APTITUDE HEALTH®

EPICS

EPICS CONGRESS COVERAGE: ASH 2020 – FOCUS ON NHL AND CLL

December 10, 2020

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BACKGROUND

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- On December 10, 2020, during the Virtual 62nd ASH Congress, Aptitude Health convened a group of experts in NHL and CLL to a small closed-session panel
- The goal of the panel was to discuss recent select studies presented at the ASH conference on NHL and CLL and their possible impact on real-world clinical practice

FACULTY EXPERTS

Chair
Brad Kahl, MD

John Allan, MD

Raul Cordoba, MD, PhD

Stefan Barta, MD, MS

Kieron Dunleavy, MD

Paolo Caimi, MD

Nitin Jain, MD

AGENDA

EPICS

Time	Topic	Speaker/Moderator
5 min	Welcome and Introductions	Brad Kahl, MD
10 min	**Advances in Early DLBCL**	Kieron Dunleavy, MD
10 min	Discussion	All
5 min	*Key Takeaways*	Brad Kahl, MD
10 min	**Advances in Relapsed/Refractory DLBCL**	Raul Cordoba, MD, PhD
20 min	Discussion	All
5 min	*Key Takeaways*	Brad Kahl, MD
10 min	**Advances in CAR T**	Paolo Caimi, MD
20 min	Discussion	All
5 min	*Key Takeaways*	Brad Kahl, MD
10 min	**Advances in MCL, FL, MZL**	John Allan, MD
20 min	Discussion	All
5 min	*Key Takeaways*	Brad Kahl, MD
10 min	**BREAK**	
10 min	**Advances in T-Cell Lymphoma and Others**	Stefan Barta, MD, MS
20 min	Discussion	All
5 min	*Key Takeaways*	Brad Kahl, MD
10 min	**Advances in CLL**	Nitin Jain, MD
15 min	Discussion	All
5 min	*Key Takeaways*	Brad Kahl, MD
5 min	Wrap-up and Close	Brad Kahl, MD

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Advances in Early DLBCL

Presenter: Kieron Dunleavy, MD

Moderator: Brad Kahl, MD

EARLY DLBCL: SELECTED ABSTRACTS (1/4)

597: Safety and Efficacy of Induction and Maintenance Avelumab Plus R-CHOP in Patients With DLBCL: Analysis of the Phase II AvR-CHOP Study

E.A. Hawkes, et al

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EARLY DLBCL: SELECTED ABSTRACTS (2/4)

401: Single-Agent Mosunetuzumab Is a Promising Safe and Efficacious Chemotherapy-Free Regimen for Elderly/Unfit Patients With Previously Untreated DLBCL

A.J. Olszewski, et al

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EARLY DLBCL: SELECTED ABSTRACTS (3/4)

3028: A Phase Ib, Open-Label, Randomized Study to Assess Safety and Preliminary Efficacy of Tafasitamab (MOR208) or Tafasitamab + Lenalidomide in Addition to R-CHOP in Patients with Newly Diagnosed DLBCL: Analysis of the Safety Run-in Phase

D. Baleda, et al

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EARLY DLBCL: SELECTED ABSTRACTS (4/4)

533: Double-Hit Signature With TP53 Abnormalities Predicts Poor Survival in Patients With Germinal Center B-Cell Like (GCB) DLBCL Treated With R-CHOP

J.Y. Song, et al

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EARLY DLBCL: DISCUSSION (1/2)

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EARLY DLBCL: DISCUSSION (2/2)

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Advances in R/R DLBCL

Presenter: Raul Cordoba, MD, PhD

Moderator: Brad Kahl, MD

R/R DLBCL: SELECTED ABSTRACTS (1/8)

598: Phase 1b/2 Study of ViPOR (Venetoclax, Ibrutinib, Prednisone, Obinutuzumab, and Lenalidomide) in R/R B-Cell Lymphoma: Safety, Efficacy and Molecular Analysis

C. Melani, et al

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R/R DLBCL: SELECTED ABSTRACTS (2/8)

599: Polatuzumab Vedotin Plus Venetoclax With Rituximab in R/R DLBCL: Primary Efficacy Analysis of a Phase Ib/II Study

G. Gritti, et al

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R/R DLBCL: SELECTED ABSTRACTS (3/8)

