



EPICS

CONGRESS COVERAGE: EHA/ICML 2021 – FOCUS ON LYMPHOMA

Tuesday, June 29, 2021

FULL REPORT

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VIRTUAL CLOSED-DOOR ROUNDTABLE



PANEL: Key experts in lymphoma
➢ 3 from US
➢ 3 from Europe



DATE:
June 29, 2021



SELECTED EHA and ICML 2021 ABSTRACT PRESENTATIONS by key experts

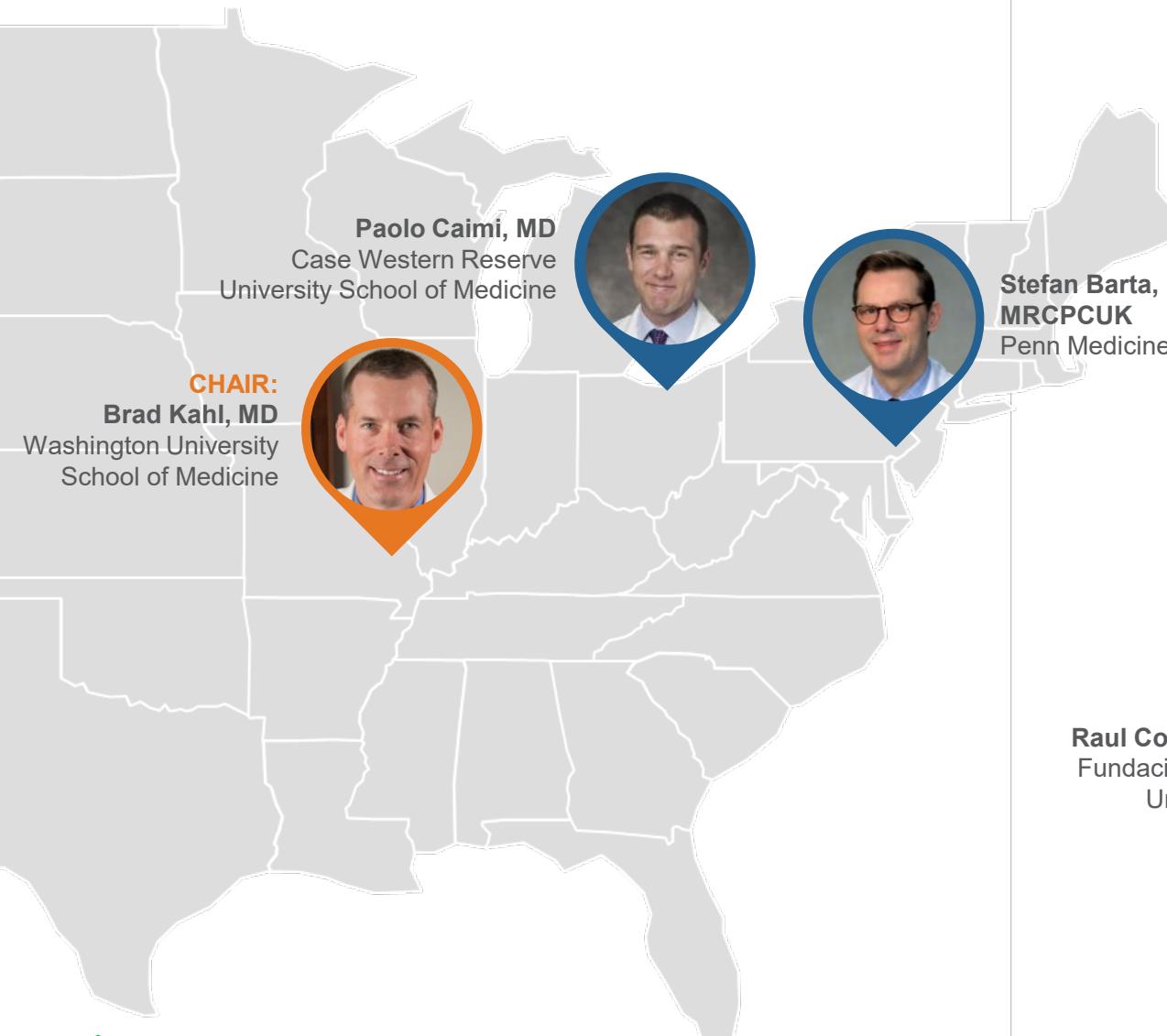


LYMPHOMA-SPECIFIC DISCUSSIONS
on latest research updates, therapeutic advances, and their application in clinical decision-making



