Meet The Professor

Optimizing the Management of Chronic Lymphocytic Leukemia

Thursday, January 9, 2025
5:00 PM – 6:00 PM ET

Faculty

Jennifer Woyach, MD

Moderator

Neil Love, MD

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Commercial Support

This activity is supported by educational grants from AstraZeneca Pharmaceuticals LP and Lilly.

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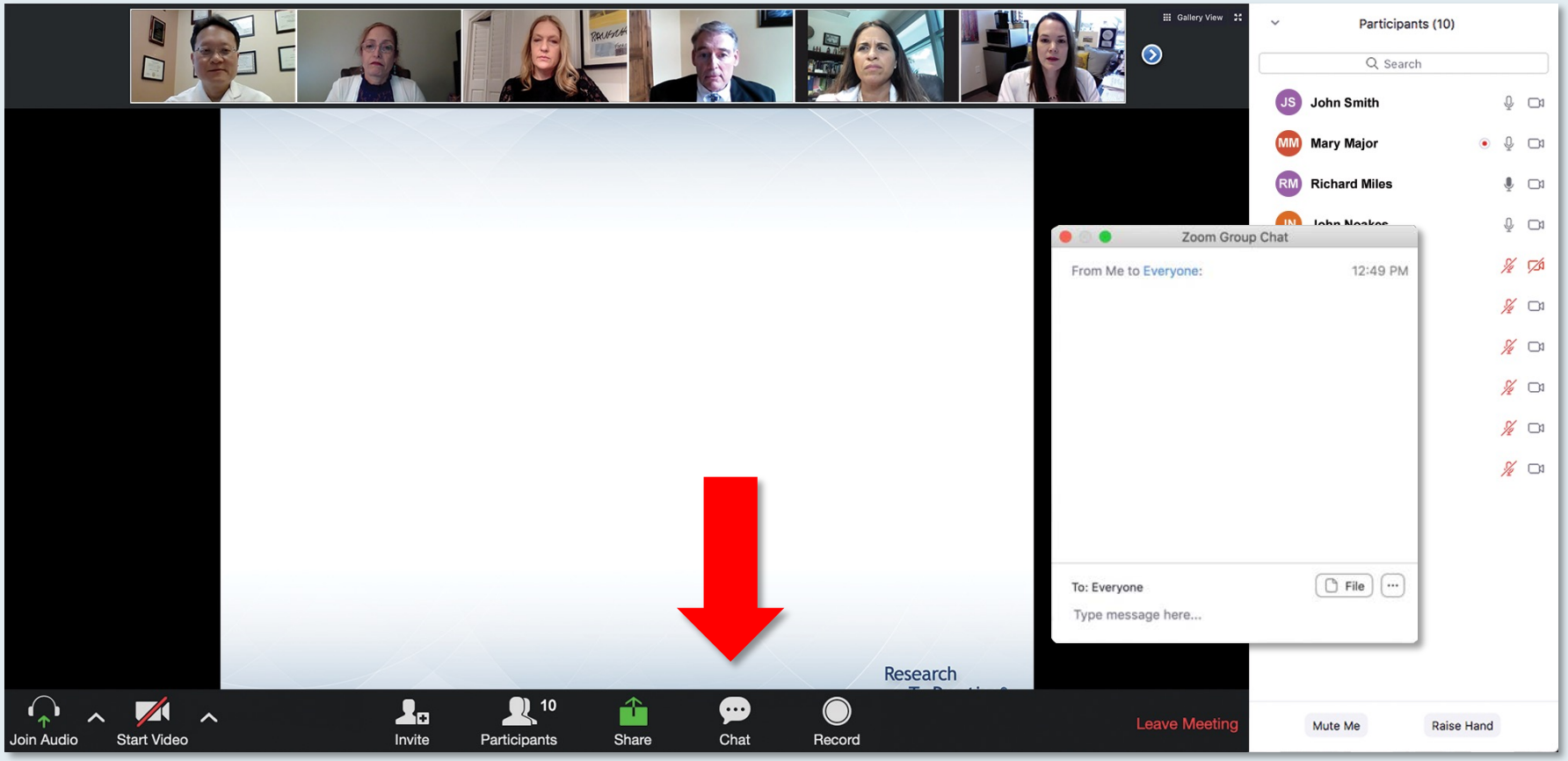

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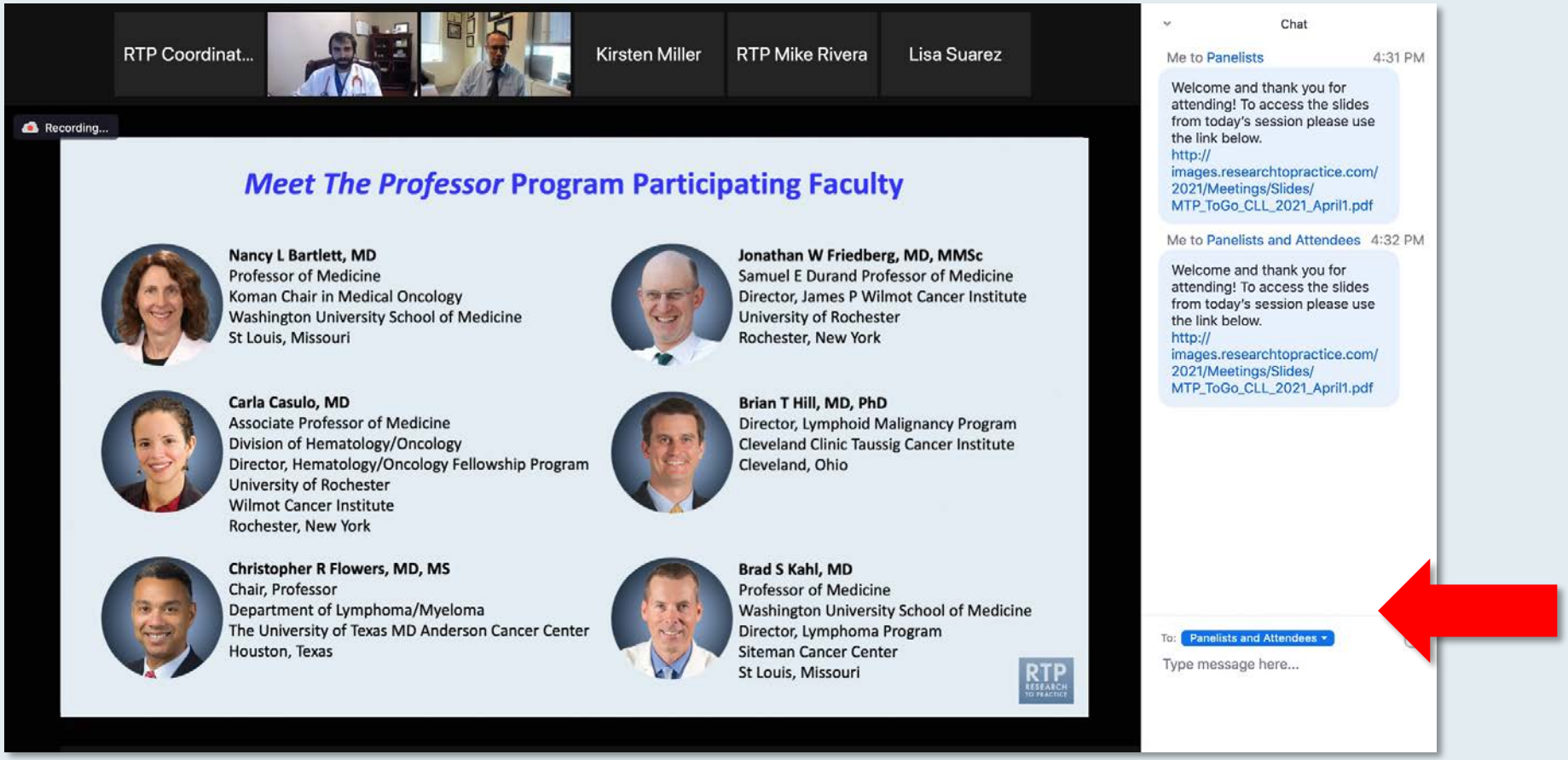

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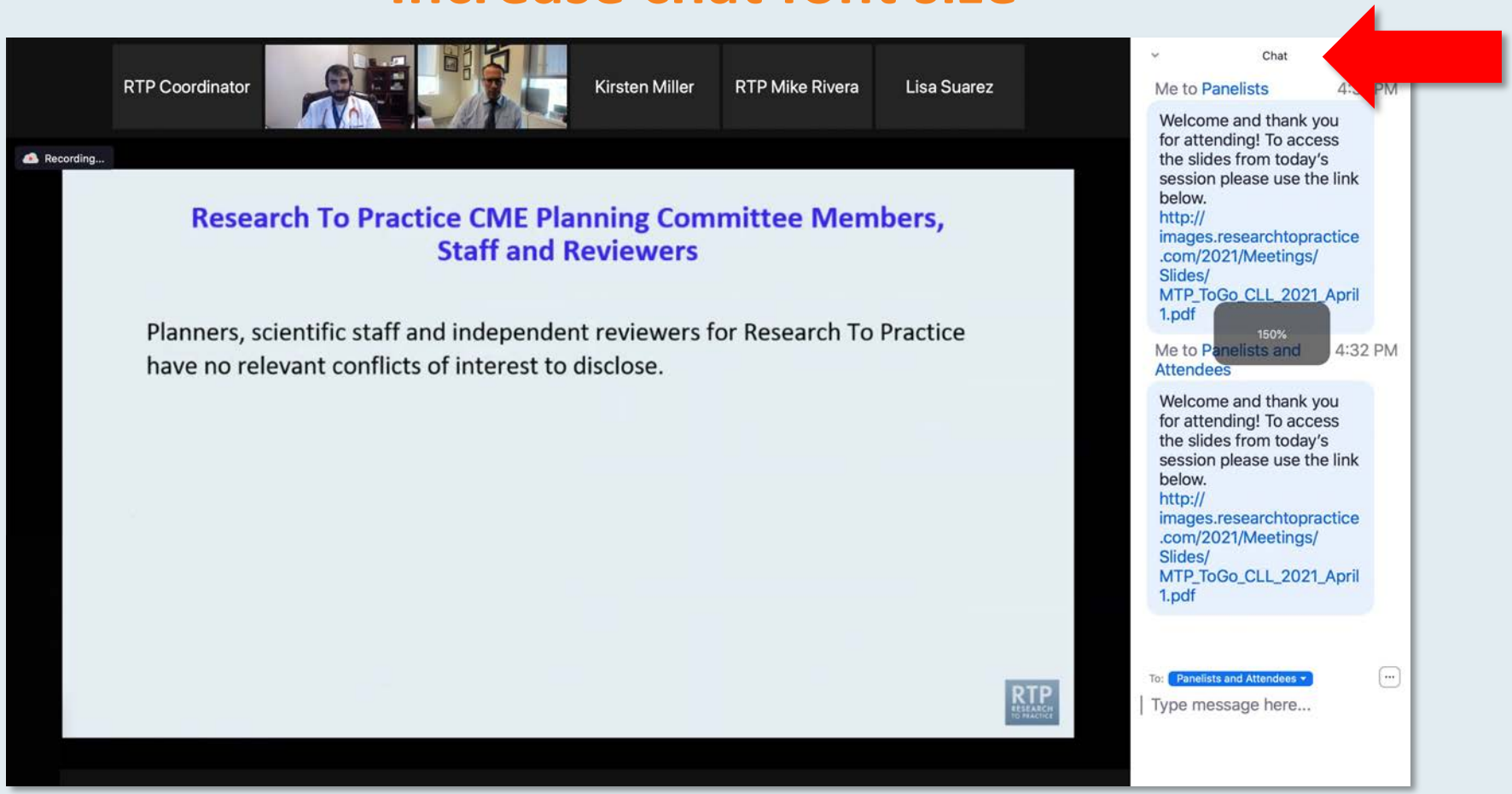

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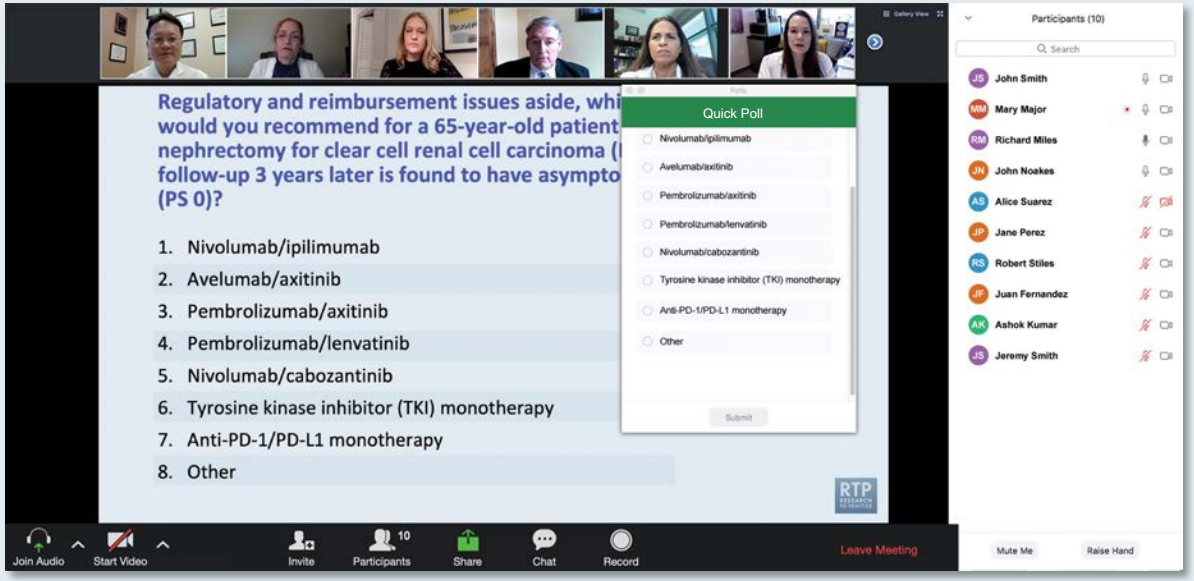

