KEY INSIGHTS:
TREATING ADULT ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)

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University of Colorado
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WELCOMING REMARKS

KEY INSIGHTS: TREATING ADULT ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)

Lizette Figueroa-Rivera, MA
Senior Director, Education & Support
The Leukemia & Lymphoma Society
Washington, DC

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PRESENTATION

KEY INSIGHTS: TREATING ADULT ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)

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DISCLOSURES

KEY INSIGHTS: TREATING ADULT ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)

Marc Schwartz, MD

- **Consulting/Speaker fees:** Jazz, Autolus, Kite

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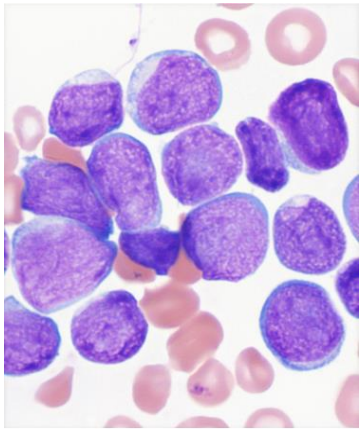
DIAGNOSIS OF ALL



Presenting signs/symptoms:

- Elevated WBC with circulating leukemia cells (blasts)
- Pancytopenia
- Extramedullary disease (ie, mediastinal mass)

Immunophenotype (Flow cytometry, IHC)

Early precursors: CD34, TdT, CD117

Lymphoid:

B cell: **CD19, cCD22, CD79a**, CD10, CD19, CD20, sCD22, CRLF2, PAX-5

T cell: **cytoplasmic CD3**, CD2, CD4, CD5, CD7, CD8

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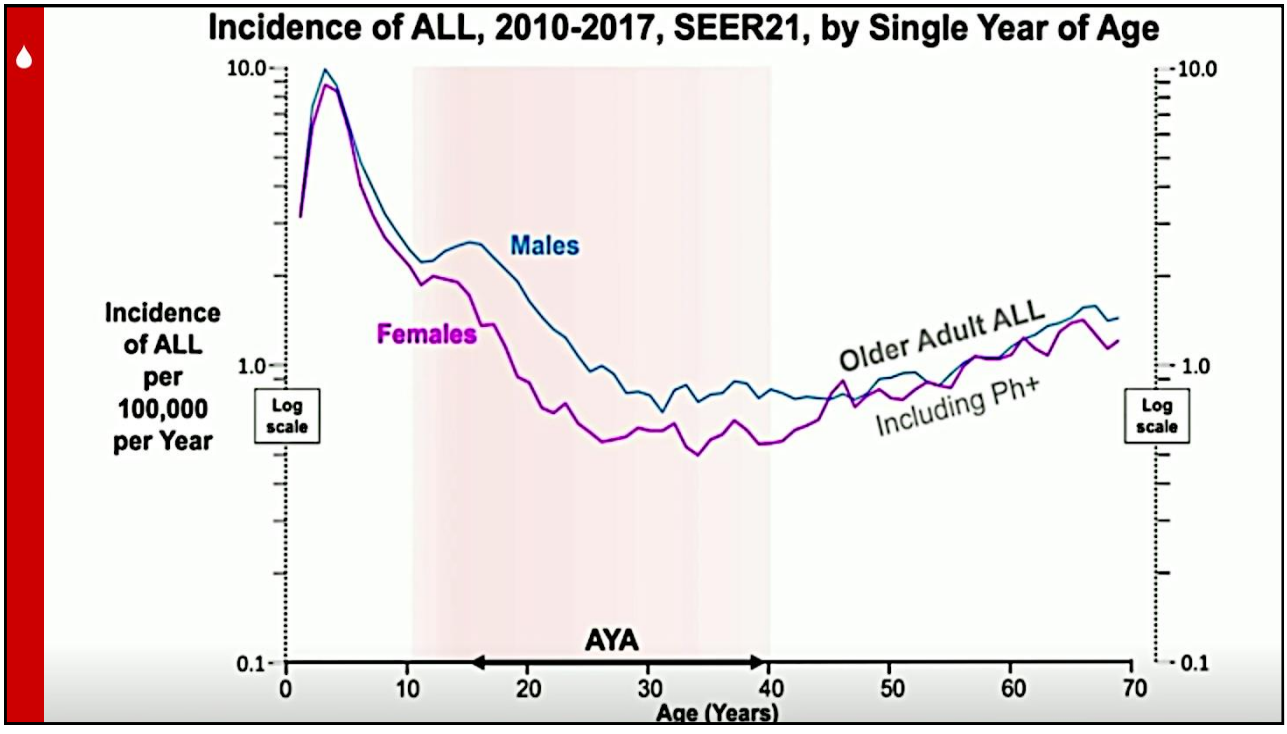

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ALL GENETICS: PEDIATRIC VERSUS ADULT

	Pediatric	Adult
Incidence	Peak 1-5 years	Nadir age 40
% of acute leukemia	80-85%	30%
Cases per year (US)	3,000	3,000
Chromosomes		
Ph+/BCR-ABL1	**3%**	**20-30%**
MLL - t(4; 11)	1-2%	7%
TEL/AML1	20%	2%
Hyperdiploid	25%	5%
Ph/BCR-ABL1-like	10-15%	20-25%
T cell	10-15%	20-25%
Mature B	1-2%	3-5%

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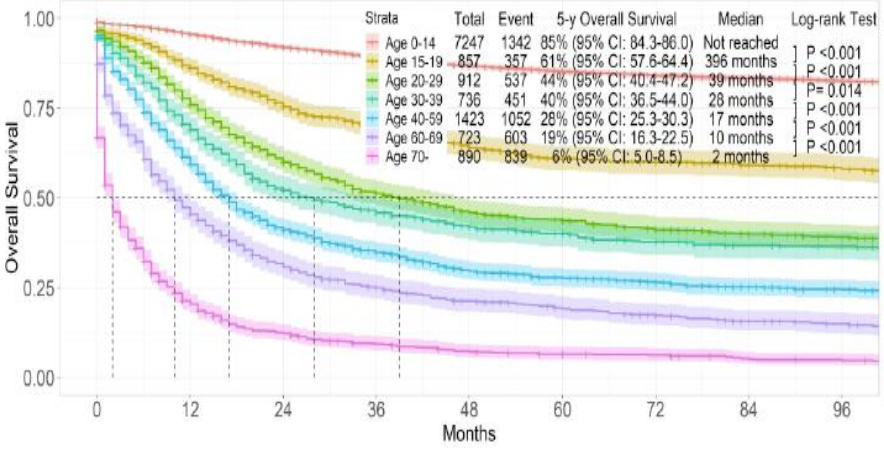
ALL OUTCOMES: EFFECT OF AGE



