MOLECULAR partners

ASH Investors Meeting

Saturday, 10 December 2022 / 7:30-9:30pm

New Orleans, USA

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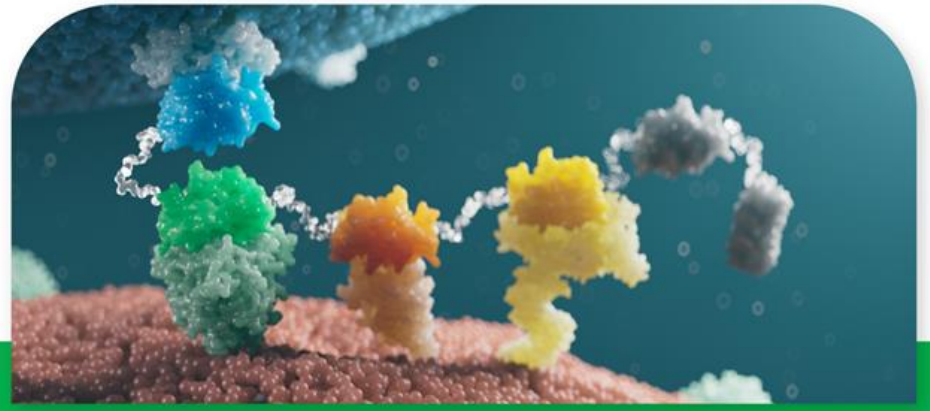
MOLECULAR PARTNERS TO HOST 64TH ANNUAL ASH MEETING & EXPOSITION RECEPTION



Join us at the Windsor Court Hotel to discuss the details of MP0533, our tetra-specific DARPin candidate for AML.

RECEPTION SPEAKERS:

NICOLAS LEUPIN, M.D.
Chief Medical Officer at Molecular Partners

CARSTEN RIETHER, PH.D.
Associate Professor, Principal Investigator and Head of Research at the Department of Medical Oncology, Inselspital, University Hospital and University of Bern

GAIL ROBOZ, M.D.
Professor of Medicine and Director of the Clinical and Translational Leukemia Program at the Weill Medical College of Cornell University

ADRIAN OCHSENBEIN, M.D.
Head of Research Group, Ochsenbein Lab and Chairman, Department of Medical Oncology at the University of Bern

CLICK HERE TO RSVP

Saturday, December 10th, 2022 | 7:30-9:30 PM CST
300 Gravier St., New Orleans, LA 70130

Our Team

Seth Lewis
SVP Investor Relations, Communications and Strategy

Michael Stumpp, PhD
EVP Projects Molecular Partners

Anne Goubier, DVM, PhD
SVP Biology, Molecular Partners

Philippe Legenne, MD
VP Clinical Development &
External Scientific Relations

Nicolas Leupin, MD, PhD
Chief Medical Officer, Molecular Partners

Agenda

Time	Content	Speaker	Duration
7:30-7:35pm	Intro	Seth Lewis and Nicolas Leupin, MD	05min
7:35-7:40pm	Welcome speakers, some words on MP0533	Nicolas Leupin, MD	05min
7:40-8:15pm	Framing of AML; scene setting; big unmet medical need Some successful targets in AML; Why selecting just one if you can take them all? Clinical Plan for MP0533	Gail Roboz, MD Adrian Ochsenbein, MD Carsten Riether, PhD Nicolas Leupin, MD	10min 10min 10min 05min
8:15-8:40pm	Panel Discussion	all	25min
Followed by	Reception		

Speakers

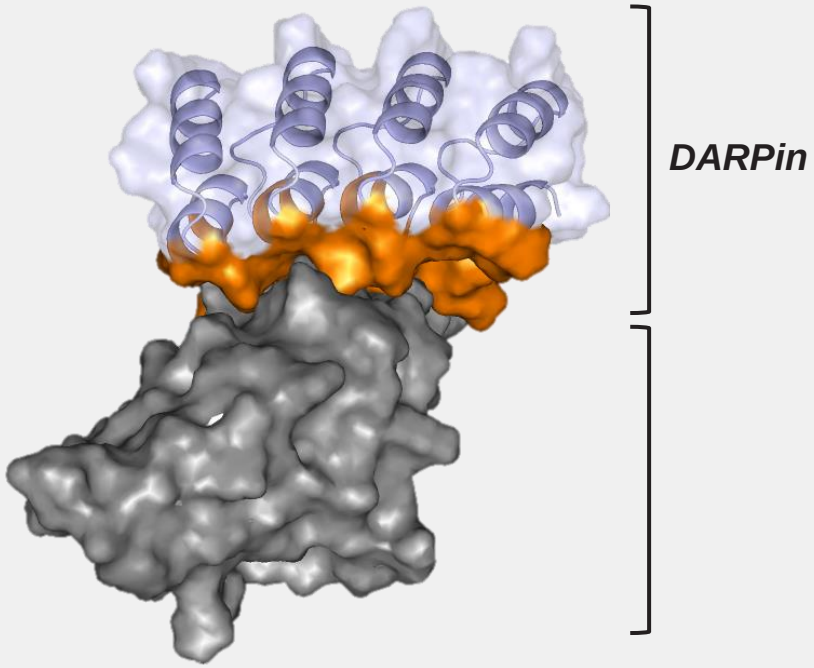
- **Prof. Dr. Gail Roboz, MD**
  - Weill Medical College of Cornell University and the New York - Presbyterian Hospital in New York City
  - Director of the Clinical and Translational Leukemia Program

- **Prof. Dr. Adrian Ochsenbein, MD**
  - University Hospital Bern
  - Head Medical Oncology
  - Department for BioMedical Research (DBMR)

- **Prof. Dr. Carsten Riether PhD**
  - University Hospital Bern
  - Member of Board of Directors of Department for BioMedical Research (DBMR)

DARPins: Multi-specificity-enabled possibilities

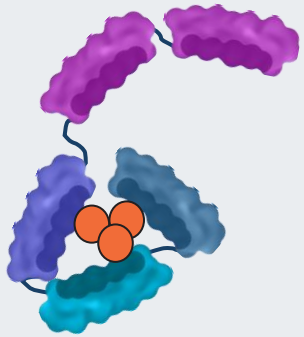
DARPins are binding proteins derived from natural ankyrin repeat proteins



Multi-specificity-enabled possibilities

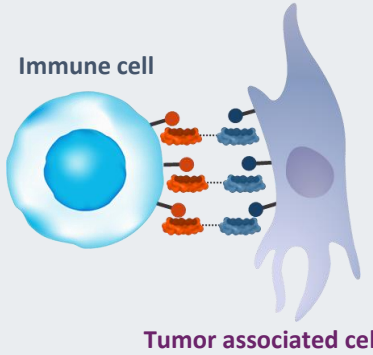
Ensovibep

Multidimensional binding to create superior affinity



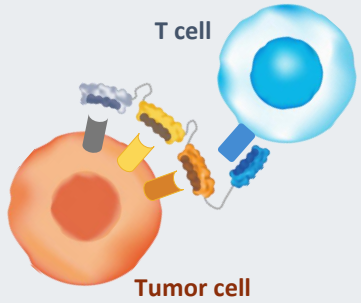
MP0310 & MP0317

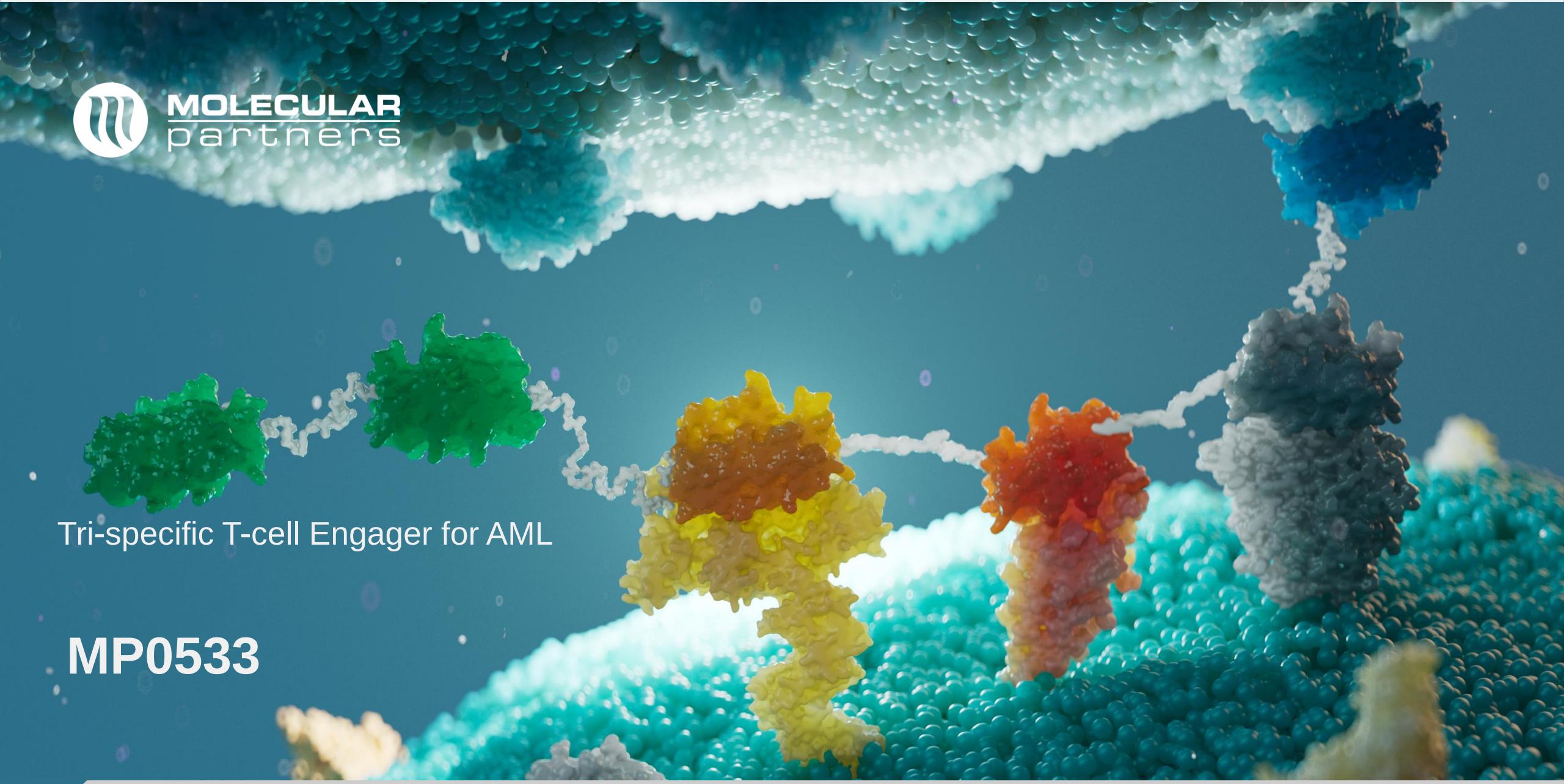
Tumor localized clustering activates effector cells in tumor