INSIGHTS REPORT
including postmeeting analyses and actionable recommendations

PANEL CONSISTING OF 3 US AND 3 EUROPEAN LYMPHOMA EXPERTS



MEETING AGENDA

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Time (CEST)	Topic	Speaker/Moderator
16.00 – 16.05	Welcome and Introductions	Brad Kahl, MD
16.05 – 16.20	Update on DLBCL	Andrew Davies, BSc, BM, FRCP, PhD
16.20 – 16.40	Discussion and Key Takeaways	
16.40 – 16.55	Update on Indolent NHLs (FL and MCL)	Pier Luigi Zinzani, MD, PhD
16.55 – 17.15	Discussion and Key Takeaways	
17.15 – 17.30	Update on T-Cell Lymphoma	Stefan K. Barta, MD, MS, MRCPCUK
17.30 – 17.50	Discussion and Key Takeaways	
17.50 – 18.00	Break	
18.00 – 18.15	Update on CLL	Raul Cordoba, MD, PhD
18.15 – 18.30	Discussion and Key Takeaways	
18.30 – 18.45	CAR Ts	Paolo Caimi, MD
18.45 – 18.55	Discussion and Key Takeaways	
18.55 – 19.00	Summary and Closing Remarks	Brad Kahl, MD





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CONGRESS HIGHLIGHTS

KEY TAKEAWAYS: DLBCL (1/2)

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Guiding 1L therapy with genetic subtyping is feasible. Early data on mosunetuzumab are exciting, especially in the elderly. Tafasitamab regimens are seen as having promising efficacy and tolerability, both in 1L and in R/R DLBCL

Genetic subtype guided rituximab-based immunochemotherapy improves outcome in newly diagnosed DLBCL: first report of a



KEY TAKEAWAYS: DLBCL (2/2)

EPICS

Many promising studies were presented, but nothing appears to be immediately practice changing

Safety and efficacy of CD37-targeting naratuximab emtansine plus rituximab in DLBCL and other NHLs - a phase 2 study—(EHA) Levy



KEY TAKEAWAYS: INDOLENT NHLs (FL AND MCL) (1/2)

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Novel therapies are promising, but further data are needed for treatment selection and sequencing

The combination of venetoclax, lenalidomide and rituximab in patients with newly diagnosed mantle cell lymphoma induces high

KEY TAKEAWAYS: INDOLENT NHLs (FL AND MCL) (2/2)

EPICS

Novel therapies are promising, but further data are needed for treatment selection and sequencing

SAKK 36/13 – ibrutinib plus bortezomib and ibrutinib maintenance for R/R mantle cell lymphoma: final report of a phase I/II trial of the



KEY TAKEAWAYS: T-CELL LYMPHOMAS (1/2)

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Emerging data support current approaches and suggest that allo-SCT could address unmet needs in PTCL

Impact of etoposide and autologous stem-cell transplantation on survival among young patients with PTCL in The Netherlands; a



KEY TAKEAWAYS: T-CELL LYMPHOMAS (2/2)

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Data for emerging agents appear promising, but further studies are needed before practice will be affected

Comparison of chidamide-contained treatment modalities versus chemotherapy in relapsed or refractory PTCL—(EHA) Cai #EP549



KEY TAKEAWAYS: CLL (1/2)

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Emerging data support expanded use of venetoclax in fixed-duration therapies and the ELEVATE-TN regimen in high-risk CLL. Debulking approach is emerging as the new trend for reducing TLS

Venetoclax-obinutuzumab for previously untreated chronic lymphocytic leukemia: 4-year follow-up analysis of the randomized CLL14

KEY TAKEAWAYS: CLL (2/2)

EPICS

Fixed-duration venetoclax-based therapies are attractive, and later-generation BTKi are coming of age

CAPTIVATE primary analysis of first-line treatment with fixed-duration ibrutinib plus venetoclax for CLL/SLL—(ICML) Tam #32



KEY TAKEAWAYS: CAR T (1/2)

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Multiple advances are underway in the CAR T space but not yet ready. Better prediction of hematotoxicity will be useful for management of CAR T patients

First results of DLBCL patients treated with CAR-T cells and enrolled in DESCAR-T registry. a French real-life database for CAR-T

KEY TAKEAWAYS: CAR T (2/2)

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EHA data support the use of axi-cel in R/R FL, especially in patients with POD24

A comparison of clinical outcomes from ZUMA-5 (axicabtagene ciloleucel) and the international SCHOLAR-5 external control cohort in





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Update on DLBCL

KEY TAKEAWAYS: DLBCL

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Overall

Data from EHA and ICML are seen as reinforcement for current practices/confirmation of findings with longer-term follow-up

ADCs

The CD37-targeting ADC nataximab emtansine has promising activity in combination with rituximab in SCT-ineligible R/R



KEY TAKEAWAYS: DLBCL

EPICS

Molecular targeted therapies are promising in DLBCL

Experts believe a strategy of genetic screening and adapting therapy accordingly could become feasible. They expect clinical practice to

Bispecifics and mAbs (continued)

Tafasitamab is seen as generally well tolerated with activity as a single agent and in combination with



