
OncoVerity
We Seek a World Where Cancer Never Wins

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First-in-class mAb powered by cutting-edge precision medicine – broad therapeutic application across cancer and autoimmune diseases

argenx

cusatuzumab

First in class, high-affinity anti-CD70 antibody

Ideal target in cancer and autoimmune

Broad therapeutic application

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uchealth

Anschutz

RefinedScience

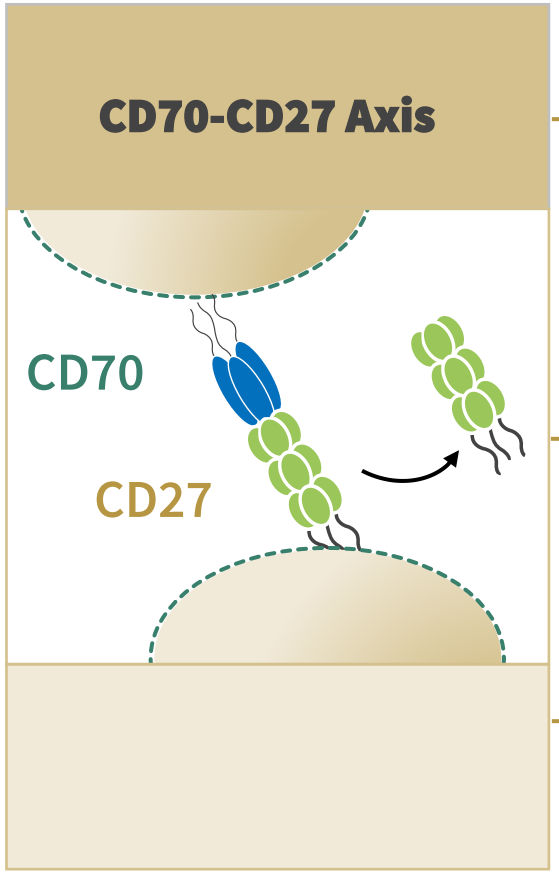
Novel precision medicine solutions

Inclusion criteria **enriched** for potential responders

Cutting-edge analytics and correlative science

Early launch of phase 3 planning or early termination if failing

CD70: an ideal target with broad application in diseases with high unmet need



Healthy Cells

- Tightly regulated during normal hematopoiesis
- Primarily expressed on activated T and B cells
- Limited expression makes CD70 an ideal therapeutic target

Cancer

- CD70 expression upregulated in several hematologic and solid cancers
- Supports malignant cell survival, proliferation, and immune evasion
- Targeting CD70 in cancer has significant therapeutic potential

Autoimmune Diseases

- CD70 signaling contributes to activation, expansion, and survival of autoreactive T-cells, promoting chronic inflammation and tissue damage
- Restricted expression of CD70 on immune cells makes it a potentially attractive target for more targeted and less toxic therapeutic approach

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References: Flieswasser et al, J Exp Clin Cancer 2022: Liu et al, J. Biol Chem 2021:; Kumar et al, Cancer Letters (611) 2025; Han et al, Seminars in Arthritis and Rheumatism 2016.

