APTITUDE HEALTH®

EPICS

Acute Lymphocytic Leukemia (ALL) in 2023 and Beyond – Focus on Combination Therapies

December 1, 2023

Full Report

Report Contents

EPICS

Meeting Snapshot

EPICS

EPICS

VIRTUAL CLOSED-DOOR ROUNDTABLE

DATE:
December 1, 2023

DISEASE STATE AND DATA PRESENTATIONS by key experts

INSIGHTS REPORT including postmeeting analyses and actionable recommendations

PANEL: Key experts in ALL

- 10 from North America
- 4 from Europe
- 1 from Australia

LEUKEMIA-SPECIFIC DISCUSSIONS on therapeutic advances and their application in clinical decision-making

Panel Consisting of 15 Worldwide Leukemia Experts

EPICS

Aaron Logan, MD, PhD
University of California,
San Francisco

Andre Schuh, MD, FRCPC
Princess Margaret Cancer Centre

Wendy Stock, MD
University of Chicago
Medicine

CO-CHAIR:
Gail J. Roboz, MD
Weill Cornell Medicine

Daniel J. DeAngelo, MD, PhD
Harvard Medical School

Selina Luger, MD
University of Pennsylvania,
Perelman School of
Medicine

Tobias Menne, MD, PhD
Newcastle upon Tyne
Hospitals

Jae Park, MD
Memorial Sloan Kettering
Cancer Center

Nicola Gökbuget, MD
University Hospital
Frankfurt

Ibrahim Aldoss, MD
City of Hope

CO-CHAIR:
Elias Jabbour, MD
University of Texas
MD Anderson Cancer Center

Nicolas Boissel, MD, PhD
Hôpital Saint-Louis

Renato Bassan, MD
Ospedale dell'Angelo and
Ospedale SS

Shaun Fleming, MBBS (Hons), FRACP, FRCPA
Melbourne Haematology,
Richmond, VIC, Australia

Bijal Shah, MD
Moffitt Cancer Center

APTITUDE HEALTH®

Meeting Agenda

EPICS

Time (CST)	Topic	Presenter
8.00 AM – 8.10 AM	**Welcome and Introductions**	Elias Jabbour, MD
8.10 AM – 8.25 AM	**Blinatumomab in First Line and Maintenance for ALL**	Nicola Gökbuget, MD
8.25 AM – 8.45 AM	Discussion	Elias Jabbour, MD; Gail Roboz, MD
8.45 AM – 9.00 AM	**Backbone Therapies for First-Line AYA ALL**	Nicolas Boissel, MD, PhD
9.00 AM – 9.25 AM	Discussion	Elias Jabbour, MD; Gail Roboz, MD
9.25 AM – 9.40 AM	**Backbones for First-Line Ph-Positive ALL**	Elias Jabbour, MD
9.40 AM – 10.10 AM	Discussion	Elias Jabbour, MD; Gail Roboz, MD
10.10 AM – 10.20 AM	Break	
10.20 AM – 10.35 AM	**Backbones for First-Line Ph-Negative ALL – Transplant Ineligible**	Andre Schuh, MD
10.35 AM – 11.05 AM	Discussion	Elias Jabbour, MD; Gail Roboz, MD
11.05 AM – 11.20 AM	**Backbones for First-Line Ph-Negative ALL – Transplant Eligible**	Ibrahim Aldoss, MD
11.20 AM – 11.50 AM	Discussion	Elias Jabbour, MD; Gail Roboz, MD
11.50 AM – 12.00 PM	**Final Conclusions and Wrap-Up**	Elias Jabbour, MD; Gail Roboz, MD

APTITUDE HEALTH®

EPICS

Blinatumomab in First Line and Maintenance for ALL

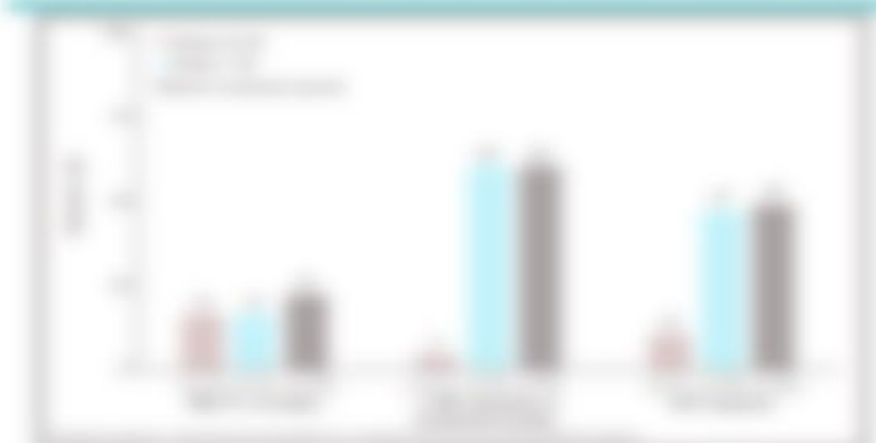
Blinatumomab in First Line and Maintenance for ALL (1/5)

Presented by Nicola Gökbuget, MD

EPICS

Approaches in Younger Patients – Ph-Negative ALL

Phase III GMALL trial[1]



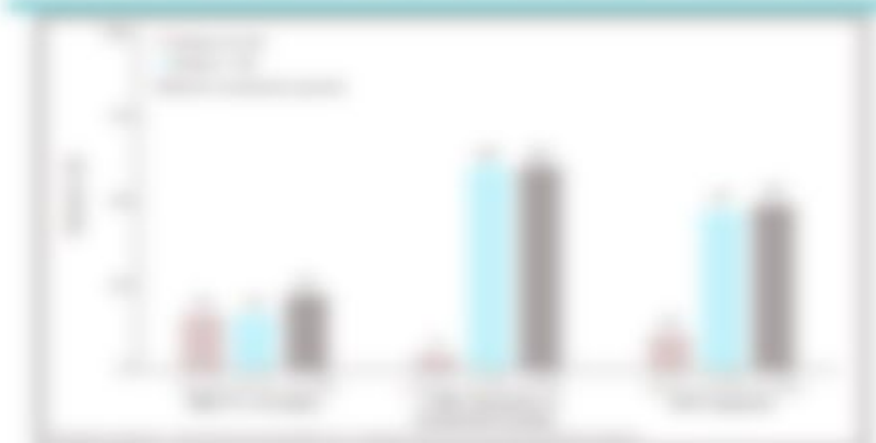
Blinatumomab in First Line and Maintenance for ALL (2/5)

