Case Studies in Immunotherapy for the Treatment of Acute Leukemia

November 15, 2021

11:30 a.m. – 12:30 p.m. ET

Society for Immunotherapy of Cancer

Cancer Immunotherapy GUIDELINES

The Practical Management Pearls and Case Studies Webinars are part of the Cancer Immunotherapy Clinical Practice Guidelines Advanced Webinar Series supported, in part, by grants from Amgen and Merck & Co. Inc. (as of 9/15/2021).

Webinar faculty

Steven D. Gore, MD – *National Cancer Institute**

Jorge Cortes, MD – *Georgia Cancer Center*

*Dr. Gore is serving in his personal capacity

Learning objectives

- Plan immunotherapy treatment regimens for challenging patient populations
- Identify management strategies for uncommon and/or atypically responsive toxicities
- Select appropriate treatment strategies for patients with relapsed and/or unresponsive acute leukemia
- Articulate the potential risks and benefits for proceeding with any other possible interventions specific to acute leukemia in the context of an immunotherapy treatment plan

Webinar outline

- Development of the guideline
- CAR T cells
- Bispecifics (AML)
- Antibody-drug conjugates
- Key takeaways

Development of the Guideline

Open access Position article and guidelines

Journal for ImmunoTherapy of Cancer

The Society for Immunotherapy of Cancer (SITC) clinical practice guideline on immunotherapy for the treatment of acute leukemia

Michael M Boyiadzis,[1] Ivan Aksentijevich,[2] Daniel A Arber,[3] John Barrett,[4] Renier J Brentjens,[5] Jill Brufsky,[1] Jorge Cortes,[6] Marcos De Lima,[7] Stephen J Forman,[8] Ephraim J Fuchs,[9] Linda J Fukas,[10] Steven D Gore,[11] Mark R Litzow,[12] Jeffrey S Miller,[13] John M Pagel,[14] Edmund K Waller,[15] Martin S Tallman[5]

Development of the Guideline

- Developed according to the Institute of Medicine's Standards for Developing Trustworthy Clinical Practice Guidelines
- Panel consisted of 17 experts in the field
- Recommendations are based upon published literature evidence, or clinical evidence where appropriate
- Consensus was defined at 75% approval among voting members

Webinar outline

- Development of the guideline
- CAR T cells (new approvals in adults)
- Bispecifics (AML)
- Antibody-drug conjugates
- Key takeaways

Case 1: CAR T (new approvals in adults)

- 42 year old female
- Diagnosed with ALL with t(4;11); no CNS leukemia
- Received HCVAD; CR after 1 cycle
  - MRD+ after induction
- Relapse after 4 cycles of therapy
- Received FLAG-Ida with no response
- Inotuzumab ozogamicin: no response after 2 cycles
- POMP x1 cycle to bridge to CART cells
- Initiated lymphodepletion followed by Brexucabtagene autoleucel (Tecartus)

POLL QUESTION

What treatment would you consider now?

a) Blinatumomab
b) Brexucabtagene autoleucel
c) Stem cell transplant
d) Pediatric chemotherapy regimen
e) Supportive care only

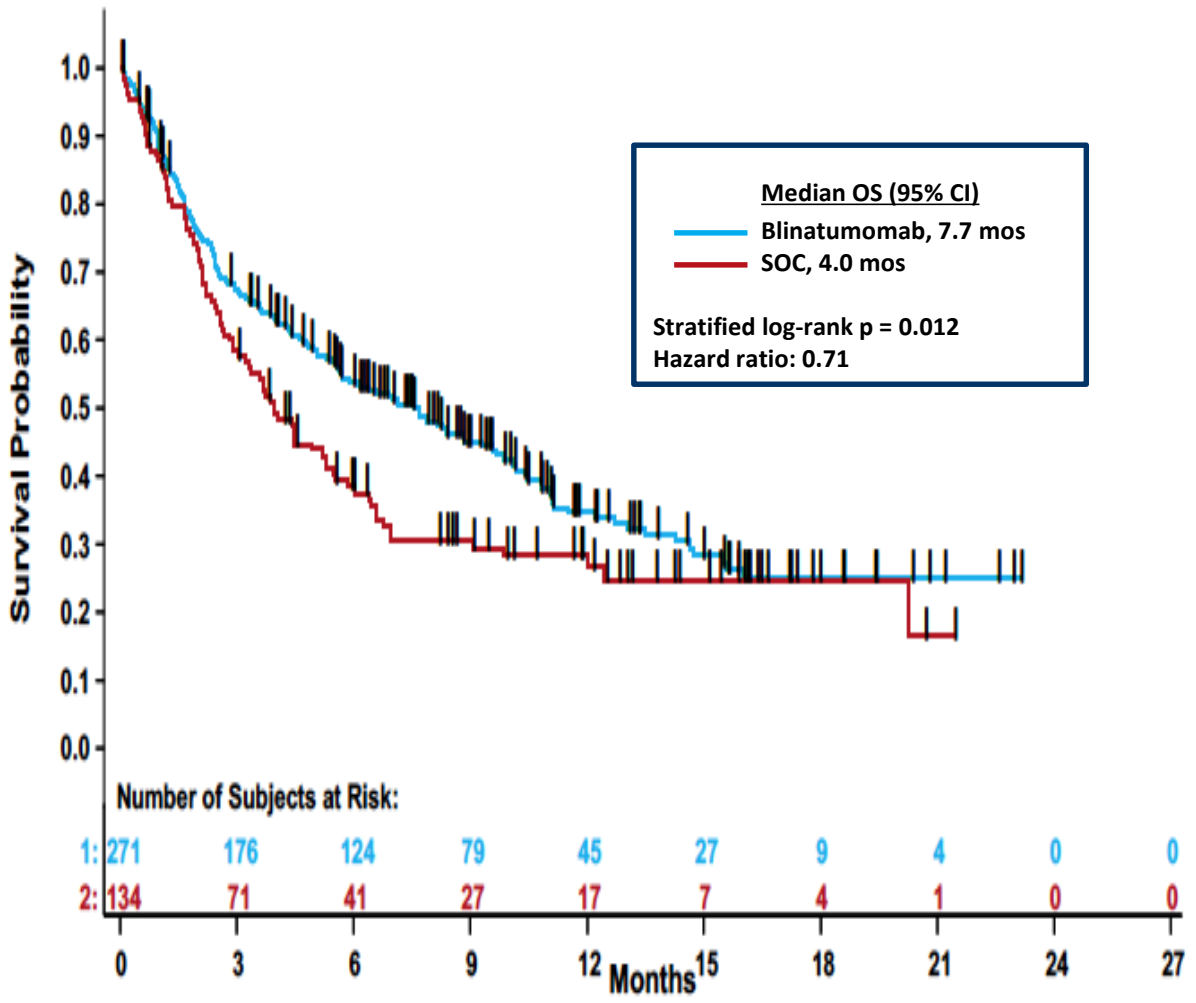
Case 1: CAR T (new approvals in adults)

- POMP x1 cycle to bridge to CART cells
- Initiated lymphodepletion with fludarabine
- Received Brexucabtagene autoleucel (Tecartus)

Blinatumomab or Inotuzumab vs Standard Chemotherapy in R-R ALL

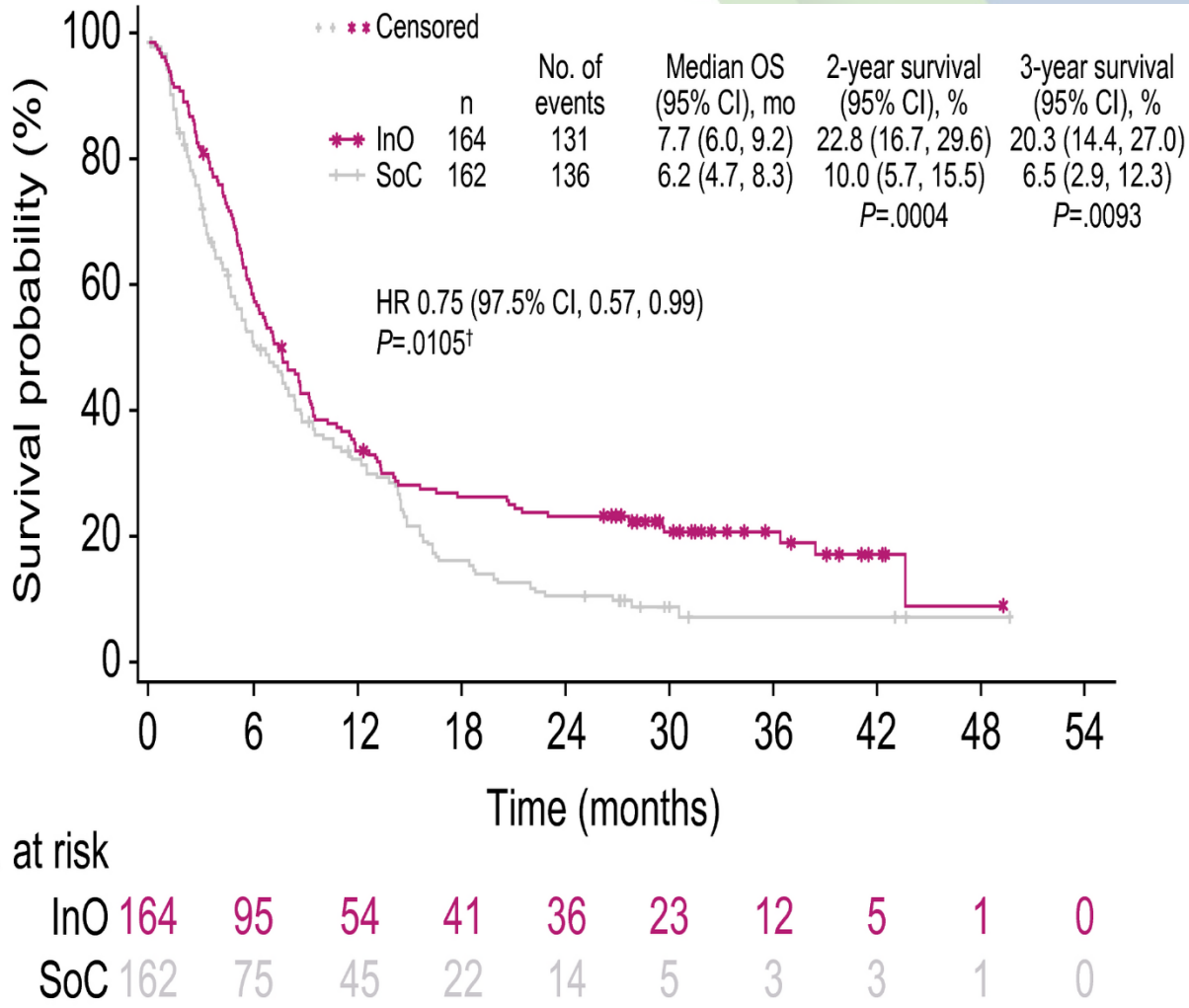
Marrow CR:

Blina vs SOC: 44% vs 25%



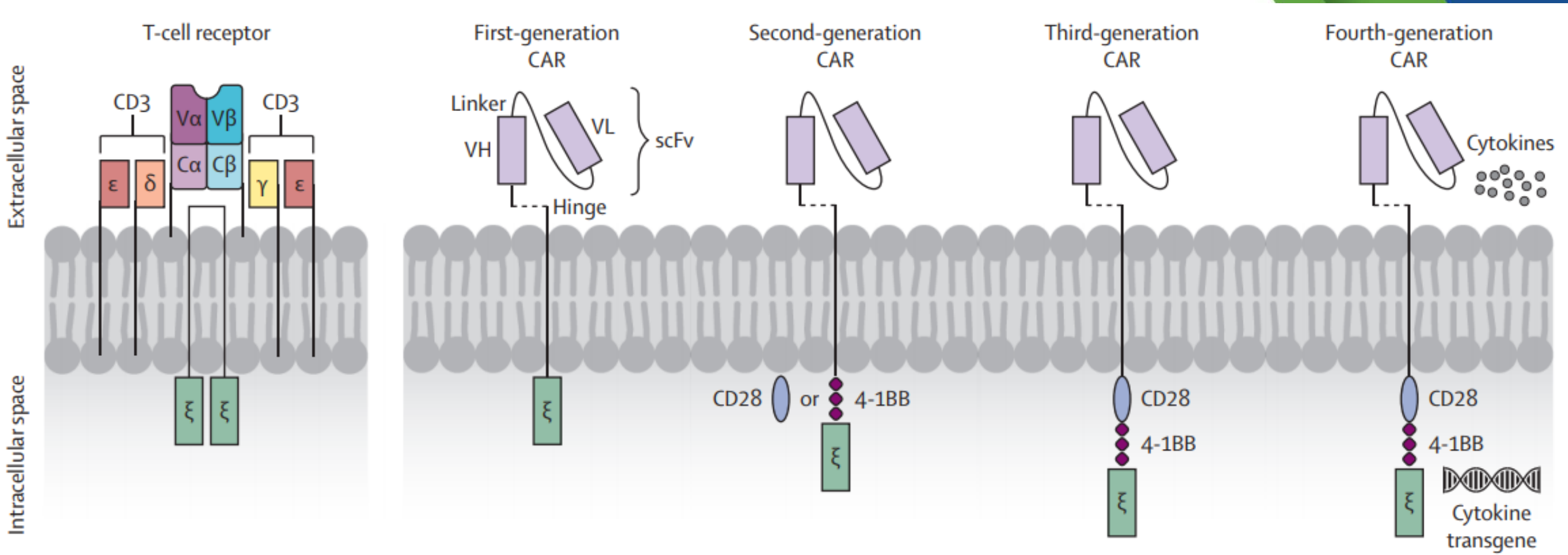
Kantarjian et al. NEJM 2017; 376: 836-47

Ino vs SOC: 74% 31%



Kantarjian et al. NEJM 2019; 375: 740

Antigen Targets in CAR-T Trials



Singh et al. Lancet Oncol. 2020 Mar;21(3):e168-e178.

CAR T development: From discovery to FDA approval

Discovery to FDA approval ~25 years

Dec 01, 1989
First Ab-TCR CAR
(Z. Eschhar)

Jan 15, 1993
First scFv-CAR
(Z. Eschhar)

Aug 01, 1995
In vivo demonstration of anti-tumor activity of scFv-CAR
(Hwu, Eschhar, Rosenberg)

Oct 15, 2006
First clinical data with scFv-CAR
(Kershaw, Eschhar, Rosenberg, Hwu)

May 28, 2009
First CD19 CAR in NHL
(Kochenderfer and Rosenberg)

Jul 28, 2010
First clinical data with CD19 CAR (NCI) in NHL
(Kochenderfer and Rosenberg)

Aug 25, 2011
First clinical data with CD19 CAR in CLL
(Porter and June)

Apr 18, 2013
First clinical data with CD19 CAR in ALL
(Grupp and June)

Multicenter ALL / lymphoma trials

FDA approvals
Aug 30, 2017
Kymriah
Oct 18, 2017
Yescarta

Slide Courtesy, Sattva Neelapu, MDACC

Brexucabtagene autoleucel: A new Indication

TECARTUS® (brexucabtagene autoleucel) suspension for intravenous infusion
Initial U.S. Approval: 2020

WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITIES
See full prescribing information for complete boxed warning.

- **Cytokine Release Syndrome (CRS), including life-threatening reactions, occurred in patients receiving TECARTUS. Do not administer TECARTUS to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids (2.2, 2.3, 5.1).**
- **Neurologic toxicities, including life-threatening reactions, occurred in patients receiving TECARTUS, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with TECARTUS. Provide supportive care and/or corticosteroids, as needed (2.2, 2.3, 5.2).**
- **TECARTUS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program (5.3).**

----------RECENT MAJOR CHANGES----------

Indications and Usage (1.2)	10/2021
Dosage and Administration (2.1, 2.2)	10/2021
Warning and Precautions, Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (5.4)	10/2021
Warning and Precautions, Severe Infections (5.6)	02/2021

----------INDICATIONS AND USAGE----------

TECARTUS is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:

- Adult patients with relapsed or refractory mantle cell lymphoma (MCL).
  This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
- Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

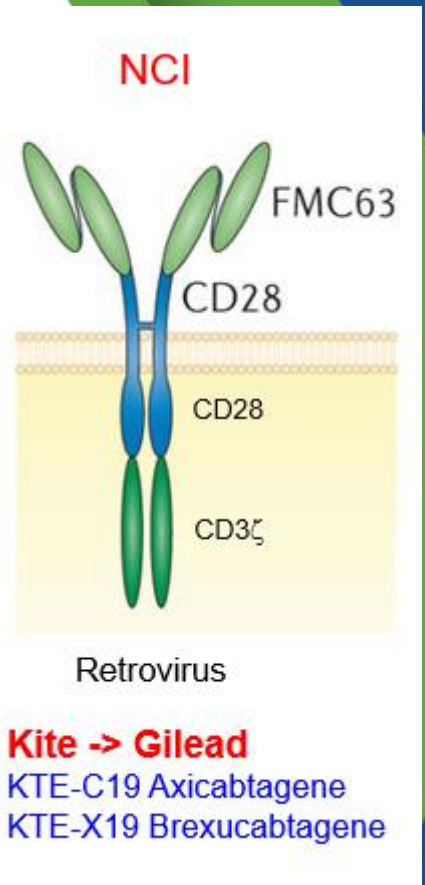
Tecartus (brexucabtagene autoleucel) prescribing information

KTE-X19 for relapsed or refractory adult B-cell acute lymphoblastic leukaemia: phase 2 results of the single-arm, open-label, multicentre ZUMA-3 study

Bijal D Shah, Armin Ghobadi, Olalekan O Oluwole, Aaron C Logan, Nicolas Boissel, Ryan D Cassaday, Thibaut Leguay, Michael R Bishop, Max S Topp, Dimitrios Tzachanis, Kristen M O'Dwyer, Martha L Arellano, Yi Lin, Maria R Baer, Gary J Schiller, Jae H Park, Marion Subklewe, Mehrdad Abedi, Monique C Minnema, William G Wierda, Daniel J DeAngelo, Patrick Stiff, Deepa Jeyakumar, Chaoling Feng, Jinghui Dong, Tong Shen, Francesca Milletti, John M Rossi, Remus Vezan, Behzad Kharabi Masouleh, Roch Houot

Lancet 2021; 398: 491–502

- Autologous anti-CD19 CAR-T
- R/R B-ALL aged ≥ 18 yrs with >5% marrow blasts



Shah et al. Lancet. 2021 Aug 7;398(10299):491-502.

KTE-X19 in Adult B-ALL (ZUMA-3)

	Treated patients (n=55)
Overall complete remission or complete remission with incomplete haematological recovery	39 (71%)*
Complete remission	31 (56%)
Complete remission with incomplete haematological recovery	8 (15%)
Blast-free hypoplastic or aplastic bone marrow	4 (7%)
No response	9 (16%)
Unknown or not evaluable†	3 (5%)

Data are n (%). *95% CI 57–82, p<0·0001. †The three patients who were unknown or not evaluable died (at days 8, 15, and 18) before the first disease assessment.

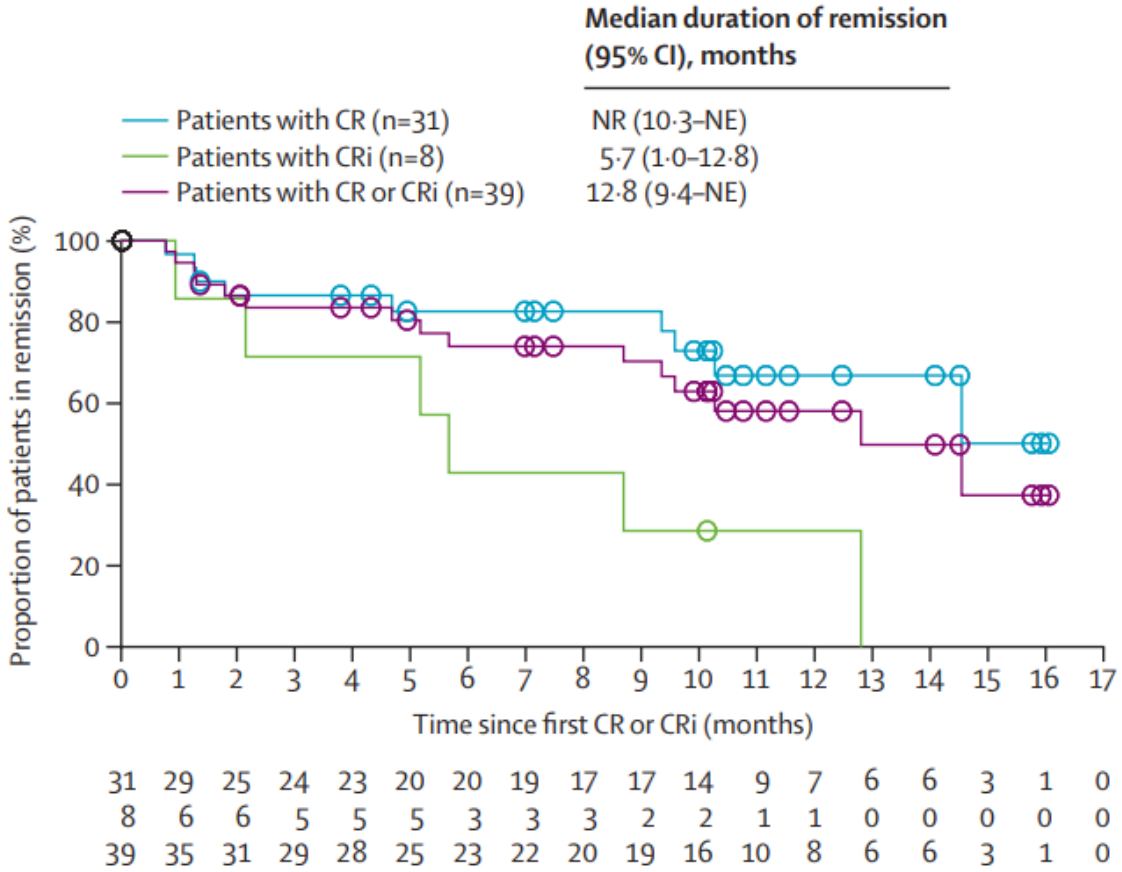
Table 2: **Rate of overall complete remission or complete remission with incomplete haematological recovery based on central assessment**