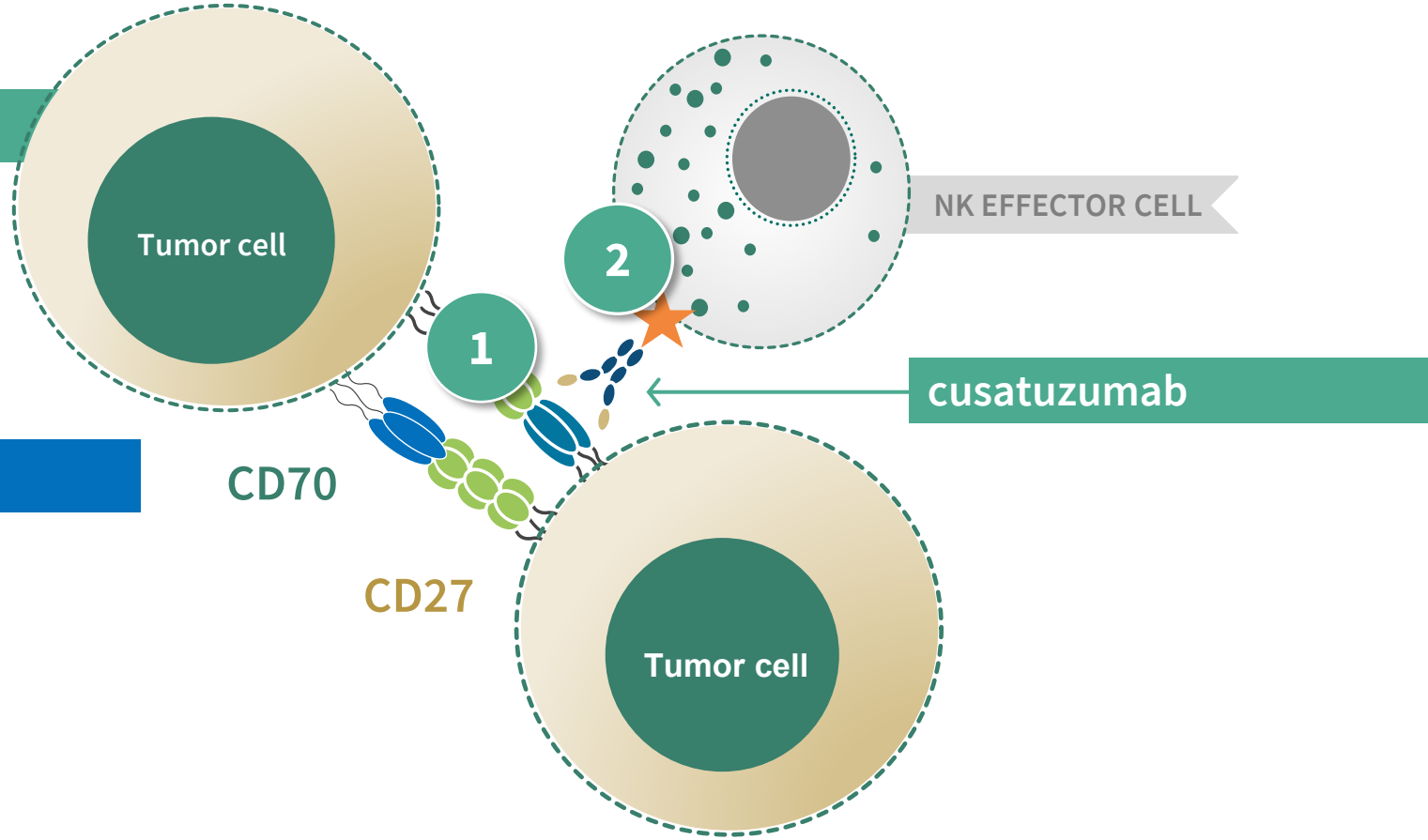
Cusatuzumab: a high-affinity, first-in-class anti-CD70 antibody engineered for CD70 blockade and enhanced ADCC

Mechanism of Action

1. Blocks CD70 proliferation and survival signal
2. Kills tumor cells through NK-ADCC

Significant Safety Advantage

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



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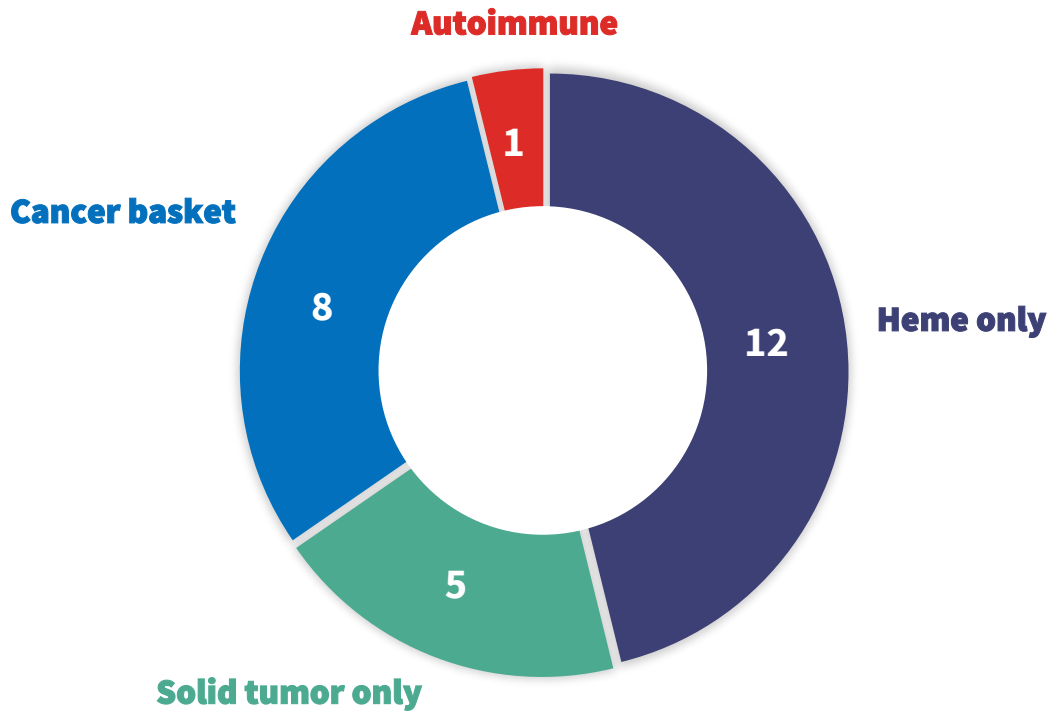
Abbreviations: LSC-Leukemic Stem Cells; HSC-Hematopoietic Stem Cells; HMA-Hypomethylating Agents; NK-Natural Killer Cells; ADCC-Antibody Dependent Cellular Cytotoxicity. References: Bertrand P et al, Genes, Chromosomes and Cancer 2013; Riether C et al, J Exp Med. 2017; Jacobs J et al Pharmacol Ther 2015; 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: leading anti-CD70 therapeutic development