Presented by Nicola Gökbuget, MD

EPICS

Approaches in Younger Patients – Ph-Negative ALL

Phase II GIMEMA LAL2317 trial[1]



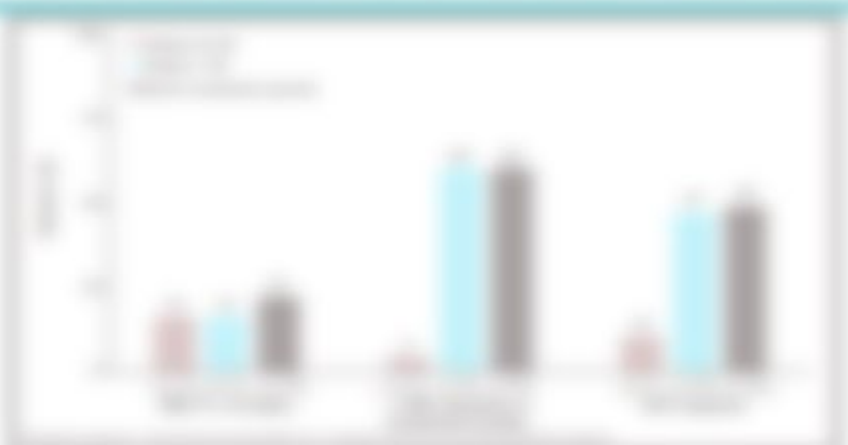
Blinatumomab in First Line and Maintenance for ALL (3/5)

Presented by Nicola Gökbuget, MD

EPICS

Approaches in Younger Patients – Ph-Negative ALL

Phase II study of hyper-CVAD with sequential blinatumomab ± inotuzumab



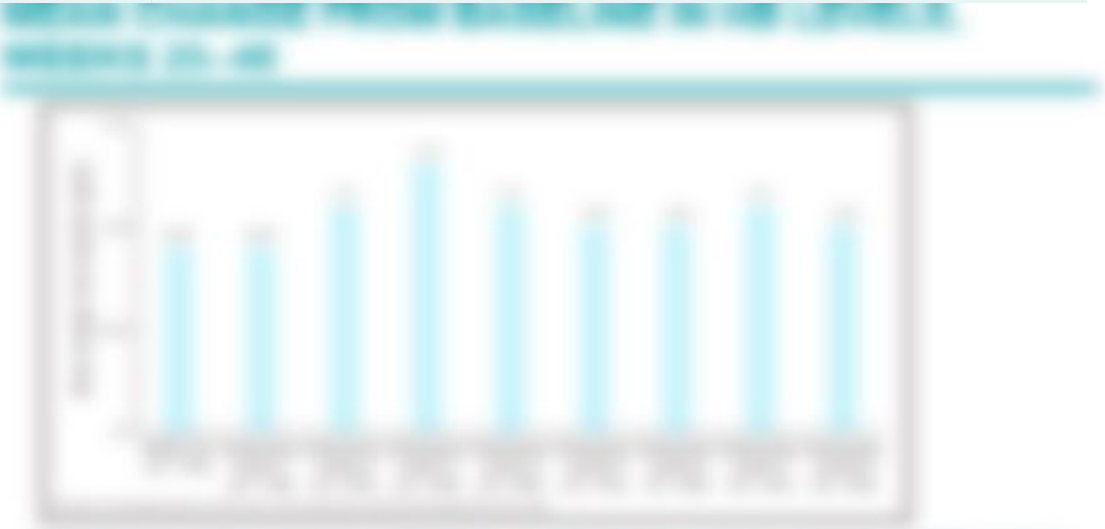
Blinatumomab in First Line and Maintenance for ALL (4/5)

Presented by Nicola Gökbuget, MD

EPICS

Approaches in Older Patients – Ph-Negative ALL

Phase II Alliance A041703 trial[1]



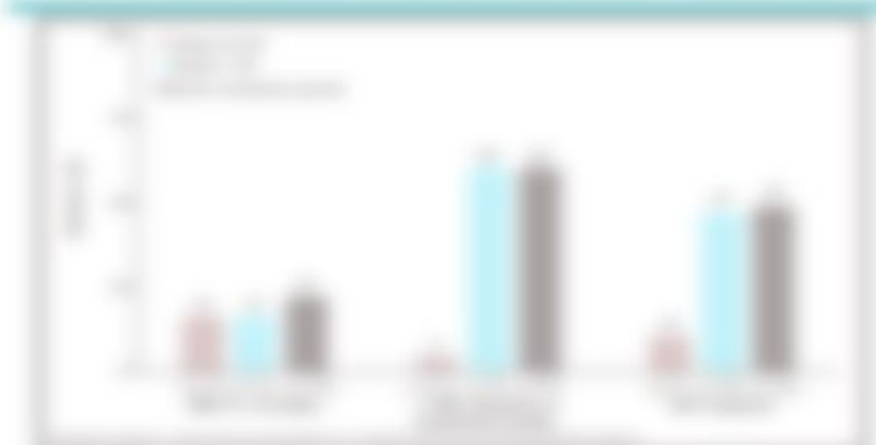
Blinatumomab in First Line and Maintenance for ALL (5/5)

Presented by Nicola Gökbuget, MD

EPICS

Approaches in Older Patients – Ph-Negative ALL

Phase III ECOG 1910 trial[1]



APTITUDE HEALTH®

EPICS

Key Insights

Blinatumomab in First Line and Maintenance for ALL

Blinatumomab in First Line and Maintenance for ALL (1/4)