5-year OS:

- **<15yo = >80%**
- **15-40yo = 40-60%**
- **40-60yo = 20-40%**
- **>60yo = <20%**

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SEER data: 1980-2017

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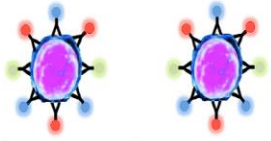
MINIMAL RESIDUAL DISEASE IN ALL

Flow Cytometry



Leukemia associated immunophenotype

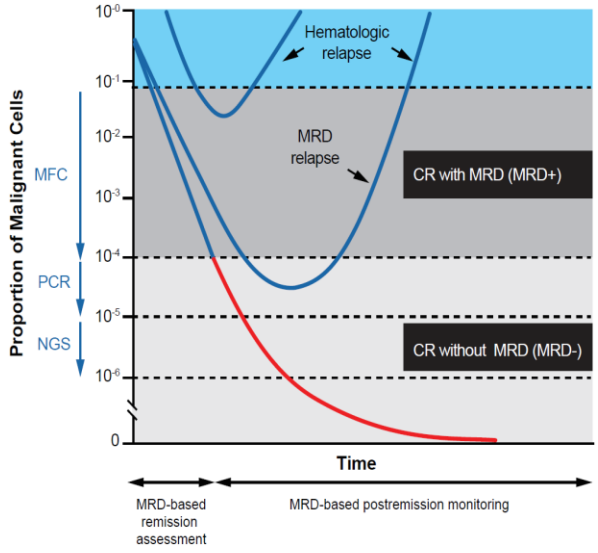
Aberrancy from normal

Sensitivity = 1x10^{-4}

NGS (ClonoSEQ)

Ig/TCR clonotype (Genetic barcode)

Sensitivity = 1x10^{-6}



Short NJ et al., *AJH* 2018

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1) Frontline blinatumomab in Ph-negative ALL: results of ECOG 1910 study
2) Frontline blinatumomab in Ph-positive ALL
3) CAR T-cell therapy for relapsed/refractory B-ALL: Brexu-cel, Obe-cel
4) Future directions in adult ALL

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1) **Frontline blinatumomab in Ph-negative ALL: results of ECOG 1910 study**
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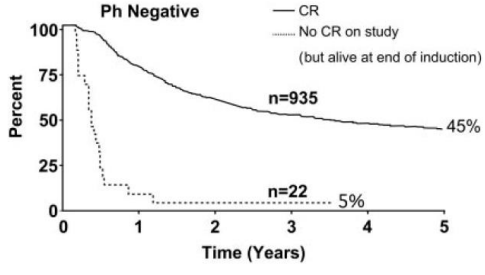
ECOG 2993/UKALL12



- Multi-agent chemotherapy regimen (induction/consolidation/maintenance) in adults 18-65 yo
- **CR rate >90%; 5-year OS 45% in Ph-negative ALL**

Goldstone, *Blood* 2008

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PEDIATRIC-INSPIRED REGIMENS IN ADULTS WITH ALL

Table 2. Summary of prospective trial results of the pediatric regimen in adolescent and adult ALL

Trial	Description	No. evaluable	Participant age, y	EFS, % (95% CI)	OS, % (95% CI)
CALGB 10403[6]	Phase 2 single-arm multicenter trial conducted by the US adult cooperative groups using a pediatric regimen based on COG AALL0232	295	17-39	3 y, 59 (54%-65%)	3 y, 73 (68%-78%)
DFCI 01-175[20]	Multicenter trial conducted in the United States and Canada utilizing a pediatric-inspired regimen	92	18-50	4 y, 58 (47%-68%)	4 y, 67 (56%-76%)
GRAALL-2003[19]	Phase 2 multicenter trial conducted by the GRAALL adult cooperative group across France, Belgium, Switzerland evaluating a pediatric-inspired regimen	225	15-60	3.5 y, 55 (48%-62%)	3.5 y, 60 (53%-66%)
GRAALL-2005[18]	Multicenter successor trial of GRAALL-2003; included a randomization to standard or hyperfractionated cyclophosphamide	787	18-59	5 y, 52.2 (48.5%-55.7%)	5 y, 58.5 (54.8%-61.9%)
PETHEMA ALL-96[55]	Multicenter trial conducted by the Spanish adult cooperative group utilizing a common pediatric regimen in adolescents and young adults with SR ALL	81	15-30	6 y, 61 (51%-72%)	6 y, 69 (59%-79%)
MDACC[24]	Single-center trial conducted by MDACC evaluating an augmented BFM pediatric regimen	106	13-39	Not provided	5 y, 60%
NOPHO ALL2008[21]	Multicenter protocol conducted by the Nordic cooperative group evaluating a common pediatric regimen across children, adolescents, and adults	221*	18-45	5 y, 74% ± 4%†	5 y, 78% ± 3%†

AYA/adults treated with pediatric regimens:

- **EFS ~55-70%**
- **OS ~60-80%**

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Muffly L (2019) *ASH Ed*

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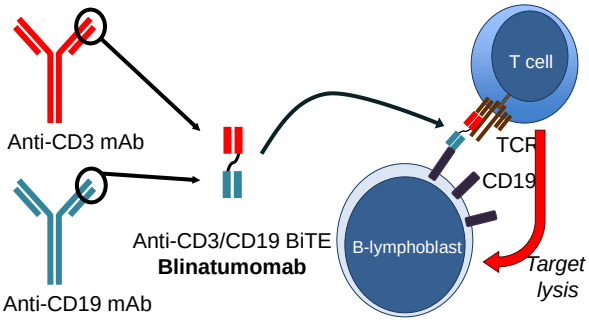
BLINATUMOMAB