Competitive Landscape
CD70 Development Programs (n=27)



Cusatuzumab's Unparalleled Clinical Advancement

Established safety and tolerability across >350 patients

This is orders of magnitude more clinical experience than any other anti-CD70 program

Established dose and schedule for its lead indication

Conducting randomized Phase 2 trial to inform and optimize Phase 3 pivotal study

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References: ***Pabst*** *et al 2023 Lancet (CULMINATE).* ***Pabst*** *T et al 2023 Haematologica (phase II 1601).* ***Riether*** *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*

350 cusatuzumab patients studied across several trials supporting future AML marketing approval

2016
Pre-Clinical Studies

Key Takeaway:

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

350 patients 6 studies

Well tolerated with **no MTD identified** across 6 studies involving 350 patients

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

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

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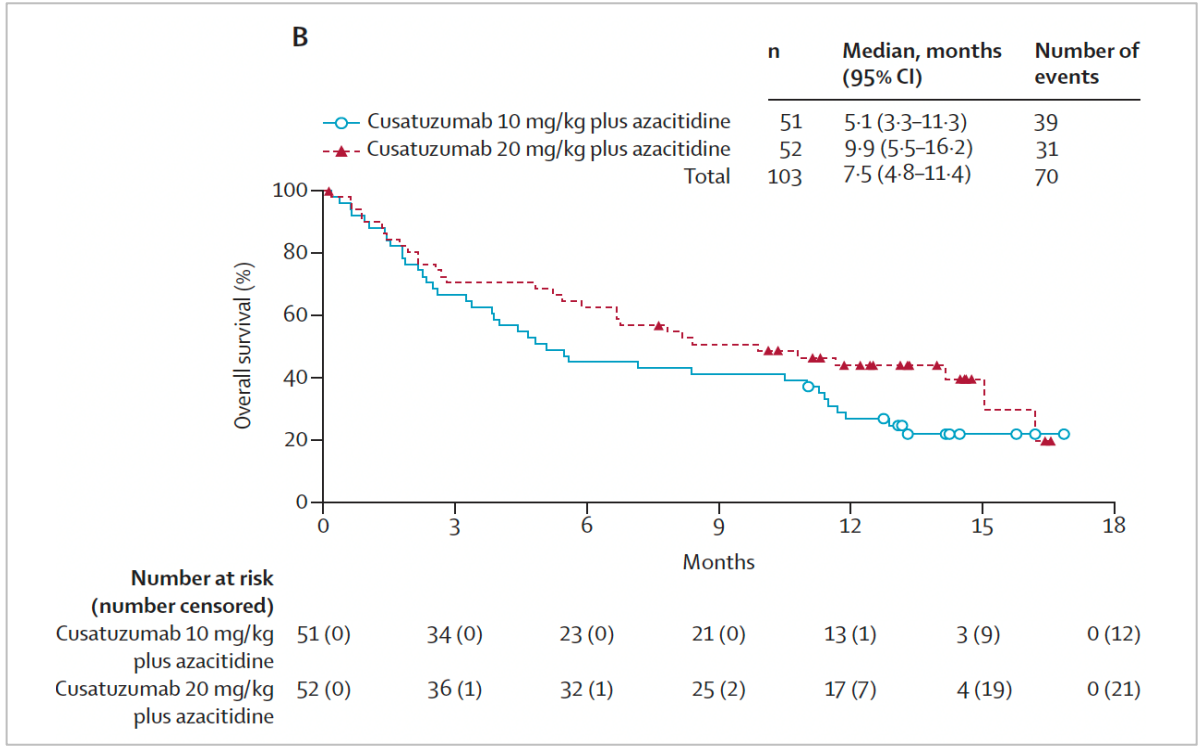
References: Dombret H et al. Blood 2015 – Phase 3 Aza (ECOG 2: 23%). ***Aftimos P*** *et al. Clin Cancer Res. 2017;23:6411-6420 .* ***Dinardo C*** *et al. NEJM 2020 – VIALE-A data (ECOG 2: 45%). .* ***Riether C*** *et al. Nature Medicine. 2020;26:1459-1467.* ***Roboz GJ*** *et al. Blood. 2021;138(suppl 1):369-372.* ***De Meulenaere A*** *et al. Clin Transl.Sci. 2021;14:2300-2313.* ***Leupin N*** *et al. Cancer. 2022;128:1004-1014.* ***Pabst*** *et al 2023 Lancet (CULMINATE).* ***Pabst*** *T et al 2023 Haematologica (phase II 1601).* ***Riether*** *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 .*
[a]Premedication consists of acetaminophen, diphenhydramine, and corticosteroids. MTD, maximum tolerated dose.