2099: Interim Results of Loncastuximab Tesirine Combined With Ibrutinib in DLBCL or MCL (LOTIS-3)

J. Depaus, et al

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R/R DLBCL: SELECTED ABSTRACTS (4/8)

1183: Efficacy and Safety of Loncastuximab Tesirine (ADCT-402) in R/R DLBCL

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R/R DLBCL: SELECTED ABSTRACTS (5/8)

400: Odronextamab (REGN1979), a Human CD20 x CD3 Bispecific Ab, Induces Durable CRs in Patients With Highly Refractory B-Cell NHL, Including Patients Refractory to CAR T Therapy

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R/R DLBCL: SELECTED ABSTRACTS (6/8)

402: Subcutaneous Epcoritamab Induces CRs With an Encouraging Safety Profile Across R/R B-Cell NHL Subtypes, Including Patients With Prior CAR-T Therapy: Updated Dose Escalation Data

M. Hutchings, et al

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R/R DLBCL: SELECTED ABSTRACTS (7/8)

403: Glofitamab Step-up Dosing Induces High Response Rates in Patients With Hard-to-Treat Refractory or Relapsed NHL

M. Hutchings, et al

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R/R DLBCL: SELECTED ABSTRACTS (8/8)

126: A Once Daily, Oral, Triple Combination of BTK Inhibitor, mTOR Inhibitor and IMiD for Treatment of R/R Richter's Transformation and De Novo DLBCL

A.R. Mato, et al

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R/R DLBCL: DISCUSSION (1/2)

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R/R DLBCL: DISCUSSION (2/2)

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Advances in CAR T Therapy

Presenter: Paolo Caimi, MD

Moderator: Brad Kahl, MD

CAR T-CELL THERAPY: SELECTED ABSTRACTS (1/8)

118: Safety and Preliminary Efficacy in Patients With R/R MCL Receiving Lisocabtagene Maraleucel in TRANSCEND NHL 001

M.L. Palomba, et al

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CAR T-CELL THERAPY: SELECTED ABSTRACTS (2/8)

700: Primary Analysis of ZUMA-5: A Phase 2 Study of Axicabtagene Ciloleucel (Axi-Cel) in Patients With R/R iNHL

C. Jacobson, et al

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CAR T-CELL THERAPY: SELECTED ABSTRACTS (3/8)

405: Interim Analysis of ZUMA-12: A Phase 2 Study of Axi-Cel as First-Line Therapy in Patients With High-Risk LBCL

S.S. Neelapu, et al

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CAR T-CELL THERAPY: SELECTED ABSTRACTS (4/8)

736: CD22-Directed CAR T Cell Therapy Mediates Durable CRs in Adults With R/R LBCL After Failure of CD19-Directed CAR T Cell Therapy and High Response Rates in Adults With R/R B-Cell ALL

S.S. Neelapu, et al

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CAR T-CELL THERAPY: SELECTED ABSTRACTS (5/8)

600: Phase 1 Alexander Study of AUTO3, the First CD19/22 Dual Targeting CAR T Cell Therapy, With Pembrolizumab in Patients With R/R DLBCL

A.R. Ramakrishnan, et al

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CAR T-CELL THERAPY: SELECTED ABSTRACTS (6/8)

404: Phase I Trial of MB-CART2019.1, a Novel CD20- and CD19-Targeting Tandem CAR, in Patients With R/R B-Cell NHL

P. Borchmann, et al

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CAR T-CELL THERAPY: SELECTED ABSTRACTS (7/8)

1194: Myc Expression and Tumor-Infiltrating T Cells Are Associated With Response in Patients (Pts) With Relapsed/Refractory Diffuse Large B-Cell Lymphoma (r/r DLBCL) Treated With Tisagenlecleucel in the JULIET Trial

U. Jaeger, et al

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CAR T-CELL THERAPY: SELECTED ABSTRACTS (8/8)

1149: Efficacy and Safety of Tisagenlecleucel in Adult Patients With R/R FL: Interim Analysis of the Phase 2 ELARA Trial

N.H. Fowler, et al

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CAR T-CELL THERAPY: DISCUSSION (1/2)

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CAR T-CELL THERAPY: DISCUSSION (2/2)

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Advances in MCL, FL, and MZL

Presenter: John Allan, MD

Moderator: Brad Kahl, MD

MCL: SELECTED ABSTRACTS (1/3)