GENETIC SUBTYPE GUIDED RITUX-BASED IMMUNOCHEMOTHERAPY IMPROVES OUTCOME IN NEWLY DIAGNOSED DLBCL: FIRST REPORT OF A RANDOMIZED PHASE 2 STUDY

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PROMISING TOLERABILITY AND EFFICACY RESULTS FROM DOSE-ESCALATION IN AN ONGOING PHASE IB/II STUDY OF MOSUNETUZUMAB WITH POLATUZUMAB VEDOTIN FOR R/R B-CELL NHL

GHOSH ET AL. 2021 ASH #S222

MOSUNETUZUMAB MONOTHERAPY FOR ELDERLY/UNFIT PATIENTS WITH 1L DLBCL CONTINUES TO SHOW PROMISING SAFETY AND EFFICACY WITH DURABLE COMPLETE RESPONSES

OLSZEWSKI ET AL. 2021 EHA #EP503

FIRST-MIND: A PHASE IB, OPEN-LABEL, RANDOMIZED STUDY TO ASSESS SAFETY OF TAFASITAMAB OR TAFA + LENALIDOMIDE IN ADDITION TO R-CHOP IN PATIENTS WITH NEWLY DIAGNOSED DLBCL

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LONG-TERM ANALYSES FROM L-MIND, A PHASE II STUDY OF TAFA + LENALIDOMIDE (LEN) ADDED TO R-CHOP IN PTS WITH R/R DLBCL

DUEL ET AL. 2021 ICML #28

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SAFETY AND EFFICACY OF CD37-TARGETING NARATUXIMAB EMTANSINE + RITUX IN DLBCL AND OTHER NHLS - A PHASE 2 STUDY

LEVY ET AL. 2021 EHA #LBA1903

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SUBCUTANEOUS EPCORITAMAB IN PATIENTS WITH R/R B-CELL NHL: SAFETY PROFILE AND ANTI-TUMOR ACTIVITY

MOUS ET AL. EHA 2021 #EP499 AND HUTCHINGS ET AL. ICML 2021 #16

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GLOFITAMAB STEP-UP DOSING: UPDATED EFFICACY DATA SHOW HIGH CR RATES IN HEAVILY PRETREATED R/R NHL PATIENTS

CARLO-STELLA ET AL. 2021 EHA #EP501 AND ICML #15

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DURATION OF RESPONSE TO LONCASTUXIMAB TESIRINE IN R/R DLBCL BY DEMOGRAPHIC AND CLINICAL CHARACTERISTICS: SUBGROUP ANALYSES FROM LOTIS 2

ZINZANI ET AL. 2021 EHA #7546 AND ICML #177

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Update on Indolent NHLs (FL and MCL)

KEY TAKEAWAYS: iNHLs

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Multiple studies reinforce current treatment practices

The FOLL12 trial results are seen as conclusive evidence

Other studies show promise, but further data are needed

Experts are impressed with the activity signals and the excellent



RESPONSE ADAPTED POST INDUCTION THERAPY IN FL: UPDATED RESULTS OF THE FOLL12 TRIAL BY THE FONDAZIONE ITALIANA I INFOMI (FII)

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CHRONOS-3: RANDOMIZED PHASE III STUDY OF COPANLISIB PLUS RITUXIMAB VS RITUXIMAB/PLACEBO IN RELAPSED iNHL

ZINZANI ET AL. 2021 EHA #S211

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INDUCTION R² FOLLOWED BY MAINTENANCE IN PATIENTS WITH R/R MCL: INTERIM ANALYSIS FROM THE PHASE 3B MAGNIFY STUDY

SHARMAN ET AL. 2021 ICML #63

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SAKK 36/13 - IBRUTINIB PLUS BORTEZOMIB AND IBRUTINIB MAINTENANCE FOR R/R MCL: FINAL REPORT OF A PH I/II TRIAL OF THE EUROPEAN MCL NETWORK

NOVAK ET AL. 2021 ICML #062

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IMMUNE PRIMING WITH NIVOLUMAB FOLLOWED BY NIVOLUMAB & RITUXIMAB IN 1ST LINE FOLLICULAR LYMPHOMA: PHASE II 1ST FLOR STUDY

HAWKES ET AL. 2021 ICML #81



EFFICACY AND SAFETY OF IBRUTINIB + RITUXIMAB AS 1L TREATMENT FOR INDOLENT MCL. RESULTS OF THE GELTAMO IMCL-2015 STUDY

GINÉ ET AL. 2021 ICML #60

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Update on T-Cell Lymphoma



KEY TAKEAWAYS: TCL

EPICS

Multiple studies reinforce current treatment practices

The current practice of using CHOP or CHOEP + ASCT for young, fit patients with ALCL, AITL, or PTCL-NOS is supported