MP0533

Avidity driven TCE for tumor specificity and heterogeneity

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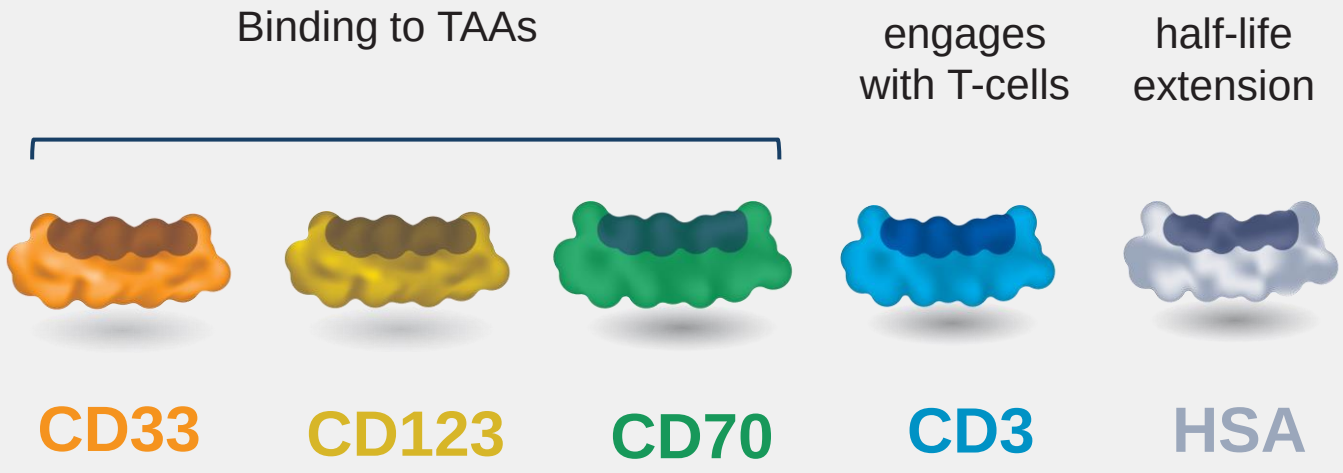
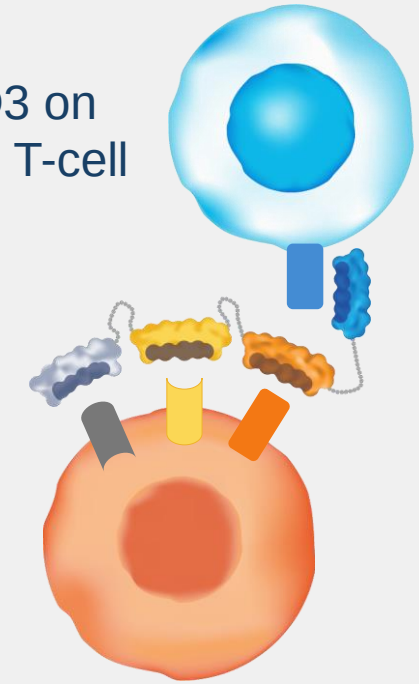
partners
Tri-specific T-cell Engager for AML
MP0533

MP0533 – Avidity-driven Selective Killing of LSC in AML





A Tri-specific T-cell Engager for AML

CD33, CD70, CD123 on the AML blast or LSC

TAA: Tumor associated antigen

MP0533 – Avidity-driven Selective Killing of LSC in AML

Clinical Problem

- **AML remains a deadly disease** for most non-transplant eligible patients
- Persistence of **Leukemic Stem Cells (LSCs)** is the driver of relapse
- Tumor antigens are also expressed on healthy cells, their targeting leading to on-target toxicity

DARPin Solution

- **MP0533**: DARPin binding to **CD33, CD70, CD123** (optimized affinity) and CD3 (T-cell activation)
  - LSC co-express CD33, CD70 and CD123, while healthy cells (HSC) show mostly mono-expression
  - Killing of cells that co-express 2 or more targets, while mono expressing cells are spared
- MP0533 preferentially **kills LSCs** opening a therapeutic window

Reason to believe

- Preclinical data from *ex-vivo* patient samples **demonstrate preferential killing of LSCs**
- ***In vivo* anti tumor activity demonstrated** with limited side effects in mouse model

Next value

- FIH **clinical site initiation underway**. mono-activity expected

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7:40-8:15pm	Framing of AML; scene setting; big unmet medical need	Gail Roboz, MD	10min
	Some successful targets in AML;	Adrian Ochsenbein, MD	10min
	Why selecting just one if you can take them all?	Carsten Riether, PhD	10min
	Clinical Plan for MP0533	Nicolas Leupin, MD	05min
8:15-8:40pm	Panel Discussion	all	25min
Followed by	Reception		

A Quick Introduction to Acute Myeloid Leukemia

Gail J. Roboz, M.D.

Professor of Medicine and Director of the Clinical and Translational Leukemia Program at the Weill Medical College of Cornell University

Acute Myeloid Leukemia (AML)

- AML is the most common acute leukemia in adults and is genetically heterogeneous
- An estimated 69,700 people are living with AML in the United States (2019)
- The 5-year relative survival rate is 30.5%
- Estimates for 2022:
  - 20,050 new cases will be diagnosed
  - 11,540 deaths from AML

Cancer Stat Facts: Leukemia — Acute Myeloid Leukemia (AML). Available at: https://seer.cancer.gov/statfacts/html/amyl.html.

SEER 2021 AML Statistics

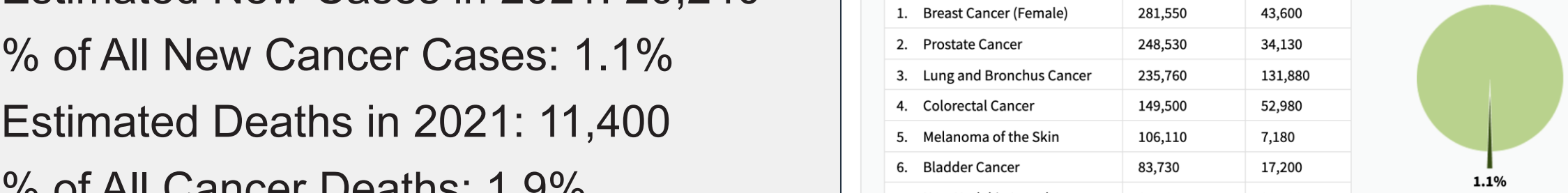
- Estimated New Cases in 2021: 20,240
- % of All New Cancer Cases: 1.1%
- Estimated Deaths in 2021: 11,400
- % of All Cancer Deaths: 1.9%
- **Percent Surviving 5 Years: 29.5%**

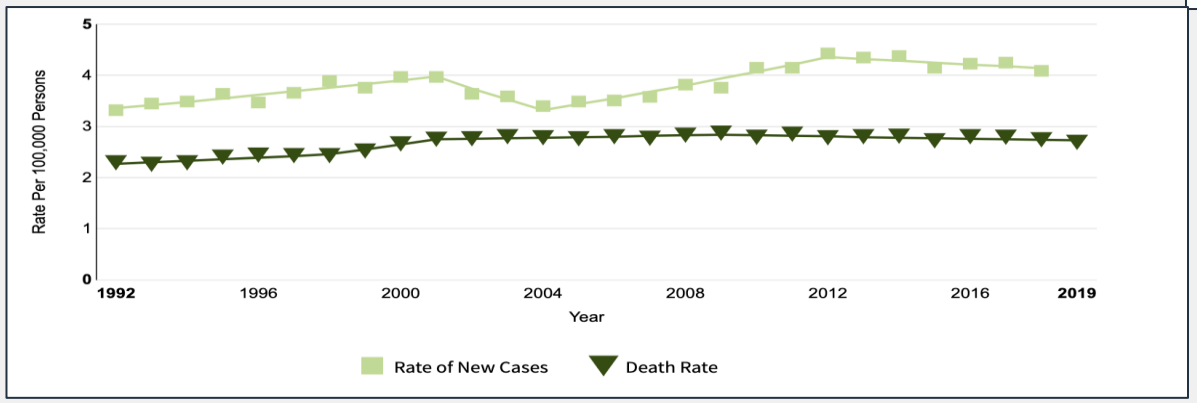
  (2011-2017)

How Common Is This Cancer?

	Common Types of Cancer	Estimated New Cases 2021	Estimated Deaths 2021
1.	Breast Cancer (Female)	281,550	43,600
2.	Prostate Cancer	248,530	34,130
3.	Lung and Bronchus Cancer	235,760	131,880
4.	Colorectal Cancer	149,500	52,980
5.	Melanoma of the Skin	106,110	7,180
6.	Bladder Cancer	83,730	17,200
7.	Non-Hodgkin Lymphoma	81,560	20,720
8.	Kidney and Renal Pelvis Cancer	76,080	13,780
9.	Uterine Cancer	66,570	12,940
10.	Leukemia	61,090	23,660
	-	-	-
	Acute Myeloid Leukemia	20,240	11,400

Acute myeloid leukemia represents 1.1% of all new cancer cases in the U.S.





https://seer.cancer.gov/statfacts/html/amyl.html

Risk Factors & Etiologies

Genetic disorders

- Down syndrome
- Klinefelter syndrome
- Patau syndrome
- Ataxia telangiectasia
- Shwachman syndrome
- Kostman syndrome
- Neurofibromatosis
- Fanconi anemia
- Li-Fraumeni syndrome
- Noonan syndrome

Physical and Chemical Exposures

- Benzene
- Organic solvents
- Pesticides
- Cigarette smoking
- ? Herbicides/Agent Orange
- WTC/9-11 exposure

Nontherapeutic, therapeutic radiation

Chemotherapy

- Alkylating agents
- Topoisomerase-II inhibitors
- Anthracyclines
- Taxanes

Bone marrow failure syndromes

- Dyskeratosis congenita
- Fanconi anemia

Myeloid neoplasms with germ line predisposition

- germ line mutations in CEBPA, DDX41, RUNX1, ANKRD26, ETV6, GATA2, SRP72, 14q32.2 genomic duplication (ATG2B/GSKIP)

Deschler, B., & Lübbert, M. (2006). Acute myeloid leukemia: epidemiology and etiology. *Cancer*, *107*(9), 2099-2107.
Leonard JP, Martin P, Roboz GJ. JCO 2017.

