
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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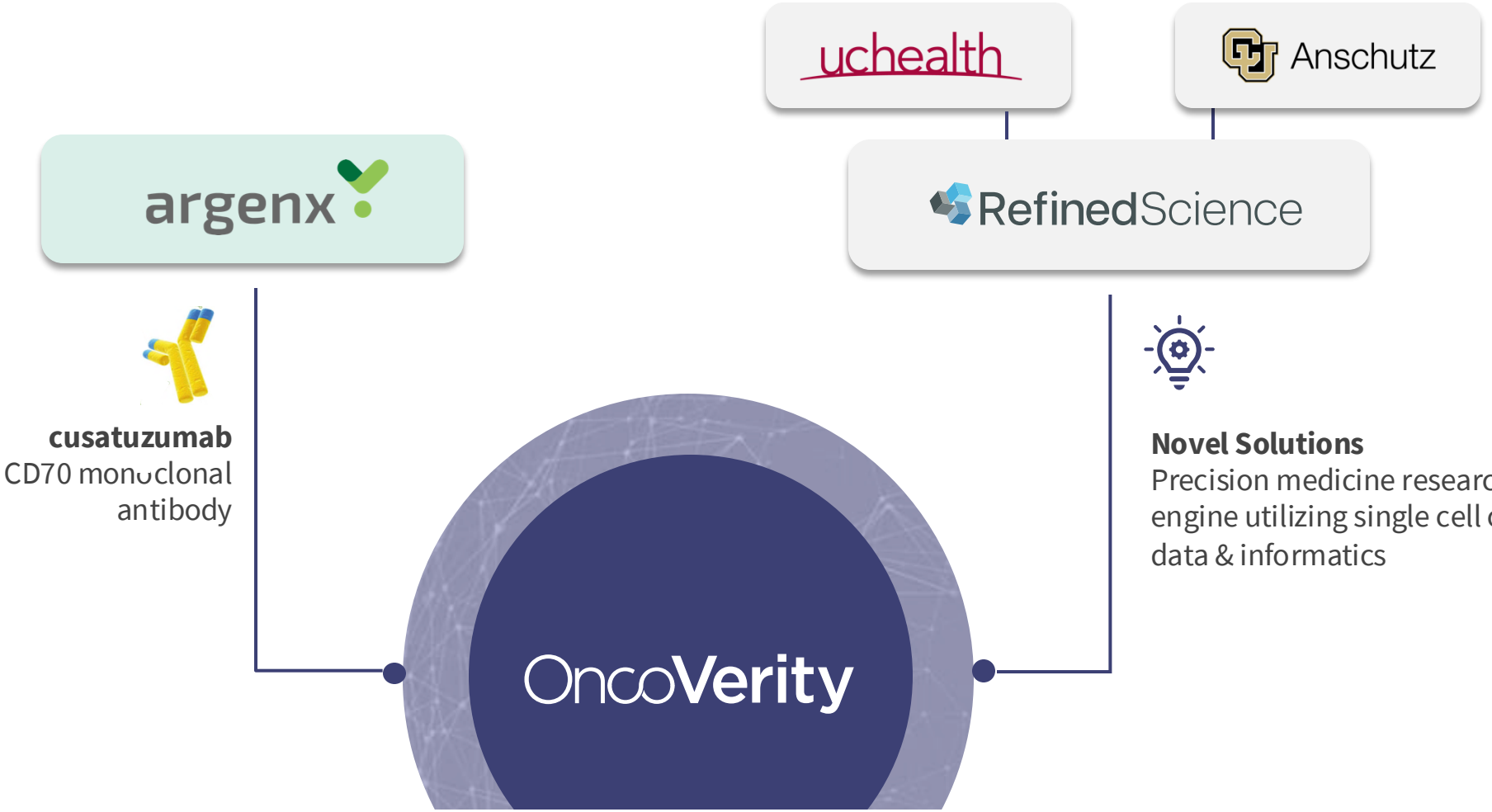
Accelerating development with state-of-the-art capabilities