Other studies show promise, but further data are needed

Single-agent venetoclax was found to have limited activity in BCL2-positive R/R PTCL



IMPACT OF ETOPOSIDE AND ASCT ON SURVIVAL AMONG YOUNG PATIENTS WITH PTCL IN THE NETHERLANDS; A NATIONWIDE, POPULATION-BASED COHORT STUDY

BRINK ET AL. 2021 EHA #S220



MULTI-CENTER PHASE II STUDY OF ROMIDEPSIN PLUS LENALIDOMIDE FOR PATIENTS WITH PREVIOUSLY UNTREATED PERIPHERAL T-CELL LYMPHOMA (PTCL)

RUAN ET AL. 2021 EHA #55

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AUTOLOGOUS OR ALLOGENEIC HEMATOPOIETIC CELL TRANSPLANTATION FOR PTCL-NOS AND ANGIOIMMUNOBLASTIC T-CELL LYMPHOMA FAILING 1L THERAPY

KAMEDA ET AL. 2021 EHA #S244

ECHELON-2 (NCT01777152), 5-YR RESULTS OF A RANDOMISED, DOUBLE-BLIND, PHASE 3 STUDY OF 1L BRENTUXIMAB VEDOTIN + CHP VS CHOP IN CD30+ PTCL

DOMÈNECH ET AL. 2021 EHA #EP506

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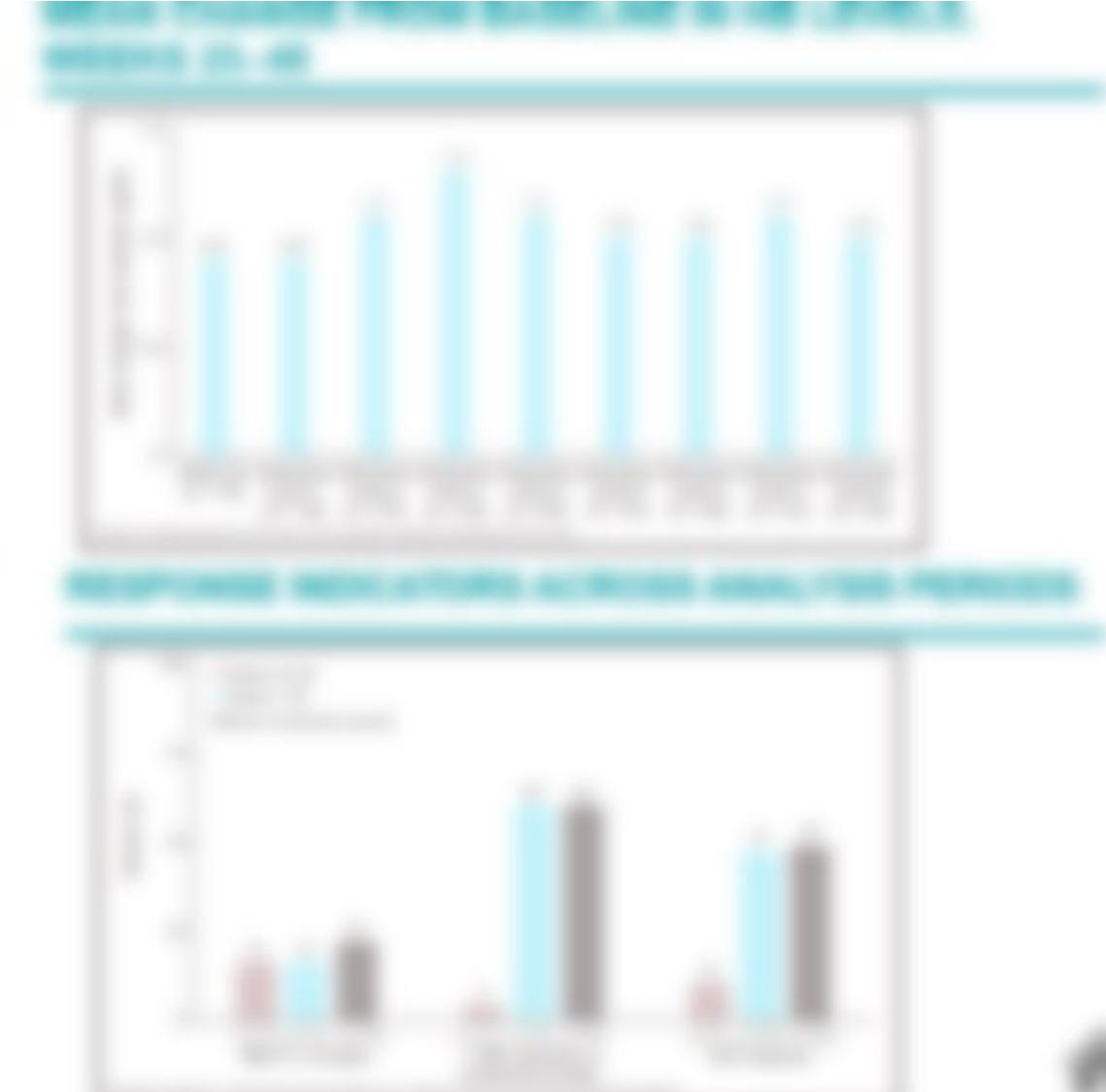
VENETOCLAX AS SINGLE AGENT IN BCL2-POSITIVE R/R PTCL. A PHASE 2 STUDY OF THE FONDAZIONE ITALIANA LINFOMI