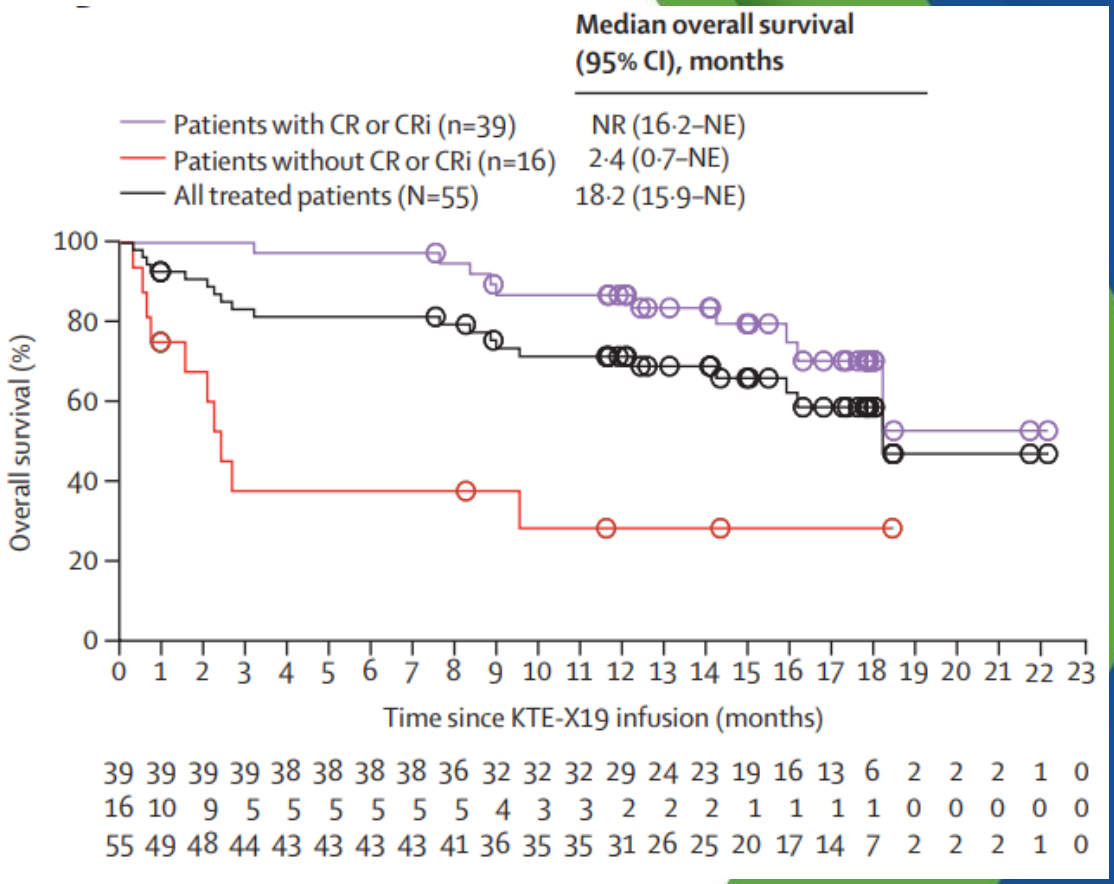
<u>38/39</u> were MRD negative

- 1 pt missed MRD sample

Shah et al. Lancet. 2021 Aug 7;398(10299):491-502.

KTE-X19 in Adult B-ALL (ZUMA-3)



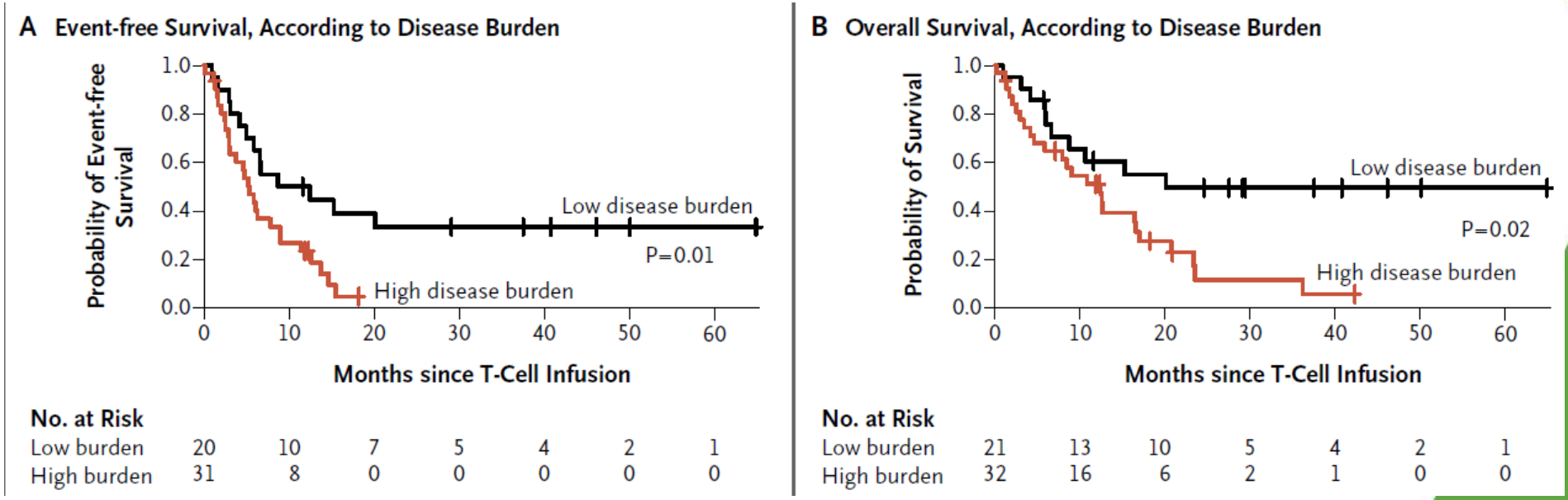


10 pts had a subsequent allo-SCT; Median DOR same with or without censoring for allo-SCT (12.8 months)

Shah et al. Lancet. 2021 Aug 7;398(10299):491-502.

CD19-CD28z CAR (MSKCC) Responses by tumor burden

- High tumor burden
  - BM blasts ≥5% (n=27)
  - BM blasts <5% + EM disease (n=5)
- Low tumor burden (MRD+ disease) (n=21)



Median EFS

Low tumor burden: 10.6 mos

High tumor burden: 5.3 mos

Median OS

Low tumor burden: 20.1 mos

High tumor burden: 12.4 mos

Park et al. NEJM. 2018;378(5):449-459.

KTE-X19 in Adult B-ALL (ZUMA-3) Safety

- Median time to CRS = 5 days
  - Grade ≥3 CRS = 24%
- Median time to ICANS = 9 days
  - Grade ≥3 ICANS = 25%
    - 1 pt died on day 8 from brain herniation
- Median duration of hospitalization after infusion was 22 days and median duration of ICU stay was 5 days
- Toci = 80%
- Steroids = 75%
- Vasopressors = 40%

Shah et al. Lancet. 2021 Aug 7;398(10299):491-502.

Management of CRS

Symptom or sign of CRS	CRS grade 1*	CRS grade 2†	CRS grade 3‡	CRS grade 4‡
Vital signs				
Temperature ≥38 °C (fever)	Yes	Any	Any	Any
Systolic blood pressure <90 mmHg (hypotension)	No	Responds to IV fluids or low-dose vasopressors	Needs high-dose or multiple vasopressors§	Life-threatening
Needing oxygen for SaO_2 >90% (hypoxia)	No	FiO_2 <40%	FiO_2 ≥40%	Needing ventilator support
Organ toxicities‖				
• Cardiac: tachycardia, arrhythmias, heart block, low ejection fraction • Respiratory: tachypnoea, pleural effusion, pulmonary oedema • GI: nausea, vomiting, diarrhoea • Hepatic: increased serum ALT, AST, or bilirubin levels • Renal: acute kidney injury (increased serum creatinine levels), decreased urine output • Dermatological: rash (less common) • Coagulopathy: disseminated intravascular coagulation (less common)	Grade 1	Grade 2	Grade 3 or grade 4 transaminitis	Grade 4 except grade 4 transaminitis

CRS grade	Symptom or sign	Management
Grade 1	Fever or organ toxicity	• Acetaminophen and hypothermia blanket for the treatment of fever • Ibuprofen can be used as second treatment option for fever, if not contraindicated • Assess for infection using blood and urine cultures, and chest radiography • Empiric broad-spectrum antibiotics and filgrastim if neutropenic • Maintenance intravenous (IV) fluids for hydration • Symptomatic management of constitutional symptoms and organ toxicities • Consider tocilizumab 8 mg/kg* IV or siltuximab 11 mg/kg IV for persistent (lasting >3 days) and refractory fever
Grade 2	Hypotension	• IV fluid bolus of 500–1,000 ml of normal saline • Can give a second IV fluid bolus if systolic blood pressure (SBP) remains <90 mmHg • Tocilizumab 8 mg/kg* IV or siltuximab 11 mg/kg IV for the treatment of hypotension that is refractory to fluid boluses; tocilizumab can be repeated after 6 h if needed • If hypotension persists after two fluid boluses and anti-IL-6 therapy, start vasopressors, consider transfer to intensive-care unit (ICU), obtain echocardiogram, and initiate other methods of haemodynamic monitoring • In patients at high-risk† or if hypotension persists after 1–2 doses of anti-IL-6 therapy, dexamethasone can be used at 10 mg IV every 6 h • Manage fever and constitutional symptoms as in grade 1
	Hypoxia	• Supplemental oxygen • Tocilizumab or siltuximab ± corticosteroids and supportive care, as recommended for the management of hypotension
	Organ toxicity	• Symptomatic management of organ toxicities, as per standard guidelines • Tocilizumab or siltuximab ± corticosteroids and supportive care, as indicated for hypotension
Grade 3	Hypotension	• IV fluid boluses as needed, as recommended for the treatment of grade 2 CRS • Tocilizumab and siltuximab as recommended for grade 2 CRS, if not administered previously • Vasopressors as needed • Transfer to ICU, obtain echocardiogram, and perform haemodynamic monitoring as in the management of grade 2 CRS • Dexamethasone 10 mg IV every 6 h; if refractory, increase to 20 mg IV every 6 h • Manage fever and constitutional symptoms as indicated for grade 1 CRS
	Hypoxia	• Supplemental oxygen including high-flow oxygen delivery and non-invasive positive pressure ventilation • Tocilizumab or siltuximab plus corticosteroids and supportive care, as described above
	Organ toxicity	• Symptomatic management of organ toxicities as per standard guidelines • Tocilizumab or siltuximab plus corticosteroids and supportive care, as described above
Grade 4	Hypotension	• IV fluids, anti-IL-6 therapy, vasopressors, and haemodynamic monitoring as defined for the management of grade 3 CRS • Methylprednisolone 1 g/day IV • Manage fever and constitutional symptoms as in grade 1 CRS
	Hypoxia	• Mechanical ventilation • Tocilizumab or siltuximab plus corticosteroids and supportive care, as described above
	Organ toxicity	• Symptomatic management of organ toxicities as per standard guidelines • Tocilizumab or siltuximab plus corticosteroids and supportive care, as described above