Cusatuzumab: a first-in-class, high-affinity anti-CD70 monoclonal antibody

→ Proven Activity in AML

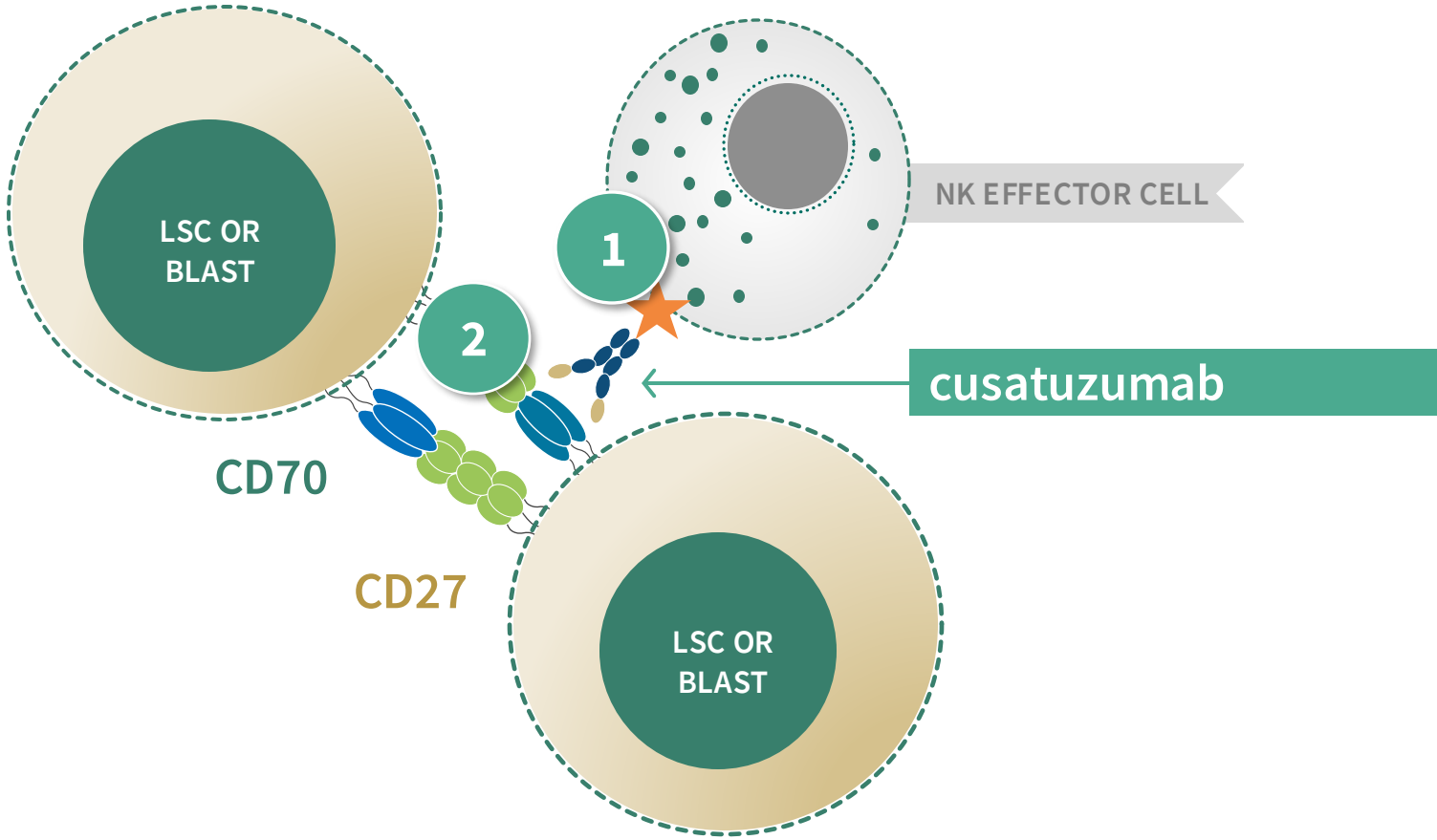
- CD70 expressed on AML blasts, selectively on LSCs, not HSC
- CD70 expression is increased after HMA and venetoclax treatment