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ZAJA ET AL. 2021 EHA #EP543

STUDY POPULATION

Characteristic	Number of patients	Percentage
Age, median (range)	56 (18-75)	
Sex (n = 11)		
Male	7	64%
Female	4	36%
Performance status (n = 11)		
0	4	36%
1	7	64%
Ann Arbor stage (n = 11)		
I	1	9%
II	2	18%
III	4	36%
IV	4	36%
BCL2 expression (n = 11)		
Positive	10	91%
Negative	1	9%
Previous treatments (n = 11)		
1	1	9%
2	3	27%
3	3	27%
4	4	36%



COMPARISON OF CHIDAMIDE-CONTAINED TREATMENT MODALITIES VERSUS CHEMOTHERAPY IN R/R PTCL

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CAI ET AL. 2021 EHA #EP549

STUDY POPULATION

PFS AND OS OVERALL AND BY IPI AND CD30 STATUS



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Update on CLL

KEY TAKEAWAYS: CLL

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Venetoclax

Venetoclax

BTK inhibitors

Acalabrutinib and zanubrutinib have demonstrated activity



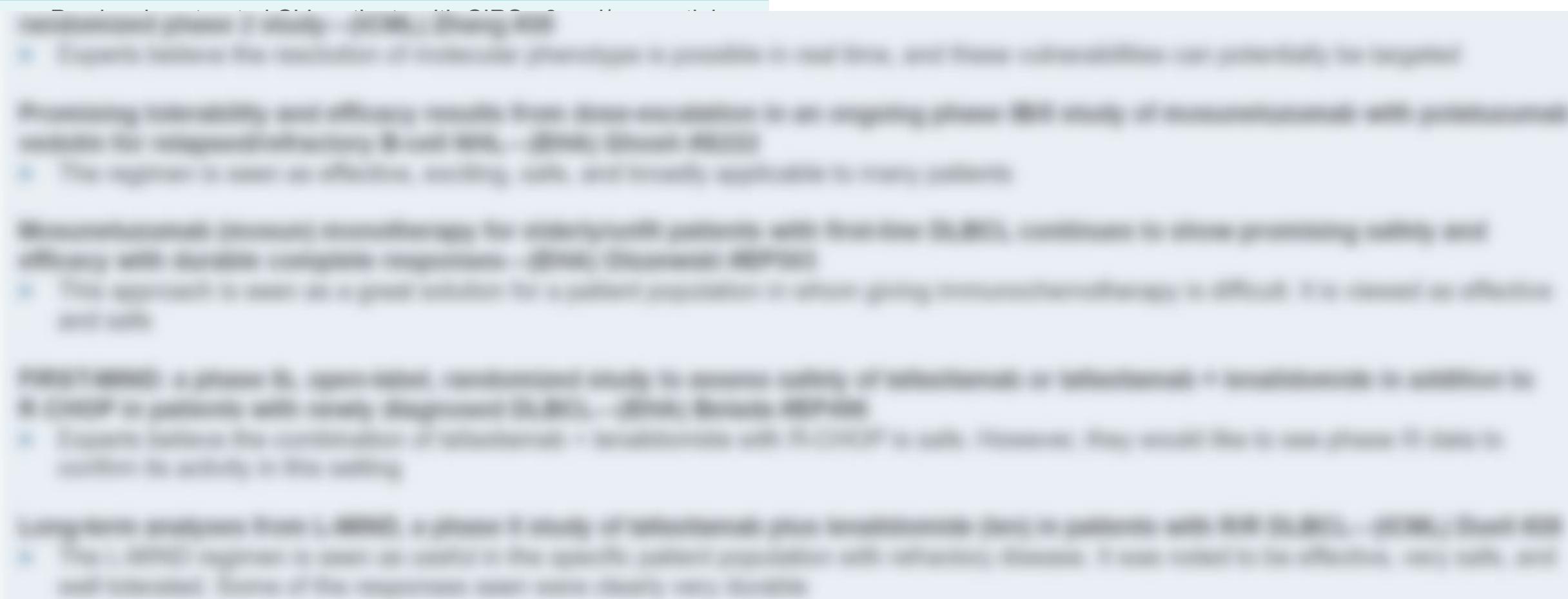
VENETOCLAX-OBINUTUZUMAB FOR PREVIOUSLY UNTREATED CLL: 4-YR FOLLOW-UP ANALYSIS OF THE RANDOMIZED CLL14 STUDY