Clinical Presentation

- Minor to life-threatening signs and symptoms
- Present for <3 months in most patients
- Signs/symptoms attributable to bone marrow failure and infiltration of tissues by blasts
- Hepatomegaly, splenomegaly, lymphadenopathy
- Bone pain
- Gingival hyperplasia, oral bleeding
- Leukemia cutis

Current AML Treatment Paradigm

Remission induction: intensive vs. non-intensive

Consolidation

- Cycles of chemotherapy
- Autologous or allogeneic stem cell transplant

Maintenance

Current AML treatments fail to completely eliminate leukemic cells

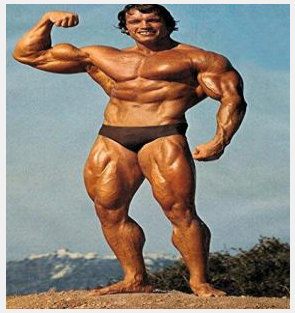
AML

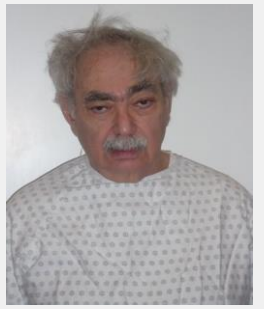
Remission

With measurable residual disease (MRD)

Relapse

Evolving diagnostic and treatment paradigm for Newly Diagnosed AML





Assessment of patient characteristics
(age, comorbidities, performance status, prior exposure to chemotherapy or radiotherapy)

Comprehensive profiling of AML
(morphology, immunophenotype, cytogenetics, molecular analysis)

Patient ELIGIBLE for intensive chemotherapy

- CBF-AML → Intensive chemo + gemtuzumab
- *FLT3* mutation → Intensive chemo + FLT3 inhibitor
- Others → Intensive chemo (i.e. 7+3)
  - Intermediate-risk cytogenetics → Add gemtuzumab
  - IDH1/2 mutation → *Add venetoclax? Add glasdegib?*
- t-AML or AML-MRC → CPX-351

Patient INELIGIBLE for intensive chemotherapy

- *FLT3* mutation → *FLT3 inhibitor +/- HMA*
- All Patients → HMA + venetoclax or LDAC + venetoclax or LDAC + glasdegib
- IDH1/2 mutation → IDH1/2 inhibitor +/- HMA

Add IDH1/2 inhibitor?

SCT and/or Maintenance

Italicized = under investigation

CBF = core binding factor

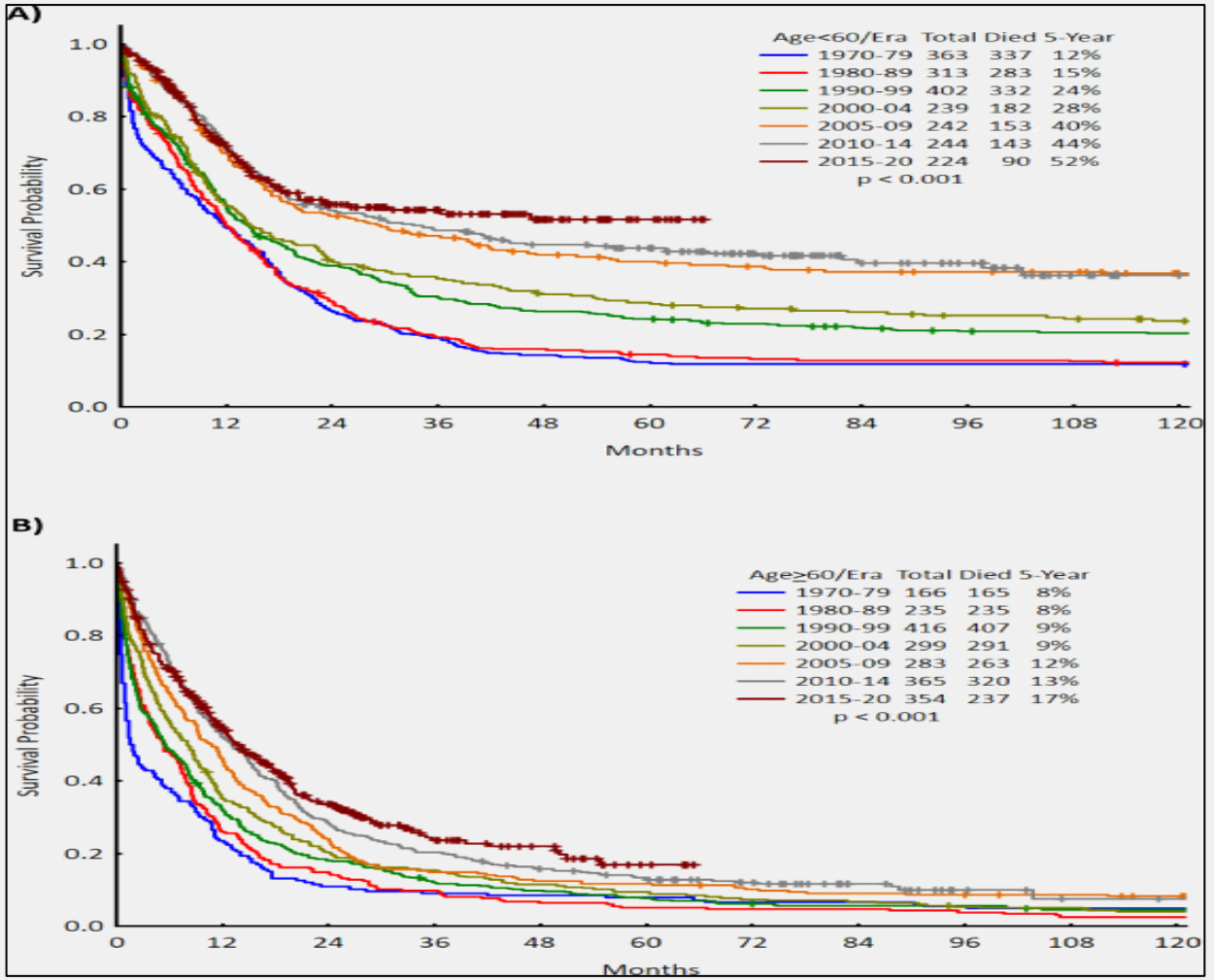
T-AML = therapy-related AML; AML-MRC = AML with MDS related changes

Richard-Carpentier & DiNardo, ASH Education Book 2019.

US and EU Drug Approvals for AML 2017-2020

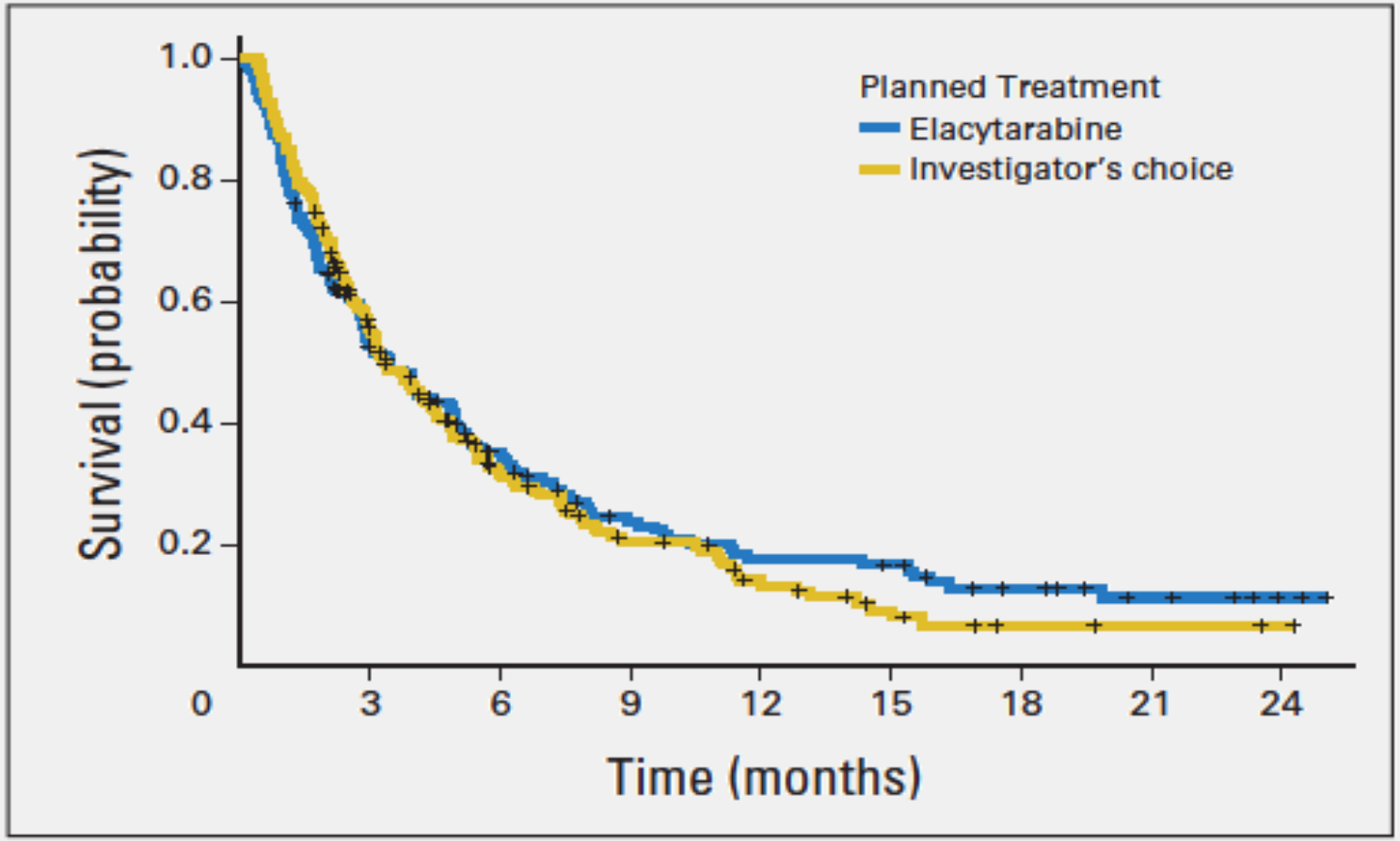
	Target	Approval		
Midostaurin (+IC)	FLT3	ND		
CPX-351	t-AML, AML-MRC	ND		
Enasidenib	IDH2	R/R		
Gemtuzumab ozogamicin (±IC)*	CD33	ND and R/R*		
Ivosidenib	IDH1	ND and R/R		
Glasdegib (+LDAC)	Sonic hedgehog pathway	ND		
Gilteritinib	FLT3	R/R		
Venetoclax (+Aza/Dec/LDAC)†	BCL-2	ND		
CC-486 (oral azacitidine)	Hypermethylation	Maintenance		