→ 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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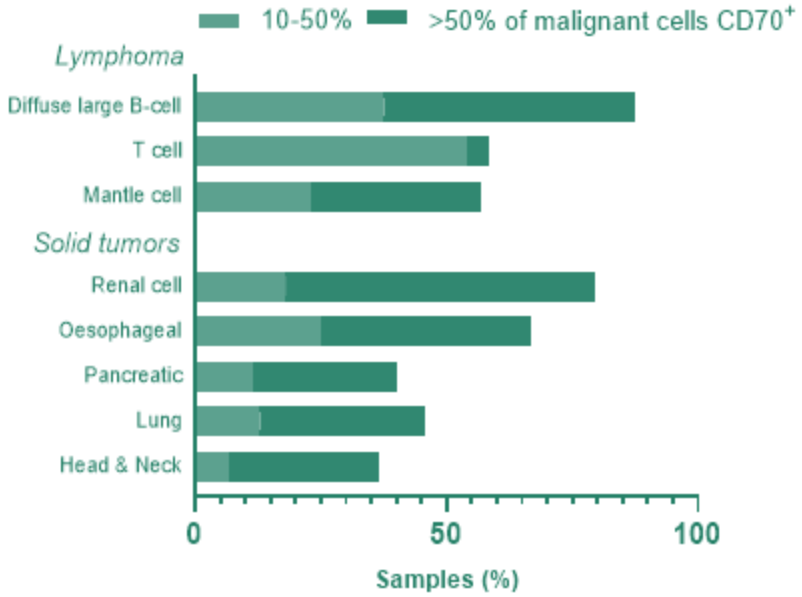
Abbreviations: LSC-Leukemic Stem Cells; HSC-Hematopoietic Stem Cells; HMA-Hypomethylating Agents; NK-Natural Killer Cells; ADCC-Antibody Dependent Cellular Cytotoxicity. References: Bertrand P et al, Genes, Chromosomes and Cancer 2013; Riether C et al, J Exp Med. 2017; Jacobs J et al Pharmacol Ther 2015; 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's potential across multiple tumor types, strong rationale in AML

CD70 is broadly implicated in various cancers 1, 2…

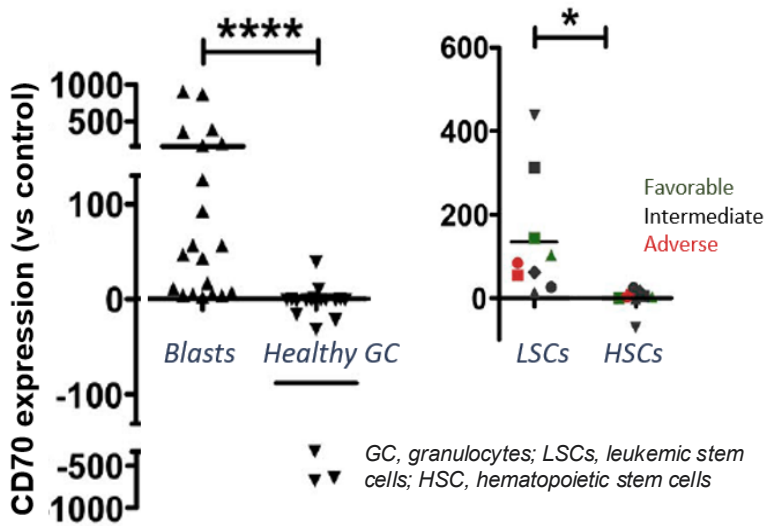
Expression on malignant cells



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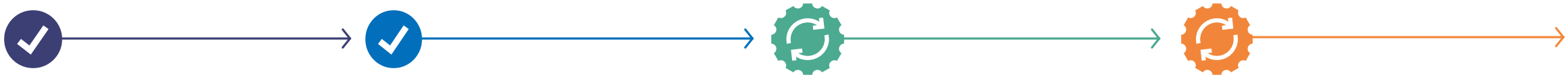
[1] Jacobs J et al. Pharmacol Ther 2015; [2] Flieswasset T et al. Cancers 2019; [3] Riether C et al. J Exp Med 2017; [4] Riether C et al. Nat Med 2020.