TOWER trial[1]: Blina vs chemo in r/r B-ALL

- CR/CRi: 33.6% vs 15.7% (*P*<0.001)
- OS: **7.7 vs 4.0 mo**; HR=0.71, *P*=**0.01**
- ORR better with lower disease burden (<50% vs >50% BM blasts)

BLAST trial[2]: MRD+ (≥10^{-3}) after chemotherapy

- 91/103 (88%) achieved MRD-negativity (<10^{-4}) after blina

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1. Kantarjian *NEJM* 2017
2. Gokbuget *Blood* 2018

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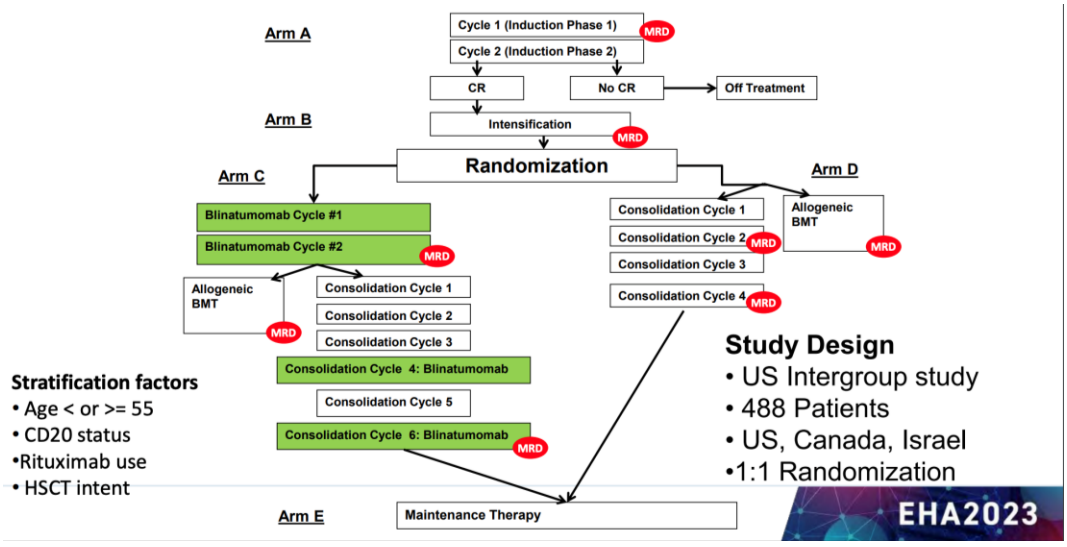
E1910: RANDOMIZED PH III ADULT FRONTLINE ALL



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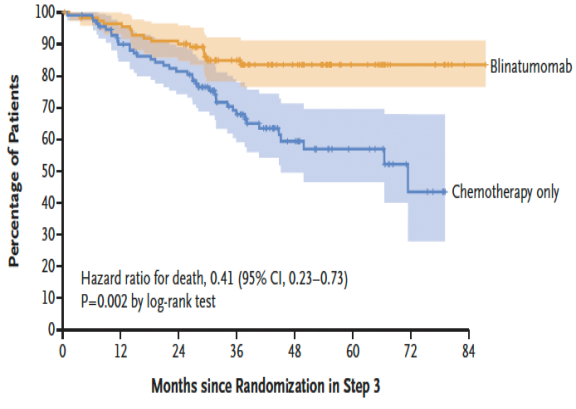
ECOG 1910



- N=224, median age 51 (30-70) MRD- by flow (10^{-4}) after induction
- **3-year overall survival in the blinatumomab group was 85%, as compared with 68% in the chemotherapy only group (*P*=0.002).**
- 22/112 (20%) patients in each group underwent allogeneic SCT

Litzow, *NEJM* 2024

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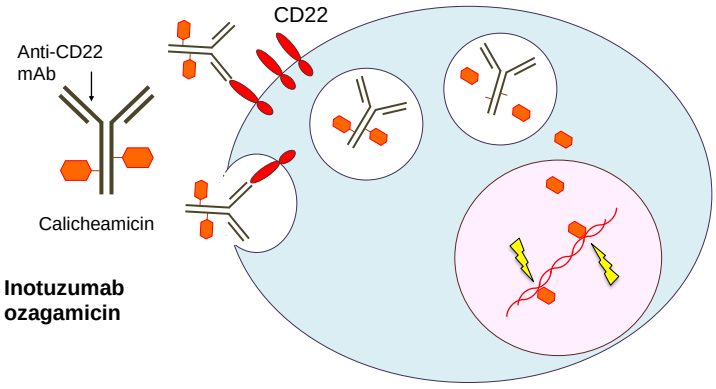
INOTUZUMAB OZOGAMICIN



INO-VATE:
InO vs chemotherapy in r/r B-ALL

- CR/CRi rate: **81% vs 29%** (*P*<0.001)
- OS: 7.7 vs 6.7 mos; HR=0.77 (*P*=0.04)

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Kantarjian *NEJM* 2016

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NOVEL AGENTS IN FRONTLINE TREATMENT OF PH-NEGATIVE B-ALL

Author	Group	Trial Design	n, Age	Outcome
Litzow[1]	ECOG	MRD- (10^{-4}) after IND/INT: Consolidation with chemotherapy vs chemotherapy + 4 cycles blinatumomab	N=224 Age: 30-70	**3-year OS: 85% (chemo+blina) vs 63% (chemo), p=.002**
Gupta[2]	COG	NCI SR ALL: consolidation with chemotherapy vs chemotherapy + 2 cycles blinatumomab	N=1440 Age: 1-10	**3-year DFS: 96% (chemo+blina) vs 88% (chemo), p=<.001**
DeAngelo[3]	Alliance	Pedi-inspired chemo with or without 2 cycles Inotuzumab after IND	N=273 Age: 18-39	**3-year DFS: 69% (INO+chemo) vs 66.7% (chemo)**
Jabbour[4]	MDACC	hyperCVAD + 4 cycles blinatumomab	N=38 Age: 29-45	3-year RFS: 73%
Stelljes[5]	GMALL	Inotuzumab (3 cycles) → consolidation chemo	>55	3-year EFS: 55%
Jabbour[6]	MDACC	minCVD+InO +/- blinatumomab	>60	5-year PFS: 48%