Overall Survival of AML over 5 Decades at MD Anderson Cancer Center



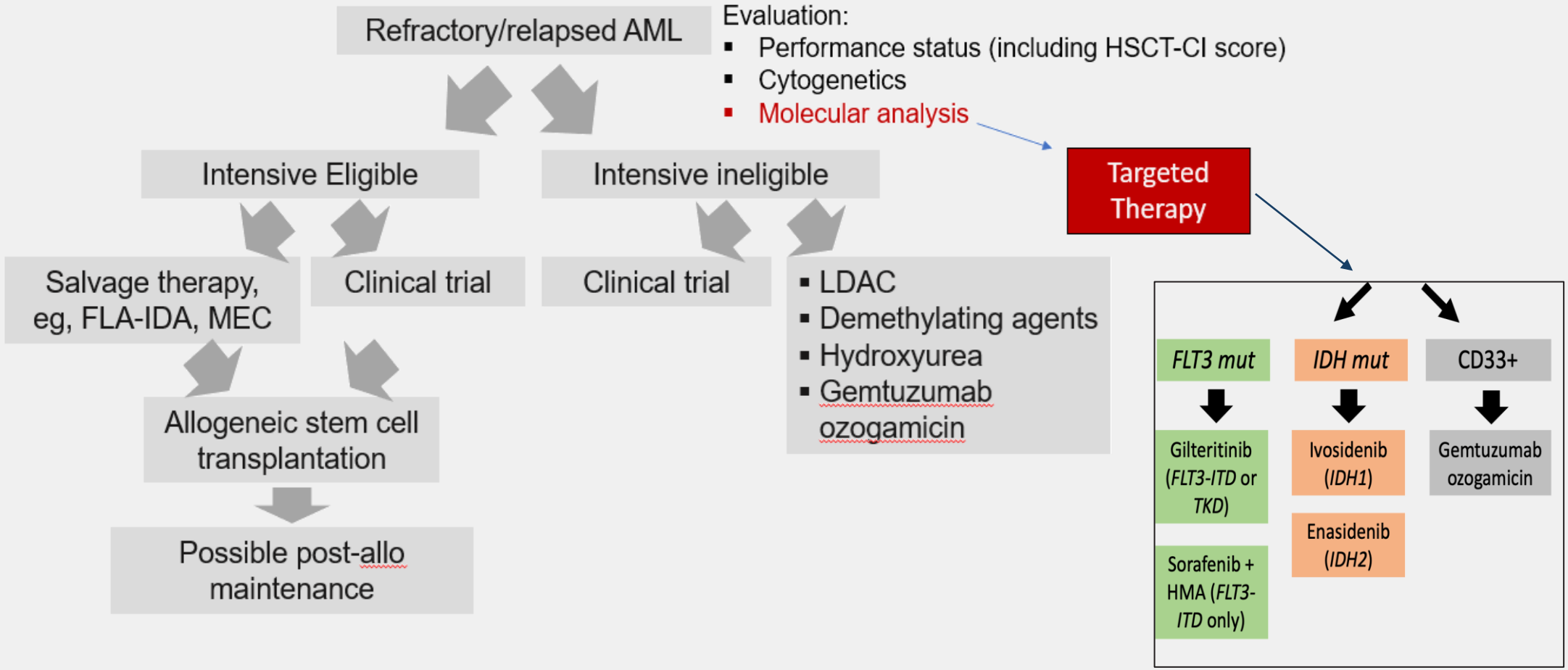
Kantarjian HM, *et al*. *Clin Lymphoma Myeloma Leuk* 2021; **21:**580–597

Randomized Trial of Elacytarabine vs. Investigator's Choice in Relapsed/Refractory AML



Roboz GJ et al. *J Clin Oncol*. 2014;32:1919-1926.

Treatment Algorithm for Relapsed/Refractory Acute Myeloid Leukemia



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Selected Targeted Approaches in AML

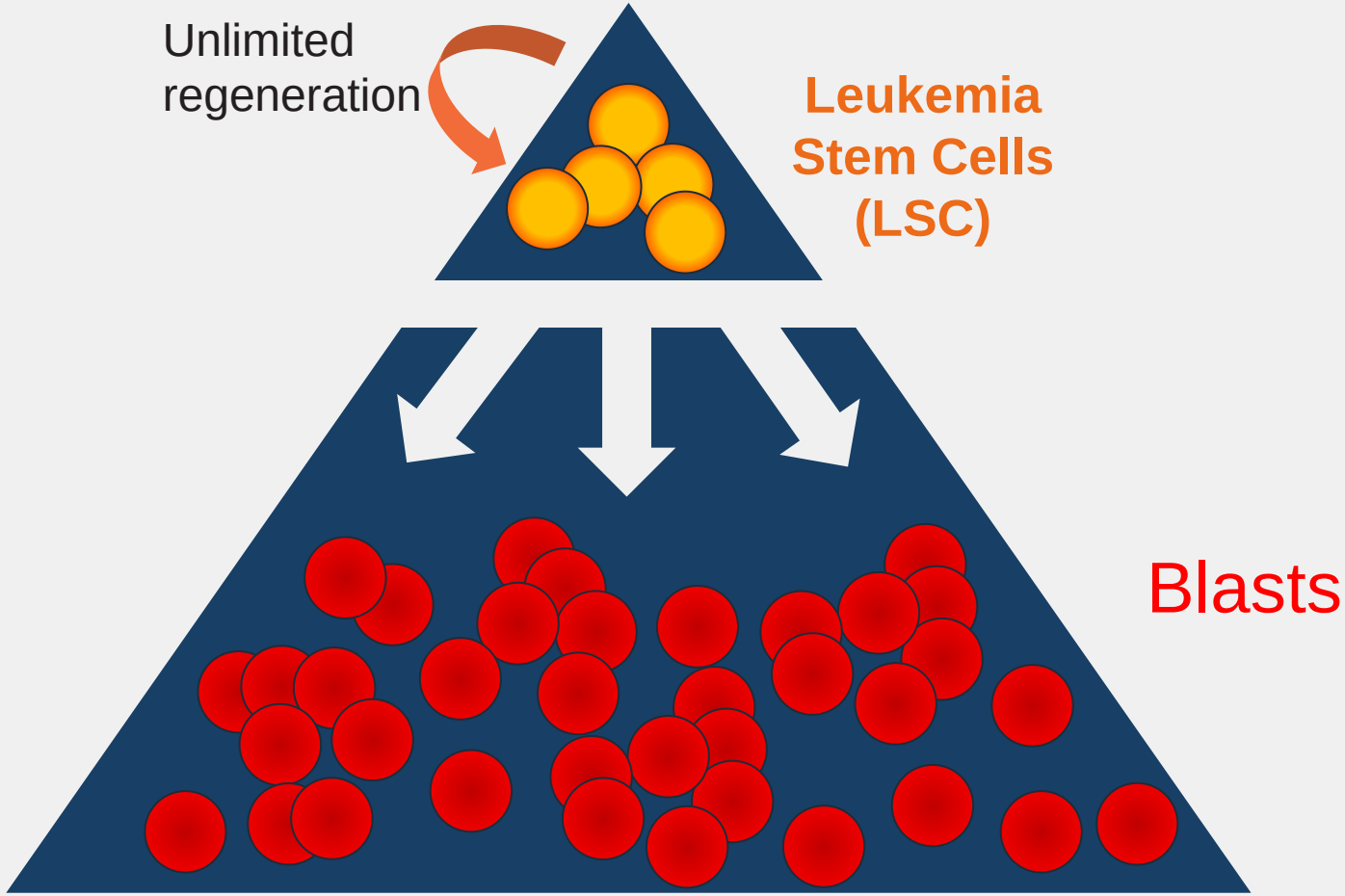
Adrian Ochsenbein, M.D.