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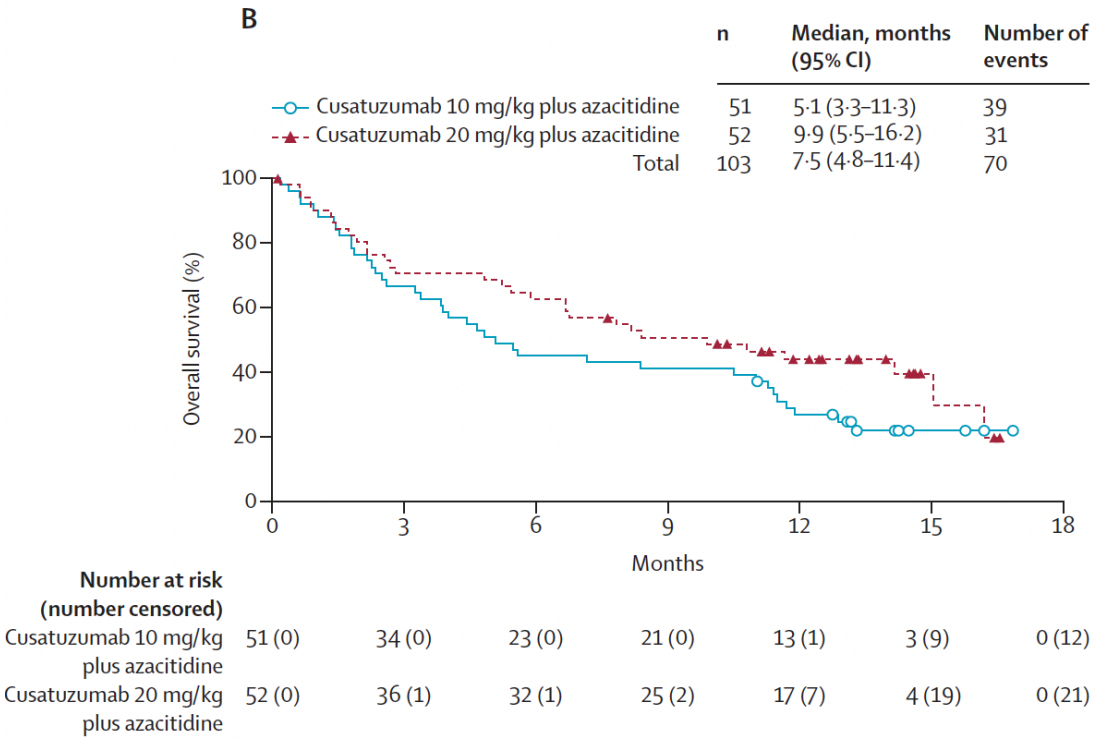
*References: Dombret H et al. Blood 2015 – Phase 3 Aza (ECOG 2: 23%), Dinardo C et al. NEJM 2020 – VIALE-A data (ECOG 2: 45%). **Pabst** et al 2023 Lancet (CULMINATE). **Pabst** T et al 2023 Haematologica (phase II 1601). **Reither** C et al. Nature Medicine (phase I 1601). **Reither** C et al. JEM (preclinical)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

CULMINATE dose-optimization study demonstrated clinical activity 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

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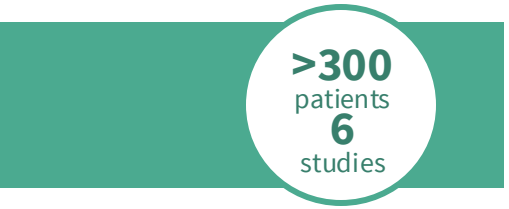
Note: Data cut-off 9 November 2021, with median follow-up of 43.1 weeks. Patients received cusatuzumab 20 mg/kg intravenously on days 3 and 17 with standard dose of azacitidine and venetoclax in 28-day cycles. AML, acute myeloid leukemia; CR, complete remission; CRh, complete remission with partial hematological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

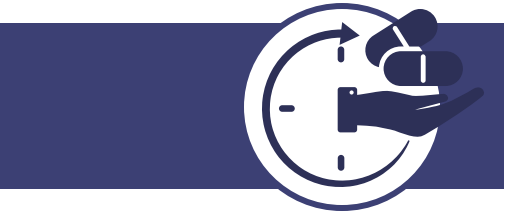
1. Roboz GJ, et al. Blood. 2021;138(suppl 1):369-372. 2. OncoVerity, data on file. 3. DiNardo CD, et al. N Engl J Med. 2020;383:617-629.