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What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Chronic Lymphocytic Leukemia

DR FARRUKH AWAN
HAROLD C SIMMONS COMPREHENSIVE CANCER CENTER

DR WILLIAM WIERDA
UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER

DR BITA FAKHRI
STANFORD UNIVERSITY SCHOOL OF MEDICINE

DR JEFF SHARMAN
SARAH CANNON RESEARCH INSTITUTE

DR KERRY A ROGERS
OHIO STATE UNIVERSITY

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Year in Review: Clinical Investigator Perspectives on the Most Relevant New Datasets and Advances in Oncology

EGFR-Mutant Non-Small Cell Lung Cancer

A CME/MOC-Accredited Live Webinar

Wednesday, January 15, 2025
5:00 PM – 6:00 PM ET

Faculty

Enriqueta Felip, MD, PhD
Helena Yu, MD

Moderator

Neil Love, MD

RTP Year in Review 2025

Teaching Cases from Investigators: The Application of Available Research to the Clinical Care of Patients with Hepatocellular Carcinoma

A CME Symposium Held in Conjunction with the 2025 ASCO® Gastrointestinal Cancers Symposium

Thursday, January 23, 2025

6:15 PM – 8:15 PM PT (9:15 PM – 11:15 PM ET)

Faculty

Anthony El-Khoueiry, MD

Richard S Finn, MD

Aiwu Ruth He, MD, PhD

Stacey Stein, MD

Moderator

Stephen “Fred” Divers, MD

RTP RESEARCH TO PRACTICE

What Clinicians Want to Know: Biomarker Assessment and Related Treatment Decision-Making for Patients with Colorectal Cancer

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Friday, January 24, 2025

6:00 PM – 8:00 PM PT (9:00 PM – 11:00 PM ET)

Faculty

Arvind Dasari, MD, MS

Van K Morris, MD

Jenny Seligmann, MBChB, MRCP, PhD

Eric Van Cutsem, MD, PhD

Moderator

Christopher Lieu, MD

RTP RESEARCH TO PRACTICE

What Clinicians Want to Know: Addressing Current Questions Related to the Use of Antibody-Drug Conjugates in the Management of Bladder Cancer and Hormonal Therapy-Based Interventions in the Management of Prostate Cancer

A CME Symposium Held in Conjunction with the 2025 ASCO® Genitourinary Cancers Symposium

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7:00 PM – 9:00 PM PT (10:00 PM – 12:00 AM ET)

Faculty

Neeraj Agarwal, MD, FASCO

Andrew J Armstrong, MD, ScM

Terence Friedlander, MD

Matthew D Galsky, MD

Moderator

To be announced.

RTP RESEARCH TO PRACTICE

What Clinicians Want to Know: Addressing Current Questions Related to the Management of Renal Cell Carcinoma

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Tian Zhang, MD, MHS
Additional faculty to be announced.

Moderator

Sumanta Kumar Pal, MD

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Save The Date

Fourth Annual
National General Medical Oncology Summit

A Multitumor CME/MOC-, NCPD- and ACPE-Accredited Educational Conference Developed in Partnership with Florida Cancer Specialists & Research Institute

Friday to Sunday, February 28 to March 2, 2025

Fontainebleau Hotel, Miami Beach, Florida

Moderated by Neil Love, MD

Thank you for joining us!

Information on how to obtain CME and ABIM MOC credit will be provided at the conclusion of the activity in the Zoom chat room. Attendees will also receive an email in 1 to 3 business days with these instructions.

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Department of Internal Medicine
The Ohio State University Comprehensive Cancer Center
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MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

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Contributing Faculty

Catherine C Coombs, MD
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Division of Hematology/Oncology
Department of Medicine
UCI Health
Orange County, California

Matthew S Davids, MD, MMSc
Associate Professor of Medicine
Harvard Medical School
Director of Clinical Research
Division of Lymphoma
Dana-Farber Cancer Institute
Boston, Massachusetts

Adam Kittai, MD
Associate Professor
Division of Hematology and Medical Oncology
Assistant Director of Lymphoma Clinical Research
CLL Clinical Research Leader
Icahn School of Medicine at Mount Sinai Hospital
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Director of the Chronic Lymphocytic
Leukemia Program
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Herbert Irving Comprehensive Cancer Center
NewYork-Presbyterian/Columbia University
Irving Medical Center
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Chaitra Ujjani, MD
Clinical Director of Lymphoma
Fred Hutchinson Cancer Center
Clinical Professor
University of Washington
Seattle, Washington

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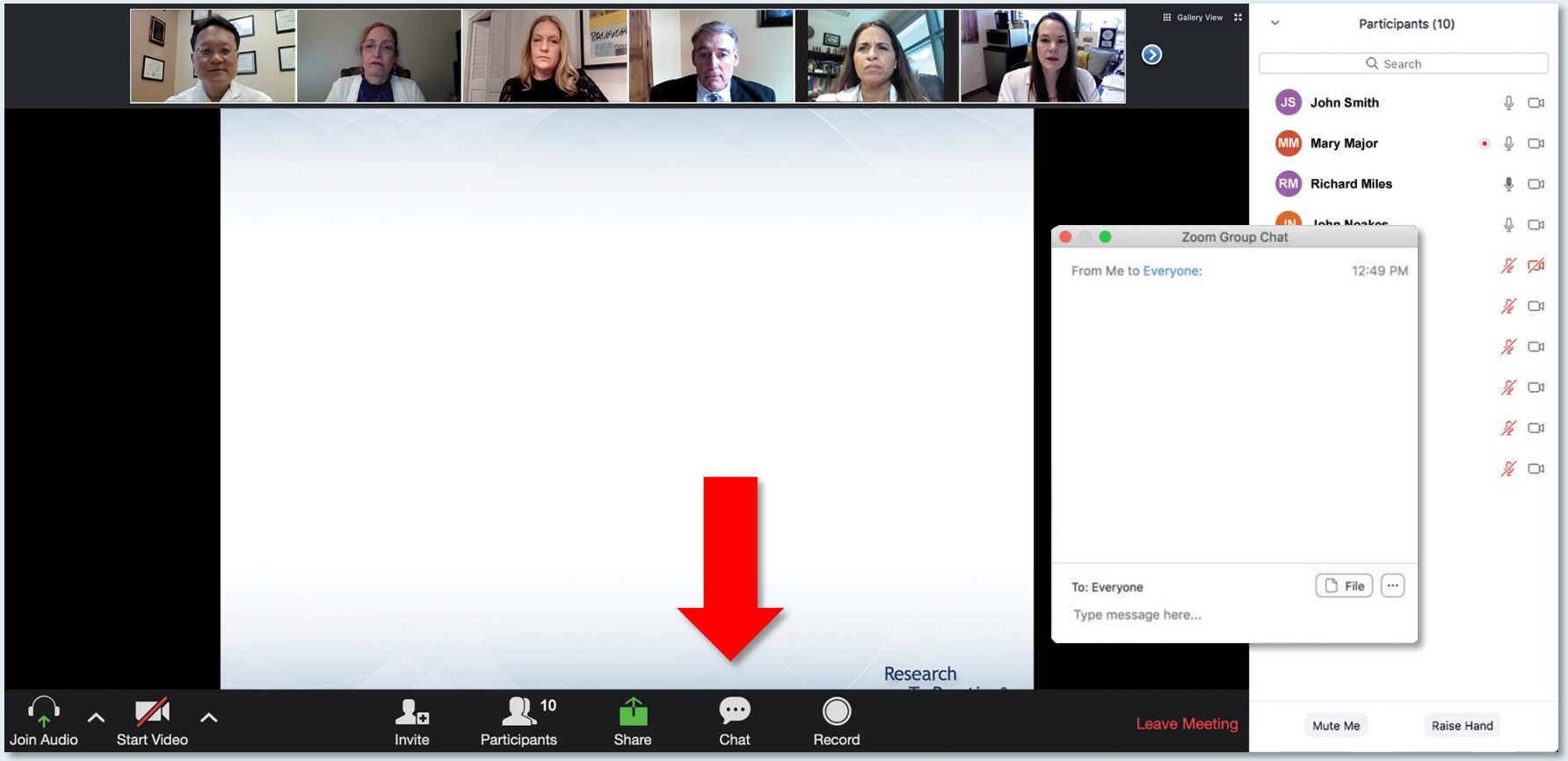

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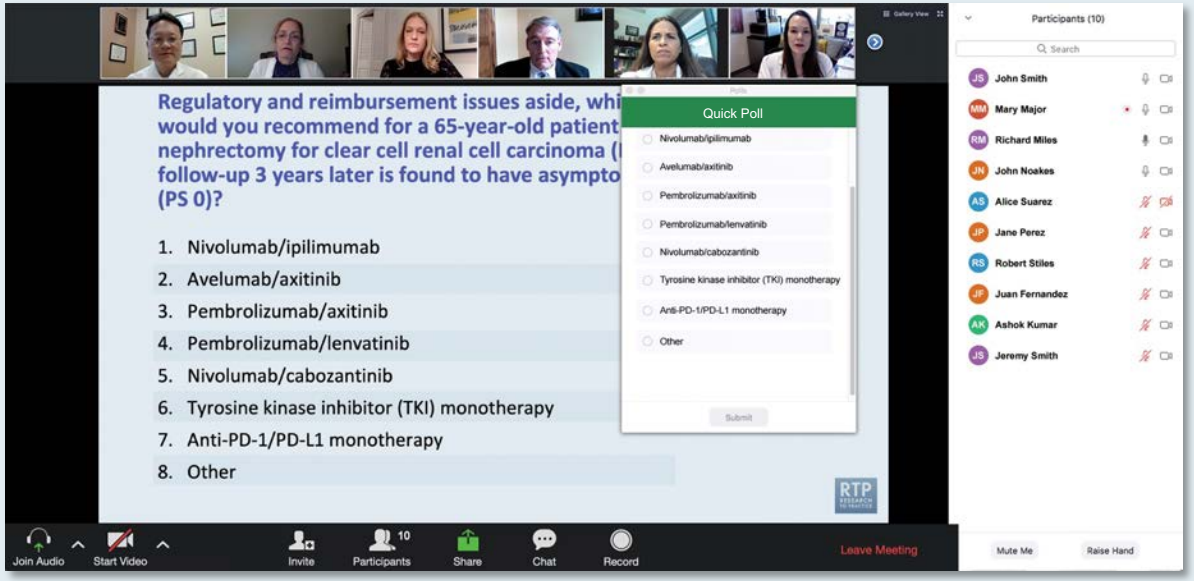

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Laurie Matt-Amaral, MD, MPH
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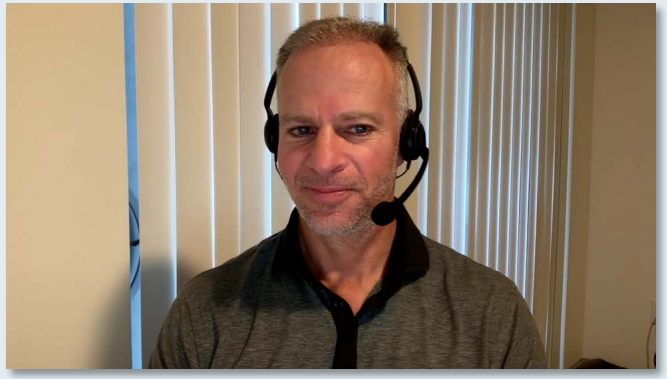
Akron, Ohio



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Boca Raton, Florida

Erik Rupard, MD
Intermountain Health
St George, Utah

Zanetta S Lamar, MD
Florida Oncology and Hematology
Naples, Florida

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Meet The Professor with Dr Woyach

Module 1: AMPLIFY — First-Line Trials of BTKi/Venetoclax

Module 2: Pirtobrutinib

Module 3: Choice of First-Line BTKi

Module 4: Cardiotoxicity of BTKi

Module 5: CLL and COVID-19 Vaccinations; Role of MRD Testing; Anti-CD20 Antibodies

Module 6: Transformed CLL

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Module 4: Cardiotoxicity of BTKi

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Module 6: Transformed CLL

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Case Presentation: 46-year-old African American man with progressive lymphadenopathy in the neck is diagnosed with CLL/SLL (trisomy 12, SF3B1 mutation)

Dr Erik Rupard (St George, Utah)