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 cusatuzamab 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 Message | Insights

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

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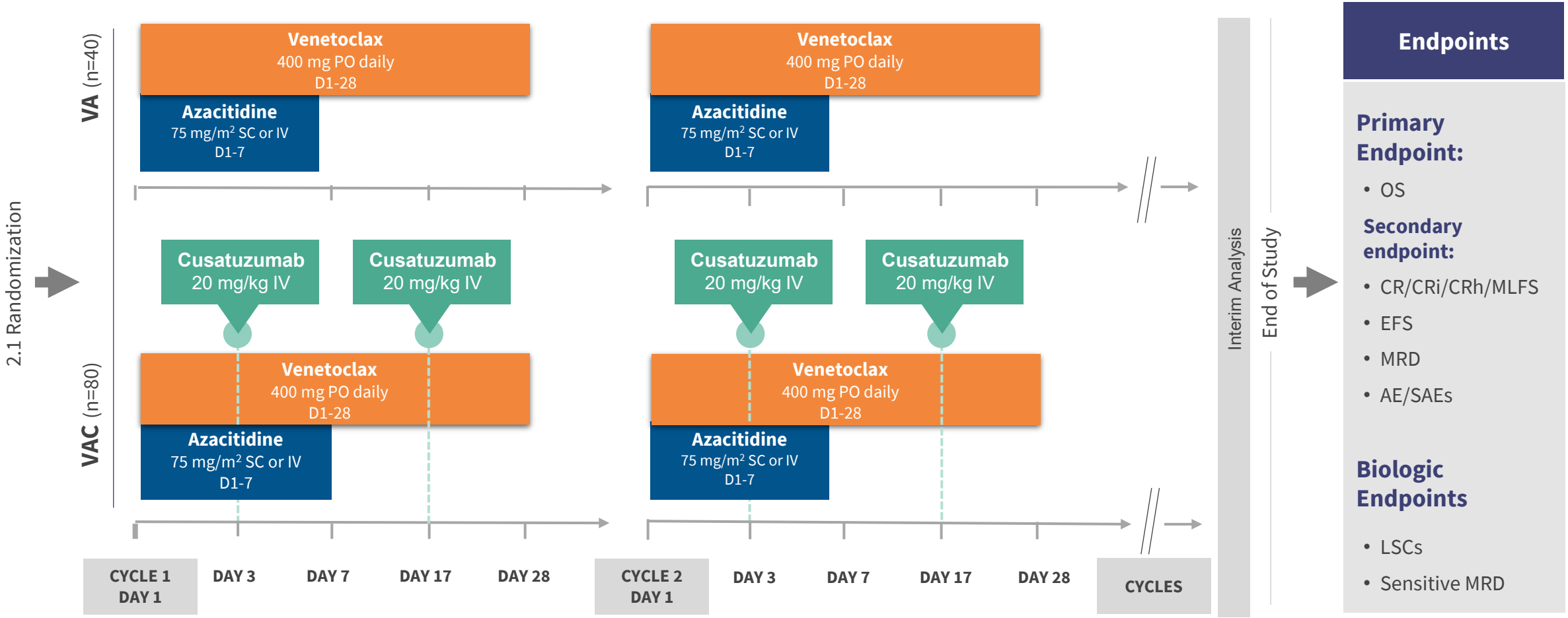
Note: Data cut-off 9 November 2021, with median follow-up of 43.1 weeks. Patients received cusatuzumab 20 mg/kg intravenously on days 3 and 17 with standard dose of azacitidine and venetoclax in 28-day cycles. AML, acute myeloid leukemia; CR, complete remission; CRh, complete remission with partial hematological 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.

