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EPICS

EPICS: LEUKEMIA IN 2020 AND BEYOND

September 14–15, 2020

FACULTY EXPERTS

Chair
Elias Jabbour, MD

Naval Daver, MD

Amir Fathi, MD

Guillermo Garcia-Manero, MD

Rami Komrokji, MD

Aaron Logan, MD, PhD

Jae Park, MD

Javier Pinilla, MD, PhD

Jerald Radich, MD

Richard M. Stone, MD

AGENDA DAY 1 (1/2)

EPICS

Time	Topic	Speaker/Moderator
4.00 PM – 4.10 PM **10 min**	Welcome and Introductions	Elias Jabbour, MD
4.10 PM – 4.20 PM **10 min**	CML: First-Line TKI Landscape (including RFS/TFR)	Javier Pinilla, MD, PhD
4.20 PM – 4.45 PM **25 min**	Key Questions and Topics for Discussion	
4.45 PM – 4.55 PM **10 min**	CML: Relapsed/Refractory and New Targets	Jerald Radich, MD
4.55 PM – 5.20 PM **25 min**	Key Questions and Topics for Discussion	
5.20 PM – 5.30 PM **10 min**	*BREAK*	
5.30 PM – 5.40 PM **10 min**	ALL: Genetic Subsets	Aaron Logan, MD, PhD
5.40 PM – 5.55 PM **15 min**	Key Questions and Topics for Discussion	

AGENDA DAY 1 (2/2)

EPICS

Time	Topic	Speaker/Moderator
5.55 PM – 6.05 PM **10 min**	ALL: Role of Monoclonal Antibodies and Bispecific Engagers	Elias Jabbour, MD
6.05 PM – 6.25 PM **20 min**	Key Questions and Topics for Discussion	
6.25 PM – 6.35 PM **10 min**	ALL: Role of CAR T Cells	Jae Park, MD
6.35 PM – 6.55 PM **20 min**	Key Questions and Topics for Discussion	
6.55 PM – 7.00 PM **5 min**	Wrap-up and Overview	Elias Jabbour, MD

AGENDA DAY 2 (1/2)

EPICS

Time	Topic	Speaker/Moderator
4.00 PM – 4.05 PM **5 min**	Agenda Review	Elias Jabbour, MD
4.05 PM – 4.15 PM **10 min**	MDS: Low-Risk Disease	Guillermo Garcia-Manero, MD
4.15 PM – 4.40 PM **25 min**	Key Questions and Topics for Discussion	
4.40 PM – 4.50 PM **10 min**	MDS: High-Risk Disease	Rami Komrokji, MD
4.50 PM – 5.15 PM **25 min**	Key Questions and Topics for Discussion	
5.15 PM – 5.25 PM **10 min**	*BREAK*	
5.25 PM – 5.35 PM **10 min**	AML: Patient Subsets (including ELN classification, prognostic groups, unfit elderly)	Richard Stone, MD
5.35 PM – 5.50 PM **15 min**	Key Questions and Topics for Discussion	

AGENDA DAY 2 (2/2)

EPICS

Time	Topic	Speaker/Moderator
5.50 PM – 6.00 PM **10 min**	AML: Targeting FLT3 and BCL-2	Naval Daver, MD
6.00 PM – 6.20 PM **20 min**	Key Questions and Topics for Discussion	
6.20 PM – 6.30 PM **10 min**	AML: New Therapeutic Targets	Amir Fathi, MD
6.30 PM – 6.45 PM **15 min**	Key Questions and Topics for Discussion	
6.45 PM – 7.00 PM **15 min**	Wrap-up and Overview	Elias Jabbour, MD

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CML: First-Line TKI Landscape (including RFS/TFR)

JAVIER PINILLA, MD, PHD

Current State of CML Treatment 2020

Key slide

AP, accelerated phase; BC, blast crisis; CML, chronic myeloid leukemia; TKI, tyrosine kinase inhibitor.

Selected Larger Clinical Trials of TFR Relative to Depth and Duration of MR – Completed Trials

Consec, consecutive; DMR, deep molecular response; MR, molecular response; TFR, treatment-free remission; UMRD, undetectable molecular residual disease.