Cusatuzumab's 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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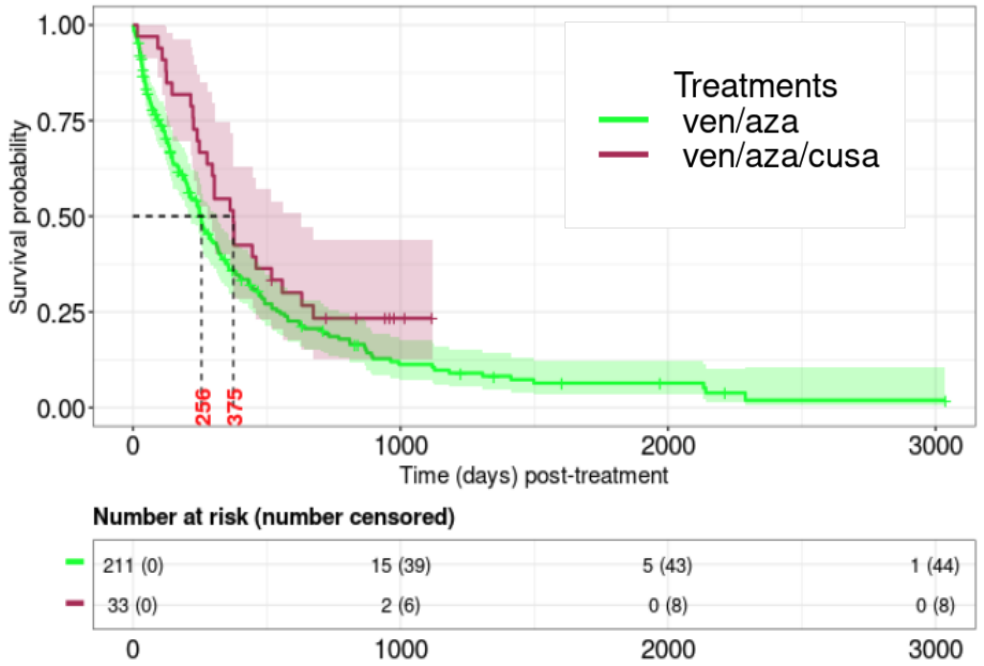
1. Roboz GJ, et al. Blood. 2021;138(suppl 1):369-372. 2. Pabst T, et al. Haematologica. 2023:108:1793-1802. 3. Pabst T, et al. Lancet Haematol. 2023;10;e902-912. 4. Riether C, et al. Nature Medicine. 2020;26:1459-1467. 5. De Meulenaere A, et al. Clin Transl.Sci. 2021;14:2300-2313. 6. Leupin N, et al. 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 supports cusatuzumab 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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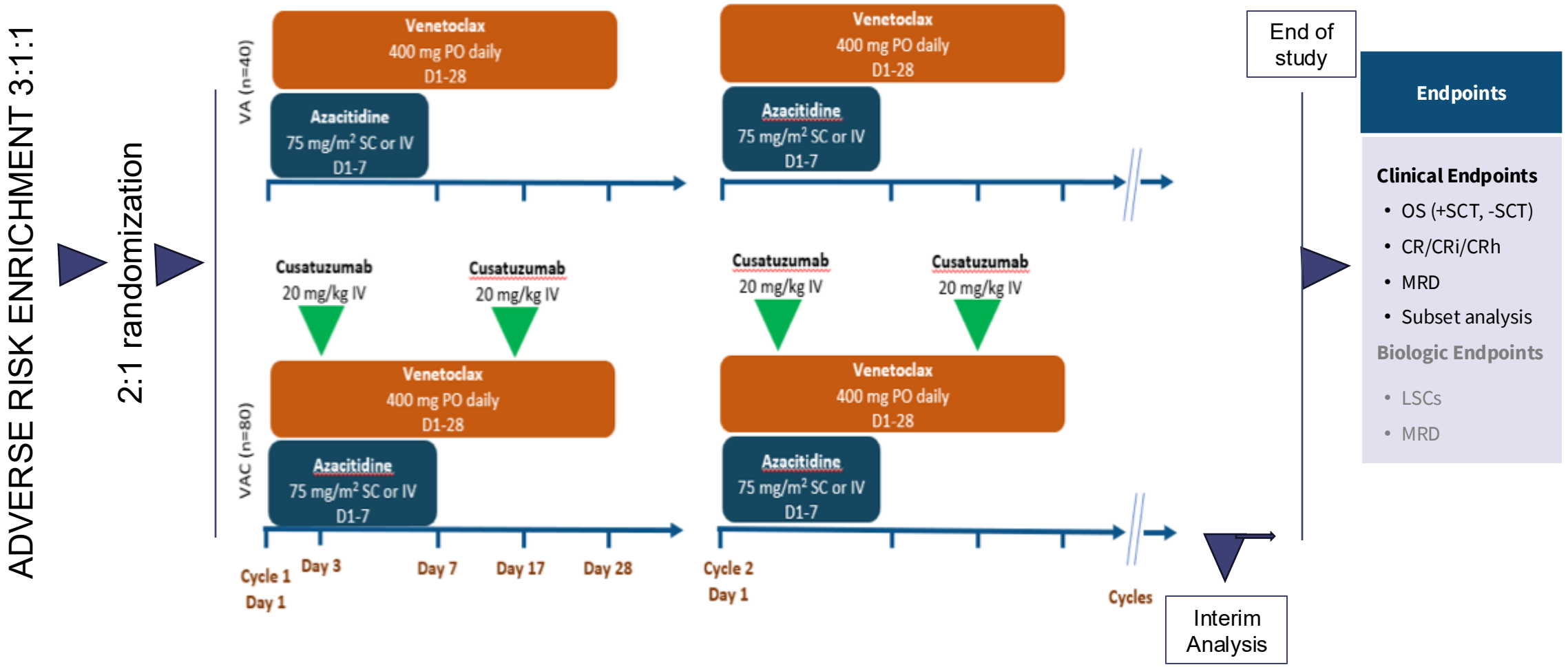
Note: Patients receiving potentially curative hematopoietic stem cell transplant were excluded from the ELEVATE and retrospective control cohort analysis. AML, acute myeloid leukemia; aza, azacitidine; CR, complete remission; CRi, complete remission with incomplete hematological recovery; cusa, cusatuzumab; OS, overall survival; ven, venetoclax. OncoVerity, data on file.