- Litzow, *NEJM* 2024
- Gupta *NEJM* 2025
- DeAngelo *ASH* 2024
- Jabbour, *Lancet Hemat* 2022
- Stelljes, *JCO* 2024
- Jabbour, *Lancet Hemat* 2025

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PH-NEGATIVE B-ALL: KEY TAKEAWAYS AND QUESTIONS

- For pediatric and adult patients achieving remission after chemotherapy, adding blinatumomab (2-4 cycles) to post-remission chemotherapy improves outcomes by reducing risk of relapse.

Questions:

- With addition of blinatumomab, can we reduce amount/intensity of chemotherapy backbone?
- Role for other novel agents (inotuzumab, CAR T, other targeted agents)?

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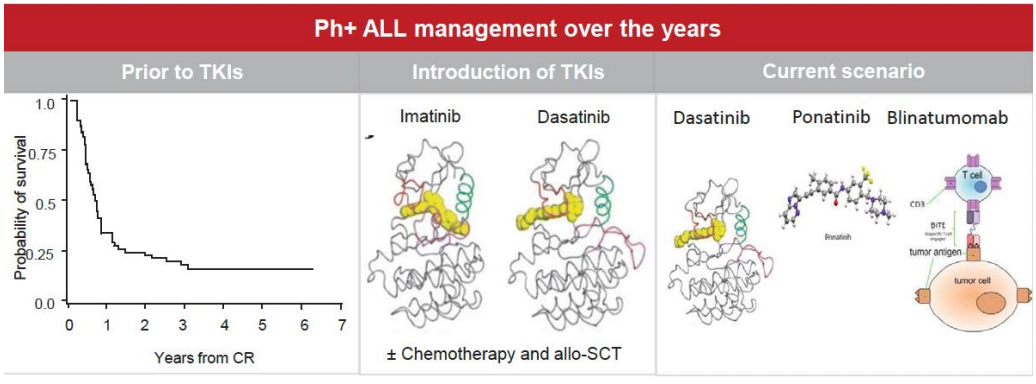

- Long-term OS with SCT: ~30-40%
- Long-term OS without SCT: <20%

- Long-term OS with SCT: ~60-70%
- Long-term OS without SCT: ~40-50%

- Long-term OS: ~80-90%

Chiaretti, *Blood Adv* 2024

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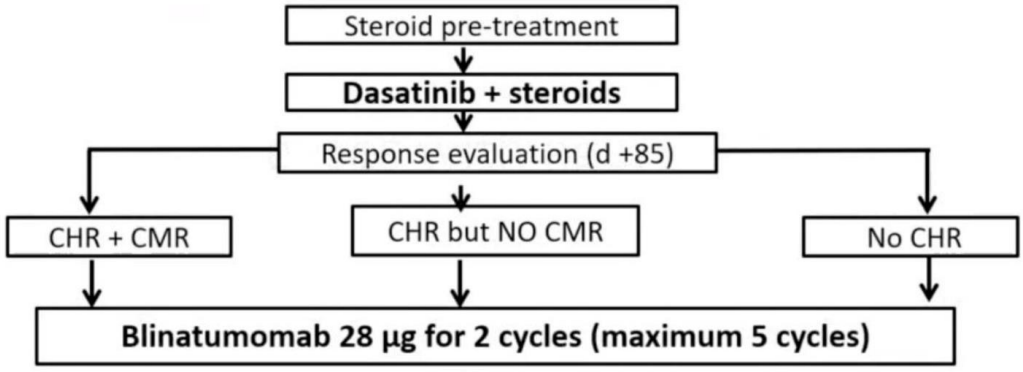
GIMEMA D-ALBA TRIAL



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Foa NEJM 2020

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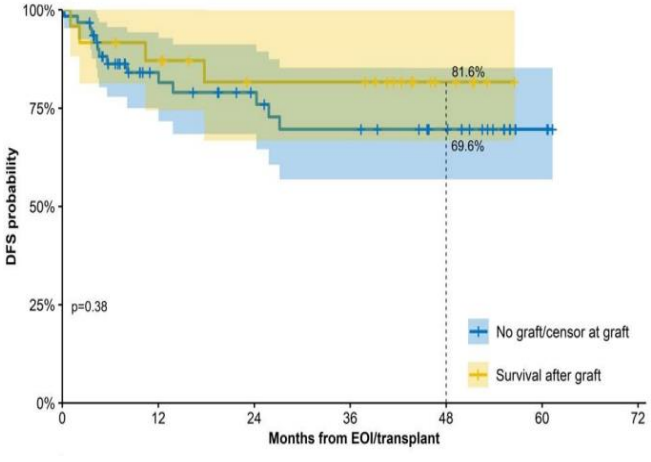
GIMEMA D-ALBA TRIAL



- N=63; median age = 54 (23-82)
- Of 59 patients evaluable for response:
  - 2 (3%) progressed during blina
  - 24 (45%) underwent allogeneic SCT in CR1
  - 33 (56%) continued TKI maintenance alone
- **2-year DFS (entire cohort) = 75.8%**

Foa *JCO* 2023

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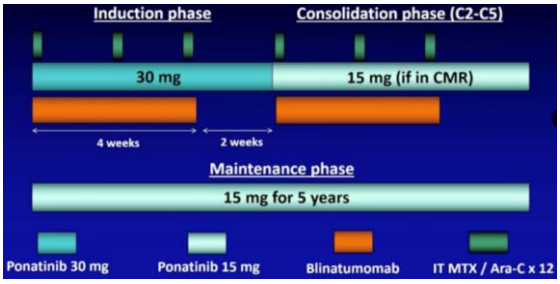
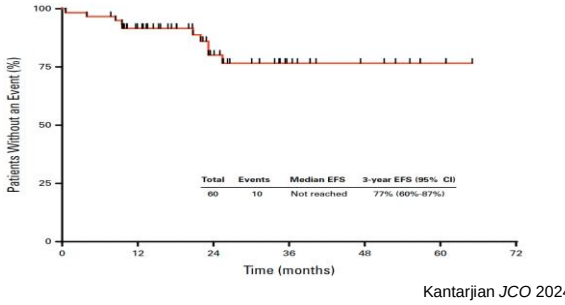
PONATINIB + BLINATUMOMAB (MDACC)