EPICS

Since experts agreed that blinatumomab is the SOC for patients with

Blinatumomab in First Line and Maintenance for ALL (2/4)

EPICS

Experts were impressed with recent data for intrathecal (IT)

Blinatumomab in First Line and Maintenance for ALL (3/4)

EPICS

Experts questioned why blinatumomab + chemotherapy is not more

1. ClinicalTrials.gov identifier: NCT02003222.

Blinatumomab in First Line and Maintenance for ALL (4/4)

EPICS

There is considerable morbidity, especially in older patients, from AEs

APTITUDE HEALTH®

EPICS

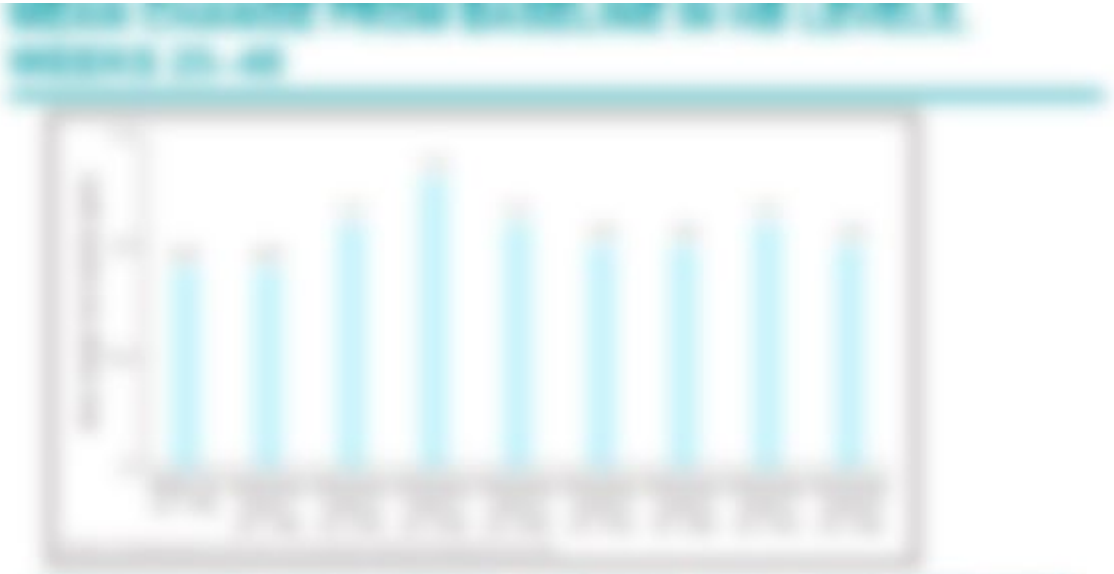
Backbone Therapies for First-Line AYA ALL

Backbone Therapies for First-Line AYA ALL (1/3)

Presented by Nicolas Boissel, MD, PhD

EPICS

Pediatric-Inspired Backbone Therapies



Backbone Therapies for First-Line AYA ALL (2/3)

Presented by Nicolas Boissel, MD, PhD

EPICS

Pediatric-Inspired Backbone Therapies

Backbone Therapies for First-Line AYA ALL (3/3)

Presented by Nicolas Boissel, MD, PhD

EPICS

Pediatric-Inspired Backbone Therapies

APTITUDE HEALTH®

EPICS

Key Insights

Backbone Therapies for First-Line AYA ALL

Backbone Therapies for First-Line AYA ALL (1/3)

EPICS

Experts strongly advocated blinatumomab's addition to consolidation

Dr. Program

We used to run out of good options and we would just regress to the mean of chemotherapy plus hasbucomab in the salvage setting, but now we have so many great choices that that really takes a backseat. It's really been exciting to have multiple options for patients after T-DM1 — again, practice changing, unprecedented.

Backbone Therapies for First-Line AYA ALL (2/3)

EPICS

MRD status following blinatumomab helps determine the need for HSCT

Dr. Pogosian

We used to run out of good options and we would just default to the mean of chemotherapy plus inotuzumab in the salvage setting, but now we have so many great choices that that really takes a backseat. It's really been exciting to have multiple options for patients after T-DM1 — again, practice changing, unprecedented.

Backbone Therapies for First-Line AYA ALL (3/3)

EPICS

Experts discussed whether blinatumomab should be incorporated

Dr Pagano

We used to run out of good options and we would just regress to the mean of chemotherapy plus inotuzumab in the salvage setting, but now we have so many great choices that that really takes a backseat. It's really been exciting to have multiple options for patients after T-DXd — again, practice changing, unprecedented.

APTITUDE HEALTH®

EPICS

Backbones for First-Line Ph-Positive ALL

Backbones for First-Line Ph-Positive ALL (1/3)