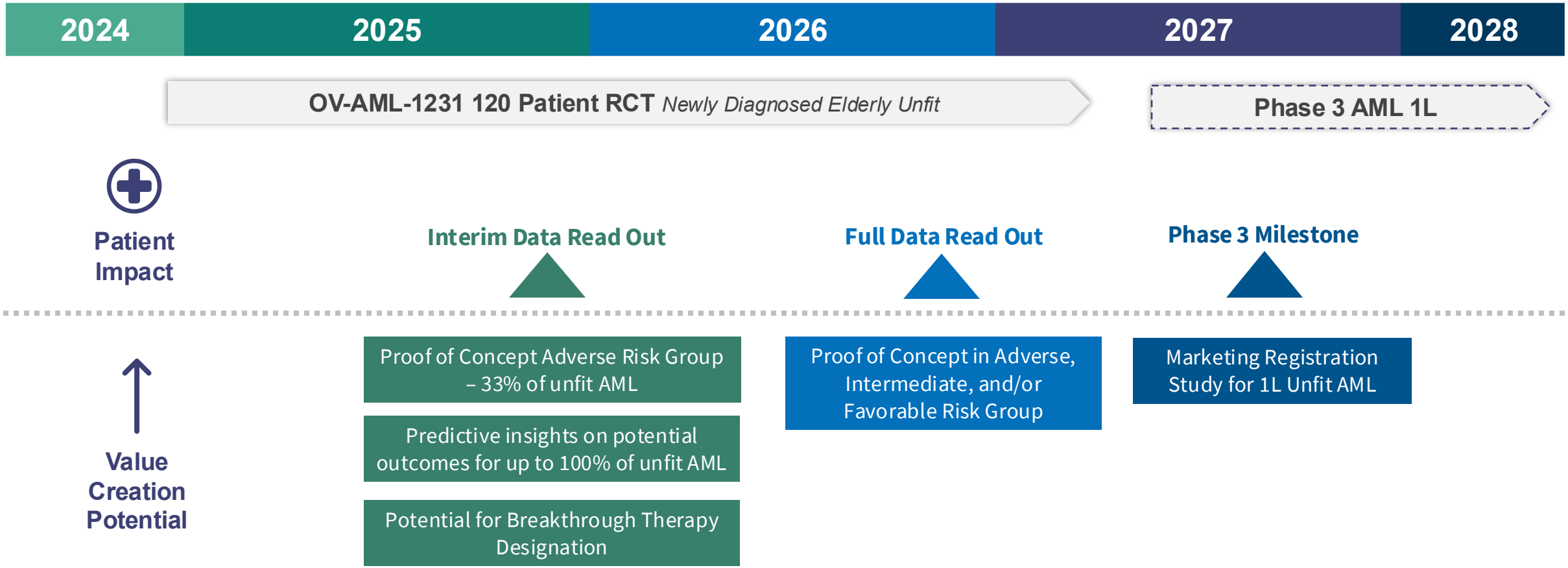
OV-AML-1231: Randomized Ph2 study of ven/aza vs ven/aza+*cusatuzumab* in newly diagnosed AML patients unfit for intensive chemotherapy