Neelapu et al. Nature Reviews Clinical Oncology 2018; 14: 47-62

Webinar outline

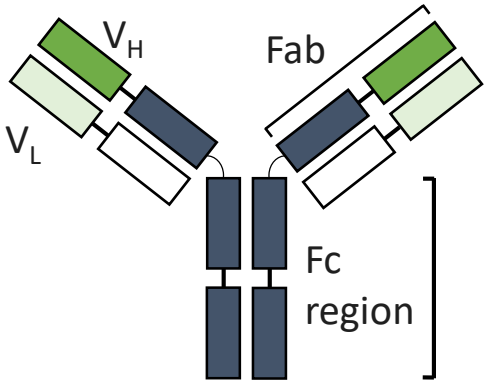
- Development of the guideline
- CAR T cells
- Bispecifics (AML)
- Antibody-drug conjugates
- Key takeaways

Novel Antibodies for AML

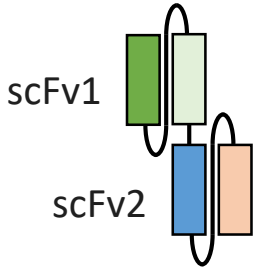
Approach	Target	Examples
Naked	CD123	CSL362
Immunotoxin	CD123	DT-IL3
	CD33	GO, SGN-CD33A, IMGN779
Bivalent	CD33	AMG 330, AMG 673
	CD123	Flotetuzumab, XmAb 14045
Tetravalent	CD33	TandAb
Novel targets	CLEC12A	MCLA-117
	PR1	HuBf4
	EphA3	KB004
	CD98	IGN523

Selected Bispecific Antibody Formats

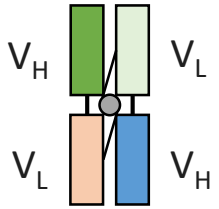
Intact IgG



BiTE

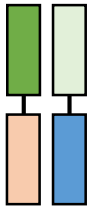


DART

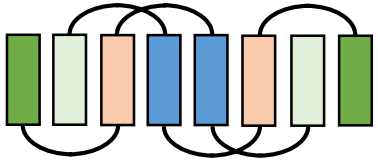


Extra disulfide bond

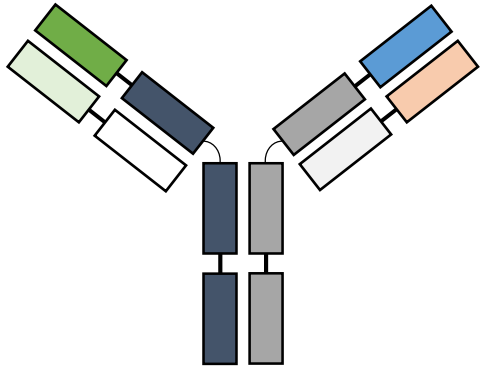
Diabody



Tandem Diabody

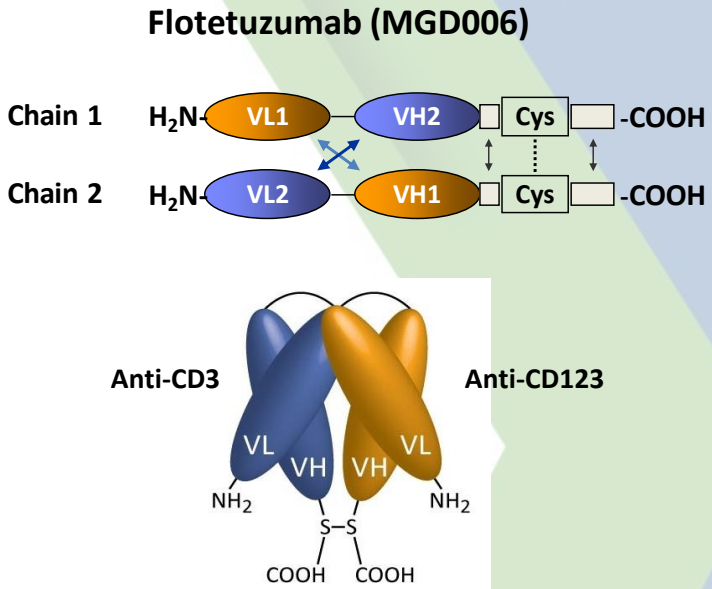


Heterodimeric IgG-Like Bispecific



Flotetuzumab (CD123 x CD3 DART) in R-R AML

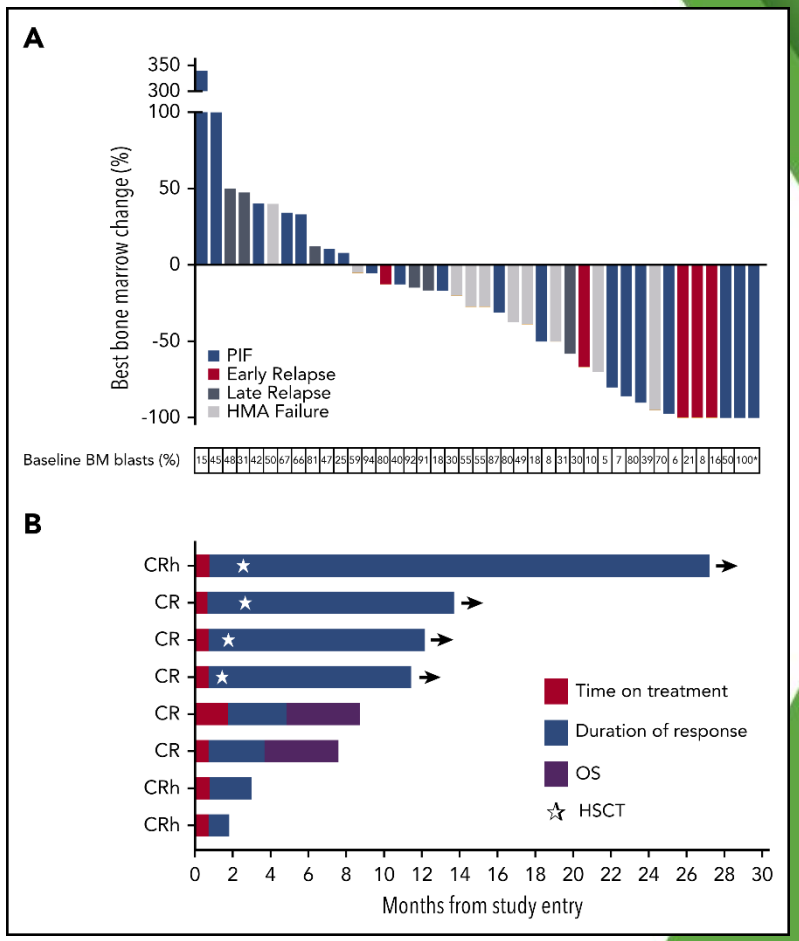
- Bispecific CD3ε and CD123 antibody (dual-affinity re-targeting (DART))
- FLZ 500 ng/kg/D CI x 4 then 4d on/3d off
- 88 adults with R/R AML (42 dose-finding, 46 phase 2)
- Recommended phase 2 dose (RP2D) of 500 ng/kg per day
- Median age 64 yrs
- CRS in 82 pts (3-4 in 7 (8%))
- Grade 3 neurologic effects in 2: 1 headache, 1 delirium (both transient, 1-4 days)
- Mitigation strategies for IRR/CRS: step-up LID schedules, temporary dose reduction or interruption, and prompt use of tocilizumab.



Uy et al. Blood 137(6):751-762

Flotetuzumab for refractory acute myeloid leukemia

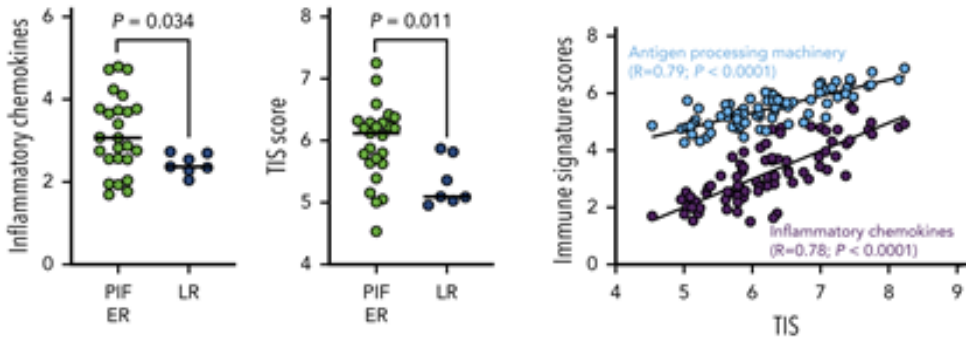
	R/R AML, % (n) n = 50	PIF/ER AML, % (n) n = 30
CR	12.0 (6)	16.7 (5)
CR/CRh	18.0 (9)	26.7 (8)
CR/CRh/CRi	20.0 (10)	30.0 (9)
CR/CRh/CRi/MLFS/PR	24.0 (12)	30.0 (9)