Presented by Elias Jabbour, MD

EPICS

The Evolving Role of TKIs

STUDY POPULATION

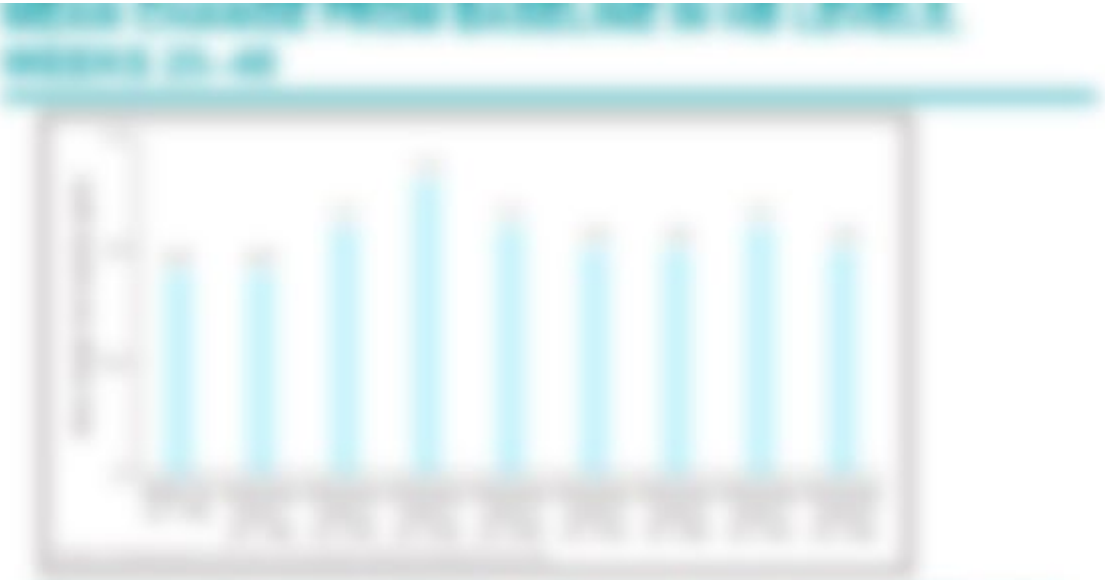
- MDCL317 study: MDS patients with ≥10% ring sideroblasts or ≥5% with *SF3B1* mutation, <5% blasts in bone marrow, non-del(5q) MDS refractory/intolerant to ESAs, or naive, average RBC transfusion burden ≥2 U/8 weeks, no prior treatment with disease-modifying agents (eg, IMiDs, HMAIs); randomized to luspatercept (n = 153) or placebo (n = 76). This subanalysis: 96/153 patients who did not achieve RBC transfusion independence (TI) for ≥8 weeks by week 23 but continued treatment through week 48

OUTCOMES

- 56% (n = 71/96) of patients achieved RBC TI for ≥8 weeks
  - 24 hours: 1 patient achieved RBC TI for ≥8 weeks
  - Median time to achieving RBC TI for ≥8 weeks was 3 months

EXPERT CONCLUSIONS

Continuing luspatercept treatment beyond week 23 provides clinical benefit in late responders and decreases the transfusion load in patients



Backbones for First-Line Ph-Positive ALL (2/3)

Presented by Elias Jabbour, MD

EPICS

The Evolving Role of TKIs

STUDY POPULATION

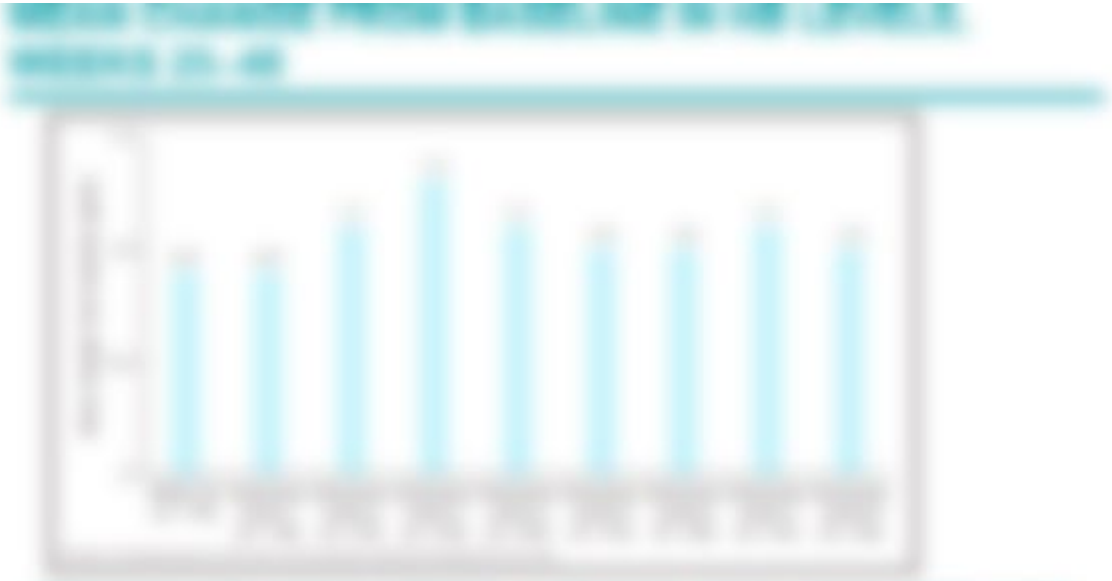
- MDCL317 study: MDS patients with ≥10% ring sideroblasts or ≥5% with *SF3B1* mutation, <5% blasts in bone marrow, non-del(5q) MDS refractory/intolerant to ESAs, or naive, average RBC transfusion burden ≥2 U/8 weeks, no prior treatment with disease-modifying agents (eg, IMiDs, HMAIs); randomized to luspatercept (n = 153) or placebo (n = 76). This subanalysis: 96/153 patients who did not achieve RBC transfusion independence (TI) for ≥8 weeks by week 23 but continued treatment through week 48

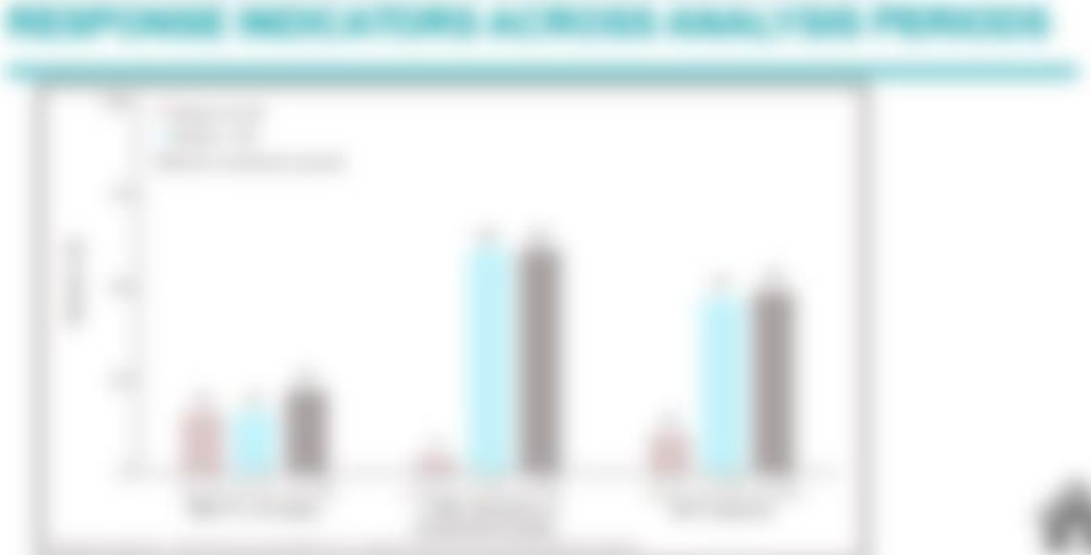
OUTCOMES

- 56% (n = 71/96) of patients achieved RBC TI for ≥8 weeks
  - 24 these 71 patients achieved RBC TI for ≥24 weeks
  - Median time to achieving RBC TI for ≥8 weeks was 3 months