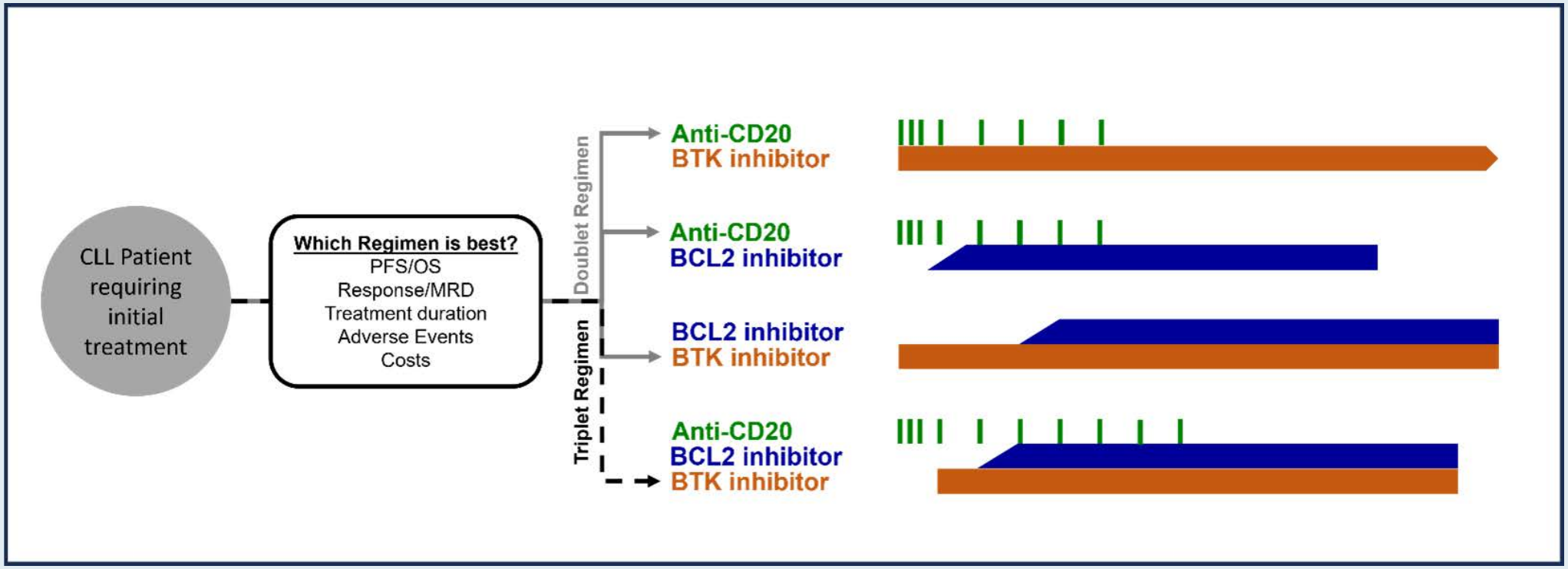
IT'S A DIFFERENT WORLD: CLL 2024 | DECEMBER 6, 2024

The evolving frontline management of CLL: are triplets better than doublets? How will we find out?

Kerry A. Rogers, Jennifer A. Woyach

Hematology Am Soc Hematol Educ Program (2024) 2024 (1): 467–473.

Evolving Front-Line Management of CLL



Rogers KA, Woyach JA. *Hematology Am Soc Hematol Educ Program* 2024;2024(1):467-73.

The NEW ENGLAND JOURNAL of MEDICINE

EDITORIALS

Time-Limited Initial Therapy for Young, Fit Patients with CLL

Jennifer A. Woyach, M.D., and John C. Byrd, M.D.

2023;388(19):1812-3.

P1009

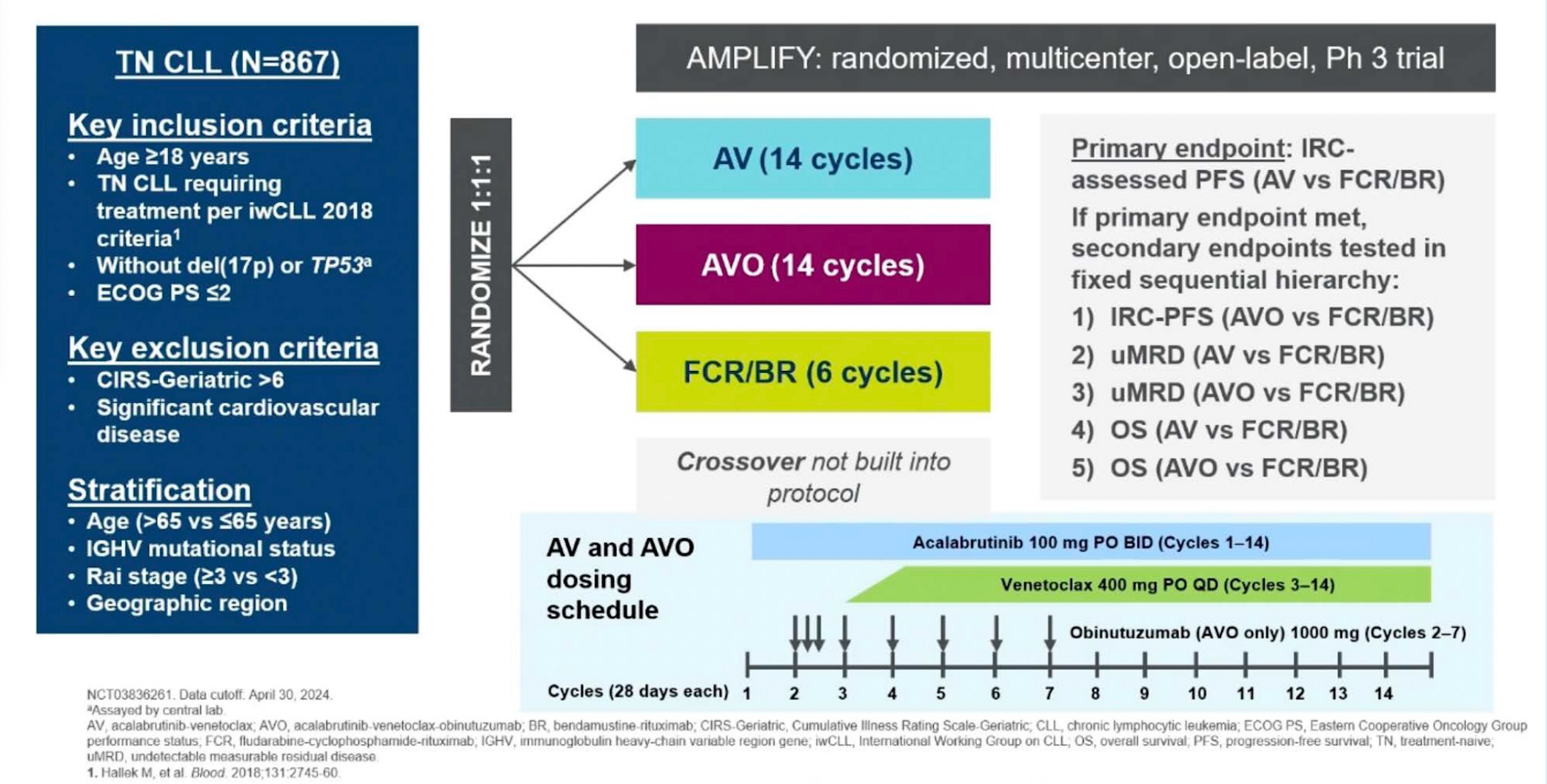
Fixed-Duration Acalabrutinib plus Venetoclax With or Without Obinutuzumab versus Chemoimmunotherapy for First-Line Treatment of Chronic Lymphocytic Leukemia: Interim Analysis of the Multicenter, Open-Label, Randomized, Phase 3 AMPLIFY Trial

Jennifer R. Brown, MD,[1] John F. Seymour, MD,[2] Wojciech Jurczak, MD,[3] Andrew Aw, MD,[4] Malgorzata Wach, MD,[5] Arpad Illes, MD,[6] Alessandra Tedeschi, MD,[7] Carolyn Owen, MD,[8] Alan Skarbnik, MD,[9] Daniel Lysak, MD,[10] Ki-Seong Eom,[11] Martin Šimkovič, MD,[12] Miguel Arturo Pavlovsky, MD,[13] Arnon P. Kater, MD,[14] Barbara Eichhorst, MD,[15] Kara Miller, MS,[16] Veerendra Munugalavadla, PhD,[16] Ting Yu, MD,[16] Marianne de Borja, MS,[17] Paolo Ghia, MD[18,19]

[1]Dana-Farber Cancer Institute, Boston, MA, USA; [2]Peter MacCallum Cancer Centre, Royal Melbourne Hospital, The University of Melbourne, Melbourne, VIC, Australia; [3]Maria Sklodowska-Curie National Institute of Oncology, Kraków, Poland; [4]University of Ottawa, Ottawa, Ontario, Canada; [5]Medical University of Lublin, Lublin, Poland; [6]University of Debrecen, Debrecen, Hungary; [7]ASST Grande Ospedale Metropolitano Niguarda, Niguarda Cancer Center, Milano, Italy; [8]University of Calgary and Foothills Medical Centre, Calgary, Canada; [9]Novant Health Cancer Institute, Charlotte, NC, USA; [10]Fakultní Nemocnice Plzen, Pilsen, Czech Republic; [11]Catholic Hematology Hospital, Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Seoul, Republic of Korea; [12]Hradec Králové, University Hospital and Charles University in Prague, Hradec Kralove, Czech Republic; [13]FUNDALEU, Clinical Research Center, Buenos Aires, Argentina; [14]Amsterdam University Medical Center, Amsterdam, on behalf of HOVON, Netherlands; [15]University Hospital Cologne, Cologne, Germany; [16]AstraZeneca, South San Francisco, CA, USA; [17]AstraZeneca, Mississauga, ON, Canada; [18]Università Vita-Salute San Raffaele, Milano, Italy; [19]IRCCS Ospedale San Raffaele, Milano, Italy

ASH 2024;Abstract 1009

AMPLIFY: An Ongoing Phase III Trial of Fixed-Duration Acalabrutinib and Venetoclax with or without Obinutuzumab for Previously Untreated CLL without Del(17p) or TP53 Mutation

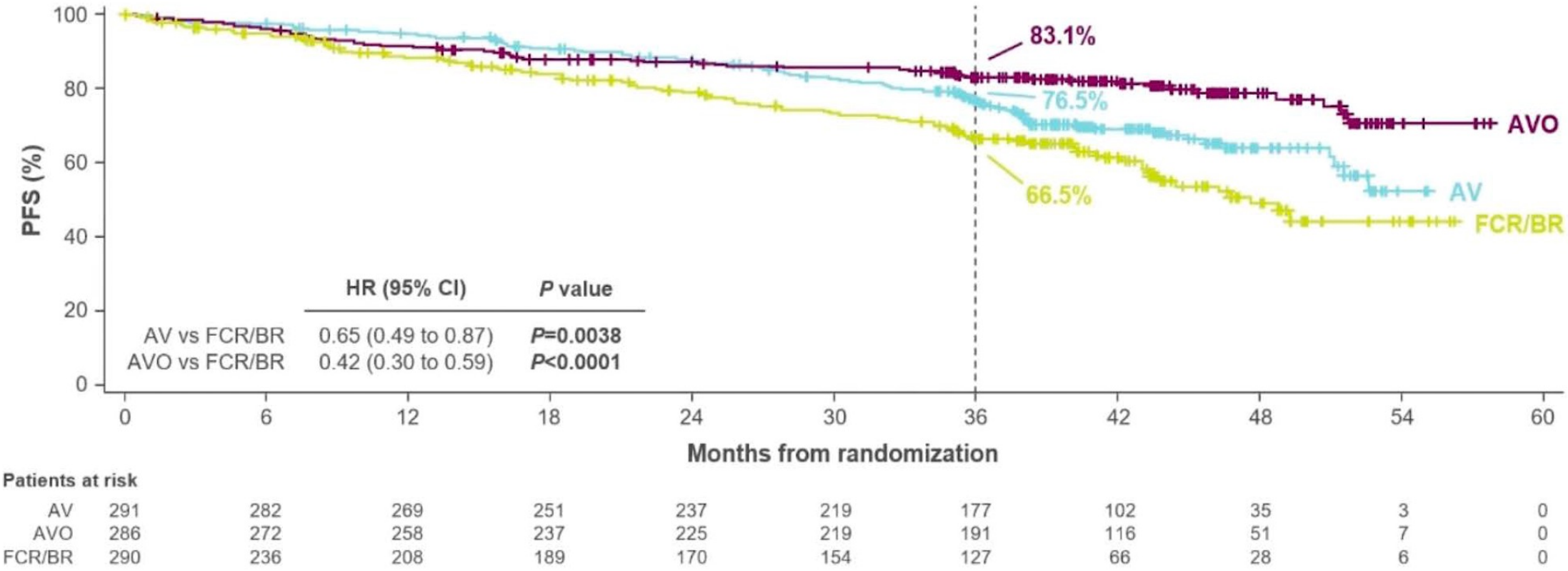


NCT03836261. Data cutoff: April 30, 2024.
[a]Assayed by central lab.
AV, acalabrutinib-venetoclax; AVO, acalabrutinib-venetoclax-obinutuzumab; BR, bendamustine-rituximab; CIRS-Geriatric, Cumulative Illness Rating Scale-Geriatric; CLL, chronic lymphocytic leukemia; ECOG PS, Eastern Cooperative Oncology Group performance status; FCR, fludarabine-cyclophosphamide-rituximab; IGHV, immunoglobulin heavy-chain variable region gene; iwCLL, International Working Group on CLL; OS, overall survival; PFS, progression-free survival; TN, treatment-naive; uMRD, undetectable measurable residual disease.
1. Hallek M, et al. *Blood*. 2018;131:2745-60.

Brown JR et al. ASH 2024;Abstract 1009.