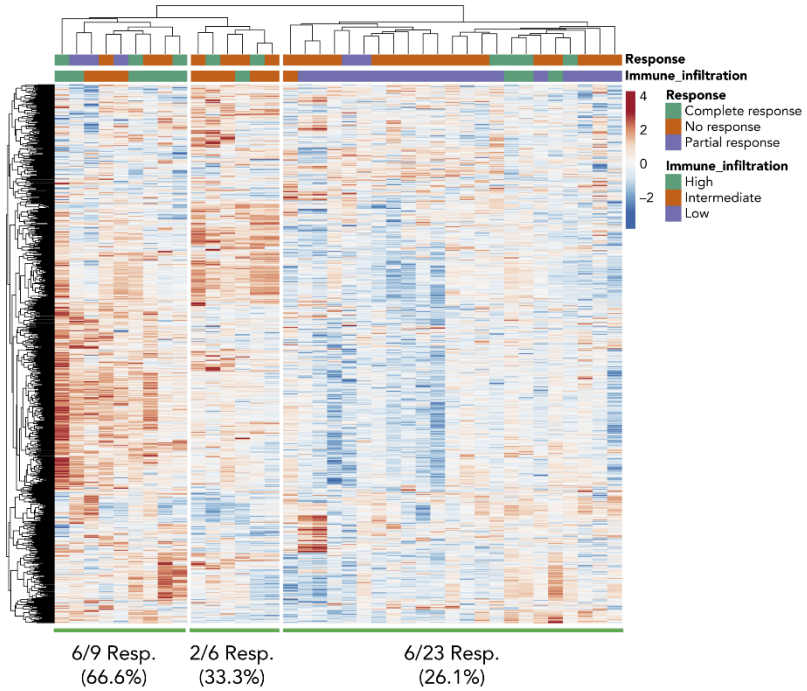
Uy et al. Blood 137(6):751-762

Biomarkers for response to Flotetuzumab

Response by inflammatory chemokine and tumor inflammation signature (TIS) scores



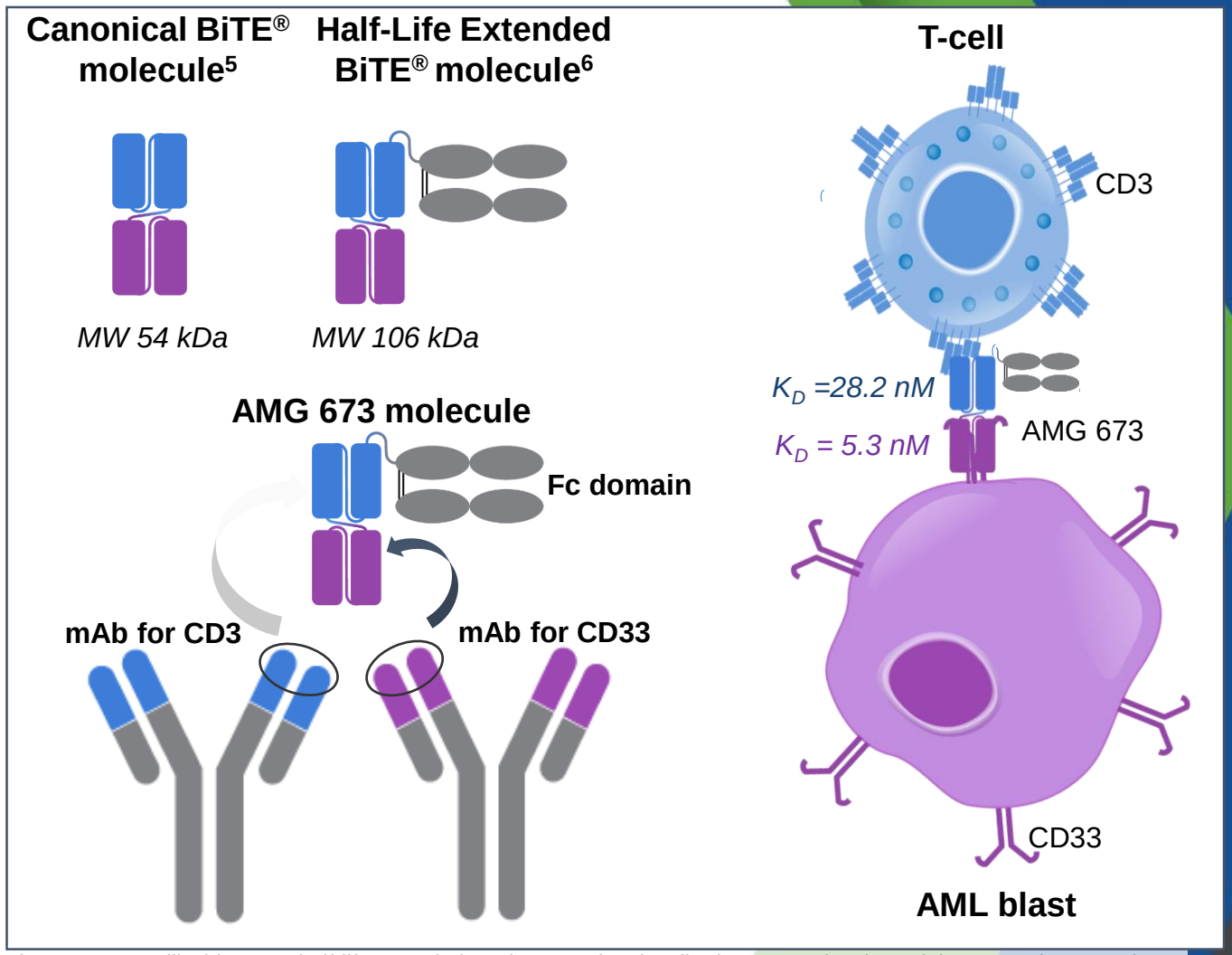
Response by immune-infiltrating signature score (based on 770 immune-related genes)



Uy et al. Blood 137(6):751-762

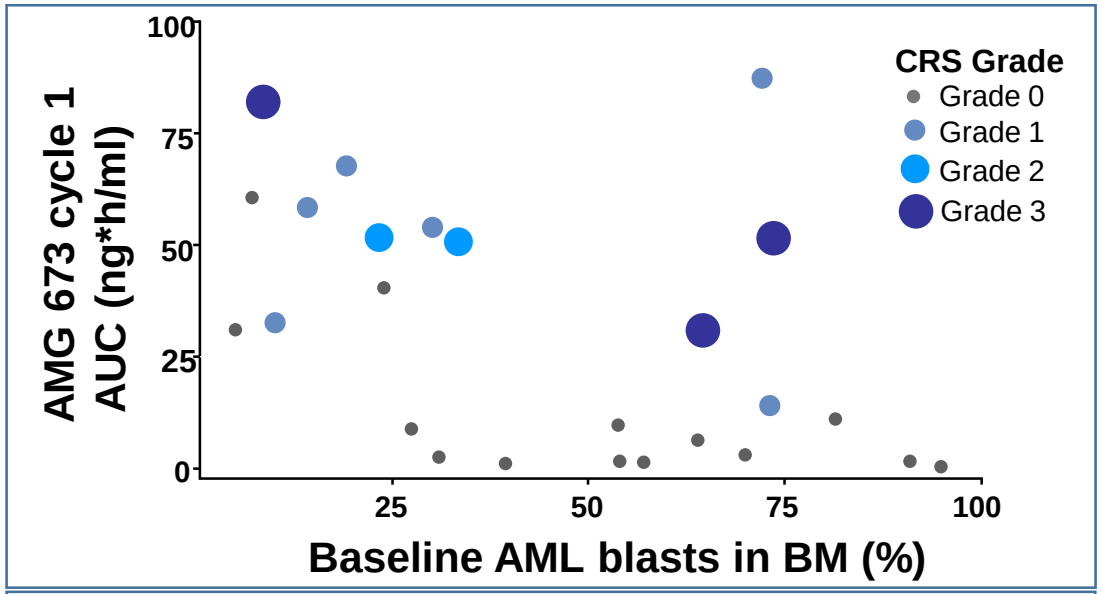
AMG 673: Background and Mechanism of Action

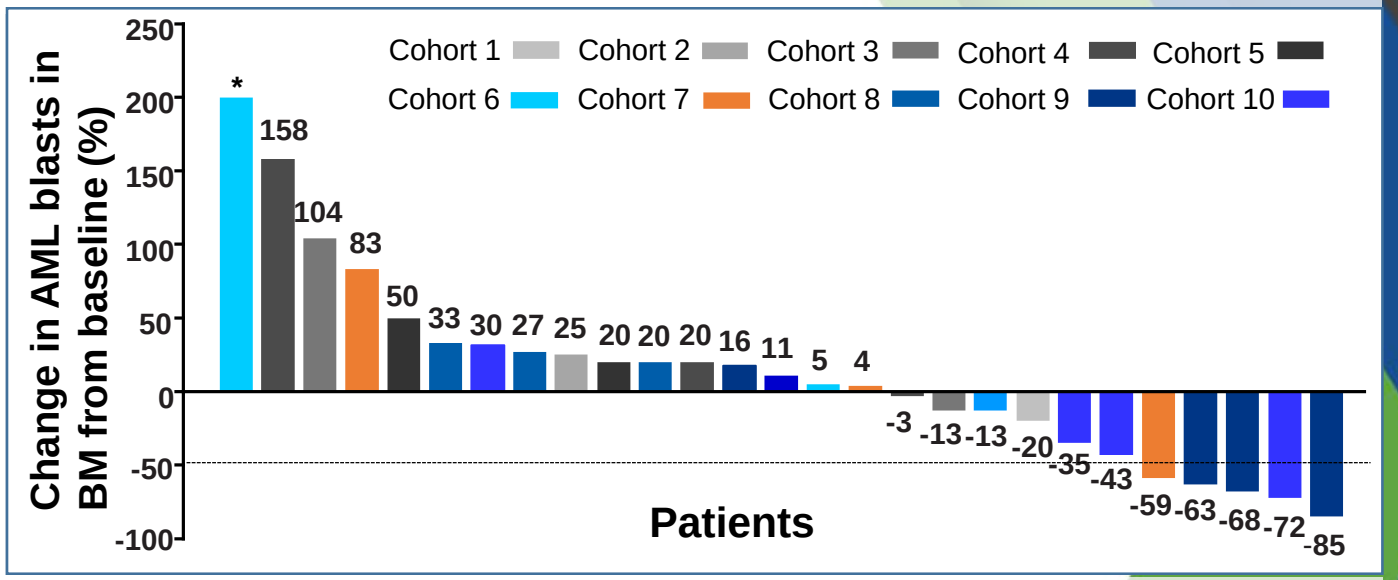
- BiTE® technology is based on a targeted immuno-oncology platform that engages T cells toward malignant cells
- AMG 673 is a HLE BiTE® molecule that binds CD3 on T cells and CD33 on AML blasts
- CD33 is expressed on ~99% of AML blasts and is a validated therapeutic target in AML[1-4]

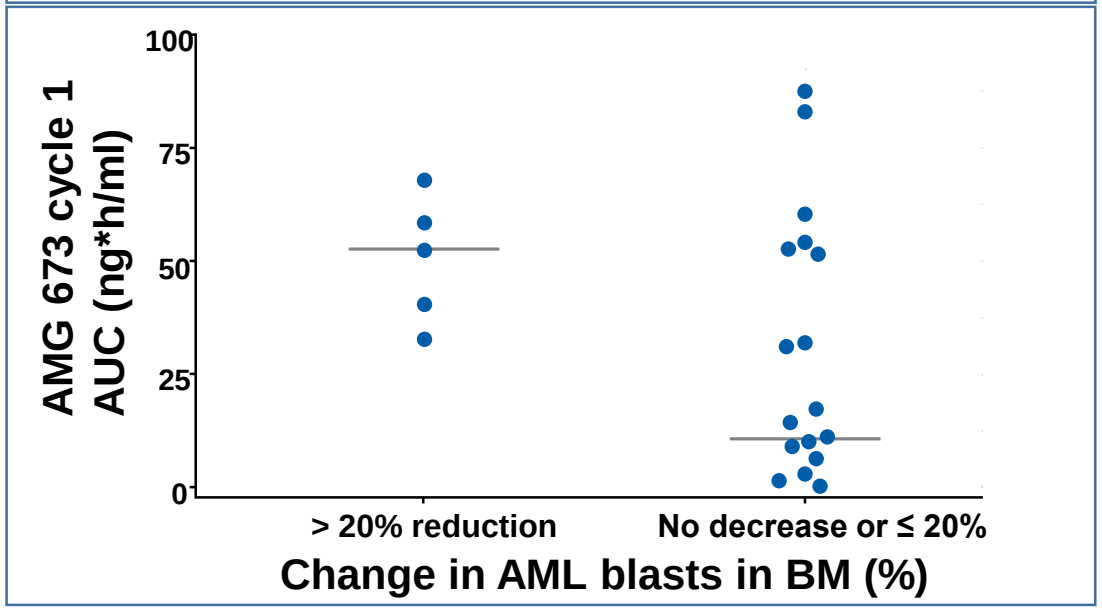


AML, acute myeloid leukemia; kDa, kilodalton; K_D, dissociation constant; BiTE®, bispecific T-cell engager; Fc, fragment crystallizable; HLE, half-life extended; mAb, monoclonal antibody; MW, molecular weight; 1. Krupka C, et al. *Blood.* 2014;123:356-365; 2. Ravandi F, et al. Abstract no. 25, presented at the 60th Annual Meeting of the American Society of Hematology; December 1, 2018; San Diego, CA; 3. Westervelt P, et al. Abstract no. 834, presented at the 60th Annual Meeting of the American Society of Hematology; December 1, 2018; San Diego, CA; 4. Bross PF, et al. *Clin Cancer Res*. 2001; 7:1490-1496; 5. Baeuerle PA, et al. *Cancer Res*. 2009;69:4941-4944; 6. Weidle UH, et al. *Cancer Genomics Proteomics*. 2013;10:1-18;