EXPERT CONCLUSIONS

Continuing luspatercept treatment beyond week 23 provides clinical benefit in late responders and decreases the transfusion load in patients





Backbones for First-Line Ph-Positive ALL (3/3)

Presented by Elias Jabbour, MD

EPICS

The Evolving Role of TKIs

STUDY POPULATION

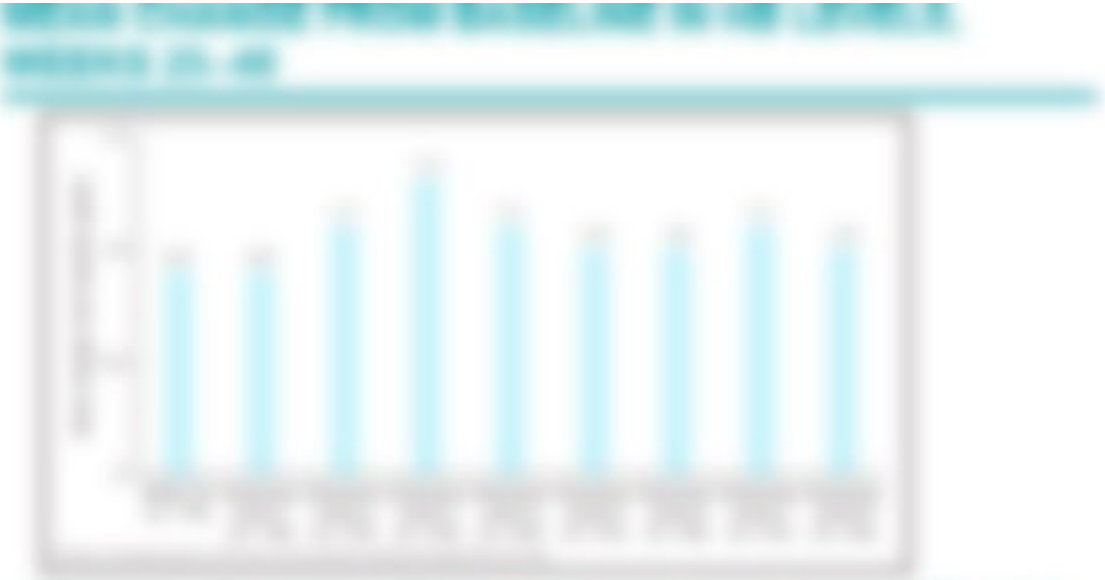
- MDCL317 study: MDS patients with ≥10% ring sideroblasts or ≥5% with *SF3B1* mutation, <5% blasts in bone marrow, non-del(5q) MDS refractory/intolerant to ESAs, or naive, average RBC transfusion burden ≥2 U/8 weeks, no prior treatment with disease-modifying agents (eg, IMiDs, HMAIs); randomized to luspatercept (n = 153) or placebo (n = 76). This subanalysis: 96/153 patients who did not achieve RBC transfusion independence (TI) for ≥8 weeks by week 23 but continued treatment through week 48

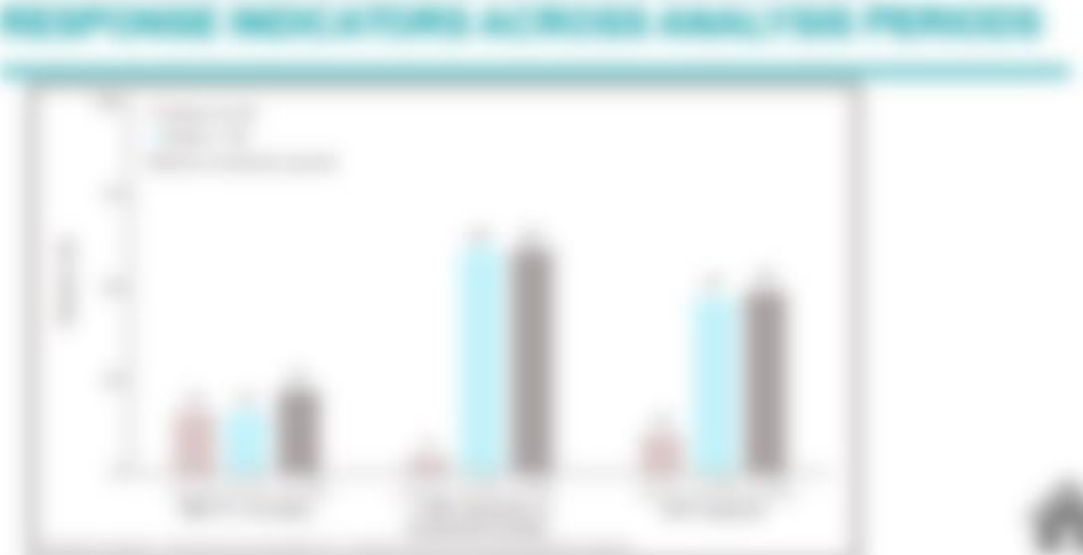
OUTCOMES

- 58% (n = 11/96) of patients achieved RBC TI for ≥8 weeks
  - 24 hours: 1 patient achieved RBC TI for ≥8 weeks
  - Median time to achieving RBC TI for ≥8 weeks was 3 months

EXPERT CONCLUSIONS

Continuing luspatercept treatment beyond week 23 provides clinical benefit in late responders and decreases the transfusion load in patients





APTITUDE HEALTH®

EPICS

Key Insights

Backbones for First-Line Ph-Positive ALL

Backbones for First-Line Ph-Positive ALL (1/3)

EPICS

Experts agreed that blinatumomab + ponatinib is a SOC for patients

Backbones for First-Line Ph-Positive ALL (2/3)

EPICS

Regional differences in reimbursement and drug availability affect rates

Dr Program

We used to run out of good options and we would just default to the mean of chemotherapy plus blinatumomab in the salvage setting, but now we have so many great choices that that really takes a backseat. It's really been exciting to have multiple options for patients after T-ONT — again, practice changing, unprecedented.