RTP RESEARCH TO PRACTICE

AMPLIFY Primary Endpoint: IRC-Assessed Progression-Free Survival



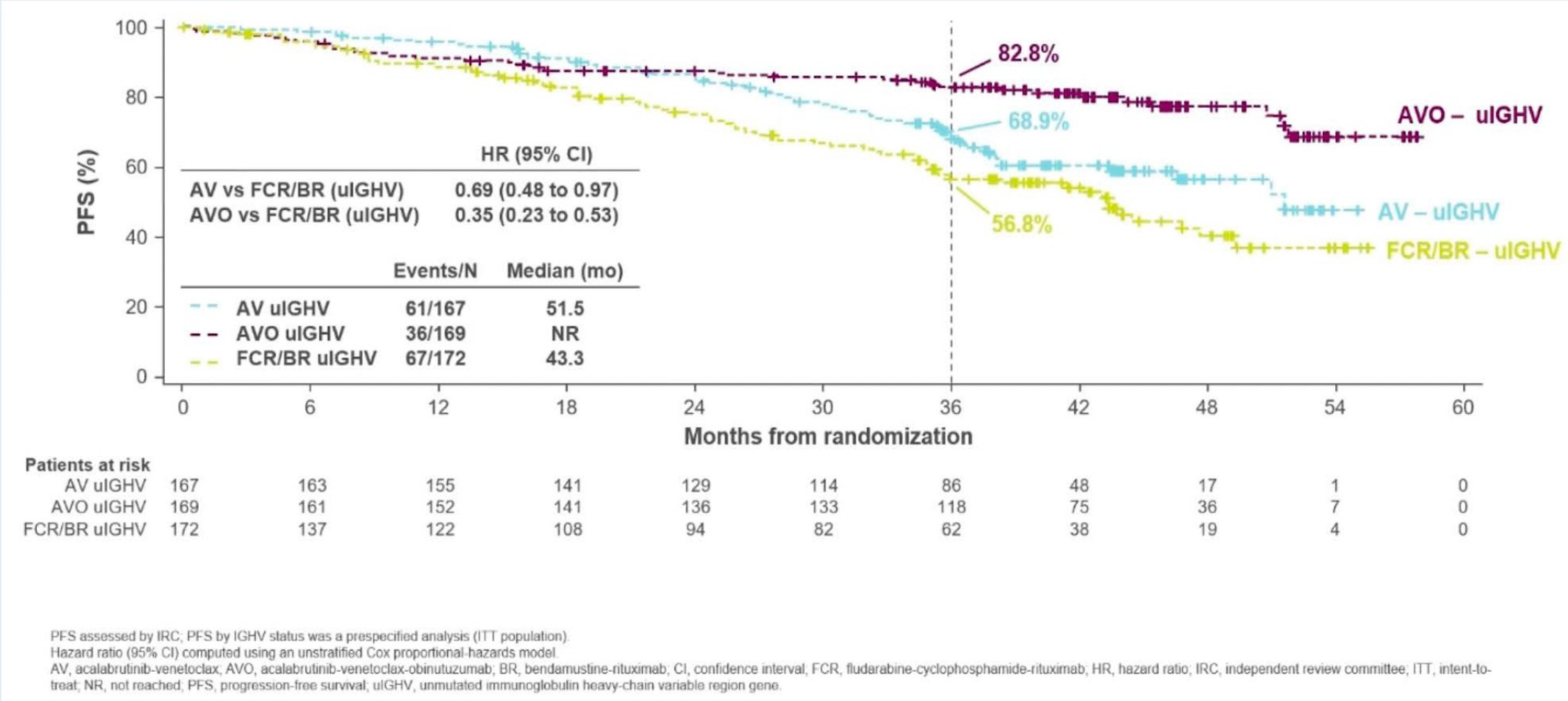
Median PFS was NR for AV and AVO, and was 47.6 mo for FCR/BR

ITT population. Median follow-up from randomization: 40.8 months (range, 0–59 months).
Hazard ratio (95% CI) computed using a Cox proportional-hazards model stratified by the randomization strata. *P*-value based on stratified log-rank test.
AV, acalabrutinib-venetoclax; AVO, acalabrutinib-venetoclax-obinutuzumab; BR, bendamustine-rituximab; CI, confidence interval; FCR, fludarabine-cyclophosphamide-rituximab; HR, hazard ratio; IRC, independent review committee; ITT, intent-to-treat; NR, not reached; PFS, progression-free survival.

Brown JR et al. ASH 2024;Abstract 1009.

RTP RESEARCH TO PRACTICE

AMPLIFY: Progression-Free Survival (PFS) in IGHV-Unmutated Subgroup

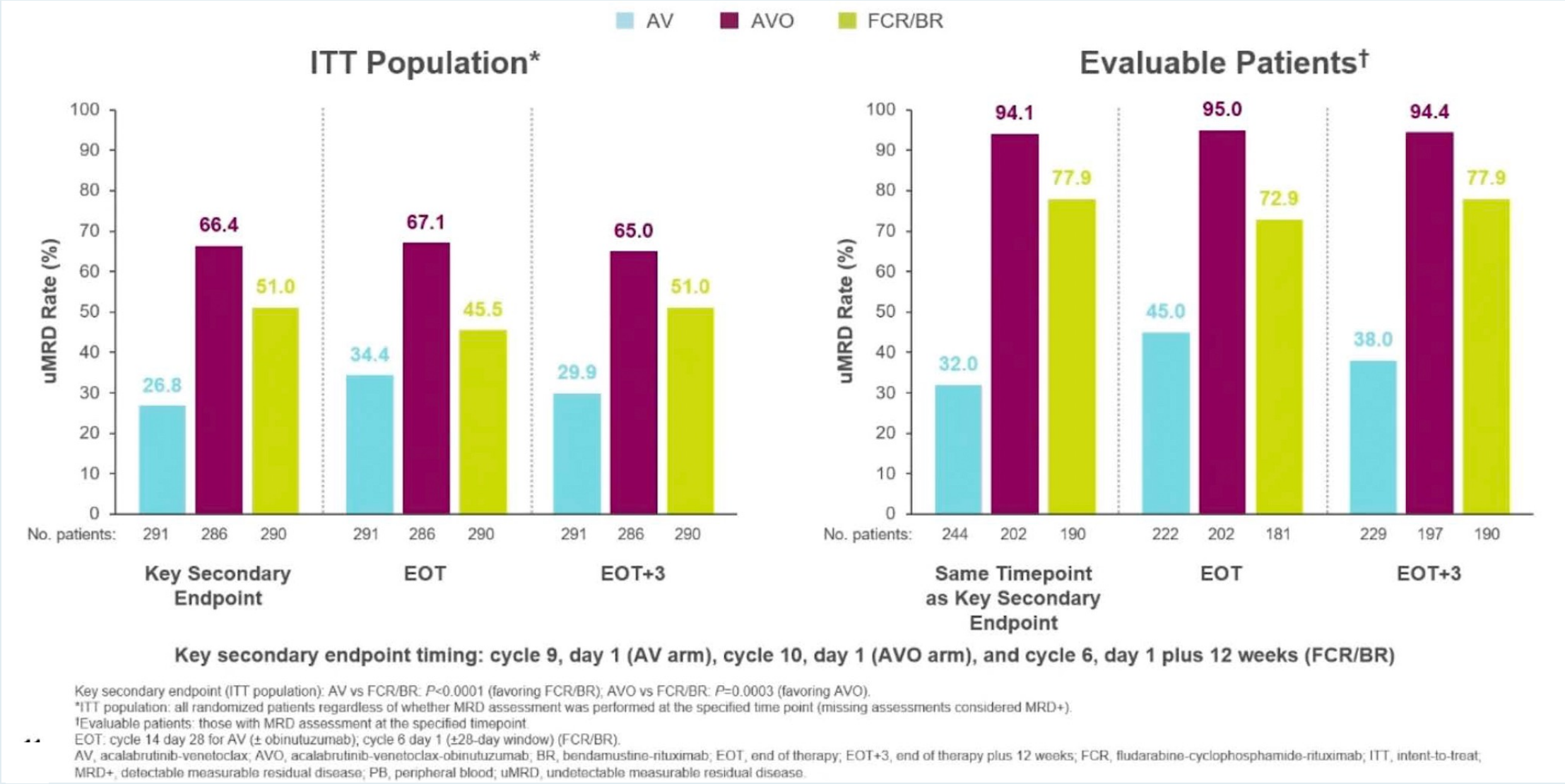


PFS assessed by IRC; PFS by IGHV status was a prespecified analysis (ITT population).
Hazard ratio (95% CI) computed using an unstratified Cox proportional-hazards model.
AV, acalabrutinib-venetoclax; AVO, acalabrutinib-venetoclax-obinutuzumab; BR, bendamustine-rituximab; CI, confidence interval; FCR, fludarabine-cyclophosphamide-rituximab; HR, hazard ratio; IRC, independent review committee; ITT, intent-to-treat; NR, not reached; PFS, progression-free survival; uIGHV, unmutated immunoglobulin heavy-chain variable region gene.

- Median PFS was not reached in all 3 treatment arms in the IGHV-mutated subgroup

Brown JR et al. ASH 2024;Abstract 1009.

AMPLIFY: Undetectable Measurable Residual Disease (uMRD) Rates (Flow Cytometry [$<10^{-4}$] in Peripheral Blood)



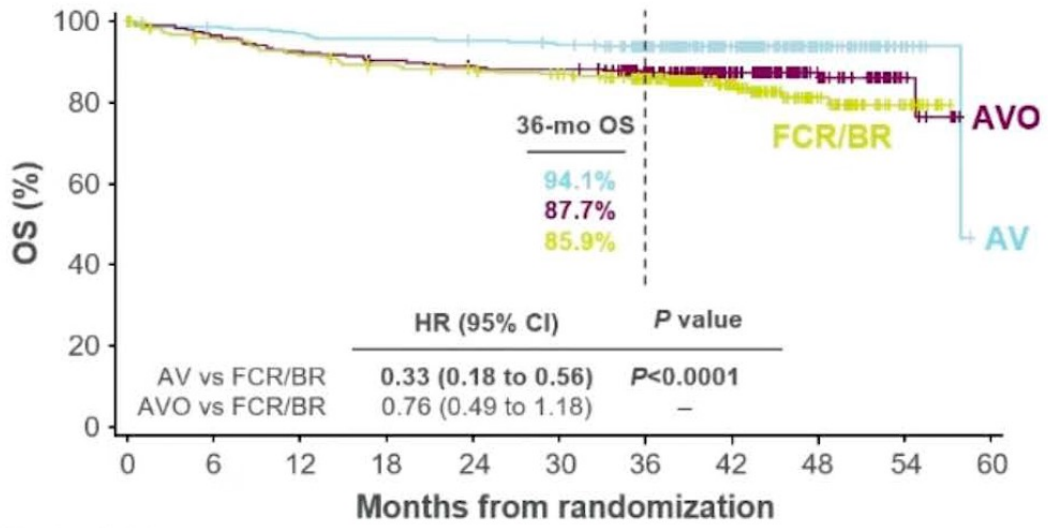
Key secondary endpoint timing: cycle 9, day 1 (AV arm), cycle 10, day 1 (AVO arm), and cycle 6, day 1 plus 12 weeks (FCR/BR)

Key secondary endpoint (ITT population): AV vs FCR/BR: $P<0.0001$ (favoring FCR/BR); AVO vs FCR/BR: $P=0.0003$ (favoring AVO).
*ITT population: all randomized patients regardless of whether MRD assessment was performed at the specified time point (missing assessments considered MRD+).
†Evaluable patients: those with MRD assessment at the specified timepoint.
EOT: cycle 14 day 28 for AV (± obinutuzumab); cycle 6 day 1 (±28-day window) (FCR/BR).
AV, acalabrutinib-venetoclax; AVO, acalabrutinib-venetoclax-obinutuzumab; BR, bendamustine-rituximab; EOT, end of therapy; EOT+3, end of therapy plus 12 weeks; FCR, fludarabine-cyclophosphamide-rituximab; ITT, intent-to-treat; MRD+, detectable measurable residual disease; PB, peripheral blood; uMRD, undetectable measurable residual disease.

Brown JR et al. ASH 2024;Abstract 1009.