AL-SAWAF ET AL. 2021 EHA #S146

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STUDY POPULATION

PFS BY TREATMENT ARM



BENDAMUSTINE, FOLLOWED BY OBINUTUZUMAB, ACALABRUTINIB AND VENETOCLAX IN R/R CLL: CLL2-BAAG TRIAL OF THE GCLLSG

CRAMER ET AL. ICML 2021 #34

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STUDY POPULATION



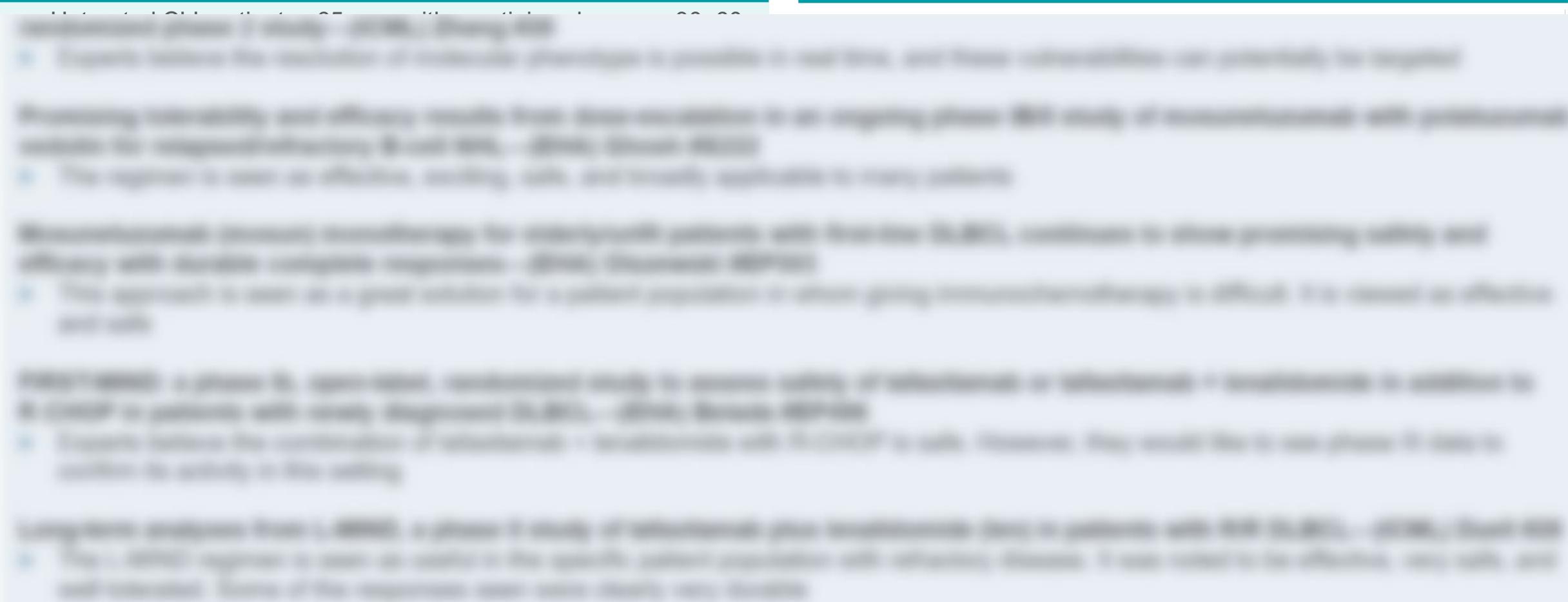
ACALABRUTINIB ± OBINUTUZUMAB VS OBIN + CHLORAMBUCIL IN TREATMENT-NAÏVE CLL: ELEVATE-TN 4-YEAR FOLLOW-UP

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SHARMAN ET AL. EHA 2021 #S148

STUDY POPULATION

PFS BY TREATMENT ARM



PRIMARY ANALYSIS OF THE FIXED-DURATION COHORT FROM THE PHASE 2 CAPTIVATE STUDY OF 1L IBRUTINIB + VEN FOR CLL/SLL

ALLAN ET AL. 2021 EHA #S147

STUDY POPULATION

ORR OF IBRUTINIB + VENETOCLAX



MRD-GUIDED OR FIXED 12 CYCLES OF VEN CONSOLIDATION AFTER VEN + OBIN IN 1L FCR UNFIT CLL: PRIMARY ENDPOINT OF HOVON 139/GIVE