APTITUDE HEALTH®

Backbones for First-Line Ph-Positive ALL (3/3)

EPICS

There was no consensus among experts as to the optimal length of TKI

Dr Pagano

We used to run out of good options and we would just default to the mean of chemotherapy plus blinatumomab in the salvage setting, but now we have so many great choices that that really takes a backseat. It's really been exciting to have multiple options for patients after T-CAR — again, practice changing, unprecedented.

APTITUDE HEALTH®

EPICS

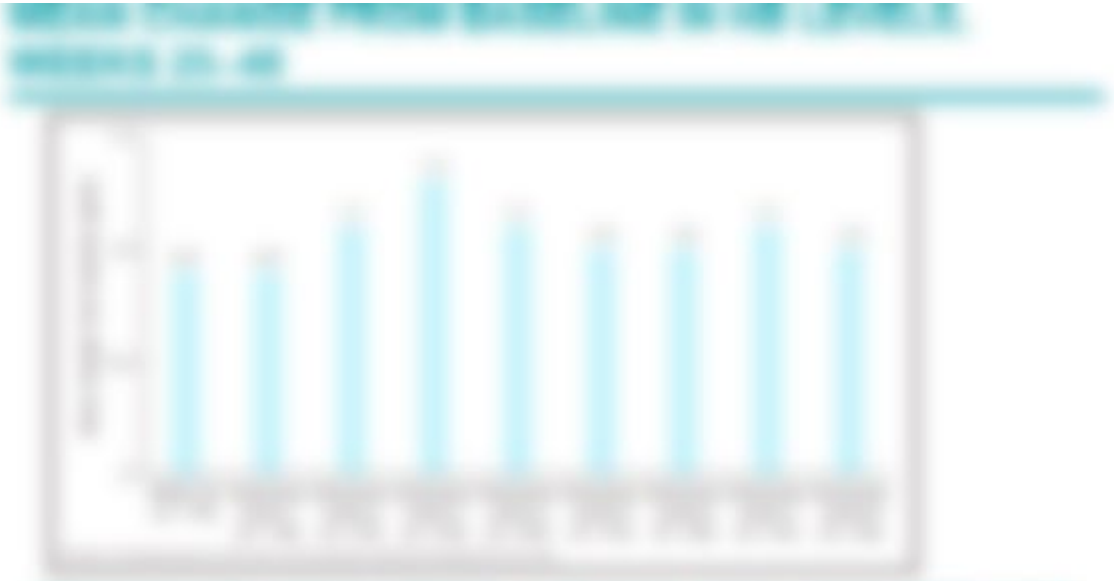
Backbones for First-Line Ph-Negative ALL – Transplant Ineligible

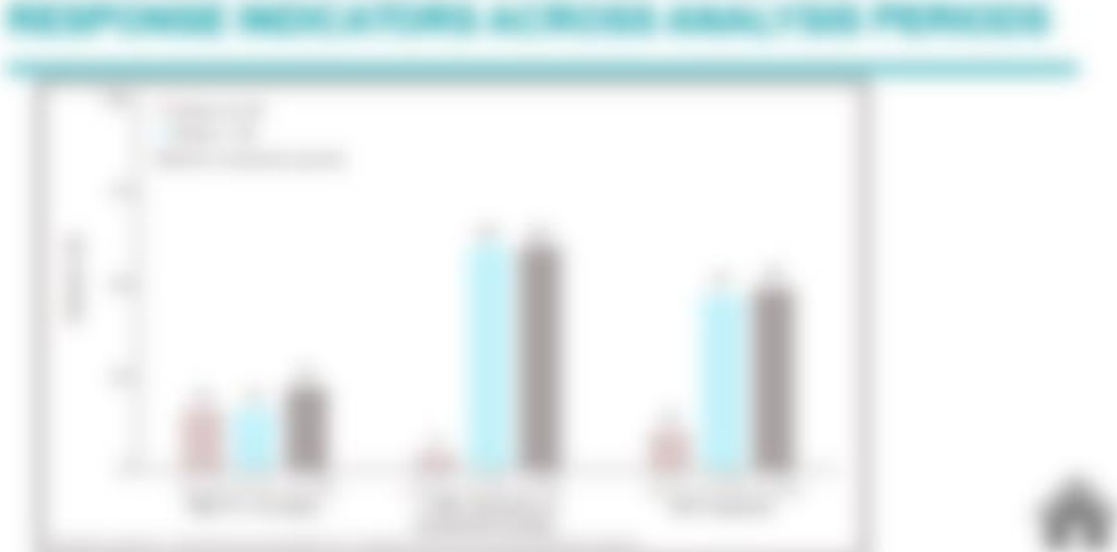
Backbones for First-Line Ph-Negative ALL – Transplant Ineligible (1/2)