AMPLIFY: Overall Survival

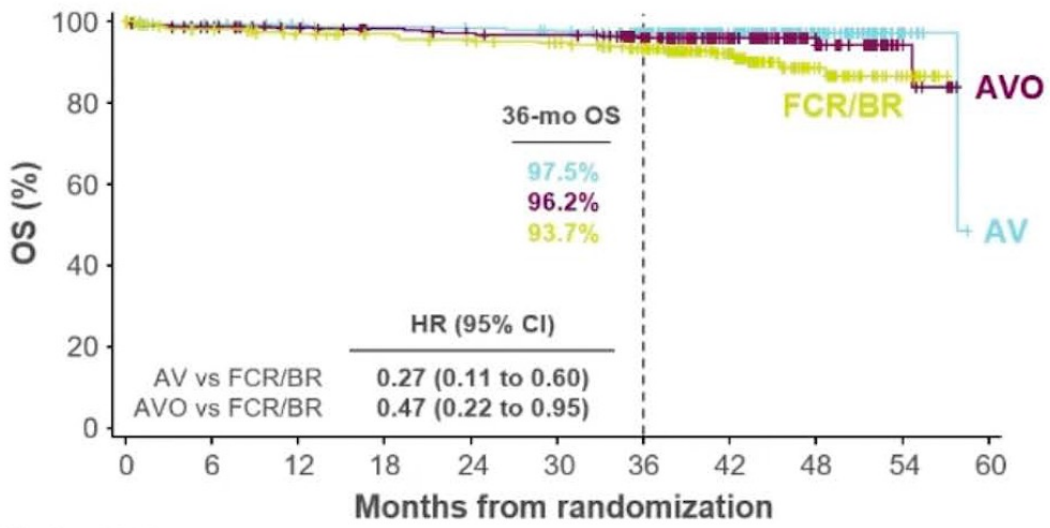
OS Prolonged With AV vs FCR/BR



Patients at risk

AV	291	286	281	277	275	270	233	142	58	10	0
AVO	286	276	265	257	252	250	223	143	64	10	0
FCR/BR	290	247	236	228	223	217	182	98	45	13	0

OS Prolonged With AV and AVO vs FCR/BR (COVID-19 Deaths Censored)



Patients at risk

AV	291	286	281	277	275	270	233	142	58	10	0
AVO	286	276	265	257	252	250	223	143	64	10	0
FCR/BR	290	247	236	228	223	217	182	98	45	13	0

COVID-19 deaths: 10 (AV), 25 (AVO), 21 (FCR/BR)

ITT population.
Hazard ratio (95% CI) computed using a Cox proportional-hazards model stratified by the randomization strata. *P*-value based on stratified log-rank test.
AV, acalabrutinib-venetoclax; AVO, acalabrutinib-venetoclax-obinutuzumab; BR, bendamustine-rituximab; CI, confidence interval; FCR, fludarabine-cyclophosphamide-rituximab; HR, hazard ratio; ITT, intent-to-treat; OS, overall survival.

Brown JR et al. ASH 2024;Abstract 1009.

RTP RESEARCH TO PRACTICE

AMPLIFY: Adverse Events of Special Interest

	AV (n=291)		AVO (n=284)		FCR/BR (n=259)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Any ECI	222 (76.3)	136 (46.7)	242 (85.2)	188 (66.2)	185 (71.4)	141 (54.4)
Cardiac events	27 (9.3)	5 (1.7)	34 (12.0)	7 (2.5)	9 (3.5)	3 (1.2)
Atrial fibrillation	2 (0.7)	1 (0.3)	6 (2.1)	2 (0.7)	2 (0.8)	2 (0.8)
Ventricular tachyarrhythmias[a]	2 (0.7)	0	3 (1.1)	0	0	0
Hypertension	12 (4.1)	8 (2.7)	11 (3.9)	6 (2.1)	7 (2.7)	2 (0.8)
Hemorrhage	94 (32.3)	3 (1.0)	86 (30.3)	6 (2.1)	11 (4.2)	1 (0.4)
Major hemorrhage	3 (1.0)	3 (1.0)	8 (2.8)	6 (2.1)	2 (0.8)	1 (0.4)
Neutropenia (any)[b]	108 (37.1)	94 (32.3)	143 (50.4)	131 (46.1)	132 (51.0)	112 (43.2)
Infections (any)	148 (50.9)	36 (12.4)	153 (53.9)	67 (23.6)	82 (31.7)	26 (10.0)
Second primary malignancies	15 (5.2)	5 (1.7)	12 (4.2)	5 (1.8)	2 (0.8)	0
Excl. non-melanoma skin	8 (2.7)	5 (1.7)	7 (2.5)	4 (1.4)	1 (0.4)	0
Tumor lysis syndrome	1 (0.3)	1 (0.3)	1 (0.4)	1 (0.4)	8 (3.1)	8 (3.1)

Data are n (%). ECIs listed by category and sub-category.
[a]Ventricular tachyarrhythmias consisted of ventricular extrasystoles (n=1 in AV arm; n=2 in AVO arm) and ventricular tachycardia (n=1 each in AV and AVO arms).
[b]Includes neutropenia, neutrophil count decreased, and febrile neutropenia.
AEs with an onset date or that worsen on or after the date of first dose and up to and including 30 days following the date of last dose of treatment or up to the day prior to start of subsequent anti-CLL therapy, whichever comes first.
AE, adverse event; AV, acalabrutinib-venetoclax; AVO, acalabrutinib-venetoclax-obinutuzumab; BR, bendamustine-rituximab; ECI, event of clinical interest; FCR, fludarabine-cyclophosphamide-rituximab.

Brown JR et al. ASH 2024;Abstract 1009.

Phase II Study of Acalabrutinib/Venetoclax/Obinutuzumab (AVO) for Patients with Previously Untreated CLL Enriched for High-Risk Disease

- 72 patients with treatment-naïve CLL, including those with TP53 aberration (n = 45) received AVO

- Primary endpoint: Rate of complete response with bone marrow undetectable measurable residual disease at start of cycle 16
  - Overall population: 42%
  - Patients with TP53 aberration: 42%

- 4-year survival rates for patients without TP53 aberration:
  - 4-year PFS 96%
  - 4-year OS 100%

- 4-year survival rates for patients with TP53 aberration:
  - 4-year PFS 70%
  - 4-year OS 88%

- Serious adverse events were reported in 28% of patients

Davids MS et al. ASH 2024;Abstract 1865.

RTP RESEARCH TO PRACTICE

Prospective Randomized Phase 2 Study of Acalabrutinib + Obinutuzumab or Venetoclax in Previously Untreated CLL

Kittai AS et al.

ASH 2024;Abstract 4634.1.

Combination of Zanubrutinib + Venetoclax for Treatment-naive CLL/SLL With del(17p) and/or *TP53*: Preliminary Results From SEQUOIA Arm D

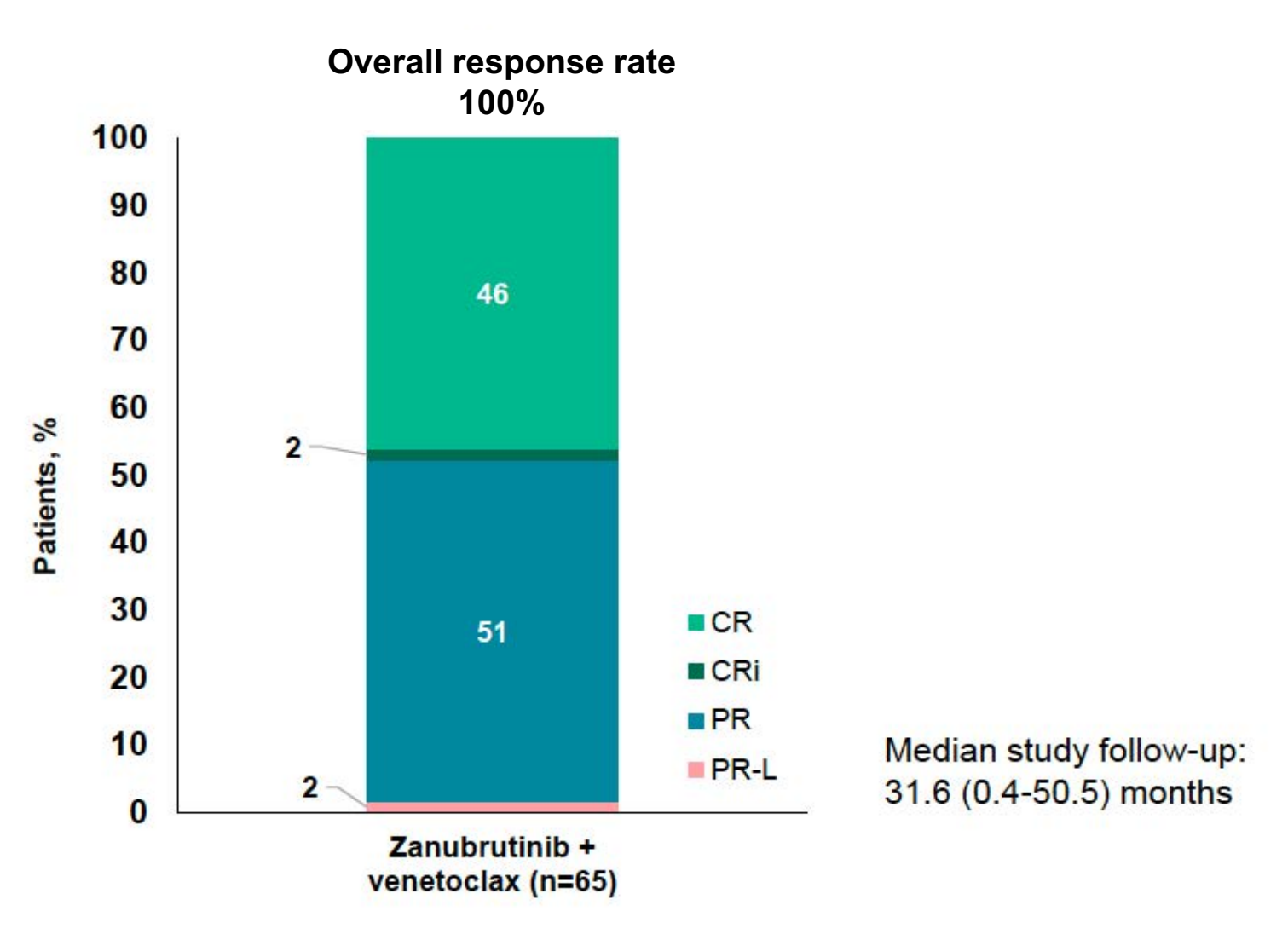
Shuo Ma,[1] Talha Munir,[2] Masa Lasica,[3] Mazyar Shadman,[4,5] Alessandra Tedeschi,[6] Emmanuelle Ferrant,[7] Ian W. Flinn,[8] Wojciech Janowski,[9] Monica Tani,[10] Tadeusz Robak,[11] Jennifer R. Brown,[12] Constantine S. Tam,[13] Tian Tian,[14] Emily Mantovani,[14] Stephanie Agresti,[14] Linlin Xu,[14] Aileen Cohen,[14] Wojciech Jurczak,[15] **Paolo Ghia**[16,17]

[1]Robert H. Lurie Comprehensive Cancer Center, Northwestern University Feinberg School of Medicine, Chicago, IL, USA; [2]Leeds Teaching Hospitals NHS Trust, Leeds, UK; [3]St Vincent's Hospital Melbourne, Fitzroy, VIC, Australia; [4]Fred Hutchinson Cancer Research Center, Seattle, WA, USA; [5]University of Washington, Seattle, WA, USA; [6]ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy; [7]Département Hématologie, CHU de Lyon-Sud, Lyon-Sud, France; [8]Tennessee Oncology/OneOncology, Nashville, TN, USA; [9]Calvary Mater Newcastle Hospital, Waratah, NSW, Australia; [10]Hematology Unit, Santa Maria delle Croci Hospital, Ravenna, Italy; [11]Medical University of Łódź, Copernicus Memorial Hospital, Łódź, Poland; [12]Dana-Farber Cancer Institute, Boston, MA, USA; [13]Alfred Hospital and Monash University, Melbourne, VIC, Australia; [14]BeiGene USA, Inc, San Mateo, CA, USA; [15]Maria Sklodowska-Curie National Research Institute of Oncology, Kraków, Poland; [16]IRCCS Ospedale San Raffaele, Milan, Italy; [17]Università Vita-Salute San Raffaele, Milan, Italy

Presented at the EHA2024 Hybrid Congress; June 13-16, 2024; Madrid, Spain

Abstract S160

SEQUOIA Arm D: Response with Zanubrutinib and Venetoclax for Patients with Treatment-Naïve High-Risk CLL with Del(17p) and/or TP53 Mutation



Ma S et al. EHA 2024;Abstract S160.