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121: VLS-101, a ROR1-Targeting Antibody-Drug Conjugate, Demonstrates a Predictable Safety Profile and Clinical Efficacy in Patients With Heavily Pretreated MCL and DLBCL

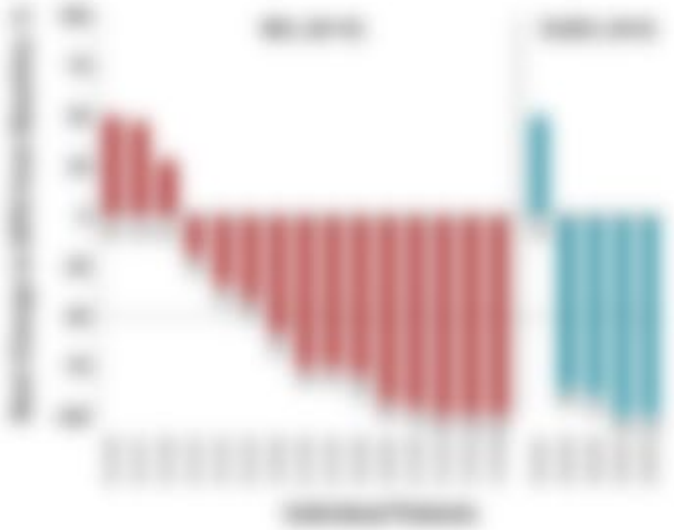
M. Wang, et al

Background

- Phase I dose-escalation study of VLS-101, a ROR1-targeting ADC, in patients with heavily pretreated MCL and DLBCL
- Primary objective was to refine estimates of MTD and recommended dosing regimen

Results

- 32 patients were enrolled, including 15 patients with MCL
- DLTs were G4 neutropenia and G3 diarrhea
- G4 neutropenia occurred in 28% of patients; G-CSF successfully ameliorated neutropenia
- On-study reversible G3 neuropathy occurred in 9% of patients; no G4 neuropathy occurred
- ORR was 47% (3 CR, 4 PR) for MCL cohort and 80% (2 CR, 2 PR) for DLBCL cohort
- 8 responding patients have ongoing responses ranging from 23 weeks to 58 weeks



Key takeaways: VLS-101 demonstrated a manageable and predictable safety profile and encouraging efficacy, with durable responses in advanced MCL and DLBCL. Experts mentioned neuropathy as a potential concern and the need to identify the best histologies in which to test this agent.

MCL: SELECTED ABSTRACTS (2/3)

EPICS

122: Venetoclax, Lenalidomide and Rituximab for Patients With R/R MCL – Data From the Nordic Lymphoma Group NLG-MCL7 (VALERIA) Phase I Trial: Stopping Treatment in Molecular Remission Is Feasible

M. Jerkeman, et al

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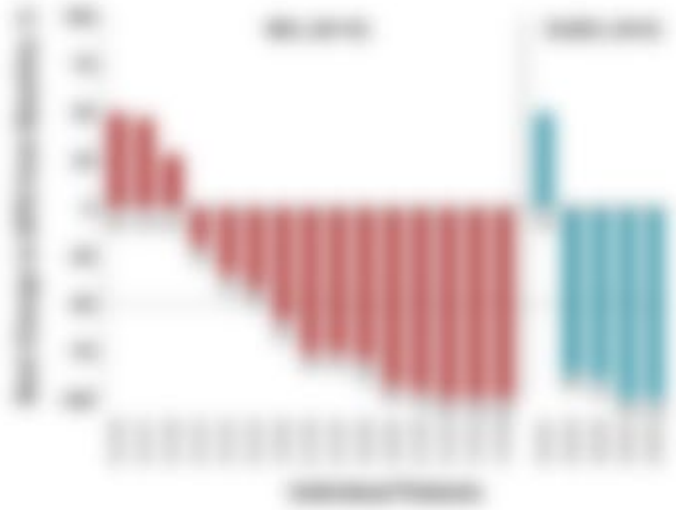

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MCL: SELECTED ABSTRACTS (3/3)

117: LOXO-305, A Next Generation, Highly Selective, Non-Covalent BTK Inhibitor in Previously Treated MCL, Waldenström's Macroglobulinemia, and Other NHL: Results From the Phase 1/2 BRUIN Study

M. Wang, et al

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FL: SELECTED ABSTRACTS (1/3)