1. Shanmuganathan. Hematology Am Soc Hematol Educ Program. 2018; 2018:168; 2. Shah. *Leuk Lymphoma.* 2020;61:650.

Key slide

KEY UPDATES ON CML – FIRST-LINE TKI LANDSCAPE

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- With tyrosine kinase inhibitor (TKI) therapy, most patients with chronic myeloid

DISCUSSION: CML – FIRST-LINE TKI LANDSCAPE (1/2)

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- Experts believe there is still no biology-based approach to predict which patients

DISCUSSION: CML – FIRST-LINE TKI LANDSCAPE (2/2)

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- Regarding combination therapies in the first-line setting, expert opinion is that

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CML: Relapsed/Refractory and New Targets (including mutation testing)

JERALD RADICH, MD

Top Genes Predictive of Good and Poor Response

Key slide

KEY UPDATES ON CML: RELAPSED/REFRACTORY AND NEW TARGETS

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- CML, previously thought to be a homogeneous disease driven mostly by the *BCR-*

DISCUSSION: CML – RELAPSED/REFRACTORY AND NEW TARGETS (1/3)

- Experts believe the development of new BCR-ABL inhibitors is not a high priority because bypass

DISCUSSION: CML – RELAPSED/REFRACTORY AND NEW TARGETS (2/3)

EPICS

- The experts think the main role for asciminib is in patients for whom a second-

DISCUSSION: CML – RELAPSED/REFRACTORY AND NEW TARGETS (3/3)

- While the current approach for minimal residual disease (MRD) assessment in

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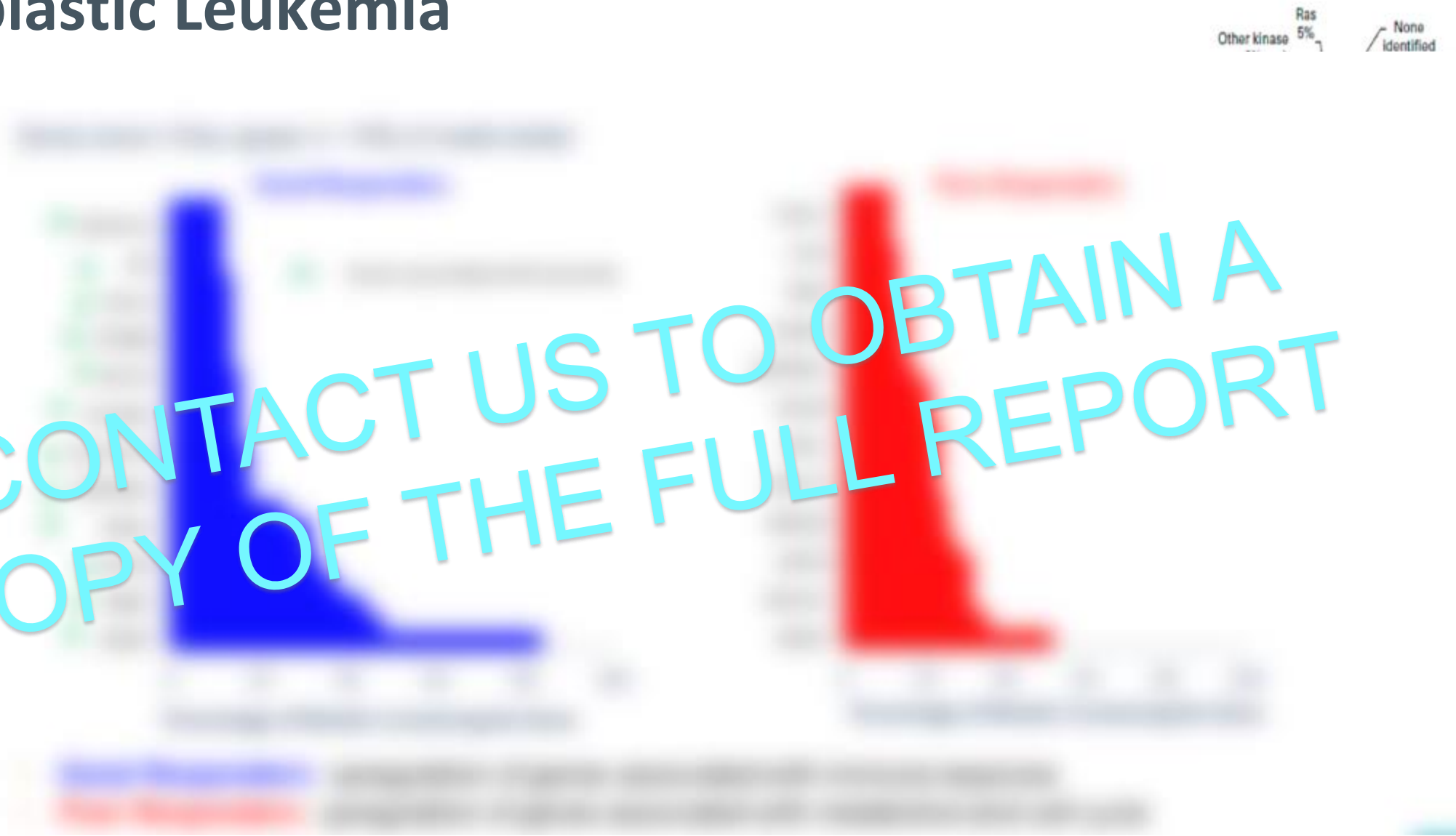
ALL: Genetic Subsets