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LEVIN ET AL. 2021 EHA #S149

STUDY POPULATION

PFS BY TREATMENT ARM



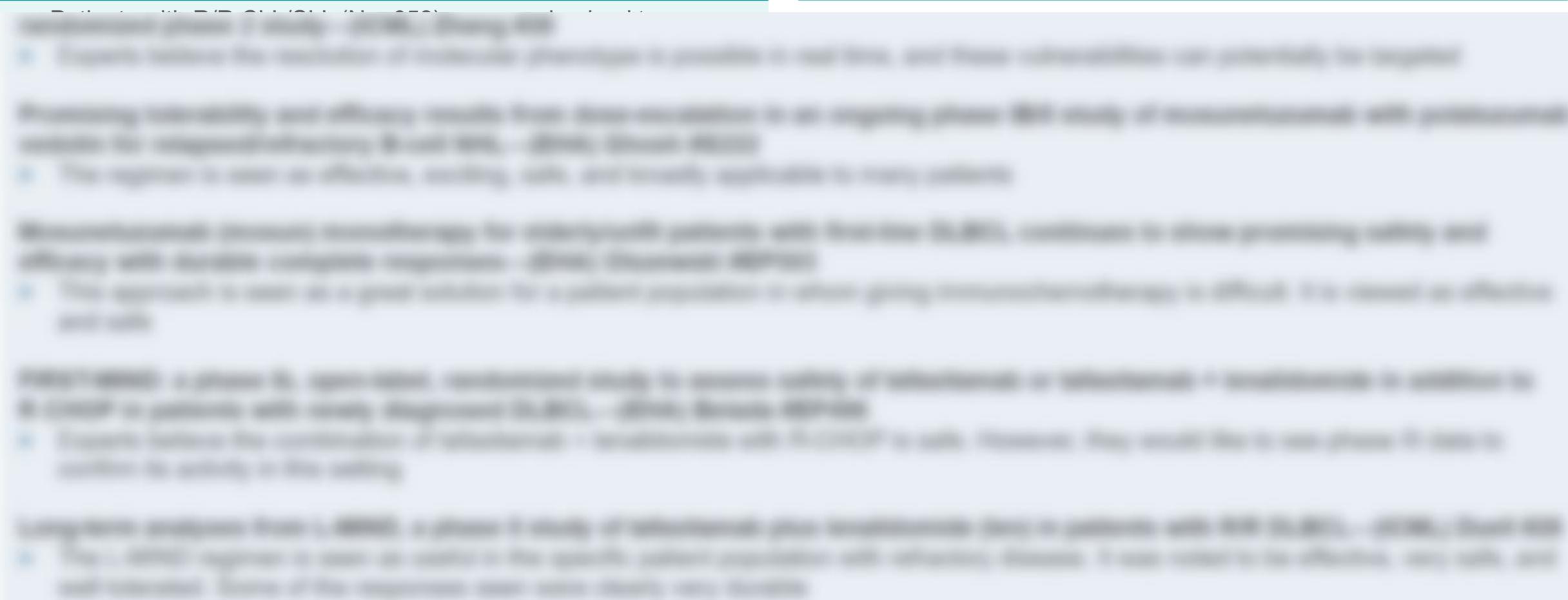
FIRST INTERIM ANALYSIS OF ALPINE: ZANUBRUTINIB VS IBRUTINIB IN PATIENTS WITH RELAPSED/REFRACTORY CLL/SLL

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HILLMEN ET AL. 2021 EHA #LB1900

STUDY POPULATION

PFS BY TREATMENT ARM



FIXED-DURATION IBRUTINIB AND VENETOCLAX (I+V) VS CHLORAMBUCIL PLUS OBINUTUZUMAB (CLB+O) FOR 1L CLL: PRIMARY ANALYSIS OF GLOW STUDY