Presented by Andre Schuh, MD

EPICS

Blinatumomab or InO as Single Agents



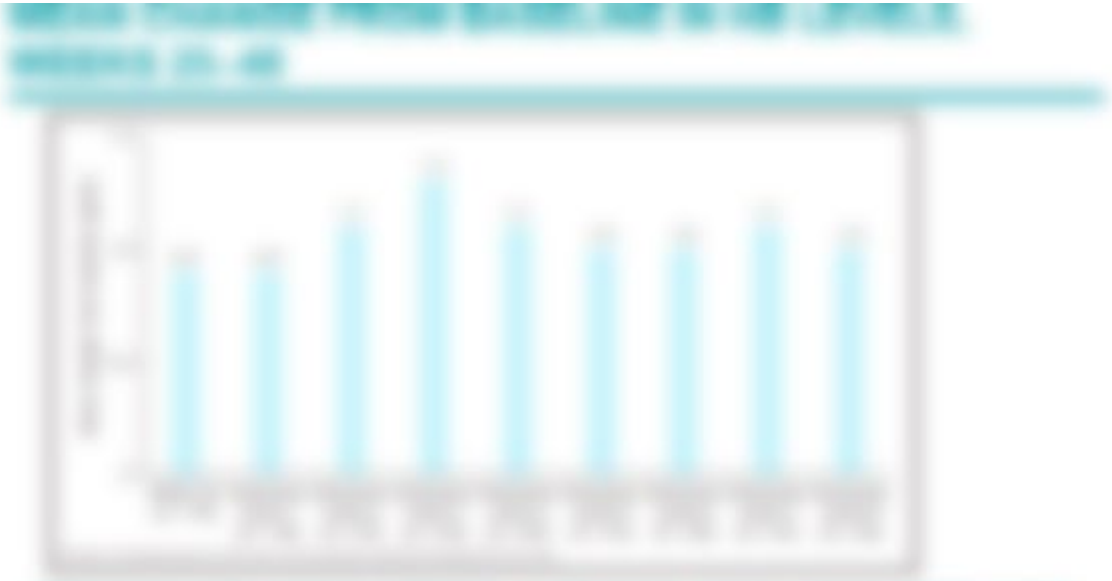


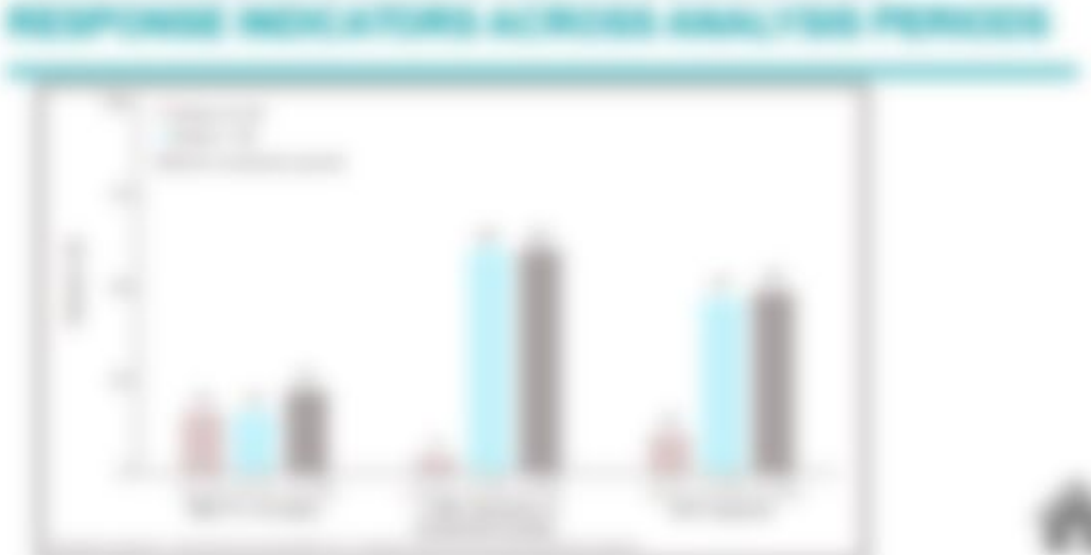
Backbones for First-Line Ph-Negative ALL – Transplant Ineligible (2/2)

Presented by Andre Schuh, MD

EPICS

Blinatumomab and InO in Combination





APTITUDE HEALTH®

EPICS

Key Insights

Backbones for First-Line Ph-Negative ALL – Transplant Ineligible

Backbones for First-Line Ph-Negative ALL – Transplant Ineligible (1/3)

EPICS

APTITUDE HEALTH®

Backbones for First-Line Ph-Negative ALL – Transplant Ineligible (2/3)

EPICS

CAR T cells were mentioned as a valid option for older transplant-

Backbones for First-Line Ph-Negative ALL – Transplant Ineligible (3/3)

EPICS

Asparaginase-based regimens are widely used by experts across all age

APTITUDE HEALTH®

EPICS

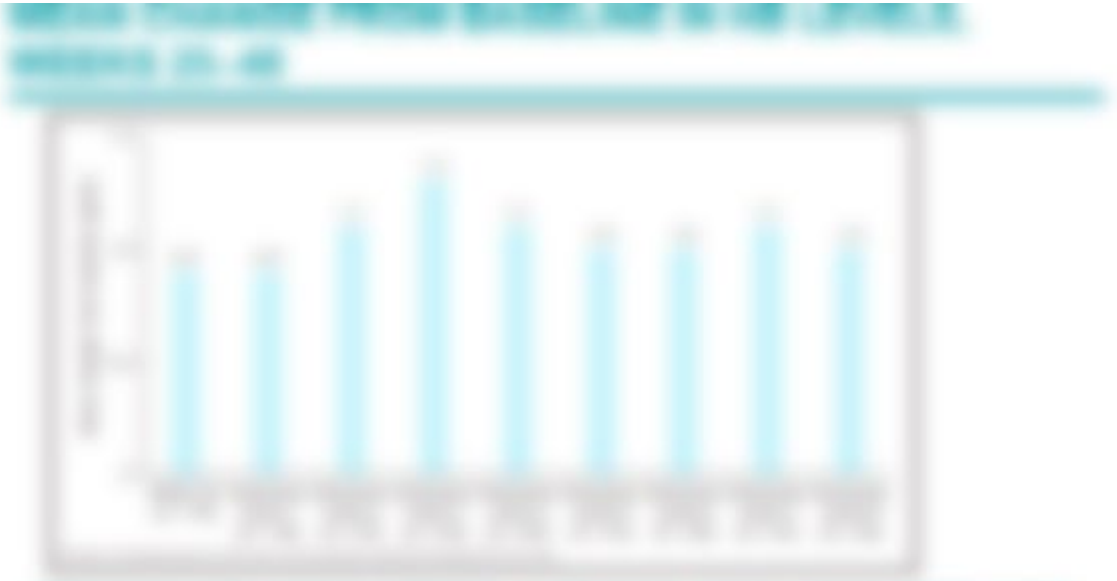
Backbones for First-Line Ph-Negative ALL – Transplant Eligible