- N=60 patients, median age 60 (20-83)
- MRD-negativity by NGS (10^{-6}) = 98%
- **3-year EFS = 77%**
- 2/60 (3%) underwent allogeneic SCT in CR1

Kantarjian *JCO* 2024

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BLINATUMOMAB PLUS TKI (CHEMO-FREE) APPROACH IN PH+ ALL:

- TKI+blinatumomab without systemic chemotherapy results in long-term relapse-free survival in ~75% of patients
- Ponatinib + blinatumomab produces deep molecular remission in nearly all patients, which appears to be sustained in a majority (but not all) patients without allogeneic SCT

Questions:

- Is there a role for systemic chemotherapy before/after blinatumomab to mitigate relapse risk? Role for CD19 CAR T in high-risk patients after blina/ponatinib?
- Question: For patients achieving sustained deep molecular remission, when can we stop TKI?

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1) Frontline blinatumomab in Ph-negative ALL: results of ECOG 1910 study

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4) **Future directions in adult ALL**

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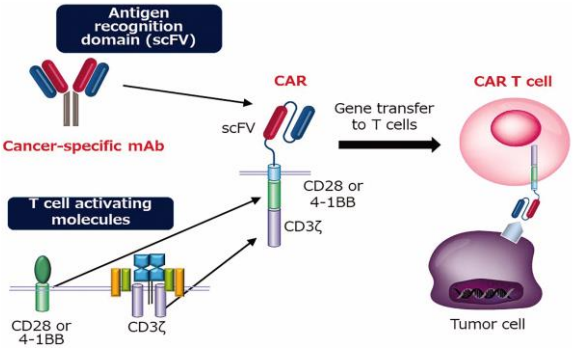
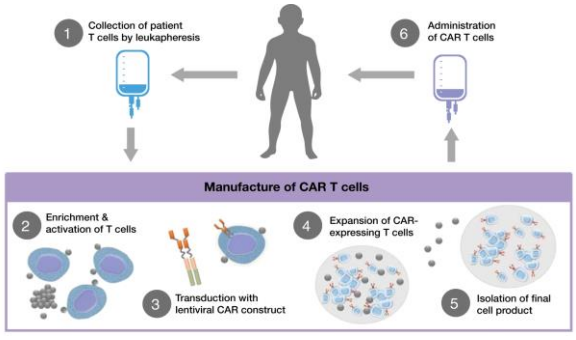
CAR T-CELL THERAPY IN B-ALL





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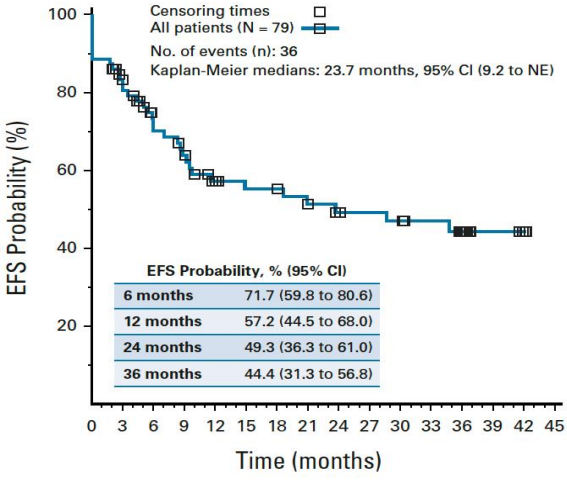
ELIANA: TISAGENLECLEUCEL



- 4-1BB CAR
- 79 pts (age 3-24) with R/R B-ALL (≥2 prior lines)
- **ORR = 82%; Median EFS = 24 months**

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Laetsch *JCO* 2023

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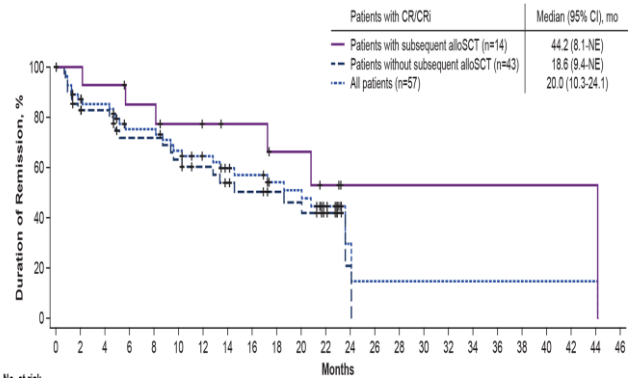
BREXUCABTAGENE AUTOLEUCEL IN ADULT R/R B-ALL: ZUMA-3



- CD28 co-stim domain
- **CR/CRi: 73%; Median RFS = 11.6 months**
- Gr 3-4 CRS 24%, Gr 3-4 neurotoxicity 25%

Shah *J Hem Onc* 2022

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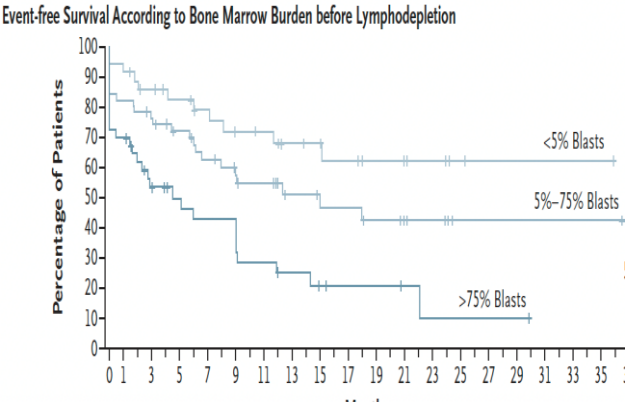
OBECABTAGENE AUTOLEUCEL (OBE-CEL) IN ADULT R/R B-ALL: FELIX STUDY