https://ashpublications.org/blood/article/144/Supplement%201/1504.2/529435/Trial-in-Progress-A-Multicenter-Open-Label

Key data catalysts: OV-AML-1231 interim results expected in 2025

Hypothesis: Increase AML patient survival with cusa



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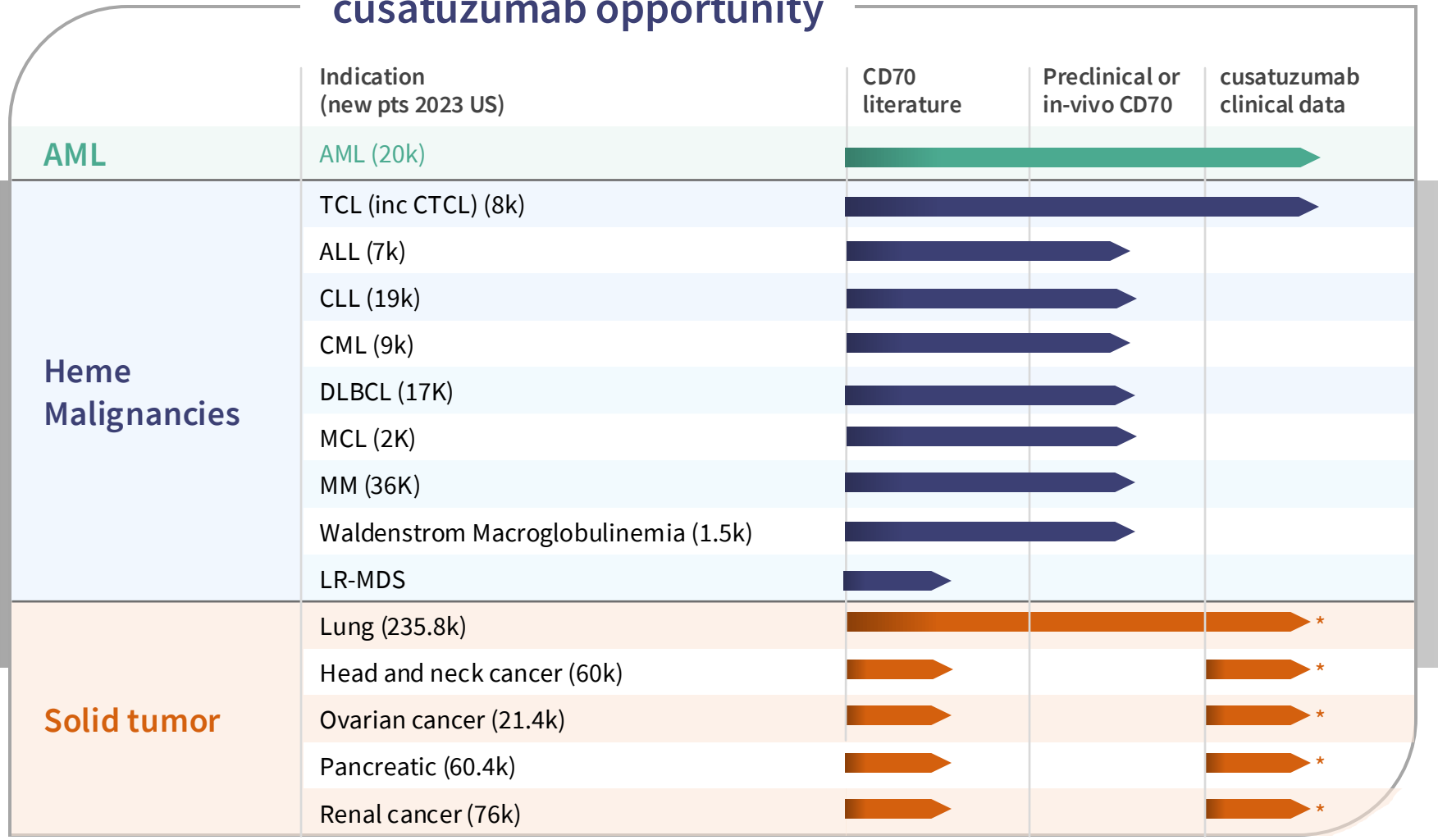
Pipeline Expansion: Additional indications beyond AML