Backbones for First-Line Ph-Negative ALL – Transplant Eligible (1/3)

Presented by Ibrahim Aldoss, MD

EPICS

Pediatric-Inspired Regimens in AYA Patients

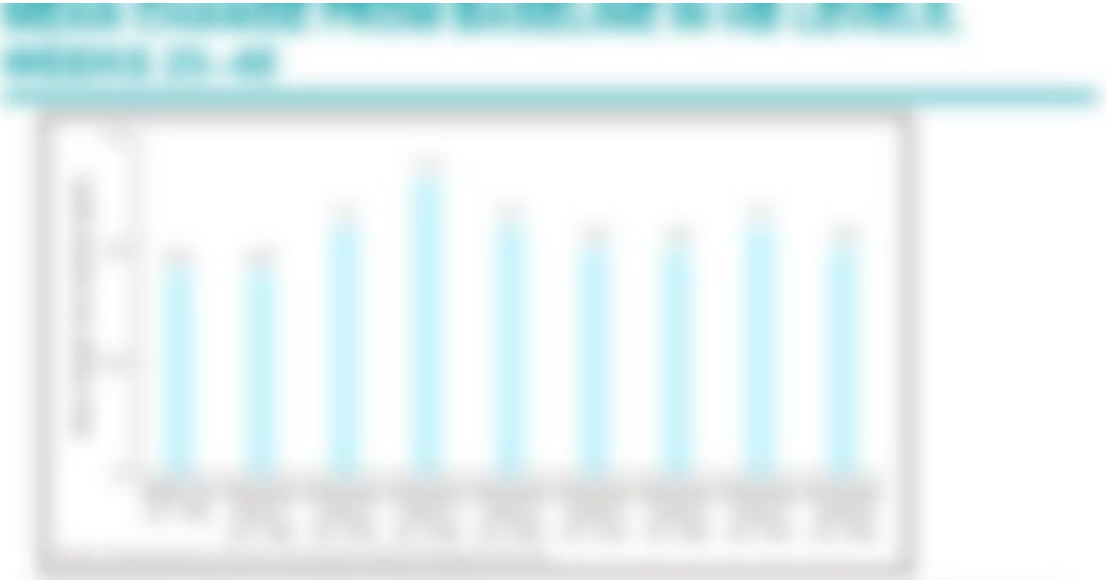


Backbones for First-Line Ph-Negative ALL – Transplant Eligible (2/3)

Presented by Ibrahim Aldoss, MD

EPICS

Blinatumomab and Low-Intensity Chemotherapy in Older Patients

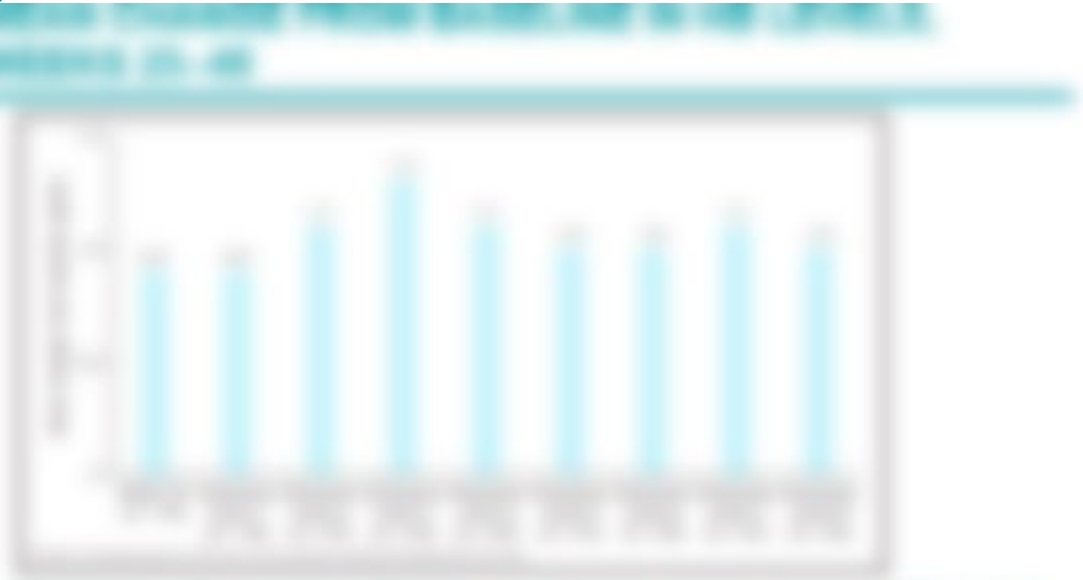


Backbones for First-Line Ph-Negative ALL – Transplant Eligible (3/3)

Presented by Ibrahim Aldoss, MD

EPICS

Fractionated InO and Low-Intensity Chemotherapy in Older Patients



APTITUDE HEALTH®

EPICS

Key Insights

Backbones for First-Line Ph-Negative ALL – Transplant Eligible

Backbones for First-Line Ph-Negative ALL – Transplant Eligible (1/3)

EPICS

Experts transplant fewer patients due to availability of potentially

Backbones for First-Line Ph-Negative ALL – Transplant Eligible (2/3)

EPICS

Experts believe blinatumomab ± inotuzumab is a SOC for patients with

Backbones for First-Line Ph-Negative ALL – Transplant Eligible (3/3)

EPICS

Regional differences in drug reimbursement affect usage of the

APTITUDE HEALTH®

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

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

UK 6th Floor, 2 Kingdom Street
London, W2 6BD, United Kingdom

aptitudehealth.com