- 4-1BB CAR
- N=127 (median age 47, 20-81)
- **ORR=77%, Median EFS = 11.9 months**
- Gr 3-4 CRS 2.4%, Gr 3-4 neurotox 7.1%

Roddie *NEJM* 2024

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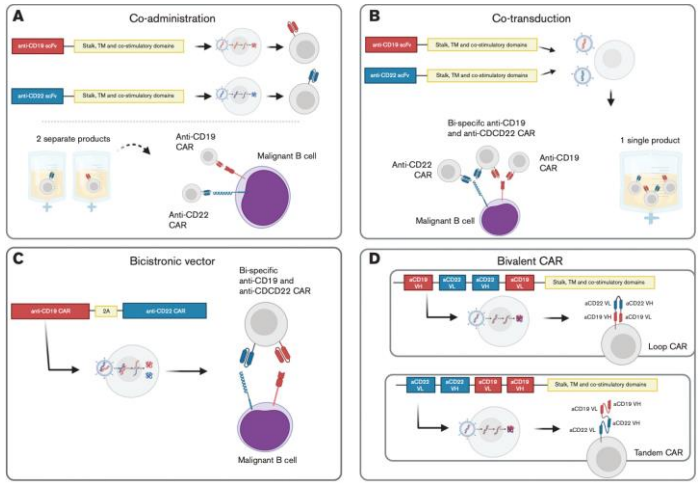
DUAL-TARGETING CAR T CELLS (CD19/CD22)

2 mechanisms of relapse after CD19 CAR T:

- CD19+ relapse due to loss of CAR T-cell persistence
- CD19- relapse due to antigen escape



Oliveira Canedo *Blood Adv* 2024

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Reference	phase	CAR construct	n°	In vivo expansion	Rate of CR	CD22⁺	CD19⁺ CD22⁺	CD19⁻ CD22⁺	Persistence	EFS/OS
Wang et al, 2020[117]; Wuhan, China	1	Coadministration Third-generation CAR Sequential, day 0-4	51 (age 9-62 y)	–	48/51 (96%) on day 30	23/24	0 0	1/24 (CD19⁻/CD22^{dim})	Short persistence (4 mo median time to recovery of bone marrow B-cell hematogones)	53% 12 mo RFS
Pan et al, 2021[116]; Beijing, China	1	Coadministration Sequential, separated by 1-65 mo, once CAR19 undetectable	20 (age 1-16 y)	–	20/20 (100%) MRD-negative on day 28	1/3 (downregulation)	0 2/3	0	Good persistence (17/20 patients showed >1 y CAR T-cell persistence)	80% 18 mo RFS
Liu et al, 2021[106]; Beijing, China	1	Coadministration Sequential, separated by at least 1 mo	27 infusion 1 21 infusion 2 (age 1.6-55 y)	Similar expansion after CD19 product and CD22	23/27 CR after infusion 1 20/21 CR after infusion 2	4/21	0 2/21	0	B-cell aplasia (median) 10 mo 75% lost CD22 CAR T cells on day 60 50% had CD19 CARs on day 60	65% 18 mo EFS 84% 18 mo OS
Wang et al, 2022[77]; Shanghai, China	2	Coadministration Second-generation CAR Pooled 1:1 T-cell manufacture	225 (<20 y)	Earlier and more robust expansion for CD19-CAR T cells	192/194 (99%) MRD-negative on day 28	24/43	0 16/43	1/43	B-cell recovery: - median 74 d - ~60% by 6 mo	74% 12 mo EFS 88% 12 mo OS
Zhang et al, 2022[78]; Tianjin, China	1	Coadministration Sequential, days 1 and 2 HBD3 CD22 CAR	4 (age 18-40 y)	Peak 14-21 d	4/4 (100%) MRD-negative on day 28	2/4	0 0	1/4 (CD19⁻/CD22dim)	9 mo CAR T-cell presence in peripheral blood of 2 patients after and without HSCT. Both relapsed with CD19 and CD22 expression.	25% 18 mo EFS 50% 18 mo OS
Pan et al, 2023[17]; Beijing, China	2	Coadministration Sequential, separated by 28 d CD19 murine CD22 humanized	81 (79 received both infusions) (age 1-18 y)	CD19: peak at 9 d CD22: peak at 12 d Peak not related to dose or bone marrow burden	79/81 (98%) MRD-negative or CR at 3 mo	11/79	0 2/79	1/79	20% B-cell recovery at 12 mo 40% CAR T-cell loss at 12 mo (as undetectable CAR transgene)	79% 18 mo EFS 96% 18 mo OS
Gardner et al, 2018[107]; (PLAT-05, SCRI-CAR19x22v1) Seattle, Washington	1	Cotransduction aCD19(FMC63)-4-1BBz aCD22(m971)4-1BBz	7	Selective expansion of CD19 components - CD19 9.1% - CD22 1.2% - CD19/CD22 2.4%	4/7 (57%) MRD negative on day 21	1/4	0 2/4	1/4	–	No follow-up time reported
Annesley et al, 2021[108]; (PLAT-05, SCRI-CAR19x22v2) Seattle, Washington	1	Cotransduction	12	Product skewed toward CD22. In vivo expansion mostly CD22	11/12 (91%) MRD negative	–	– –	–	–	No follow-up available yet