AMG 673: Relationships Between CRS, Exposure, and Anti-AML Activity



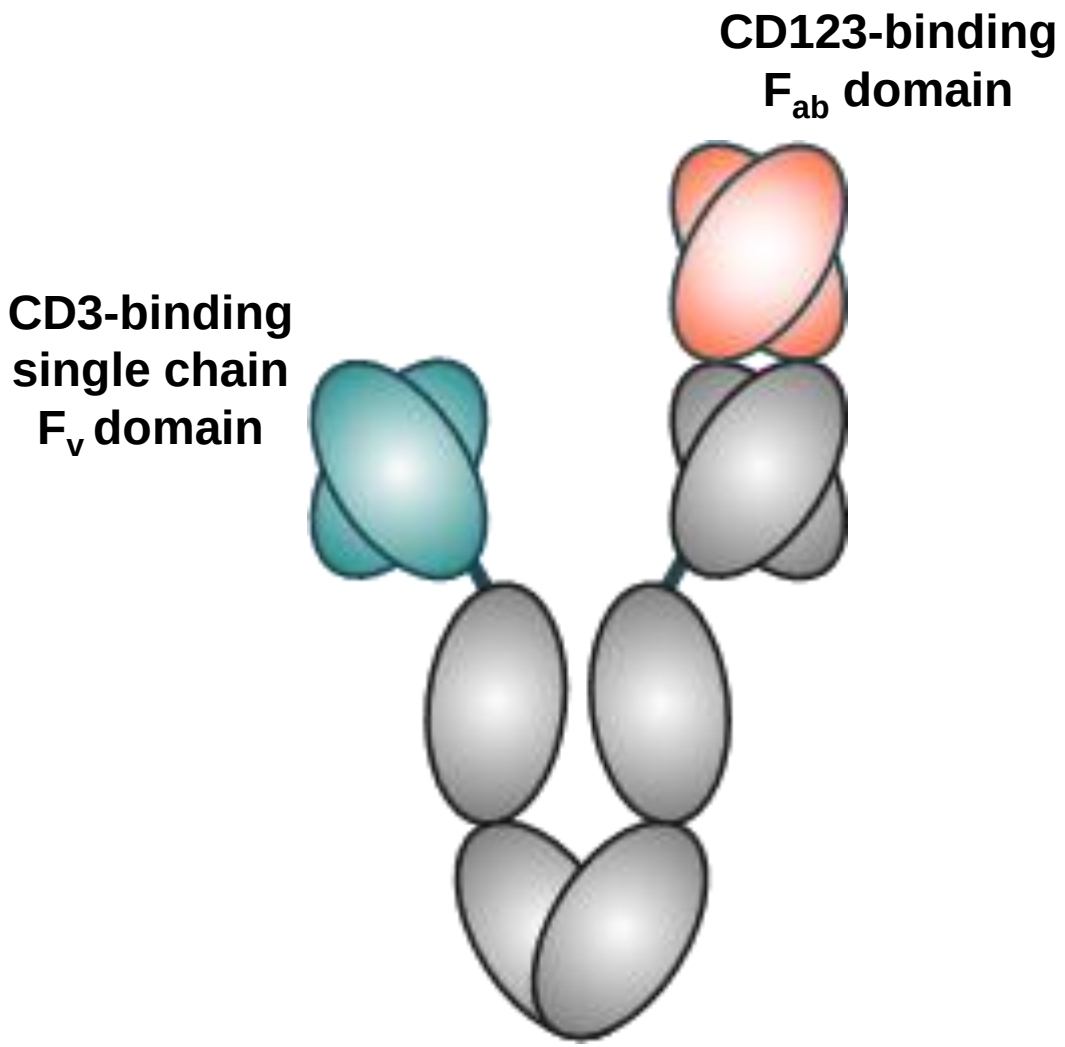




- Severity of CRS correlated with exposure to AMG 673 and leukemic burden
- Reduction in blasts was observed in 11/27 (41%) patients
  - ≥ 50% reduction in blasts in 5 patients
  - One pt (cohort 9) achieved Cri (85% reduction BM blasts)
- Reduction in blast numbers observed in patients with higher exposure to AMG 673

*The percentage change in blasts from baseline 469

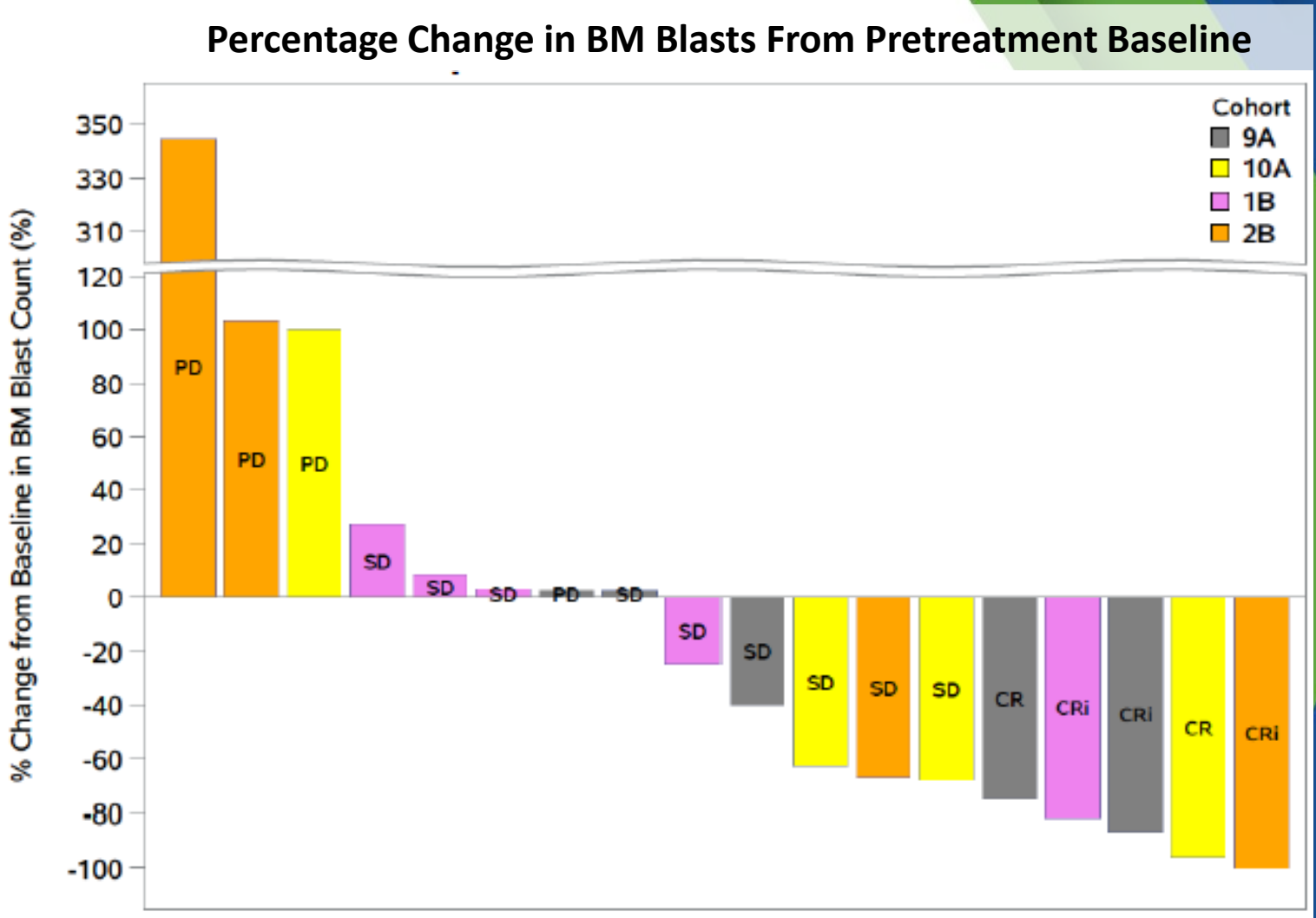
XmAb®14045: CD123 x CD3 Bispecific Antibody



- Full-length immunoglobulin molecule, dosed intermittently, in contrast to “DART” or “BiTE” antibodies that require a continuous infusion
- Stimulates targeted T cell-mediated killing of CD123-expressing cells, regardless of T cell antigen specificity
- $F_c\gamma$ receptor binding knock-out removes potential for receptor-mediated crosslinking and activation of T cells

XmAb14045 in R/R Hematologic Malignancies: Preliminary Efficacy

- CR/CRi in 5 out of 18 patients (28%) dosed with ≥ 1.3 µg/kg
- SD lasting > 3 mos in 3 patients (17%)
- BM blast reduction in 56% of patients
- Blast reduction observed in first cycle
- Clinical hematologic recovery from CRi to CR sometimes took 1-2 more cycles



Ravandi. ASH 2018. Abstr 763.