702: Mosunetuzumab Shows Promising Efficacy in Patients With Multiply Relapsed FL: Updated Clinical Experience From a Phase I Dose-Escalation Trial

S.E. Assouline, et al

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FL: SELECTED ABSTRACTS (2/3)

2064: Tazemetostat Is Associated With Lower Risk for Safety Outcomes Versus the PI3Ks Idelalisib, Duvelisib and Copanlisib, in Patients With R/R FL Who Have Received ≥2 Prior Systemic Treatments: A Matching-Adjusted Indirect Comparison of Single-Arm Trials

S.E. Assouline, et al

FL: SELECTED ABSTRACTS (3/3)

2047: Analyzing Efficacy Outcomes From the Phase 2 Study of Single-Agent Tazemetostat as Third-Line Therapy in Patients With R/R FL to Identify Predictors of Response

G. Salles, et al

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MZL: SELECTED ABSTRACTS (1/2)

338: Phase 2 Study Evaluating the Efficacy and Safety of Parsaclisib in Patients With R/R MZL (CITADEL-204)

T.J. Phillips, et al

EPICS

MZL: SELECTED ABSTRACTS (2/2)

339: Efficacy and Safety of Zanubrutinib in Patients With R/R MZL: Initial Results of the MAGNOLIA (BGB-3111-214) Trial

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MCL: DISCUSSION

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FL: DISCUSSION

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MZL: DISCUSSION

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Advances in T-Cell Lymphoma and Others

Presenter: Stefan Barta, MD, MS

Moderator: Brad Kahl, MD

T-CELL LYMPHOMA AND OTHERS: SELECTED ABSTRACTS (1/5)

40: Multi-Center Phase II Study of Oral Azacitidine (CC-486) Plus CHOP as Initial

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[redacted]

T-CELL LYMPHOMA AND OTHERS: SELECTED ABSTRACTS (2/5)

44: Duvelisib in Patients With R/R PTCL From the Phase 2 PRIMO Trial: Dose

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[redacted]

T-CELL LYMPHOMA AND OTHERS: SELECTED ABSTRACTS (3/5)

645: A Phase II Study of Pembrolizumab in Combination With Romidepsin

EPICS

[redacted]

T-CELL LYMPHOMA AND OTHERS: SELECTED ABSTRACTS (4/5)

374: Effect of Pembrolizumab Monotherapy Versus Brentuximab Vedotin (BV) on Symptoms Associated With HRQoL in R/R cHL in the Randomized, Phase 3, KEYNOTE-204 Study

P.L. Zinzani, et al

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T-CELL LYMPHOMA AND OTHERS: SELECTED ABSTRACTS (5/5)

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646: Updates From Ongoing, First-in-Human Phase 1 Dose Escalation and Expansion Study of TTI-621, a Novel Biologic Targeting CD47, in Patients With R/R Hematologic Malignancies

S. Horwitz, et al

[illegible]

T-CELL LYMPHOMA AND OTHERS: DISCUSSION (1/2)

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T-CELL LYMPHOMA AND OTHERS: DISCUSSION (2/2)

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Advances in CLL

Presenter: Nitin Jain, MD

Moderator: Brad Kahl, MD

CLL: SELECTED ABSTRACTS (1/6)

123: Ibrutinib (Ibr) Plus Venetoclax (Ven) for First-Line Treatment of CLL/SLL: 1-Year DFS Results From the MRD Cohort of the Phase 2 CAPTIVATE Study

W.G. Wierda, et al

EPICS

Background

- Phase I dose-escalation study of VLS-101, a ROR1-targeting ADC, in patients with heavily pretreated MCL and DLBCL
- Primary objective was to refine estimates of MTD and recommended dosing regimen