Reference	Trial phase	CAR construct	n°	In vivo expansion	Rate of CR	CD19⁺ CD22⁺	CD19⁺ CD22⁺	CD19⁻ CD22⁺	Persistence	EFS/OS
Ghorashian et al, 2024[109]; (CARPALL study) London, UK	1	Cotransduction aCD22-9A8-4-1BBz aCD19-CAT-4-1BBz	12 (<24 y)	Balanced expansion of all 3 components	10/12 (83%) MRD-negative at 2 mo (molecular MRD)	5/10	0 0	0	qPCR in blood (median): - CD19 CAR-T: 135 d - CD22 CAR-T: 105 d Less persistence than equal CD19 CAR product	60% 12 mo EFS 75% 12 mo OS
Cordoba et al, 2021[110]; London, UK (AMELIA study)	1	Bicistronic vector Humanized CAR (AUTO3)	15 (age 4-16 y)	Kinetics of expansion like tisa-cel	13/15 (86%) MRD-negative at 2 mo	6/13	0 2/13	1/13	119 d median time to last detection in blood (lower than tisa-cel)	32% 12 mo EFS
Dai et al, 2020[111]; Beijing, China	1	Tandem CAR	6 (age 17-44 y)	Peak at 2 wk	6/6 (100%) MRD-negative at 1 mo	2/6		1/6 (CD19⁻/CD22^{dim})	5/6 patients <5 mo persistence	
Spiegel et al, 2021[112]; Stanford, California	1	Tandem CAR	17 (age 25-76 y)	Peak at 10-14 d Higher expansion of CD8 compared with CD4	15/17 (88%) MRD-negative at 6 mo (10^{-4} sensitivity)	4/15 (1 no CD22 status reported)	0 4/15	0	All CAR-T present at day 60. No measurements undertaken thereafter.	33% 6 mo EFS
Hu et al, 2021[113]; Hangzhou, China	1	Tandem CAR Universal CRISPR/Cas9-engineered	6 (age 26-56 y)	Peak at 10-14 d	5/6 (83%) MRD-negative on day 28	0	1/6 (CD19⁺/CD22^{dim})	0 0	Patients with ongoing remission (2 patients) persistent CAR T cells >90 d Relapsed patient lost CAR T cells <90 d	-
Cui et al, 2023[114]; Suzhou, China	1b	Tandem CAR CD22 VL – CD19 VH-VL – CD22 VH – 4-1BB	47 (age 6-56 y)	–	40/47 (85%) MRD-negative on day 28	10/47	0 2/47	0	35 patients (75%) underwent consolidative HSCT at median of 2 mo from CAR T-cell infusion	69% 24 mo RFS 74% 24 mo OS
Niu et al, 2023[115]; Shanghai, China	1	Tandem CAR CD19 VL – CD22 VH – VL – CD19 VH – 4-1BB	15 (age 23-70 y) First-line MRD-positive patients and relapsed MRD-positive patients	Peak at 10 d. Higher in patients with sustained remission than in those who relapsed.	14/15 (94%) MRD-negative on day 28	4/15	0 1/15	0	3 patients with CAR T-cell persistence >90 d	77% 12 mo RFS 86% 12 mo OS
Shalabi et al, 2022[45]; Bethesda, Maryland	1	Tandem CAR	20 (age 5-34 y)	Lower expansion than CD22 CAR alone	16/20 (80%) MRD-negative at 1 mo (but 4 patients relapsed or progressive EMD)	3/12 (CD19⁺, no CD22 status reported)	0 0	1/12 (CD19⁻, no CD22 status reported)	Less persistence compared with patients receiving CD22 CAR alone (median 28 vs 85 d)	58% 12 mo RFS in responders

DUAL-TCD19/CD22 CAR T FOR B-ALL

- Outcomes thus far comparable with CD19 CAR T
- Majority of relapses are CD19+/CD22+, indicating lack of CAR persistence
- Co-administration appears to be most promising strategy, few trials reporting EFS >60-80% at or beyond 12 months

Oliveira Canedo Blood Adv 2024

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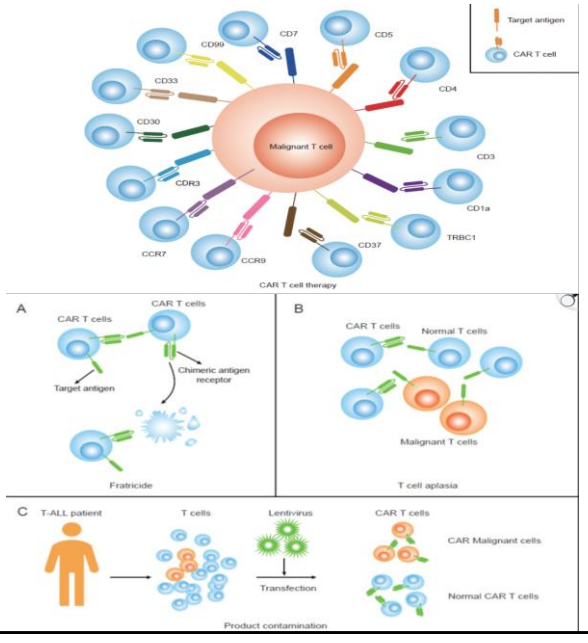
CAR T-CELL THERAPY FOR T-CELL ALL



Barriers to CAR T for T-ALL:

- Fratricide
- Product contamination by malignant T cells
- T-cell aplasia

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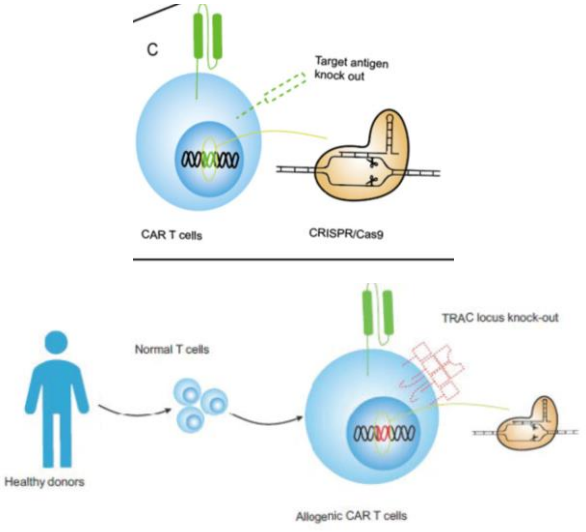
WU-CART-007 – ALLOGENEIC CD7-TARGETED CAR T PRODUCT, CRISPR/CAS9 EDITED TO DELETE CD7 AND TRAC (T-CELL RECEPTOR ALPHA CHAIN)