Head and Chairman

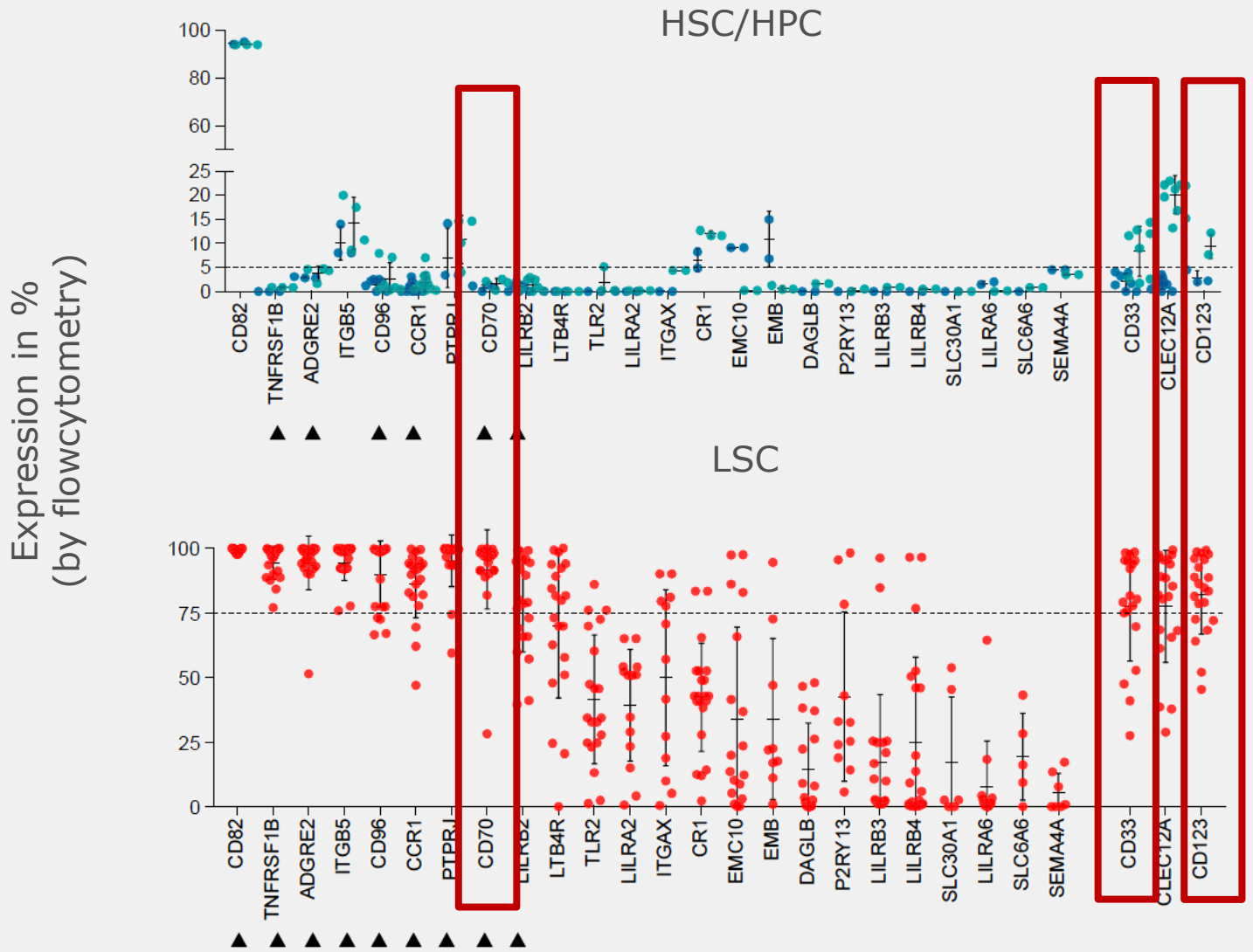
Department of Medical Oncology Inselspital, University Hospital and University of Bern

Potential new targets for the treatment of AML patients.

- Self-renewing
- Therapy-resistant
- Quiescent

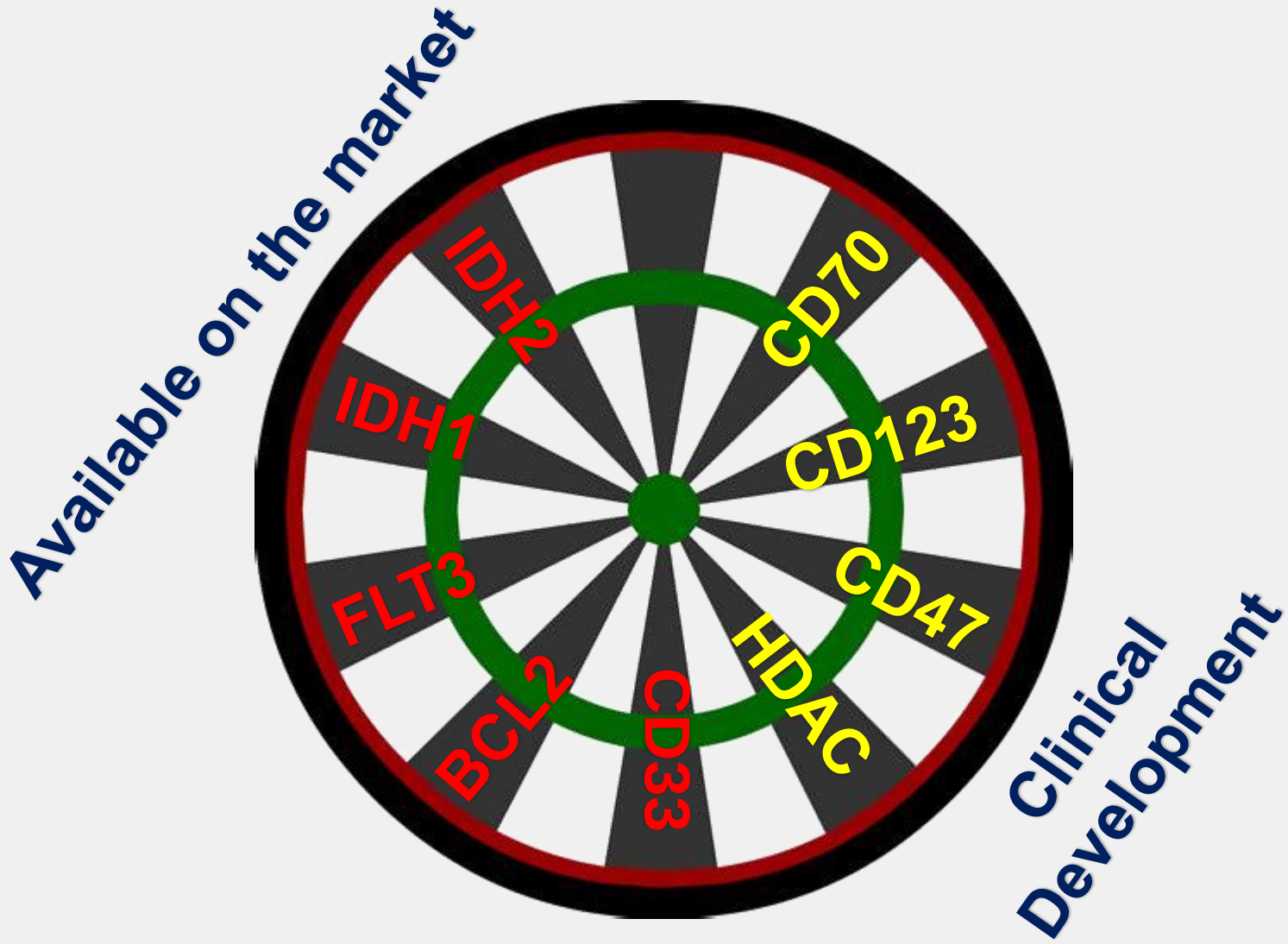


Identification of leukemia stem cell-specific surface proteins in AML



Perna et al. Cancer Cell 2017; 32, 506–519

Identification of leukemia stem cell-specific surface proteins in AML



Targeting CD70 in Non-AML Indications

Year Initiated	Drug	Indication	Efficacy	Phase of Development
2009	MDX-1203	RCC/NHL	69% SD (n=26)	Phase 1: (Completed: Nov. 2012, Development stopped)
2009	SGN-75	CD70 +NHL/RCC	2% CR, 3% PR, 35% SD (n=58)	Phase 1: (Completed: Nov. 2011, Development stopped)
2012	AMG-172	RCC	5% PR, 16% SD (n=37)	Phase 1: (Completed: Nov. 2012, Development stopped)
2013	Cusatuzumab	CD70+Neoplasms	Dose escalation: 54% SD (n=26) CTCL cohort expansion: 4% CR, 19% PR, 35% SD (n=26)	Phase 1/2 (Completed: Jul. 2020)
2014	SGN-CD70A	CD70+ NHL/RCC	RCC: 6% PR, 72% SD (n=18) NHL: 5% CR, 15% PR, 30% SD (n=20)	Phase 1: (Completed Feb. 2017, Development stopped)
2015	Cusatuzumab	Advanced NPC	Evaluable patients: 29% SD (n=7)	Phase 1: (Completed: Apr. 2018)
2017	Anti-human CD70	CD70+ Neoplasms	-	Phase 1/2: (Trial suspended, Exp. completion: Jan. 2027)
2017	4SCAR70	B-cell malignancies	-	Phase 1/2: (Recruiting, Completed: Jul. 2019)
2020	4SCAR70	BCL	-	Phase 1/2: (Recruiting, Exp. Completion: Jul. 2023)
2020	CTX130	RCC	-	Phase 1: (Recruiting, Exp. Completion: Feb. 2027)
2020	CTX130	TCL	-	Phase 1: (Recruiting, Exp. Completion: Mar. 2027)
2021	ALLO 316	RCC	-	Phase 1: (Active, not recruiting, Exp. Completion: Dec. 2022)

Flieswasser T, J Exp Clin Cancer Res 2022

Targeting CD70 for AML

Year Initiated	Drug	Indication	Efficacy	Phase of Development
2016	Cusatuzumab	AML/MDS	67% CR, 83% CR+Cri (n=12)	Phase 1/2: (Active, not recruiting. Exp. completion: Apr. 2022)
2019	Cusatuzumab	AML	27% CR, 40% CR+Cri (n=52)	Phase 2: (Active, not recruiting, Exp, completion: Dec. 2022)
2019	Cusatuzumab	AML	45.5%, CR, 77% CR+Cri (n=44)	Phase 1: (Active, not recruiting, Exp, completion: Nov. 2021)
2020	Cusatuzumab	AML	-	Phase 1: (Completed: Jul. 2021)
2020	SEA-CD70	MDS/AML	-	Phase 1: (Recruiting, Exp. Completion: Aug. 2023)
2021	CD70 CAR	AML, NHL, MM	-	Phase 1: (Recruiting, Exp. Completion: Jan. 2024)

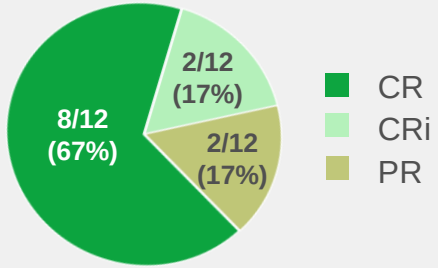
Flieswasser T, J Exp Clin Cancer Res 2022