Results

- 32 patients were enrolled, including 15 patients with MCL
- DLTs were G4 neutropenia and G3 diarrhea
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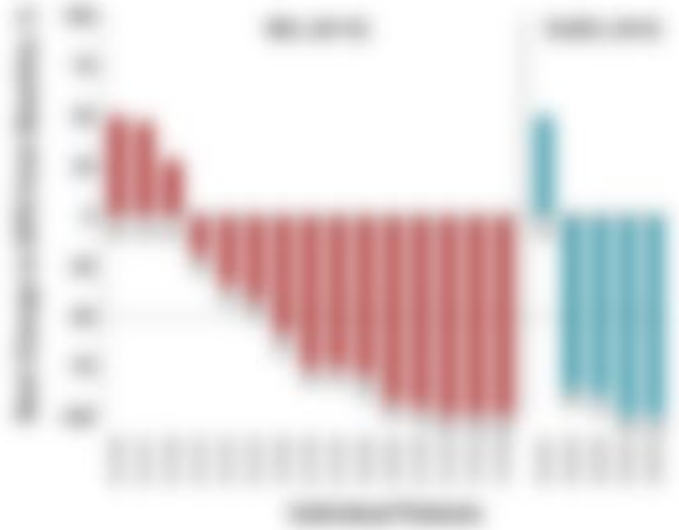

Key takeaways: VLS-101 demonstrated a manageable and predictable safety profile and encouraging efficacy, with durable responses in advanced MCL and DLBCL. Experts mentioned neuropathy as a potential concern and the need to identify the best histologies in which to test this agent.

CLL: SELECTED ABSTRACTS (2/6)

124: Continued Long Term Responses to Ibrutinib + Venetoclax Treatment for Relapsed/Refractory CLL in the Blood Cancer UK TAP CLARITY Trial

T. Munir, et al

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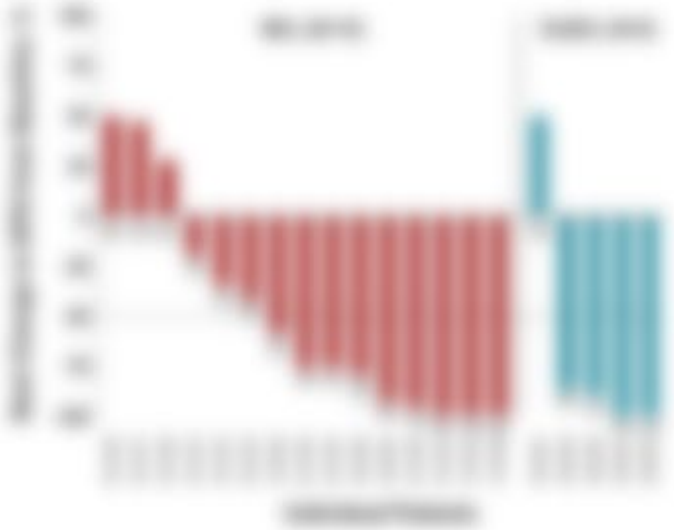

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CLL: SELECTED ABSTRACTS (3/6)

3138: Combined Ibrutinib and Venetoclax for First-Line Treatment for Patients With CLL: Focus on MRD Results

N. Jain, et al

EPICS

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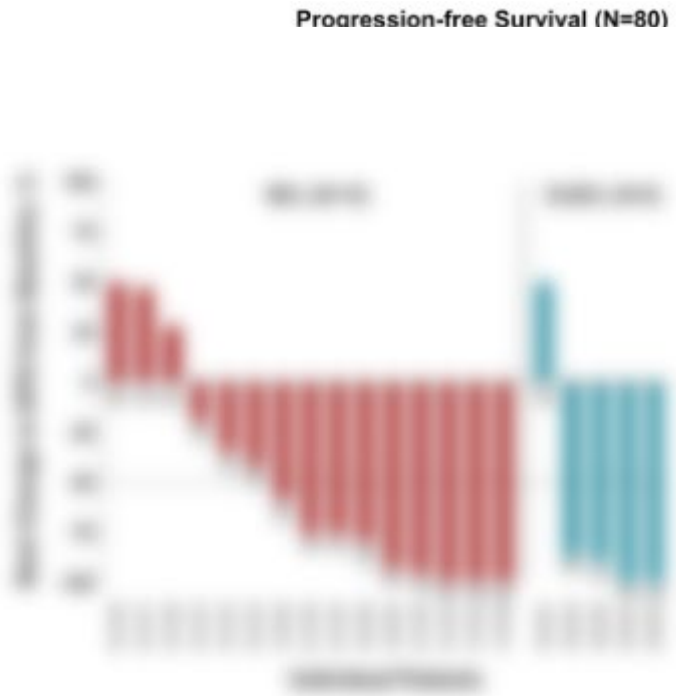

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CLL: SELECTED ABSTRACTS (4/6)