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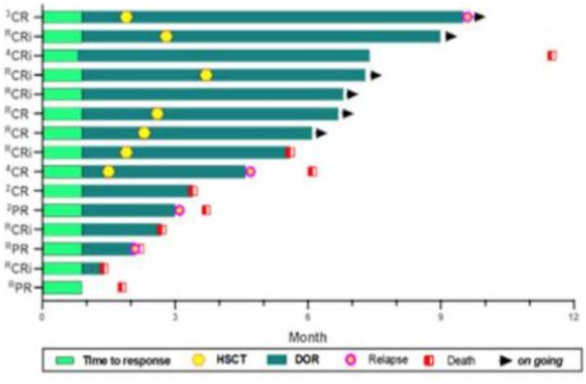

- Phase 1: 28 patients enrolled, median age 30 (14-69)
- **CR/CRi = 52.2% (all pts), 72.7% (RP2D)**
- Among responders, 7 patients proceeded to allo-SCT, 4 of which remain in CCR

Ghobadi, 2025 (pre-print)

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CAR T-CELL THERAPY IN ALL

- CD19 CAR T-cell therapy leads to responses in ~70-90% of patients with relapsed/refractory B-ALL
- In adults, data from ZUMA3 and FELIX suggest comparable response rates and durability between Brexu-cel and Obe-cel, but lower rates of high-grade CRS and ICANS with Obe-cel
- Dual-targeting (CD19/22) CAR T cells for B-ALL and CD7 CAR T cells for T-ALL likely to be next major advancements in the field

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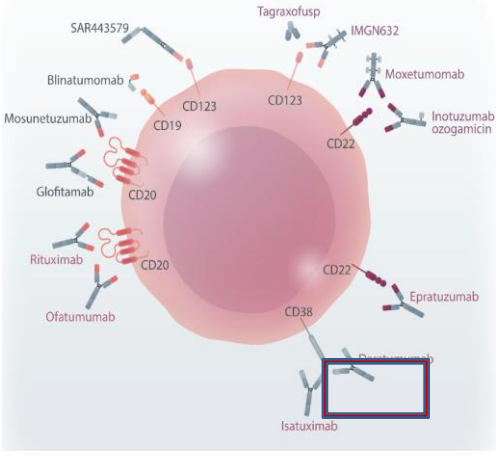
OTHER TARGETED THERAPIES IN ALL: DARATUMUMAB



DELPHINUS study
Weekly daratumumab (anti-CD38 Mab) + chemotherapy (VXLD) in R/R T-ALL/LBL

- **CR/CRi = 82.8% (n = 29)**
- 21/29 patients (72.4%) bridged to allo SCT

Bhatla, *Blood* 2024

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Thank you !

Marc.schwartz@cuanschutz.edu

School of Medicine
UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

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ASK A QUESTION

TREATING ADULT ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)

Ask a question by phone:

Press star (*) then the number 1 on your keypad.

Ask a question by web:

Click “Ask a question”
Type your question
Click “Submit”

Due to time constraints, we can only take one question per person. Once you’ve asked your question, the operator will transfer you back into the audience line.

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LLS EDUCATION & SUPPORT RESOURCES

HOW TO CONTACT US:

To contact an **Information Specialist** about disease, treatment and support information, resources and clinical trials:

Call: (800) 955-4572
Monday to Friday, 9 a.m. to 9 p.m. ET

Chat live online: www.LLS.org/InformationSpecialist
Monday to Friday, 10 a.m. to 7 p.m. ET

Email: www.LLS.org/ContactUs

CLINICAL TRIAL SUPPORT CENTER
Work one-on-one with an LLS Clinical Trial Nurse Navigator who will help you find clinical trials and personally assist you throughout the entire clinical-trial process.
www.LLS.org/Navigation

NUTRITION CONSULTATIONS
Our registered dietitian has expertise in oncology nutrition and provides free one-on-one consultations by phone or email.
www.LLSNutrition.org

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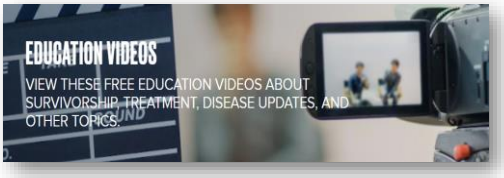
LLS EDUCATION & SUPPORT RESOURCES

Online Chats

Online Chats are free, live sessions, moderated by oncology social workers. To register for one of the chats below, or for more information, please visit **www.LLS.org/Chat**.



Education Videos

View our free education videos on disease, treatment, and survivorship. To view all patient videos, please visit **www.LLS.org/EducationVideos**.

Patient Podcast

The Bloodline with LLS is here to remind you that after a diagnosis comes hope. To listen to an episode, please visit **www.TheBloodline.org**.

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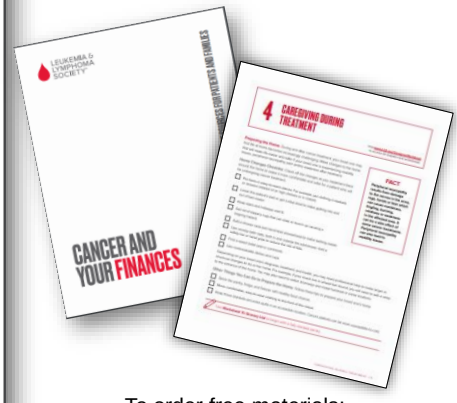
LLS EDUCATION & SUPPORT RESOURCES

The Leukemia & Lymphoma Society (LLS) offers the following financial assistance programs to help individuals with blood cancers:
www.LLS.org/Finances



To order free materials:
www.LLS.org/Booklets

The Medical Debt Case Management Program provides one-on-one, in-depth personalized support to empower patients to address their medical debt.

For more information:

LLS.org/MedicalDebt

By Phone: 1-833-507-8036
Monday to Friday: 8:30 a.m. to 5:00 p.m. EST

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THANK YOU

This program is supported by

AMGEN

Takeda | ONCOLOGY

Please complete our program evaluation

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We have one goal: A world without blood cancers

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