AARON LOGAN, MD, PHD

Genetic Alterations in Pediatric and Adult Acute Lymphoblastic Leukemia



Mullighan C. *Sem Hematol.* 2013; 50:314-324.

Lanza F, et al. *Cancers.* 2020;12(2):303.

Key slide

ALL Genetic Subtypes Summary

- B-cell ALL has distinct genetically definable subtypes with different risks for

Key slide

KEY UPDATES ON ALL: GENETIC SUBSETS

EPICS

- It is important to know that ALL in children is a very different disease than ALL in

DISCUSSION: ALL – GENETIC SUBSETS (1/2)

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- Expert opinion is that the *BCR-ABL* translocation is still the main therapeutically

DISCUSSION: ALL – GENETIC SUBSETS (2/2)

- Expert practice is generally to not recommend SCT in patients with Ph-positive

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ALL: Role of Monoclonal Antibodies and Bispecific Engagers

ELIAS JABBOUR, MD

KEY UPDATES ON ALL: ROLE OF MONOCLONAL ANTIBODIES AND BISPECIFIC ENGAGERS

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- Pivotal trials have demonstrated a role for antibody-based and bispecific agents in patients with B-

DISCUSSION: ALL – ROLE OF MONOCLONAL ANTIBODIES AND BISPECIFIC ENGAGERS (1/3)

- The experts are looking to incorporate blinatumomab, inotuzumab ozogamicin, and

DISCUSSION: ALL – ROLE OF MONOCLONAL ANTIBODIES AND BISPECIFIC ENGAGERS (2/3)

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- The experts believe pediatric patients achieve MRD negativity at a higher rate than

DISCUSSION: ALL – ROLE OF MONOCLONAL ANTIBODIES AND BISPECIFIC ENGAGERS (3/3)

- An approach to reduce neurotoxicity with blinatumomab was discussed; the protocol is to

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ALL: Role of CAR T Cells

JAE PARK, MD

Clinical Efficacy of CD19 CAR T Cells in R/R ALL

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Memorial Sloan Kettering Cancer Center .