1307: MRD-Driven Time Limited Therapy With Zanubrutinib, Obinutuzumab, and Venetoclax (BOVen) in Previously Untreated CLL

J.D. Soumerai, et al

EPICS

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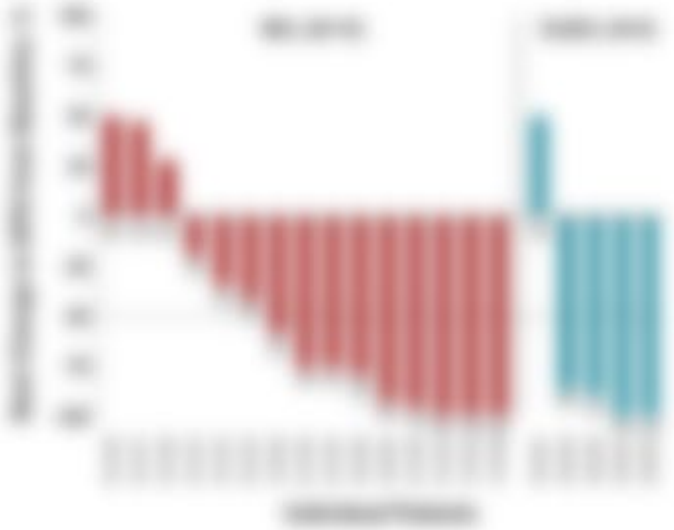

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CLL: SELECTED ABSTRACTS (5/6)

543: Umbralisib Plus Ublituximab (U2) Is Superior to Obinutuzumab Plus Chlorambucil (O+Chl) in Patients With Treatment-Naïve and R/R CLL: Results From the Phase 3 Unity-CLL Study

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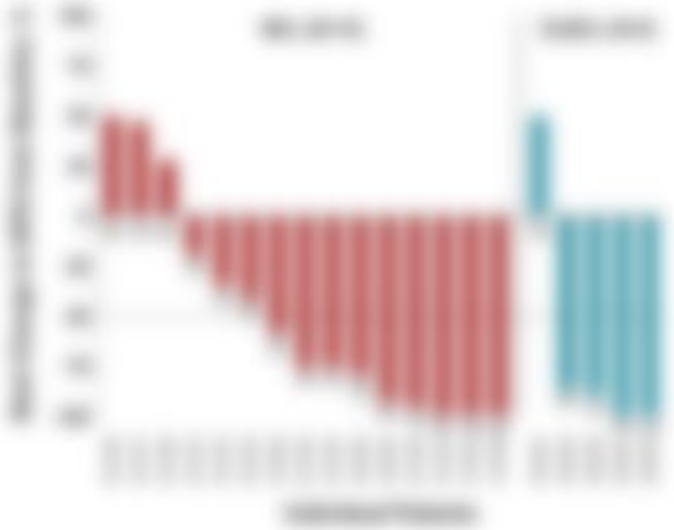

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A.R. Mato, et al

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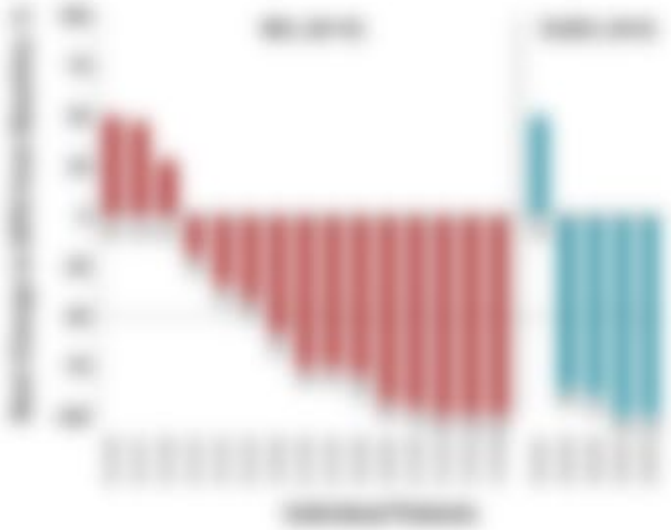

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CLL: DISCUSSION (1/2)

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CLL: DISCUSSION (2/2)

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ABBREVIATIONS

ABBREVIATIONS (1/3)

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ABBREVIATIONS (2/3)

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ABBREVIATIONS (3/3)

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