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



Endpoints

Primary Endpoint:

- OS

Secondary endpoint:

- CR/CRi/CRh/MLFS
- EFS
- MRD
- AE/SAEs

Biologic Endpoints

- LSCs
- Sensitive MRD

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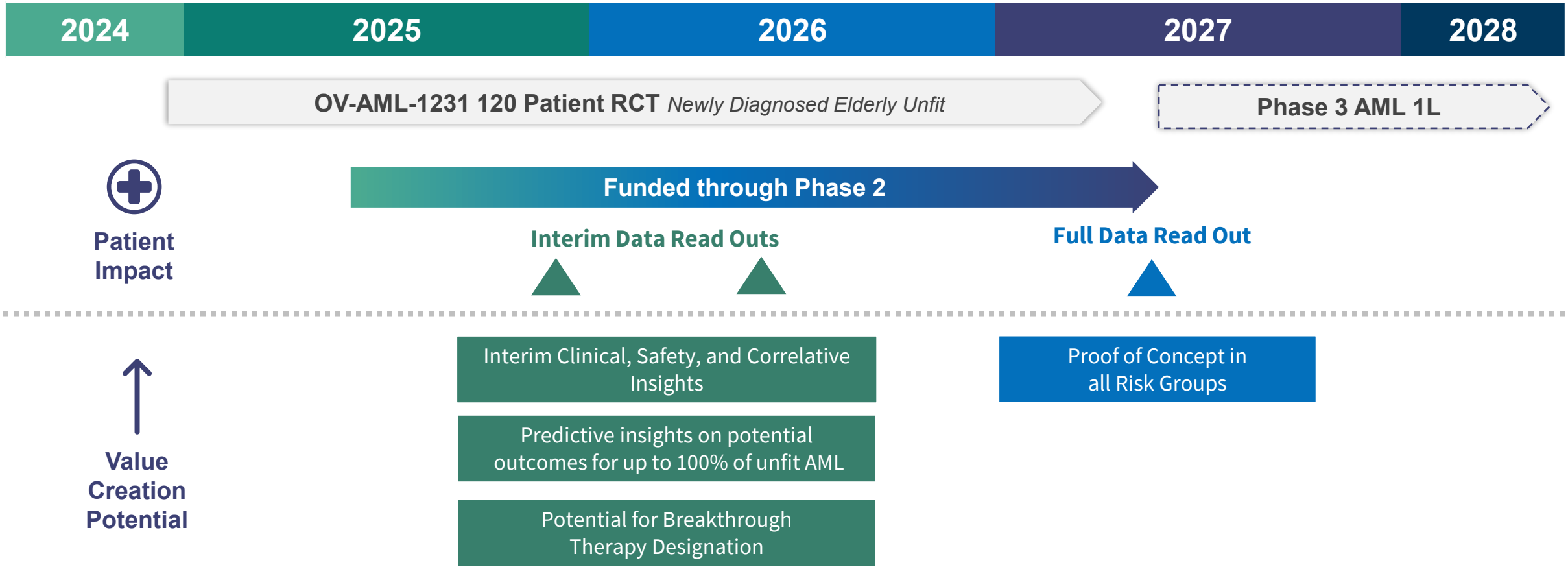
https://ashpublications.org/blood/article/144/Supplement%201/1504.2/529435/Trial-in-Progress-A-Multicenter-Open-Label