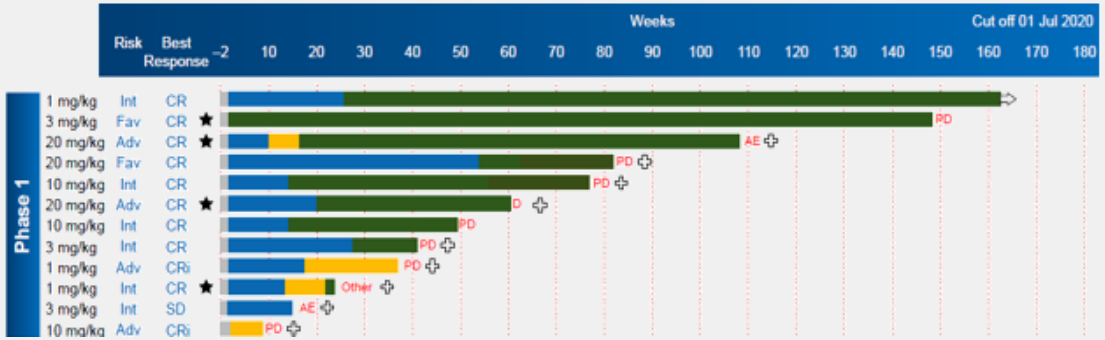
Targeting CD70

Targeting CD70 is a Very Promising Approach

However, Fracticide and On-target/Off-Tumor Toxicity Remain a Key Challenge

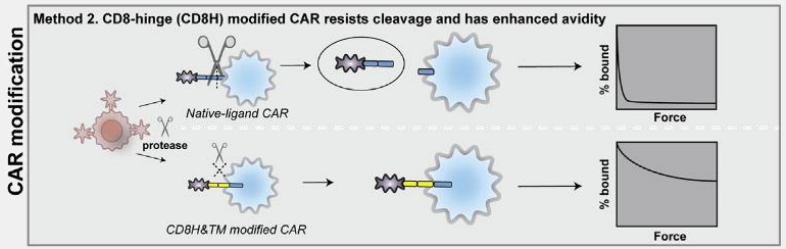
ADCC-enhanced Ab (Cusatuzumab)





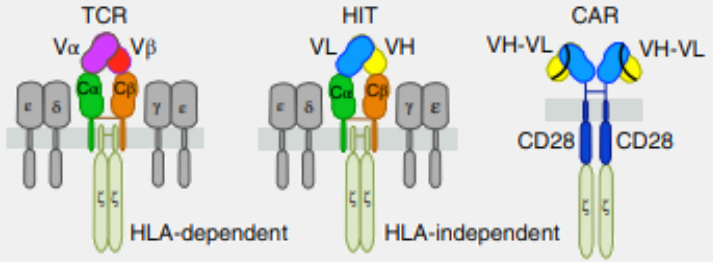
*Riether C, **Nat. Med.** 2020*

Improved CAR-T cells



Hinge modified CAR T cells

Leick MB, Cancer Cell. 2022



HLA-indendent T cell receptors (HIT)

Mansilla-Soto J, Nat Med. 2022

Targeting CD123

Challenge: On-Target, Off-Tumor Toxicity"

Expression:

- On blasts and LSCs > 90% of patients"
- On virtually all healthy myeloid and progenitor cells, megakaryocytes, B cell subsets as well as endothelial cells.

Drug	Composition and mode of action	Phase of Development
Tagraxofusp (formerly SL-401, DT388IL3)	Diphtheria toxin/IL-3 fusion protein	Phase 1/2
Talacotuzumab (formerly CSL362)	Anti-CD123 mAb	Phase 2/3
KHK2823	Humanized anti-CD123 mAb	Phase 1
IMGN632	CD123-targeted ADC	Phase 1/2
SGN-CD123A	CD123-targeted ADC	Phase 1
Flotetuzumab (formerly MGD006)	Anti-CD123 and -CD3 bispecific mAb	Phase 1/2
APVO436	CD123 and CD3ε bispecific antibody	Phase 1
JNJ-63709178	Humanized anti-CD123 and anti-CD3 bispecific antibody	Phase 1
XmAb14045 antibody with XmAb® Fc domain	Anti-CD123 and anti-CD3 bispecific mAb	Phase 1
CD123-targeted CAR T cells	T cells expressing CD123-specific CAR	Phase 1/2 studies

Targeting CD33

Challenge: On-Target, Off-Tumor Toxicity"

Expression:

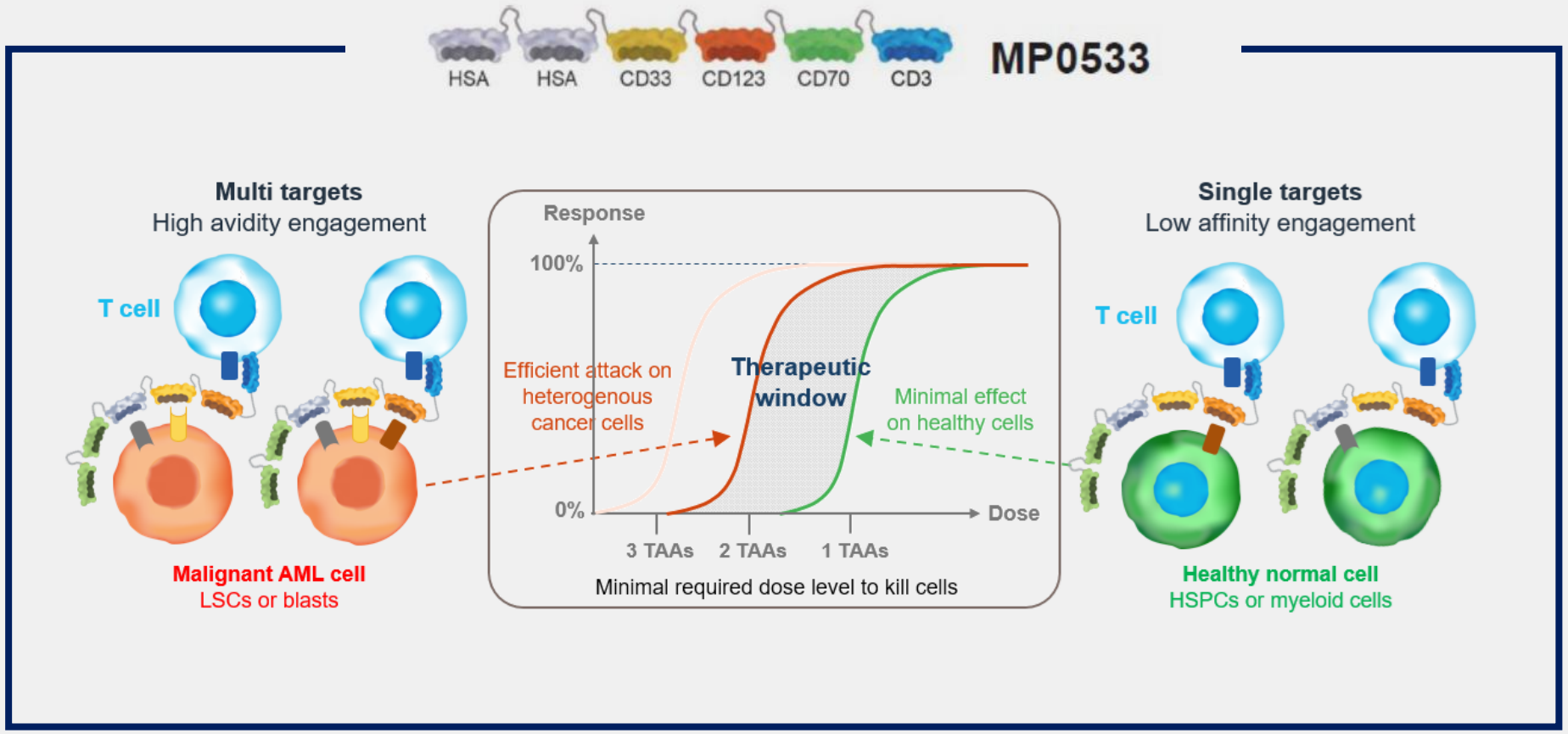
- On blasts and LSCs > 90% of patients"

- On virtually all healthy myeloid and progenitor cells, megakaryocytes, B cell subsets as well as endothelial cells.

Drug	Composition and Mechanism of Action	Phase of Development
Gemtuzumab ozogamicin	ADC-hP67.6 linked via the AcBut linker to a calicheamicin derivative	FDA approved VOD black box warning; currently in development in combination
IMGN77961	ADC-Z4618A linked via sulfo-SPD to indolinobenzodiazeprine pseudodimers	Phase I completed enrolling
BI 836858	ADCC - FcyRilla	Phase 1/2 completed enrolling
Lintuzumab-Ac225	Radioisotope conjugate-HuM195 linked to Ac225	Phase 1/2 completed enrolling
JNJ-67371244	CD33/CD3 BITE	Phase I currently enrolling
AMG 330	CD33/CD3 BITE	Phase I currently enrolling
AMV564	CD33/CD3 Tandem Diabodies	Phase I not currently enrolling
161533 TriKE	Trispecific killer engager	Phase 1/2 completed enrolling
CD33 CAR-T	CD33-specific T cells	Phase 1/2 completed enrolling
Vadastuximab talirine	ADC-h2H12ec linked to a pyrrolobenzodiazepine dimer via maleimidocaproyl-valine-alanine druglinker	Terminated development
AVE9633	ADC-huMy9 linked to maytansinoid derivative via a disulfide bond	Terminated development
Lintuzumab	ADCC - HuM195	Terminated development

ADC, antibody-drug conjugate; ADCC, antibody-directed cellular cytotoxicity;
BiTE, bispecific T-cell engager; TriKE, trispecific killer engager; VOD, veno-occlusive disease.

Targeting CD33/CD123/CD70 in AML



will be presented at ASH 2022

UNIVERSITÄT BERN

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BERN UNIVERSITY HOSPITAL

Why selecting just one if you can take them all?