KATER ET AL. 2021 EHA #LB1902

STUDY POPULATION

PFS for I+V vs CLb+O



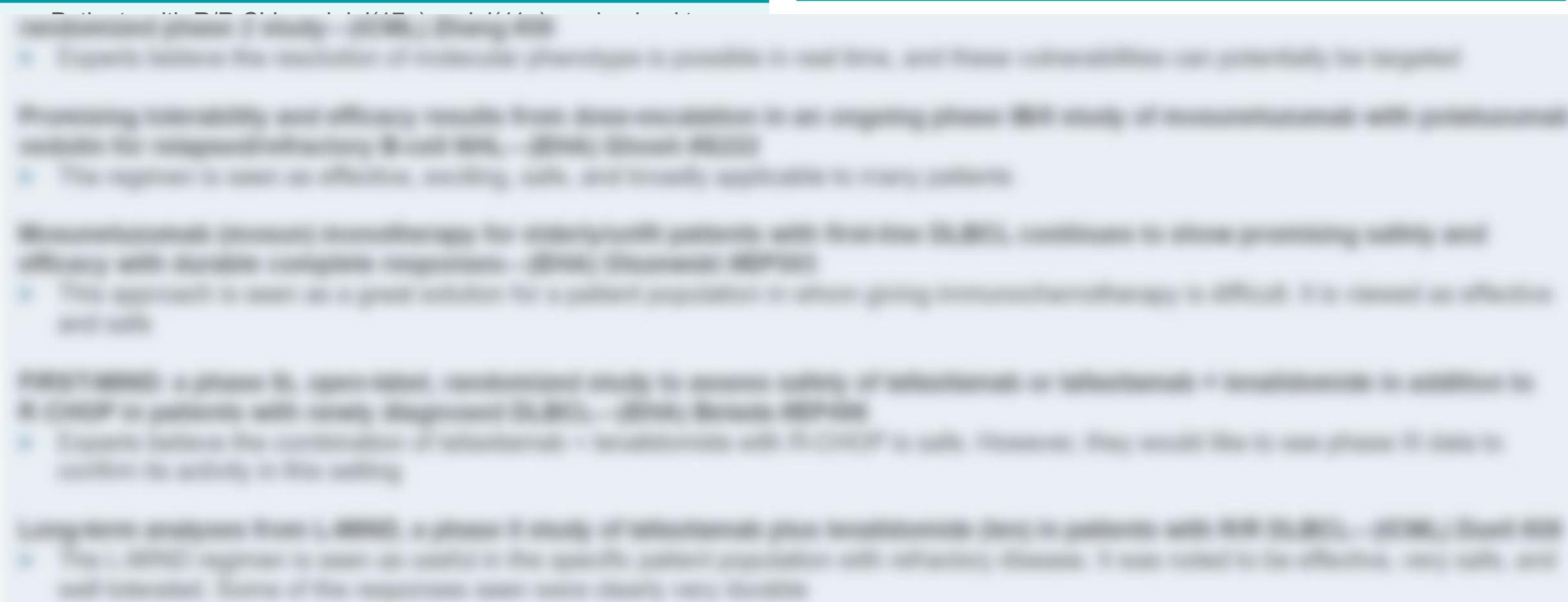
FIRST RESULTS OF A HEAD-TO-HEAD TRIAL OF ACALABRUTINIB VS IBRUTINIB IN PREVIOUSLY TREATED CLL (ELEVATE-RR)

HILLMEN ET AL. 2021 EHA #S145

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STUDY POPULATION

PFS





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CAR Ts

KEY TAKEAWAYS: CAR T

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Overall

Experts noted that it is now relatively uncommon for generation

CAR T therapies and selection

Both BMS and Kite released positive data for their CAR Ts



FIRST RESULTS OF DLBCL PATIENTS TREATED WITH CAR-T CELLS AND ENROLLED IN DESCAR-T REGISTRY, A FRENCH REAL-LIFE DATABASE FOR CAR-T CELLS IN HEMATOLOGIC MALIGNANCIES

LE GOUILL ET AL. 2021 ICML #084

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STUDY POPULATION

OS, PFS, DOR



CAR-HEMATOTOX: A DISCRIMINATIVE MODEL FOR CAR T-CELL RELATED HEMATOTOXICITY IN R/R LARGE B-CELL LYMPHOMA

RE JESKEL ET AL. 2021 JGML #082

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STUDY POPULATION

RISK FACTORS FOR NEUTROPENIA



TISA-CEL IN ADULT PATIENTS WITH R/R FOLLICULAR LYMPHOMA: PRIMARY ANALYSIS OF THE PHASE 2 ELARA TRIAL

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SCHUSTER ET AL. EHA 2021 #S210

STUDY POPULATION

RISK FACTORS FOR NEUTROPENIA



LYMPHOMA PATIENTS AFTER FAILURE OF CD19 CAR T IN THE UK

KUHN ET AL. ICML 2021 #087

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STUDY POPULATION

- > UK database of patients treated with CAR T (axi-cel n = 222; tisa-

PATTERNS OF CAR T FAILURE AND COVARIATES FOR RECEIVING POST-CAR T THERAPY

97.5% of progressions occurred by month 6

Best

Received



ZUMA-5/SCHOLAR-5 COMPARISONS

GHIONE ET AL. 2021 EHA #LB1904

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STUDY POPULATION

- > Propensity score methodology used to compare data from ZUMA-

OUTCOME COMPARISONS FOR ZUMA-5 VS SCHOLAR-5



ZUMA-5 OUTCOMES IN PATIENTS WITH POD24

JACOBSON ET AL. 2021 EHA #S213

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STUDY POPULATION

- > In ZUMA-5, axi-cel–treated patients with FL or MZL and available

PATTERNS OF CAR T FAILURE AND COVARIATES FOR RECEIVING POST-CAR T THERAPY



ABBREVIATIONS (1/2)

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ABBREVIATIONS (2/2)

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