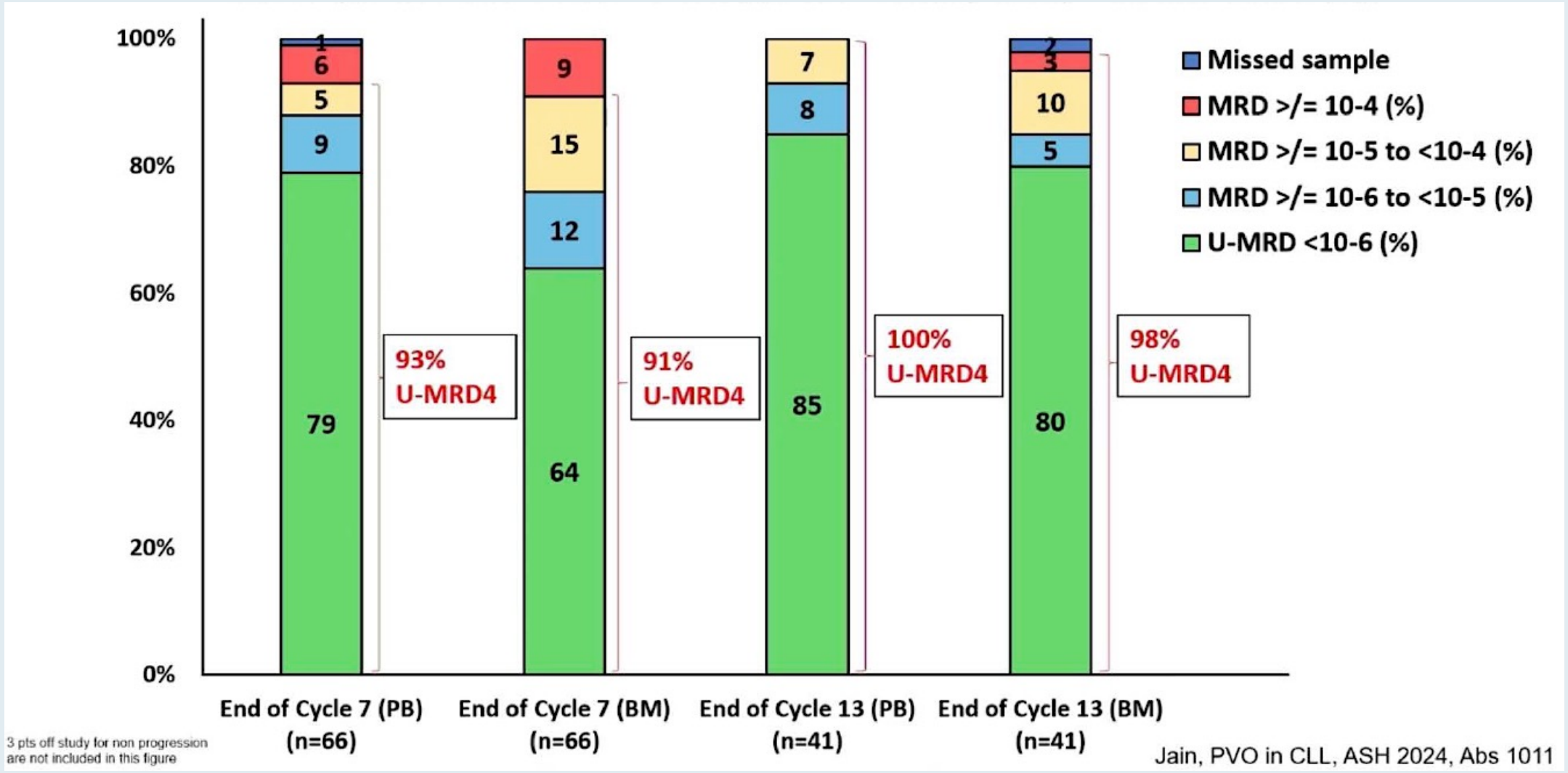
Combined Pirtobrutinib, Venetoclax, and Obinutuzumab As First-Line Treatment of Patients with Chronic Lymphocytic Leukemia (CLL)

Nitin Jain, MD, Alessandra Ferrajoli, MD, Mahesh Swaminathan, MD, Patrick K. Reville, MD, MPH, Jan A. Burger, MD, PhD, Vanthana Bharathi, MD, Himachandana Atluri, MD, Hua-Jay J Cherng, MD, Alex Bataller, MD, PhD, Elias Jabbour, MD, Tapan M. Kadia, MD, Gautam Borthakur, MD, Koichi Takahashi, MD, PhD, Kelly S. Chien, MD, Musa Yilmaz, MD, Naveen Pemmaraju, MD, Naval Daver, MD, Fadi G. Haddad, MD, Yesid Alvarado Valero, MD, Jo Ishizawa, MD, PhD, Guillermo Montalban-Bravo, MD, Naveen Garg, MD, Hyunsoo Hwang, MS, Wei Qiao, PhD, Cameron Garcia, RN, Anna Evangelio, RN, Ana Ayala, RN, Deepa Sampath, PhD, Varsha Gandhi, PhD, Michael J. Keating, MBBS, Hagop M. Kantarjian, MD, William G. Wierda, MD, PhD

Department of Leukemia
The University of Texas MD Anderson Cancer Center

ASH 2024, Abstract 1011

First-Line Pirtobrutinib, Venetoclax and Obinutuzumab: MRD at Serial Time Points in Blood and Bone Marrow



Jain N et al. ASH 2024;Abstract 1011.

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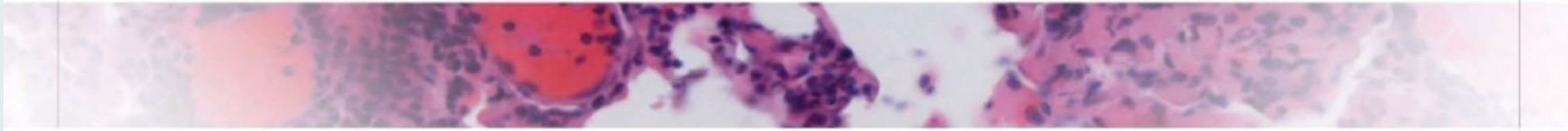


Sonrotoclax and Zanubrutinib as Frontline Treatment for CLL Demonstrates High MRD Clearance Rates with Good Tolerability: Data from an Ongoing Phase 1/1b Study BGB-11417-101

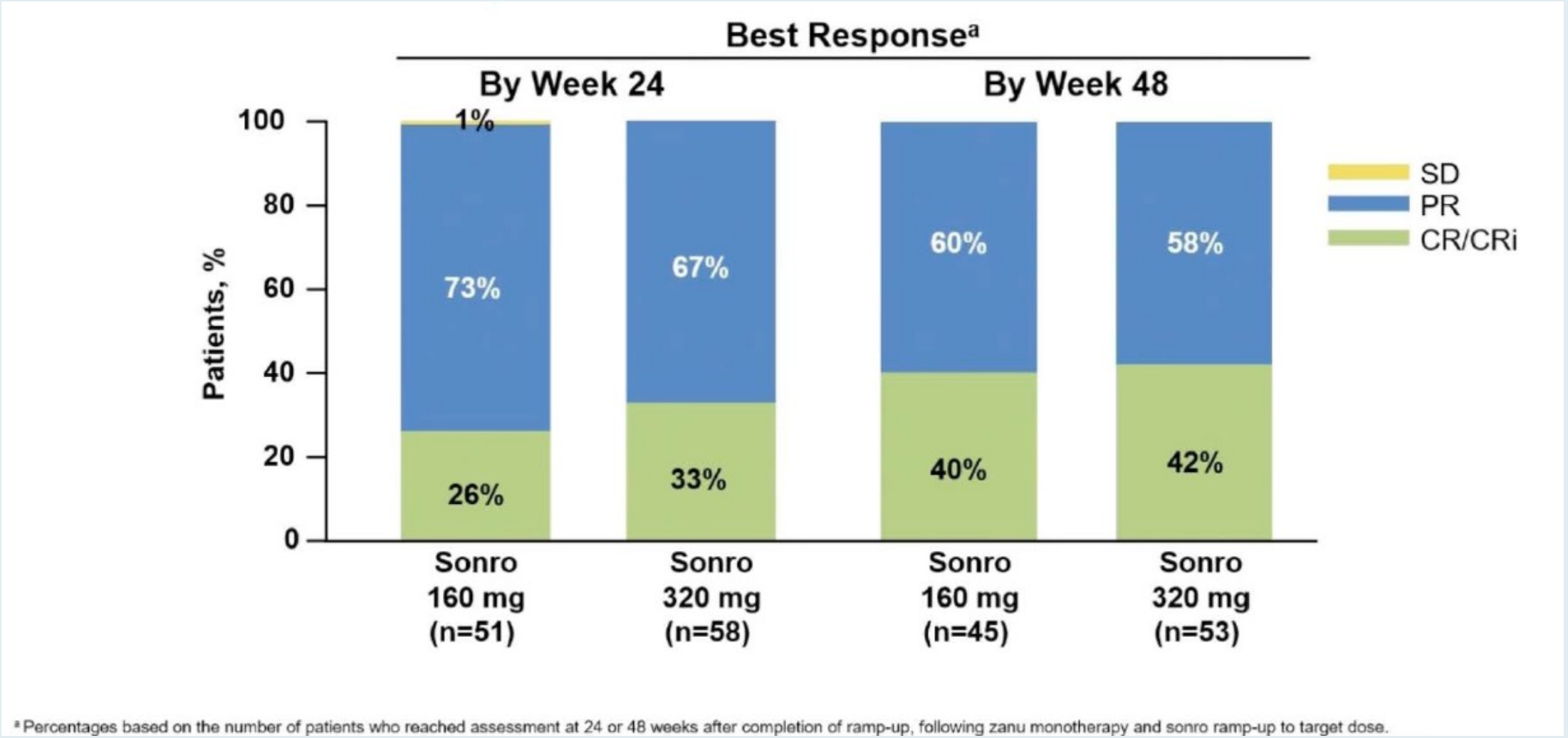
Jacob D. Soumerai,[1] Chan Y. Cheah,[2-4] Mary Ann Anderson,[5,6] Masa Lasica,[7] Emma Verner,[8,9] Stephen S. Opat,[10] Shuo Ma,[11] Robert Weinkove,[12,13] Raul Cordoba,[14] Paolo Ghia,[15,16] Sophie Leitch,[17] David Westerman,[18,19] Sheel Patel,[20] Yiqian Fang,[21] Wei Ding,[20] Haiyi Guo,[21] Constantine S. Tam[22]

[1]Massachusetts General Hospital Cancer Center and Harvard Medical School, Boston, MA, USA; [2]Sir Charles Gairdner Hospital, Nedlands, WA, Australia; [3]Medical School, University of Western Australia, Crawley, WA, Australia; [4]Linear Clinical Research, Nedlands, WA, Australia; [5]Royal Melbourne Hospital and Peter MacCallum Cancer Centre, Melbourne, VIC, Australia; [6]The Walter and Eliza Hall Institute, Melbourne, VIC, Australia; [7]St Vincent's Hospital Melbourne, Fitzroy, VIC, Australia; [8]Concord Repatriation General Hospital, Concord, NSW, Australia; [9]University of Sydney, Sydney, NSW, Australia; [10]Lymphoma Research Group, School of Clinical Sciences at Monash Health, Monash University, Clayton, VIC, Australia; [11]Robert H. Lurie Comprehensive Cancer Center, Northwestern University Feinberg School of Medicine, Chicago, IL, USA; [12]Te Rerenga Ora Blood and Cancer Centre, Te Whatu Ora Health New Zealand Capital Coast & Hutt Valley, Wellington, New Zealand; [13]Cancer Immunotherapy Programme, Malaghan Institute of Medical Research, Wellington, New Zealand; [14]Hospital Universitario Fundación Jiménez Díaz, Madrid, Spain; [15]Università Vita-Salute San Raffaele, Milano, Italy; [16]IRCCS Ospedale San Raffaele, Milano, Italy; [17]Te Whatu Ora Health New Zealand-Waitemata, Auckland, New Zealand; [18]Peter MacCallum Cancer Centre, Melbourne, VIC, Australia; [19]University of Melbourne, Melbourne, VIC, Australia; [20]BeiGene USA, Inc, San Mateo, CA, USA; [21]BeiGene (Shanghai) Co, Ltd, Shanghai, China; [22]Alfred Hospital and Monash University, Melbourne, VIC, Australia

ASH 2024;Abstract 1012

RTP RESEARCH TO PRACTICE

BGB-11417-101: First-Line Sonrotoclax with Zanubrutinib — Antitumor Activity



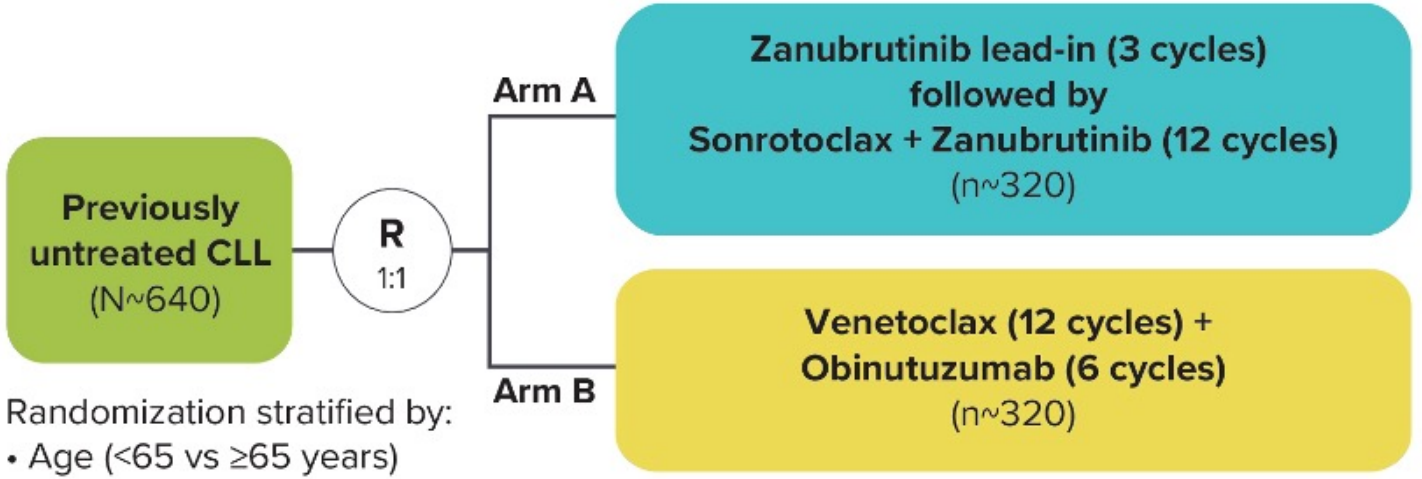
[a] Percentages based on the number of patients who reached assessment at 24 or 48 weeks after completion of ramp-up, following zanu monotherapy and sonro ramp-up to target dose.

SD = stable disease; PR = partial response; CR = complete response; CRi = complete response with incomplete count recovery

Soumerai JD et al. ASH 2024;Abstract 1012.