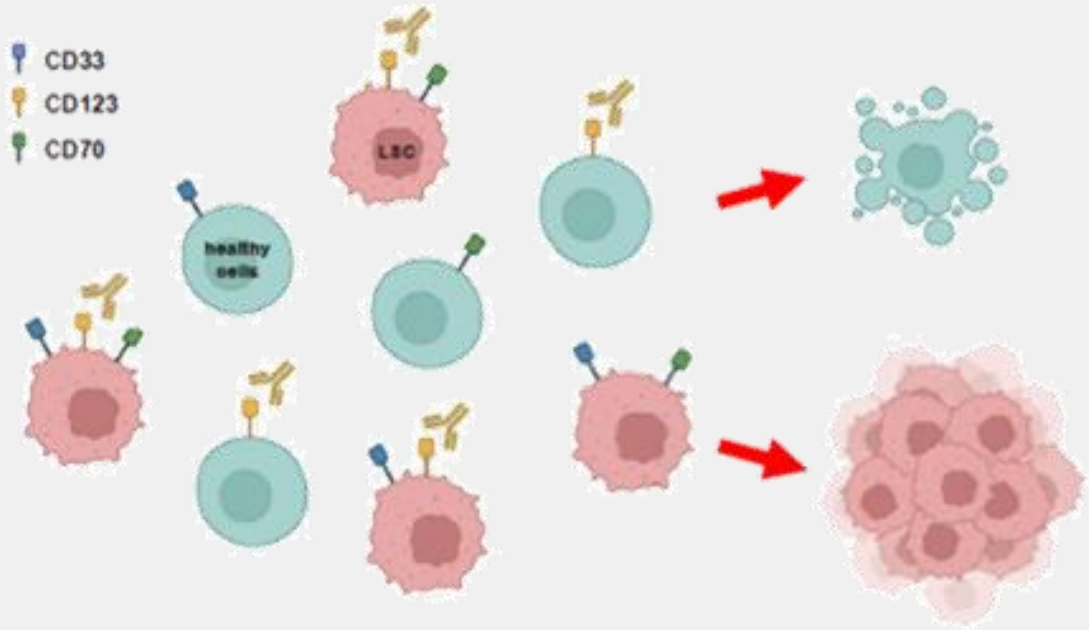
Carsten Riether, PhD

Professor

Head of Research at the Department of Medical Oncology,

Inselspital, University Hospital and University of Bern

Heterogenous expression of target antigens on LSCs in AML: Current Problem



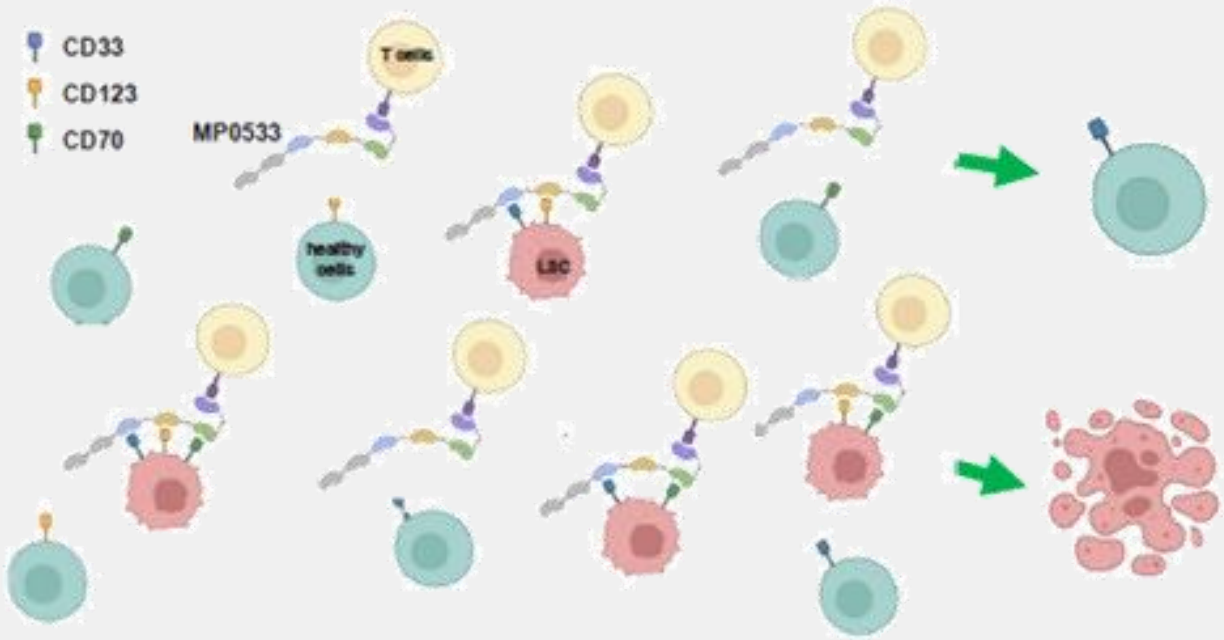
Mono-targeting agents also kill healthy cells

→ Adverse Events, DLT

Mono-targeting agents do not kill all LSCs

→ Recurrence of disease

Heterogenous expression of target antigens on LSCs in AML: Proposed Solution



MP0533 does not kill healthy cells
→ Therapeutic Window

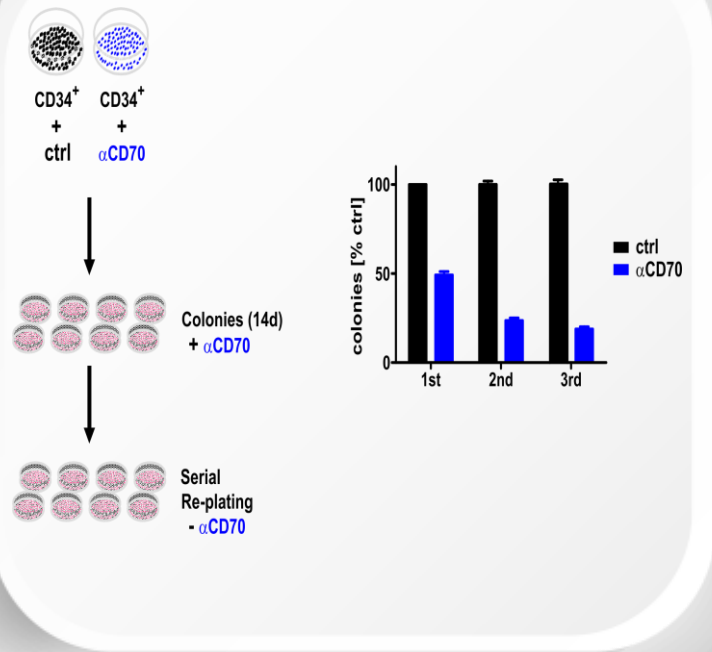
MP0533 kills all LSCs despite Ag heterogeneity
→ Long term disease control

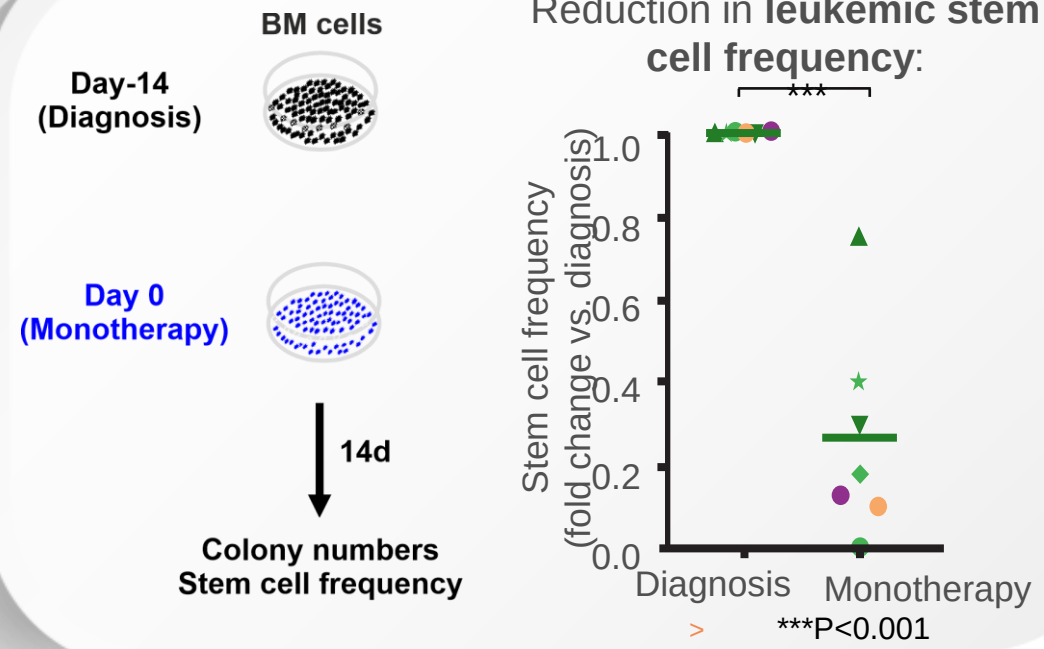
- High avidity engagement when 2-3 target antigens are co-expressed
- Low avidity engagment when only 1 antigen is expressed

How Can We Study the Effect of a Treatment on LSCs?

1. Colony formation assay (ex vivo)
2. Re-platings assays (ex vivo)
3. Gold-standard: Patient-derived xenograft model
4. Next-generation RNA sequencing analysis

Blockade of CD70/CD27 signalling reduces Stem Cell Frequency





Riether et al. J Exp Med; 214, 359-380

Riether et al. Nat Med 2020; 26, 1459 - 1467

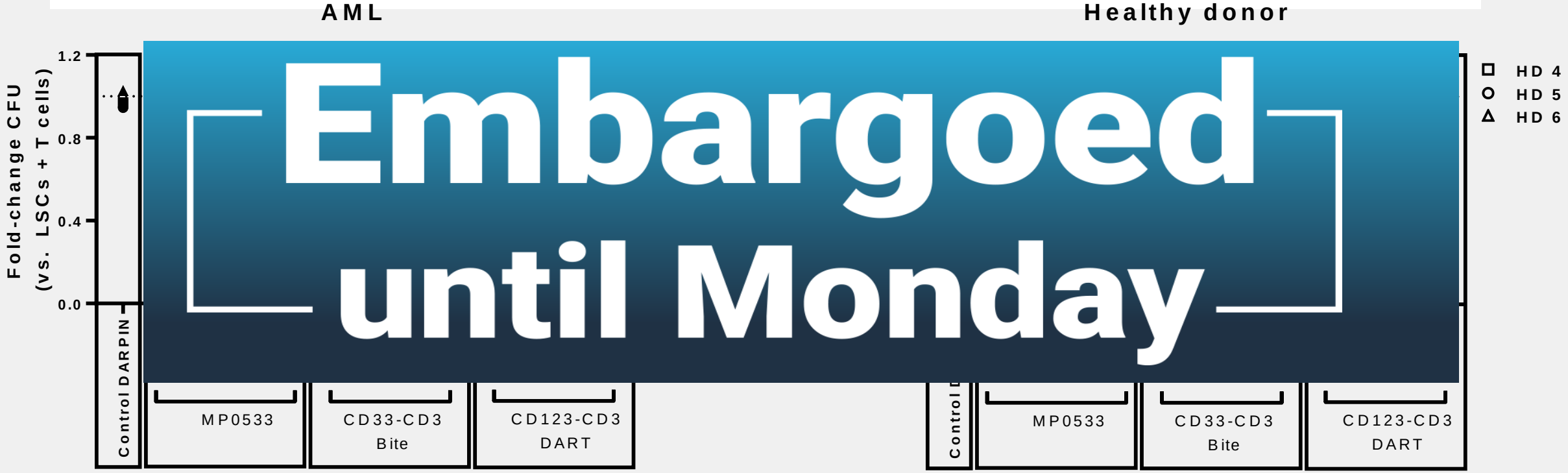
MP0533 reduces colony formation of AML LSCs