Interim results in October: A key inflection point

Hypothesis: Increase AML patient survival with cusatuzumab



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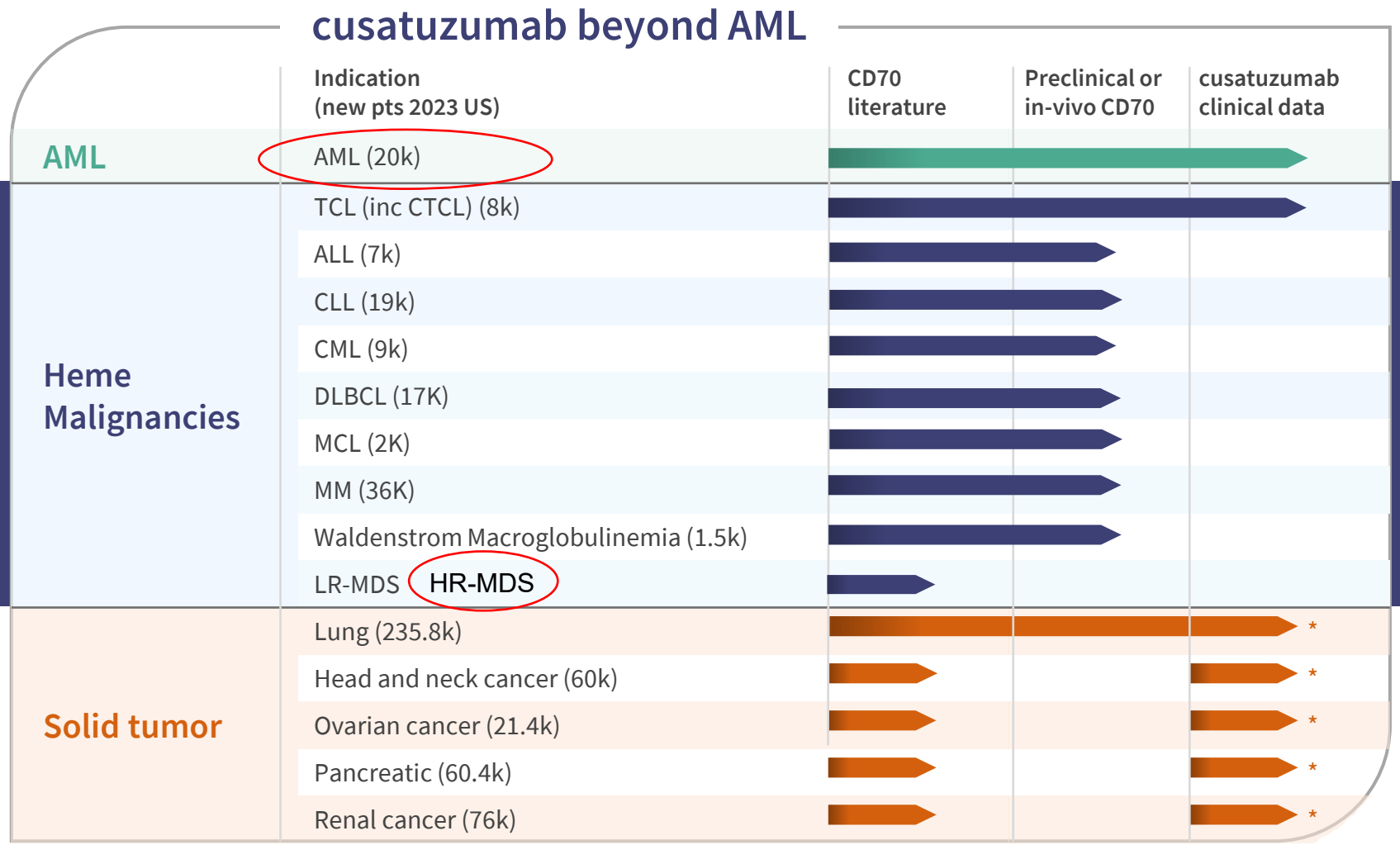
Potential additional indications beyond AML for CD70 expressing cancers



Other exploratory areas

NK cell augmentation

Cusa-ADC

Prioritized for pipeline expansion

** 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*

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Back Up

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 & 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

Michael Boyiadzis, MD, MHSc

Chief Medical Officer

- Over 25 years translational and clinical research experience in heme-oncology
- Former Professor of Medicine at the University of Pittsburgh
- Former Director of the Acute Leukemia Program and Clinical and Translational Research Center at UPMC Hillman Cancer Center

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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