CELESTIAL-TNCLL: An Ongoing Phase III Trial of Sonrotoclax (BGB-11417) and Zanubrutinib versus Venetoclax and Obinutuzumab for Treatment-Naïve CLL

- Age 18 years and above
- Confirmed CLL diagnosis, no previous treatment
- Measurable disease by CT/MRI
- ECOG PS of 0-2
- Adequate BM and organ function
- No history of, or currently suspected, Richter's transformation



Study Endpoints

Primary
- PFS (IRC; iwCLL 2018[5])

Secondary
- CRR[a] (IRC and INV)
- Rates of uMRD4 (BM and PB)[b]
- OS
- PFS (INV)
- ORR (IRC and INV)
- DOR (IRC and INV)
- Patient-reported outcomes
- Safety and tolerability

[a] Defined as CR or CR with incomplete recovery.
[b] At $<10^{-4}$ sensitivity at the first post-treatment follow-up based on next-generation sequencing by clonoSEQ® and flow cytometry.

BM = bone marrow; CRR = complete response rate; ORR = overall response rate; DOR = duration of response; INV = investigators

Shadman M et al. ASCO 2024;Abstract TPS7087.

RTP RESEARCH TO PRACTICE

Regulatory and reimbursement issues aside, have you administered or would you administer a Bruton tyrosine kinase (BTK) inhibitor in combination with venetoclax with or without an anti-CD20 antibody as first-line treatment for a patient with CLL?

 Dr Coombs	I have, in a young patient I have administered BTKi + venetoclax
 Dr Davids	I have, in a few patients who requested an all-oral, time-limited front-line treatment
 Dr Kittai	I have not, but would administer AV as preferred time-limited therapy for patients without del(17p)/TP53 mutations
 Dr Lamanna	I have, for patients wanting a time-limited, all-oral approach. I would like more data regarding re-treatment for patients with del(17p)/TP53 or complex karyotype
 Dr Ujjani	I have not, but would for the right patient once regulatory approval is received
 Dr Woyach	I have, in a young patient with IGHV-mutated CLL with no high-risk features who desired fixed-duration therapy and an all-oral regimen

BTKi = BTK inhibitor; AV = acalabrutinib/venetoclax

RTP RESEARCH TO PRACTICE

Regulatory and reimbursement issues aside, in general, if you were going to administer a BTK inhibitor in combination with venetoclax with or without an anti-CD20 antibody as first-line treatment for a patient with CLL, which would be your preferred BTK inhibitor?

 Dr Coombs	Acalabrutinib
 Dr Davids	Acalabrutinib
 Dr Kittai	Acalabrutinib
 Dr Lamanna	Zanubrutinib
 Dr Ujjani	Zanubrutinib
 Dr Woyach	Acalabrutinib

Regulatory and reimbursement issues aside, in what specific clinical situations would you prefer to administer the time-limited regimen of a BTK inhibitor in combination with venetoclax with or without an anti-CD20 antibody as first-line therapy for CLL?

 Dr Coombs	If preference for all-oral, time-limited regimen; BTKi performs better for patients with bulky LAD; AVO looks good and perhaps better than VO for patients with unmutated IGHV
 Dr Davids	If preference for an all-oral, time-limited front-line treatment, patients with TP53-aberrant CLL who want a time-limited therapy, or patients with unmutated IGHV who have very bulky LAD
 Dr Kittai	I would use this combination for younger patients without high-risk features, similar to the population studied in the AMPLIFY trial
 Dr Lamanna	BTKi/venetoclax is a great option, particularly for patients with favorable-risk disease and those who want a time-limited, all-oral approach. It is more convenient than venetoclax/obinutuzumab
 Dr Ujjani	Any patient except those with del(17p) CLL
 Dr Woyach	BTKi/Bcl-2i for a patient with IGHV-mutated CLL or a patient with IGHV-unmutated CLL desiring an all-oral, fixed-duration regimen; BTKi/Bcl-2i/anti-CD20 Ab for young, fit patient with IGHV-unmutated CLL desiring fixed-duration regimen

LAD = lymphadenopathy; AVO = acalabrutinib/venetoclax/obinutuzumab; Bcl-2i = Bcl-2 inhibitor; Ab = antibody

Regulatory and reimbursement issues aside, in what situations, if any, would you include an anti-CD20 antibody in combination with a BTK inhibitor and venetoclax as first-line treatment for a patient with CLL?

 Dr Coombs	Young, fit patient with unmutated IGHV
 Dr Davids	Patients with TP53-aberrant CLL and patients with a history of or active issues with autoimmune cytopenias, including AIHA or ITP
 Dr Kittai	I would not include an anti-CD20 antibody given its high toxicity and potentially worse OS. I do not see the benefit at this time
 Dr Lamanna	I am not yet comfortable with a triplet in front-line therapy given its increased toxicity compared to that seen with the doublet
 Dr Ujjani	Hemolysis, if rapid reduction in absolute lymphocyte count needed
 Dr Woyach	Young and fit, IGHV-unmutated CLL or other high-risk features

AIHA = autoimmune hemolytic anemia; ITP = immune thrombocytopenic purpura; OS = overall survival

RTP RESEARCH TO PRACTICE

CORRESPONDENCE

Racial disparities in chronic lymphocytic leukemia/small lymphocytic lymphoma accounting for small molecule inhibitors: A real-world cohort analysis

Kittai AS et al. *Am J Hematol* 2024 April;99(4):780-4.

TO THE EDITOR:

Racial and socioeconomic disparities in CLL/SLL: analysis of SEER data from 2006 to 2019

Adam S. Kittai,[1] Ying Huang,[1] Seema A. Bhat,[1] Electra D. Paskett,[2,3] Kerry A. Rogers,[1] Jacqueline C. Barrientos,[4] James L. Fisher,[5,*] and Jennifer A. Woyach[1,*]

***Blood Adv* 2023 June 13;7(11):2575-9.**

Phase Ib Study of Daratumumab and Ibrutinib for Symptomatic CLL

Trial identifier: NCT03447808 (active, not recruiting)
Enrollment: 15 (actual)

Eligibility

- Diagnosis of symptomatic CLL requiring active treatment
- ECOG PS 0-2
- No prior chemotherapy, immunotherapy, or targeted therapy for the treatment of CLL

→

Daratumumab

+

Ibrutinib

Primary endpoint: Safety and complete response rate

www.clinicaltrials.gov. NCT03447808. Accessed January 2025.

Meet The Professor with Dr Woyach

Module 1: AMPLIFY — First-Line Trials of BTKi/Venetoclax

Module 2: Pirtobrutinib

Module 3: Choice of First-Line BTKi

Module 4: Cardiotoxicity of BTKi

Module 5: CLL and COVID-19 Vaccinations; Role of MRD Testing; Anti-CD20 Antibodies

Module 6: Transformed CLL

RTP RESEARCH TO PRACTICE

Questions for the Faculty: Effectiveness and tolerability of pirtobrutinib for patients with CLL and disease progression on prior BTK inhibition

Dr Zanetta Lamar (Naples, Florida)

RTP
RESEARCH
TO PRACTICE

Which third-line therapy would you generally prefer for a patient with double-refractory CLL?

 Dr Coombs	Pirtobrutinib
 Dr Davids	Pirtobrutinib
 Dr Kittai	Pirtobrutinib
 Dr Lamanna	Pirtobrutinib
 Dr Ujjani	Lisocabtagene maraleucel
 Dr Woyach	Pirtobrutinib

In which line of therapy are you currently using pirtobrutinib for your patients with CLL?

 Dr Coombs	Third line
 Dr Davids	Third line
 Dr Kittai	Third line
 Dr Lamanna	Third line
 Dr Ujjani	Fourth line
 Dr Woyach	Third line

Based on current clinical trial data and your personal experience, how would you compare the global efficacy and tolerability/toxicity of pirtobrutinib to that of ibrutinib, acalabrutinib and zanubrutinib for patients with relapsed/refractory (R/R) CLL?

	Efficacy	Tolerability/toxicity
 Dr Coombs	There are not enough available data at this time	Pirtobrutinib has the least toxicity
 Dr Davids	About the same	Pirtobrutinib has the least toxicity
 Dr Kittai	There are not enough available data at this time	There are not enough available data at this time
 Dr Lamanna	There are not enough available data at this time	Pirtobrutinib has the least toxicity
 Dr Ujjani	There are not enough available data at this time	Pirtobrutinib has the least toxicity
 Dr Woyach	There are not enough available data at this time	Pirtobrutinib has the least toxicity

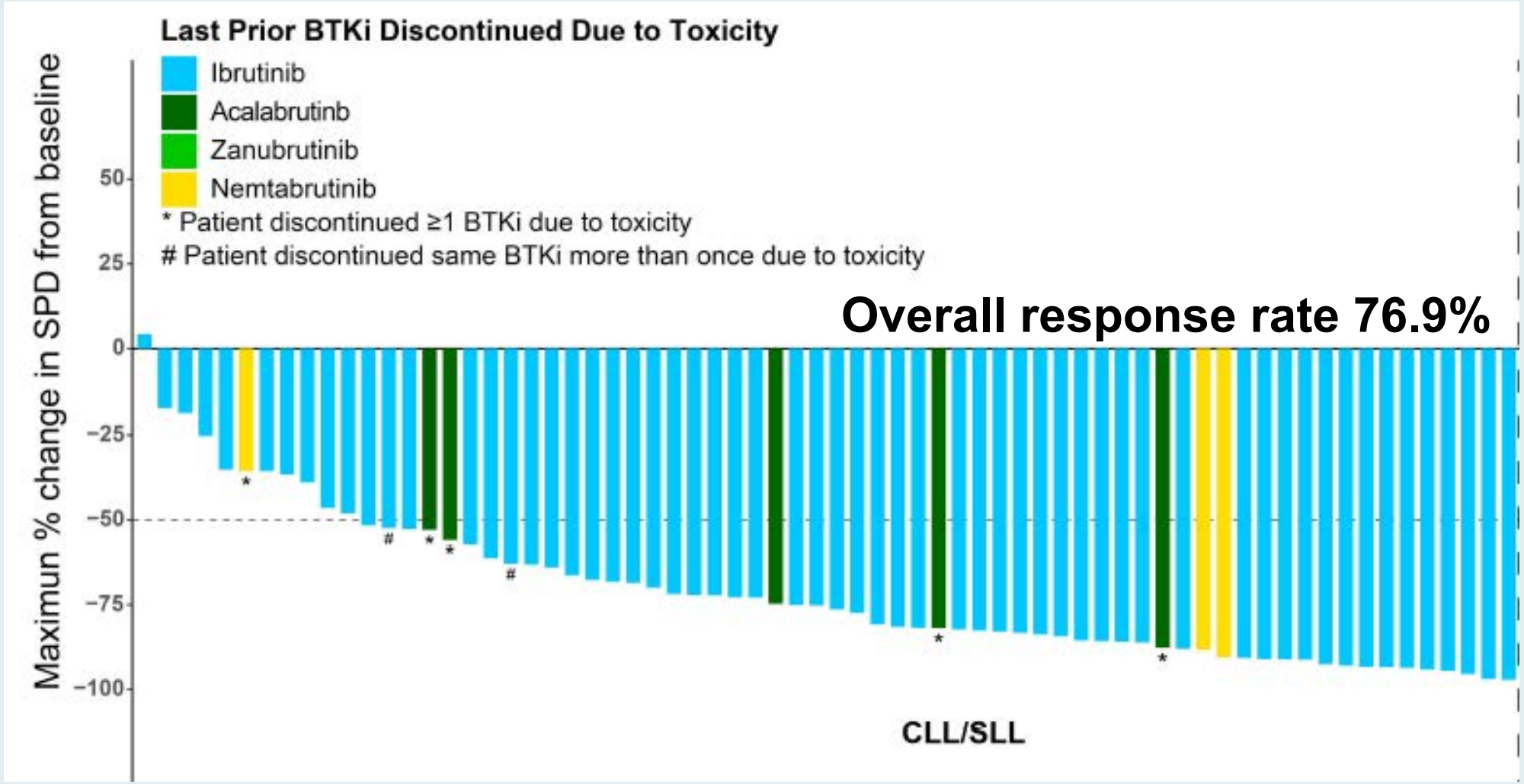
haematologica
Journal of the Ferrata Storti Foundation

Pirtobrutinib monotherapy in Bruton tyrosine kinase inhibitor-intolerant patients with B-cell malignancies: results of the phase I/II BRUIN trial

by Nirav N. Shah, Michael Wang, Lindsey E. Roeker, Krish Patel, Jennifer A. Woyach, William G. Wierda, Chaitra S. Ujjani, Toby A. Eyre, Pier Luigi Zinzani, Alvaro J. Alencar, Paolo Ghia, Nicole Lamanna, Marc S. Hoffmann, Manish R. Patel, Ian Flinn, James N. Gerson, Shuo Ma, Catherine C. Coombs, Chan Y. Cheah, Ewa Lech-Maranda, Bita Fakhri, Won Seog Kim, Minal A. Barve, Jonathon B. Cohen, Wojciech Jurczak, Talha Munir, Meghan C. Thompson, Donald E. Tsai, Katherine Bao, Nicholas A. Cangemi, Jennifer F. Kherani, Richard A. Walgren, Hongmei Han, Amy S. Ruppert, and Jennifer R. Brown

September 27 2024;[Online ahead of print].

BRUIN: Pirtobrutinib Efficacy in Patients with CLL or SLL Who Received Prior BTK Inhibitor (BTKi) Treatment



SPD = sum of product of diameters

Shah NN et al. *Haematologica* September 27 2024;[Online ahead of print].

