected to grow to $5B by 2032 with 11% CAGR

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