cusatuzumab opportunity



Pipeline Expansion

- NK Cell augmentation
- Cusa ADC

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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*

Robust intellectual property portfolio

Composition of Matter Patents:

Several issued patents in the US, Europe, and other major markets directed to the lead anti-CD70 antibody with a term extending to 2032

Method of Use Patents:

Several issued patents in the US, Europe, and other major markets directed to the treatment of myeloid malignancies, such as acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS), using the lead anti-CD70 antibody with a term extending to 2032

Pending applications in the US, Europe, and other major markets directed to combination therapies that include the lead anti-CD70 antibody in combination with a second therapy, such as a BCL-2 inhibitor or a hypomethylating agent, or in combination with an antibody directed to a leukemic stem cell target (e.g., TIM-3), with terms extending from 2038 to 2041

Methods for Targeting Therapy to a Responsive Subject

Pending applications in the US and other major markets directed to methods for identifying a subject responsive to anti-CD-70 antibody treatment and methods for treating such a subject, with terms extending from 2040 to 2043

Will pursue patent term extensions of up to 5 years, where possible in various countries, based on delays in obtaining regulatory approval

Experienced Team: Industry, clinical and research experience

Max Colao, MBA

Chief Executive Officer & Board Chairman

- Over 30 years biotech experience
- Focus in rare disease therapies
- Small and large biotech experience

Clay Smith, MD

Chief Scientific Officer

- Over 40 years experience treating cancer patients
- Over 30 years experience in oncology research, clinical care and clinical trials
- Pioneered clinical and single cell multiomics infrastructure

OUR TEAM HAS OVER A CENTURY WORTH OF COMBINED EXPERIENCE IN ONCOLOGY AND BIOPHARMA

AMGEN · Bristol Myers Squibb · Pfizer · NOVARTIS · Memorial Sloan Kettering Cancer Center · University of Colorado Anschutz Medical Campus · Penn · Kite A GILEAD Company · Duke University School of Medicine · HORIZON · MOFFITT CANCER CENTER · University of Pittsburgh School of Medicine · ...ichnos... · FDA · THE UNIVERSITY OF BRITISH COLUMBIA · Abeona THERAPEUTICS · ICON · glenmark · Aurinia · Mylan · teva · ALEXION · PURDUE

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Summary: cusatuzumab is the frontrunner in anti-CD70 development

- OncoVerity: leveraging precision medicine capabilities to advance cancer treatment
- Cusatuzumab: first in class, high-affinity anti-CD70 antibody
  multiple modes of action including NK ADCC
- Leading the advancement of anti-CD70 therapies
  Most advanced program, extensive clinical data in AML, studied in more than 300 patients
- OV-AML-1231: Randomized Ph2 study in first line unfit AML
  Interim results expected later this year
- Significant potential for anti-CD70 targeting across multiple cancer indications
- Actively seeking strategic partnerships to expand cusatuzumab's reach and impact

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