Sorted CD34+ LSC or HSC
+ Healthy donor T cells (E:T = 1:1)

MP0533 or controls

14 days colony forming assay

Counting of Colony Forming Units (CFU)



Agenda

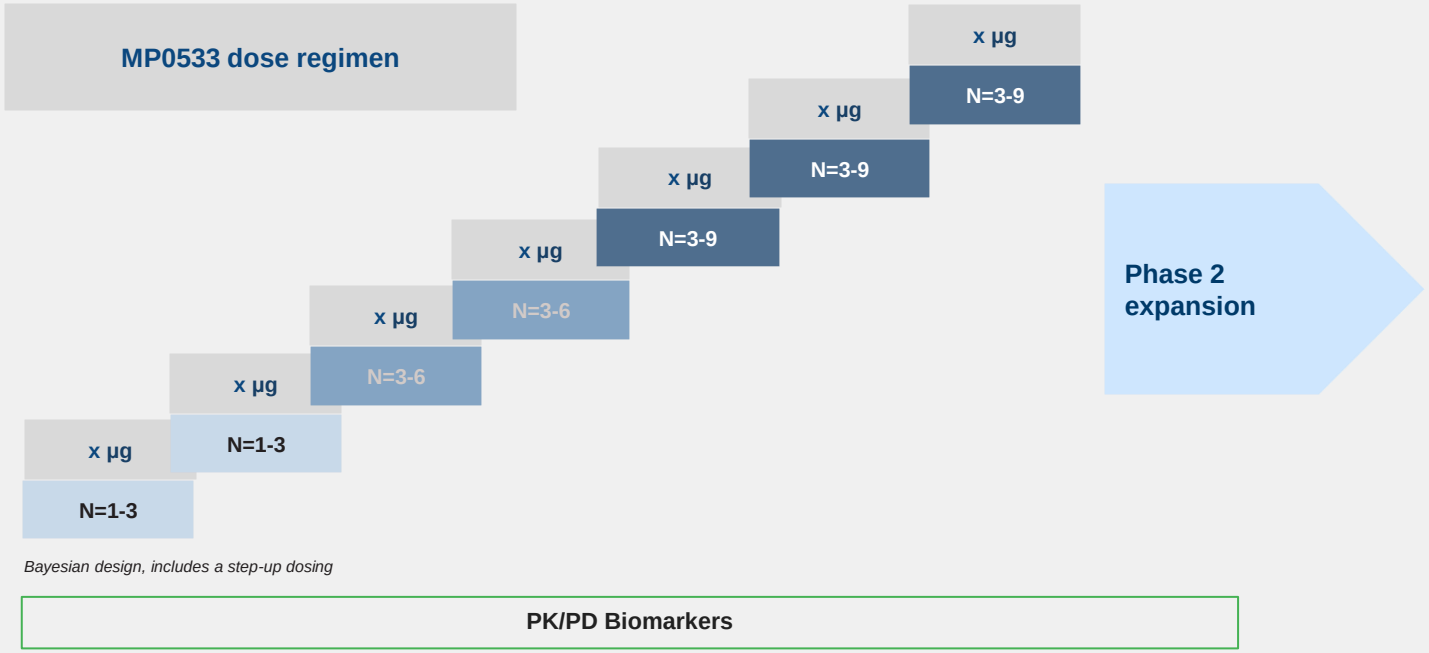
Time	Content	Speaker	Duration
7:30-7:35pm	Intro	Seth Lewis and Nicolas Leupin	05min
7:35-7:40pm	Welcome speakers, intro of MP0533	Nicolas Leupin	05min
7:40-8:15pm	Framing of AML; scene setting; big unmet medical need	Gail Roboz MD	10min
	Some successful targets in AML;	Adrian Ochsenbein MD	10min
	Why selecting just one if you can take them all?	Carsten Riether PhD	10min
	Clinical Plan for MP0533	Nicolas Leupin	05min
8:15-8:40pm	Panel Discussion	all	25min
Followed by	Reception		

Phase I Dose Escalation Trial in R/R AML patients

Patient population: **AML or MDS/AML relapsed/refractory** to HMA, induction CT or allogenic HSCT
N= 20-45 patients

Endpoints:
- DLTs, Safety, Tolerability
- Efficacy, effect on LSCs, PK, T-cell Activation, Cytokine Release

Centers: 5 sites at initiation (Switzerland/ The Netherlands)

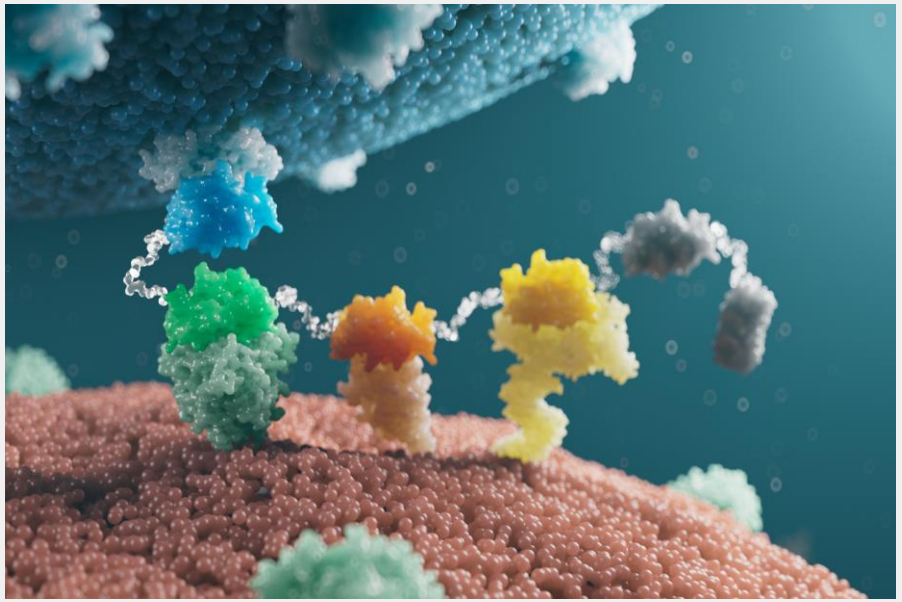


Site initiations ongoing

Abbreviations: CT = chemotherapy; DLT = Dose limiting toxicity; HMA = hypomethylating agent; HSCT = human stem cell transplantation; N = number of patients

MP0533: a Unique DARPin Solution for AML Patients

- Ensure **long term control of the disease** by eliminating LSCs
- **Control tumor heterogeneity** by targeting multiple Ag
- **Increase the therapeutic window**: optimal dose levels for efficacy with limited side effect
  - Limited killing of healthy HSCs
  - Reduced CRS



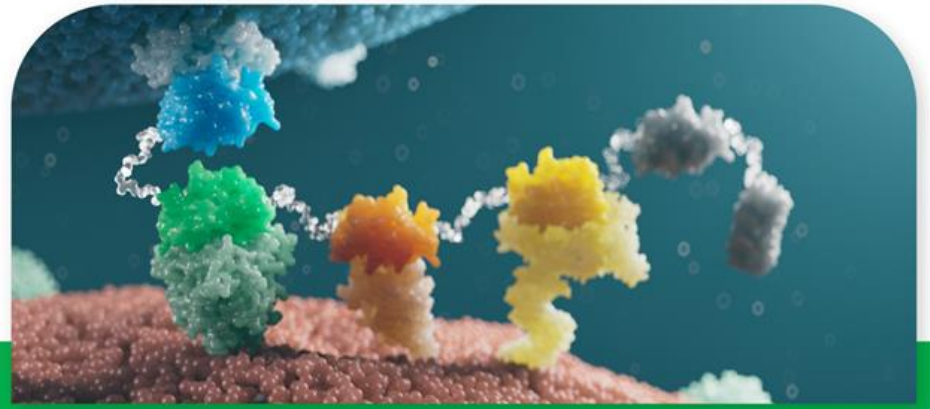
Phase 1, open-label, multicenter dose-escalation study in patients with relapsed/refractory AML and higher-risk MDS- **Sites opening next week!**

Oral Presentation at ASH on Monday

Do not forget!

Session Date	**Monday, December 12, 2022**
Session Time	4:30 PM - 6:00 PM
Session Name	Molecular Pharmacology and Drug Resistance: Myeloid Neoplasms: Immune Signaling and Antibody-therapeutic Targeting in Myeloid Neoplasms
Room	Ernest N. Morial Convention Center, 353-355
Presentation Time	**5:45 PM**
Speaker	**Anne Goubier**
Title	**MP0533: A Multispecific Darpin CD3 Engager Targeting CD33, CD123, and CD70 for the Treatment of AML and MDS Designed to Selectively Target Leukemic Stem Cells**

MOLECULAR PARTNERS TO HOST 64TH ANNUAL ASH MEETING & EXPOSITION RECEPTION



Join us at the Windsor Court Hotel to discuss the details of MP0533, our tetra-specific DARPin candidate for AML.

RECEPTION SPEAKERS:

NICOLAS LEUPIN, M.D.
Chief Medical Officer at Molecular Partners

CARSTEN RIETHER, PH.D.
Associate Professor, Principal Investigator and Head of Research at the Department of Medical Oncology, Inselspital, University Hospital and University of Bern

GAIL ROBOZ, M.D.
Professor of Medicine and Director of the Clinical and Translational Leukemia Program at the Weill Medical College of Cornell University

ADRIAN OCHSENBEIN, M.D.
Head of Research Group, Ochsenbein Lab and Chairman, Department of Medical Oncology at the University of Bern

CLICK HERE TO RSVP

Saturday, December 10th, 2022 | 7:30-9:30 PM CST
300 Gravier St., New Orleans, LA 70130