Webinar outline

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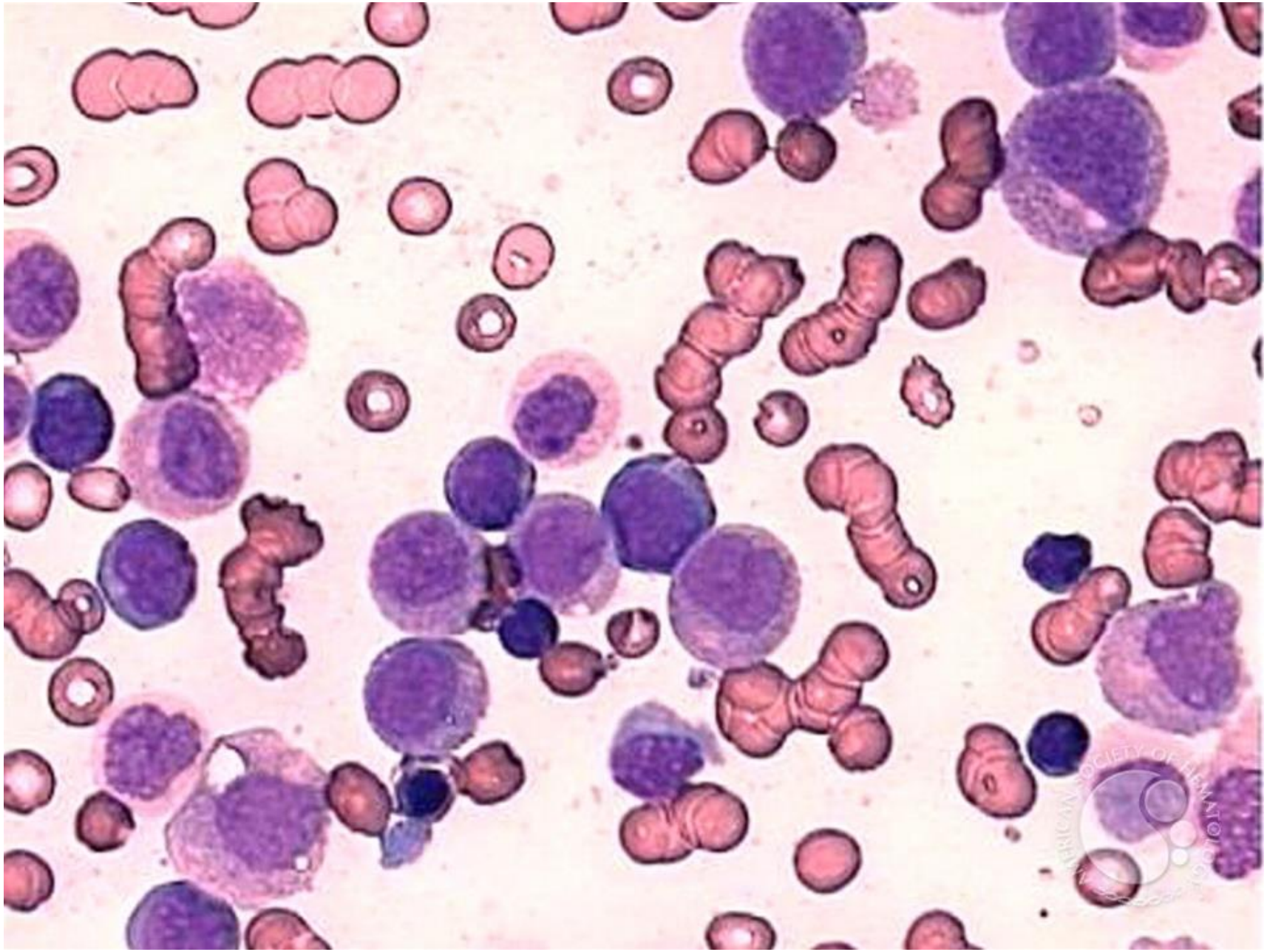
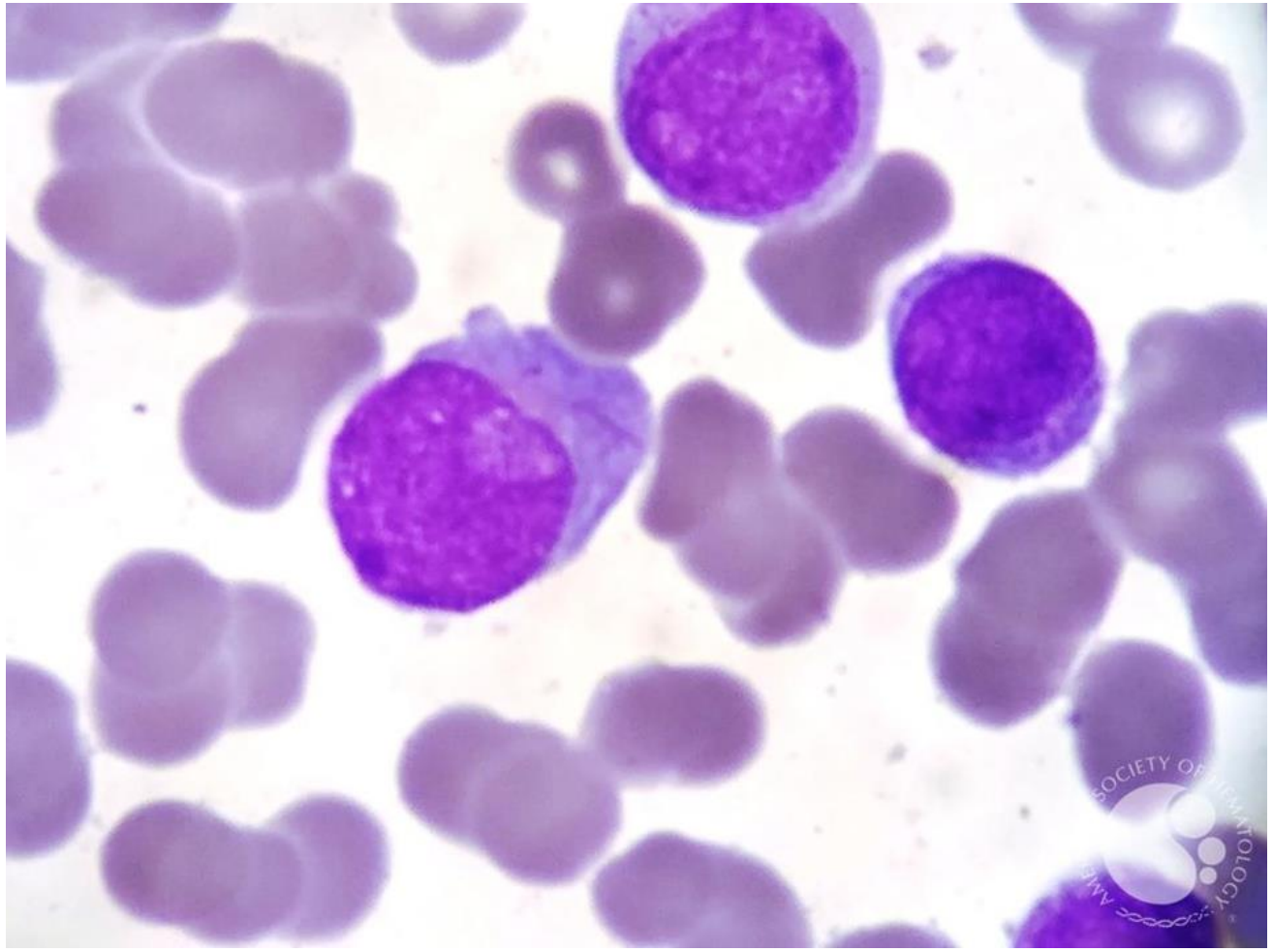
Case 3: Antibody-drug Conjugates

- 38 year old man presented with 3 weeks of fatigue, malaise and easy bruising
- Hgb 7, platelets 24,000
- WBC 26000.
  - 46% blasts, some with Auer Rods
  - Occasional Auer Rod seen in maturing elements
- Bone marrow: Acute myeloid leukemia, 60% blasts
- Ongoing maturation of myeloid series, with dysplastic changes





POLL QUESTION

- Emergent FISH: t(8;21)
  - Confirmed by PCR RUNX1-RUNX1T1. N-RAS mutated.

What therapy would you prescribe?

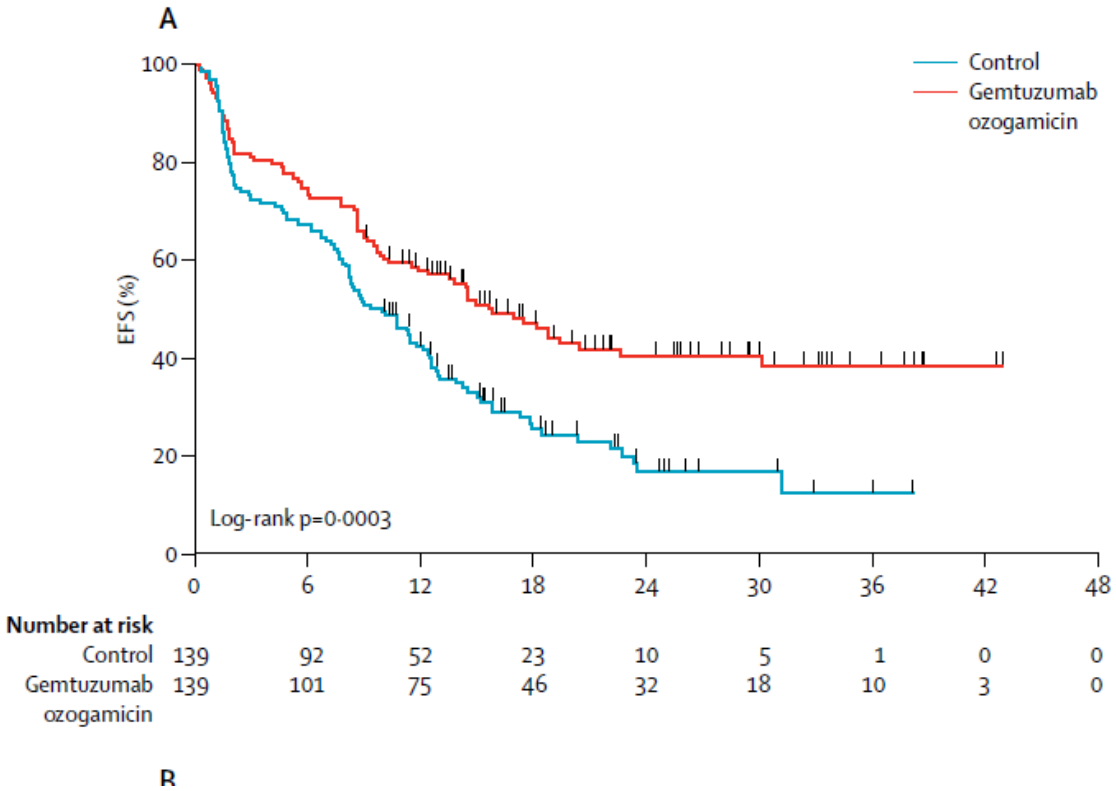
a) Azacitidine with venetoclax
b) Cytarabine and daunorubicin
c) Cytarabine and daunorubicin with gemtuzumab ozagomycin
d) Gemtuzumab Ozagomycin monotherapy
e) azacitidine with venetoclax and gemtuzumab ozagomycin

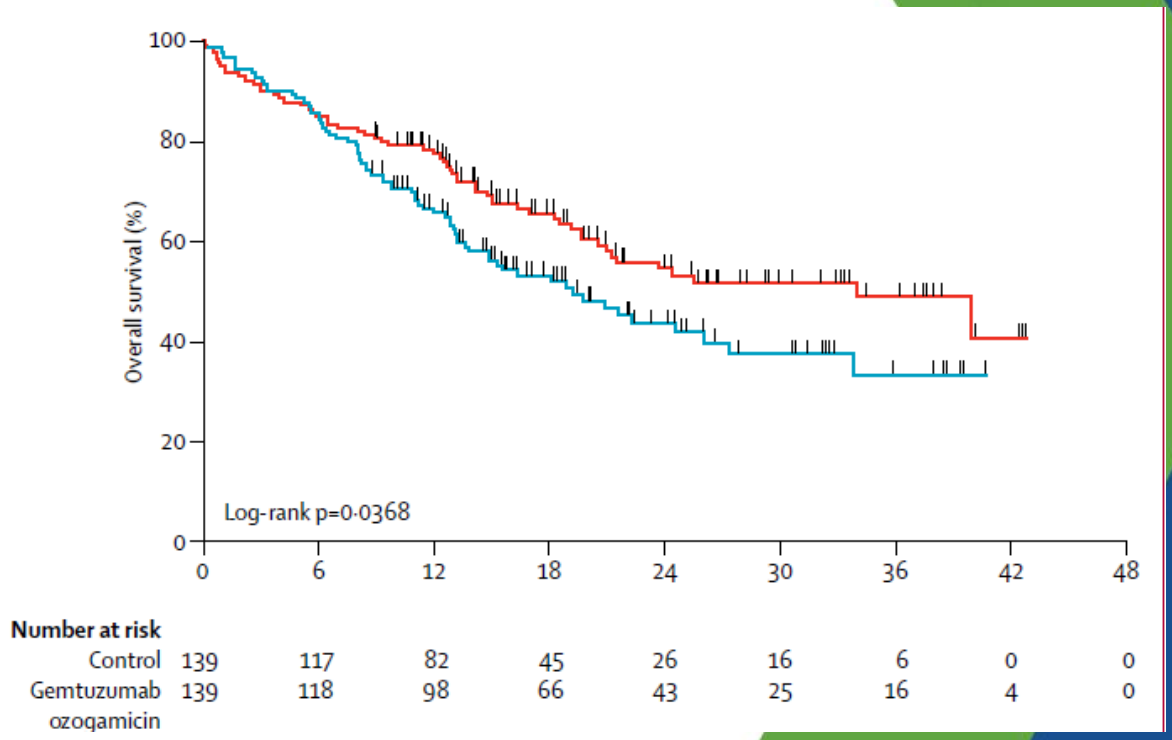
Alfa Study. Lancet 2012

- New AML age 50 – 70
- 7 plus 3 versus 7 plus 3 plus three doses of gemtuzumab
- 280 patients
- Two consolidations
  - Anthracycline containing
  - Plus minus gemtuzumab