Key slide

Clinical Course After CD19 CAR

Key slide

KEY UPDATES ON ALL: ROLE OF CAR T CELLS

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- In patients with B-cell precursor ALL, tisagenlecleucel is approved for patients ≤25

DISCUSSION: ALL – ROLE OF CAR T CELLS (1/2)

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- A criticism of pivotal trials of CAR T cells is the lack of an intent-to-treat (ITT)

DISCUSSION: ALL – ROLE OF CAR T CELLS (2/2)

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- Expert opinion is that CAR T cells have the potential to replace SCT

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MDS: Low-Risk Disease

GUILLERMO GARCIA-MANERO, MD

Treatment algorithm 2020 LR MDS

Entity	First line	Second line
Del5q- MDS isolated anemia	Lenalidomide	HMA, alloSCT
Isolated anemia, very low risk features	Growth factors	HMA, len, alloSCT
RARS post ESA	Luspatercept	HMA, len, alloSCT
Other lower risk MDS (bilineal cytopenia)	HMA	alloSCT
IDH1, IDH2, p53, SF3B1	Consider targeted approach	

Key slide

Potential new therapies targeting innate immunity and inflammation in lower-risk MDS

KEY UPDATES ON MDS: LOW-RISK DISEASE

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- In 2020, two drug approvals occurred in MDS, the first in over a decade

DISCUSSION: MDS – LOW-RISK DISEASE (1/3)

EPICS

- The experts discussed implications with the recent emergence of oral decitabine

DISCUSSION: MDS – LOW-RISK DISEASE (2/3)

EPICS

- The experts discussed the potential of luspatercept in MDS

DISCUSSION: MDS – LOW-RISK DISEASE (3/3)

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- With the availability of luspatercept and oral decitabine, experts believe iron chelation is likely no

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MDS: High-Risk Disease

RAMI KOMROKJI, MD

Treatment Algorithm 2020:
Higher-Risk MDS

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KEY UPDATES ON MDS: HIGH-RISK DISEASE

- CR >50% and median OS >2 years is the current benchmark for approval in this setting

DISCUSSION: MDS – HIGH-RISK DISEASE

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- In terms of new agents, experts see the current benchmark for survival as 1–1.5 years (ie, an agent

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AML: Patient Subsets (including ELN classification, prognostic groups, unfit elderly)

RICHARD STONE, MD

KEY UPDATES ON AML: PATIENT SUBSETS (1/2)

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- An improved understanding of the biology of AML is leading to the definition of

KEY UPDATES ON AML: PATIENT SUBSETS (2/2)

EPICS

- A potential intergroup trial proposes to evaluate different approaches to achieve

DISCUSSION: AML – PATIENT SUBSETS (1/2)

- The experts think that, given the lack of an OS benefit in patients <75 years of age

DISCUSSION: AML – PATIENT SUBSETS (2/2)

- There is concern from the experts that oral azacitidine may be inappropriately used

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AML: Targeting FLT3 and BCL-2

NAVAL DAVER, MD

Pivotal trials with FLT3 inhibitors in *FLT3*-positive AML

KEY UPDATES ON AML: TARGETING FLT3 AND BCL-2

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- There are currently 2 approved FMS-like tyrosine kinase 3 (FLT3) inhibitors in AML

DISCUSSION: AML – TARGETING FLT3 AND BCL-2 (1/3)

EPICS

- One expert mentioned that there is a difference in activity with venetoclax between

DISCUSSION: AML – TARGETING FLT3 AND BCL-2 (2/3)

EPICS

- Experts see a hard road ahead for quizartinib unless the QuANTUM-First study

DISCUSSION: AML – TARGETING FLT3 AND BCL-2 (3/3)

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- In the VIALE-A trial, the experts noted the subset of patients with an *NPM1*

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AML: New Therapeutic Targets

AMIR FATHI, MD

Combination Studies

Target Antigens and Novel Antibodies in AML

KEY UPDATES ON AML: NEW THERAPEUTIC TARGETS

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- Inhibitors of IDH1 or IDH2 are approved as single agents in patients with AML and

DISCUSSION: AML – NEW THERAPEUTIC TARGETS

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- Expert opinion is that AML will be a challenging setting for bispecific agents, since

APTITUDE HEALTH®

US Headquarters
5901-C Peachtree Dunwoody Road NE
Suite 200, Atlanta, GA 30328, US

EU Headquarters
Wilhelmina van Pruisenweg 104
2595 AN The Hague, the Netherlands

aptitude-health.com