Castaigne et al. Lancet 2012.
379: 1508

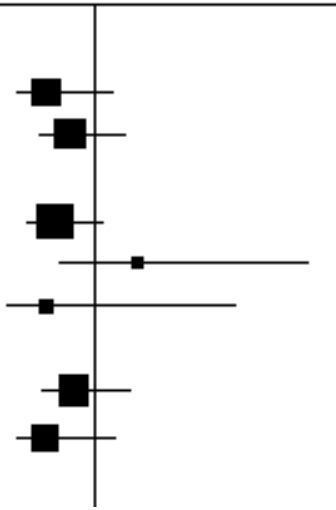
EFS (left) OS (right)



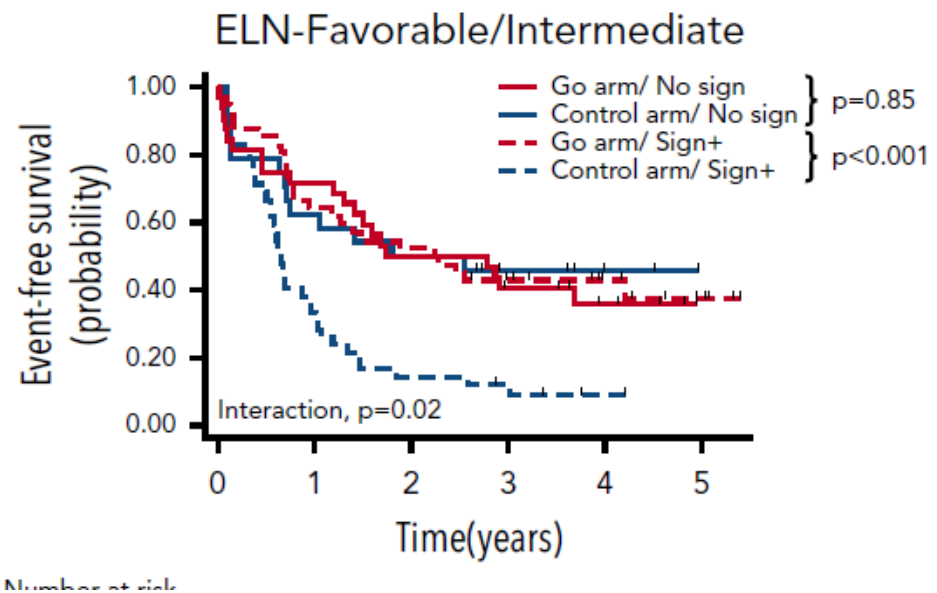


B

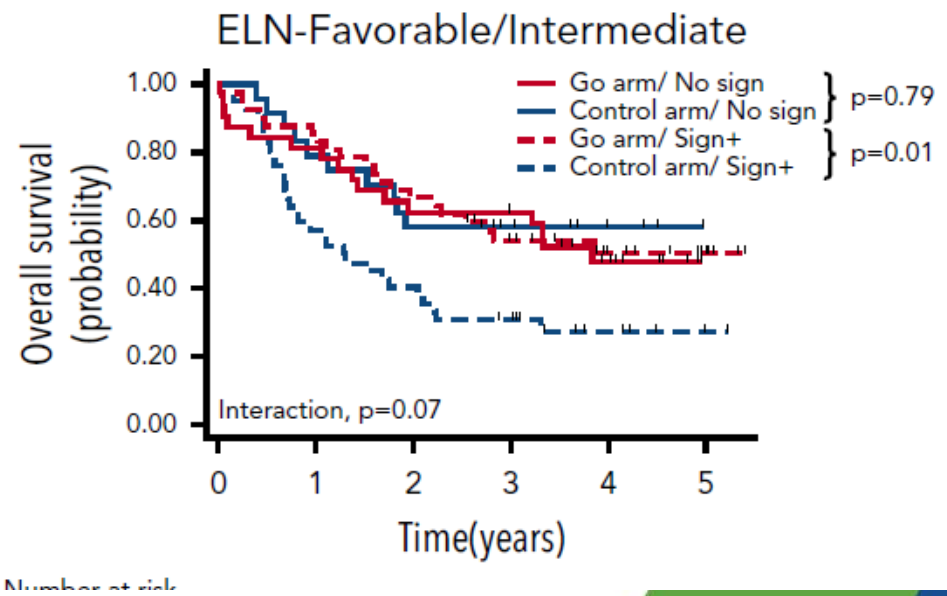
	Control		Gemtuzumab ozogamicin		Hazard ratio (CI*)	p value
	Deaths	Patients	Deaths	Patients		
Age (years)						
<60	28	53	14	39	0·51 (0·22–1·20)	
≥60	44	86	45	100	0·76 (0·44–1·31)	0·32
Cytogenetics						
Favourable or intermediate	43	97	32	94	0·59 (0·32–1·09)	
Unfavourable	23	30	22	28	1·44 (0·65–3·18)	
Unknown	6	12	5	17	0·51 (0·10–2·43)	0·31
***NPM1* status**						
Wild type	48	90	44	91	0·79 (0·46–1·36)	
Mutated	24	48	14	45	0·50 (0·21–1·20)	0·25
***FLT3*-ITD**						



D



E

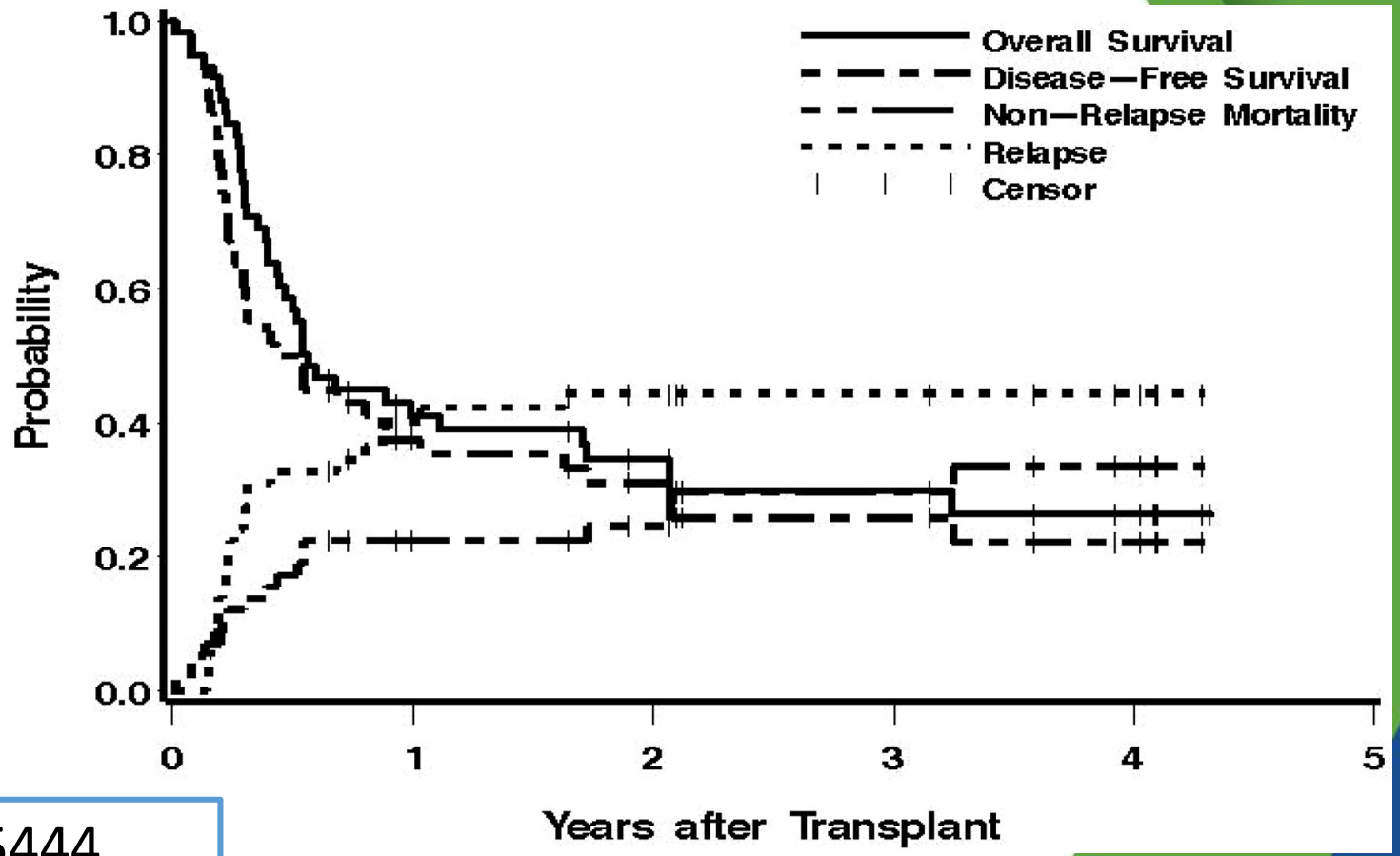


Should GO be included in all patients with good risk leukemias?

- ALFA data not confirmed elsewhere
- Chemotherapy is a bit different
- Information regarding ras and other signaling mutations may not be available at time of treatment
- Therapy does have increased toxicity

^{131}I-antiCD45 Apamistamab (Iomab-B)

- Age >50, R/R
- Single Institution
- With Flu/TBI/SCT
- 58 patients



Pagel et al. Blood 2009. 114: 5444

Sierra Study

- Age > 55
- R/R
- Randomize: Iomab transplant as immediate next treatment versus further chemotherapy first, transplant on non-response or progression
- Fully accrued September 2021 (150 patients)
- ASH Abstract 1791 (135 patients)
- Median age 65
- Prior lines: median 3 (1 – 7)

Sierra – 2

- Early Iomab arm (50 patients)
  - All engrafted
  - Dose to marrow: 14.7 Gy
  - Time to neutrophils: 14.5
  - Time to platelets: 18
- Crossover patients
  - All engrafted

Lintuzumab-AC225

- Anti-CD33
- Alpha emitter
- ASH 616: Schiller et al (UCLA)
- Phase I lintuzumab-AC225 with venetoclax
- ASH 3414: Abedin et al. (Med College Wis)
- CLAG-M with LIN-AC225
- 10/15 CR/CRi; 7 MRD undetectable

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