RTP RESEARCH TO PRACTICE

Pirtobrutinib in Relapsed/Refractory CLL/SLL: Results from BTKI Naïve Cohort in the Phase 1/2 BRUIN Study

Eyre T et al.

EHA 2024;Abstract P656.

Genomic Evolution and Resistance during Pirtobrutinib Therapy in Covalent BTK-Inhibitor (cBTKi) Pre-treated Chronic Lymphocytic Leukemia Patients: Updated Analysis from the BRUIN Study

Jennifer R. Brown[1], Sai Prasad Desikan[2], Bastien Nguyen[3], Helen Won[3], Shady I. Tantawy[2], Samuel C. McNeely[4], Narasimha Marella[3], Kevin Ebata[3], Jennifer A. Woyach[5], Krish Patel[6], Constantine S. Tam[7], Toby A. Eyre[8], Chan Y. Cheah[9,10], Nirav N. Shah[11], Paolo Ghia[12], Wojciech Jurczak[13], Minna Balbas[3], Binoj Nair[3], Paolo Abada[3], Chunxiao Wang[4], Denise Wang[3], Lindsey E. Roeker[14], Varsha Gandhi[2], William G. Wierda[2]

ASCO 2023;Abstract 326

BRUIN CLL-321: Randomized Phase III Trial of Pirtobrutinib versus Idelalisib plus Rituximab (IdelaR) or Bendamustine plus Rituximab (BR) in BTK Inhibitor Pretreated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

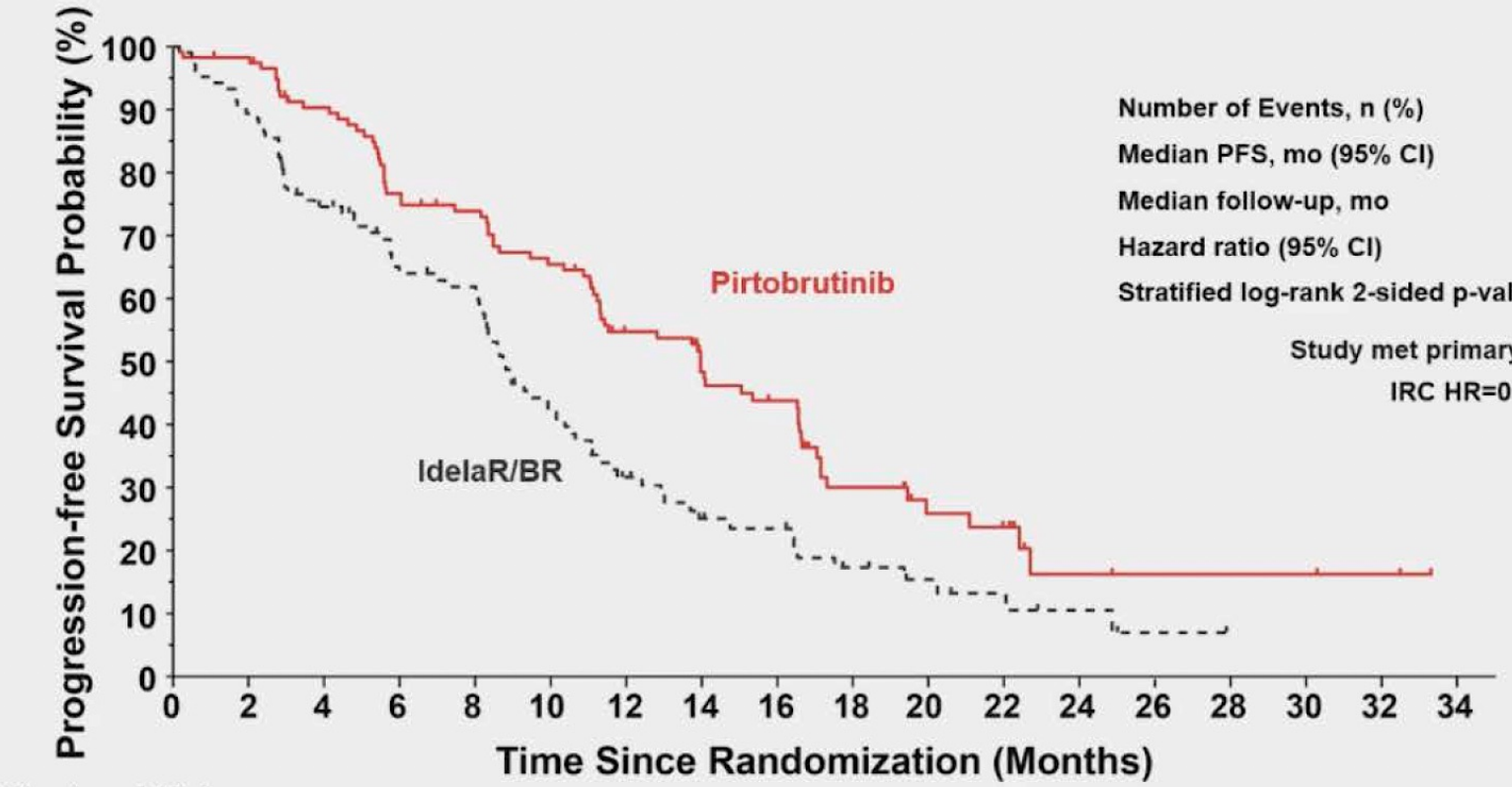
Jeff P. Sharman[1], Talha Munir[2], Sebastian Grosicki[3], Lindsey E Roeker[4], John M Burke[5], Christine Chen[6], Norbert Grzasko[7], George Follows[8], Zoltán Mátrai[9], Alessandro Sanna[10], Shuhua Yi[11], Ru Feng[12], Vu Minh Hua[13], Jadwiga Holodja[14], Wojciech Jurczak[15], Matthias Ritgen[16], Lugui Qiu[11], Francesc Bosch[17], Catherine C Coombs[18], Katherine Bao[19], Vishalkumar Patel[19], Bin Liu[19], Livia Compte[19], Ananya Guntur[19], Denise Y. Wang[19], Marisa Hill[19], Ching Ching Leow[19], Paolo Ghia[20], Paul M Barr[21]

[1] Willamette Valley Cancer Institute and Research Center, US Oncology Research, Eugene, OR, USA, [2] Department of Haematology, St. James's University Hospital, Leeds, UK, [3] Department of Hematology &Cancer Prevention, Silesian Medical University, Katowice, Poland, [4] Department of Medicine, Memorial Sloan Kettering Cancer Center New York, NY, USA, [5] Sarah Cannon Research Institute, Rocky Mountain Cancer Centers, Aurora, CO, USA, [6] Division of Medical Oncology & Hematology, Princess Margaret Cancer Centre, Toronto, ON, Canada, [7] Department of Experimental Hematooncology, Medical University of Lublin, Lublin, Poland, [8] Department of Haematology, Addenbrooke's Hospital NHS Trust, Cambridge, UK, [9] Central Hospital of Southern Pest, National Institute for Haematology and Infectology, Budapest, Hungary, [10] Department of Hematology, AOU Careggi - University of Florence, Firenze, Italy, [11] Institute of Hematology & Blood Diseases Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, Tianjin 300020, China, [12] Department of Radiation Oncology, Nanfang Hospital, Southern Medical University, Guangzhou, Guangdong, China, [13] Haematology Department, Liverpool Hospital Sydney Australia, [14] Department of Hematology, City Hospital, Legnica, Poland, [15] Maria Sklodowska-Curie National Research Institute of Oncology, Krakow, Poland, [16] Universitätsklinik Schleswig-Holstein, Campus Kiel, Germany, [17] Department of Haematology, University Hospital Vall d'Hebron, Autonomous University, Barcelona, Spain, [18] University of California Irvine, Irvine, CA, USA, [19]Eli Lilly and Company, Indianapolis, IN, USA, [20] Università Vita-Salute San Raffaele and IRCCS Ospedale San Raffaele, Milano, Italy, [21] Wilmot Cancer Institute, University of Rochester Medical Center, Rochester, NY, USA.

ASH 2024;Abstract 886

RTP RESEARCH TO PRACTICE

BRUIN CLL-321: IRC-Assessed Progression-Free Survival



	Pirtobrutinib n=119	IdelaR/BR n=119
Number of Events, n (%)	74 (62)	79 (66)
Median PFS, mo (95% CI)	**14.0** (11.2-16.6)	**8.7** (8.1-10.4)
Median follow-up, mo	19.4	17.7
Hazard ratio (95% CI)	**0.54 (0.39- 0.75)**	
Stratified log-rank 2-sided p-value	0.0002*	

Study met primary endpoint at earlier data cut (Aug 2023)

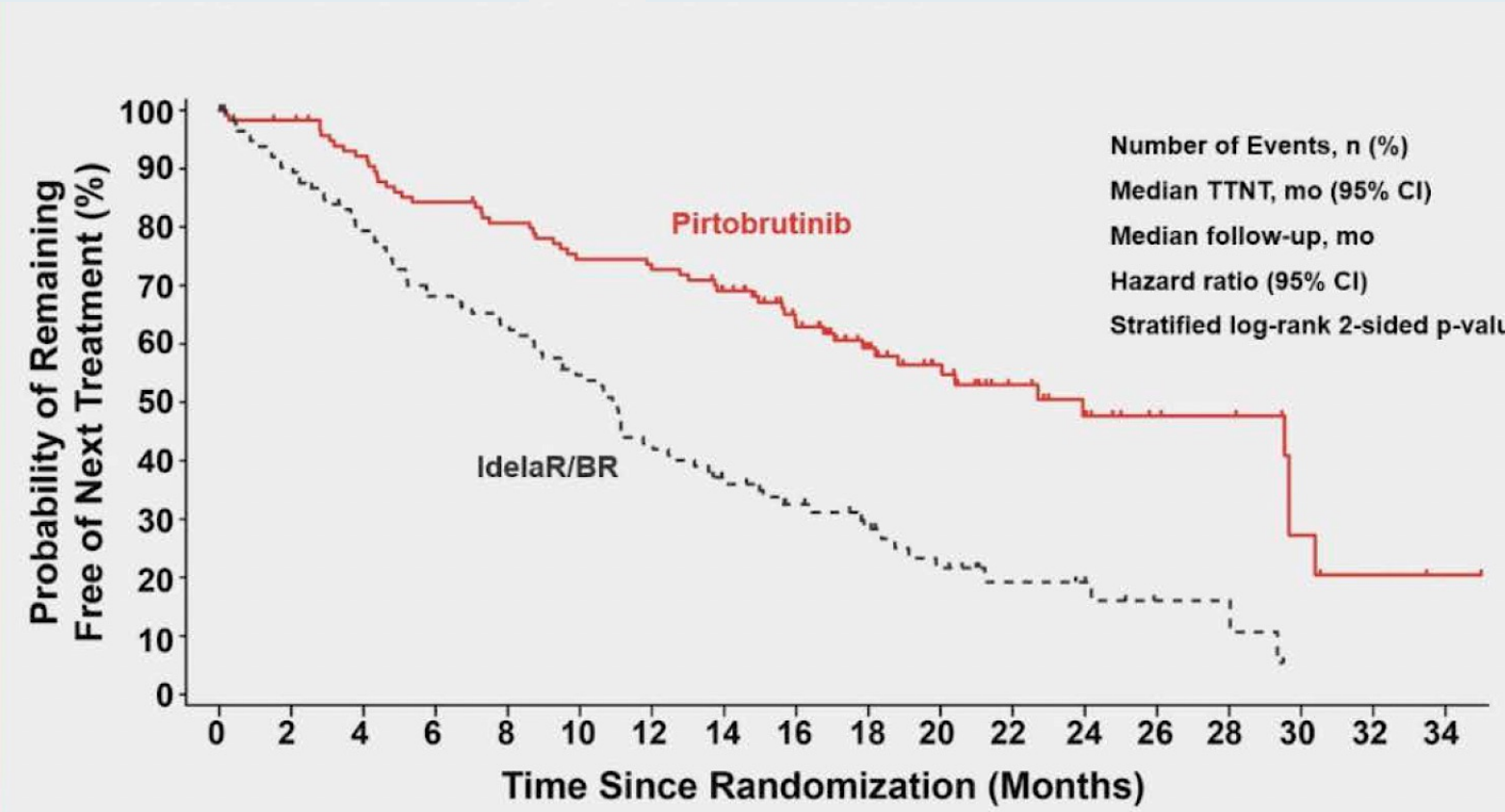
IRC HR=0.58 (95% CI 0.38- 0.89); p = 0.01

Pirtobrutinib reduced risk of progression or death by 46% according to IRC assessment

*nominal p-value. Abbreviations: BR, bendamustine + rituximab; CI, confidence interval; HR, hazard ratio (pirtobrutinib vs. IdelaR/BR); IdelaR, idelalisib + rituximab; IRC, Independent Review Committee; mo, months; PFS, progression-free survival.

Sharman JP et al. ASH 2024;Abstract 886.

BRUIN CLL-321: Time to Next Treatment



	Pirtobrutinib n=119	IdelaR/BR n=119
Number of Events, n (%)	54 (45)	82 (69)
Median TTNT, mo (95% CI)	**24.0** (17.8-29.7)	**10.9** (8.7-12.5)
Median follow-up, mo	20.0	20.2
Hazard ratio (95% CI)	**0.37 (0.25-0.52)**	
Stratified log-rank 2-sided p-value	<0.0001*	

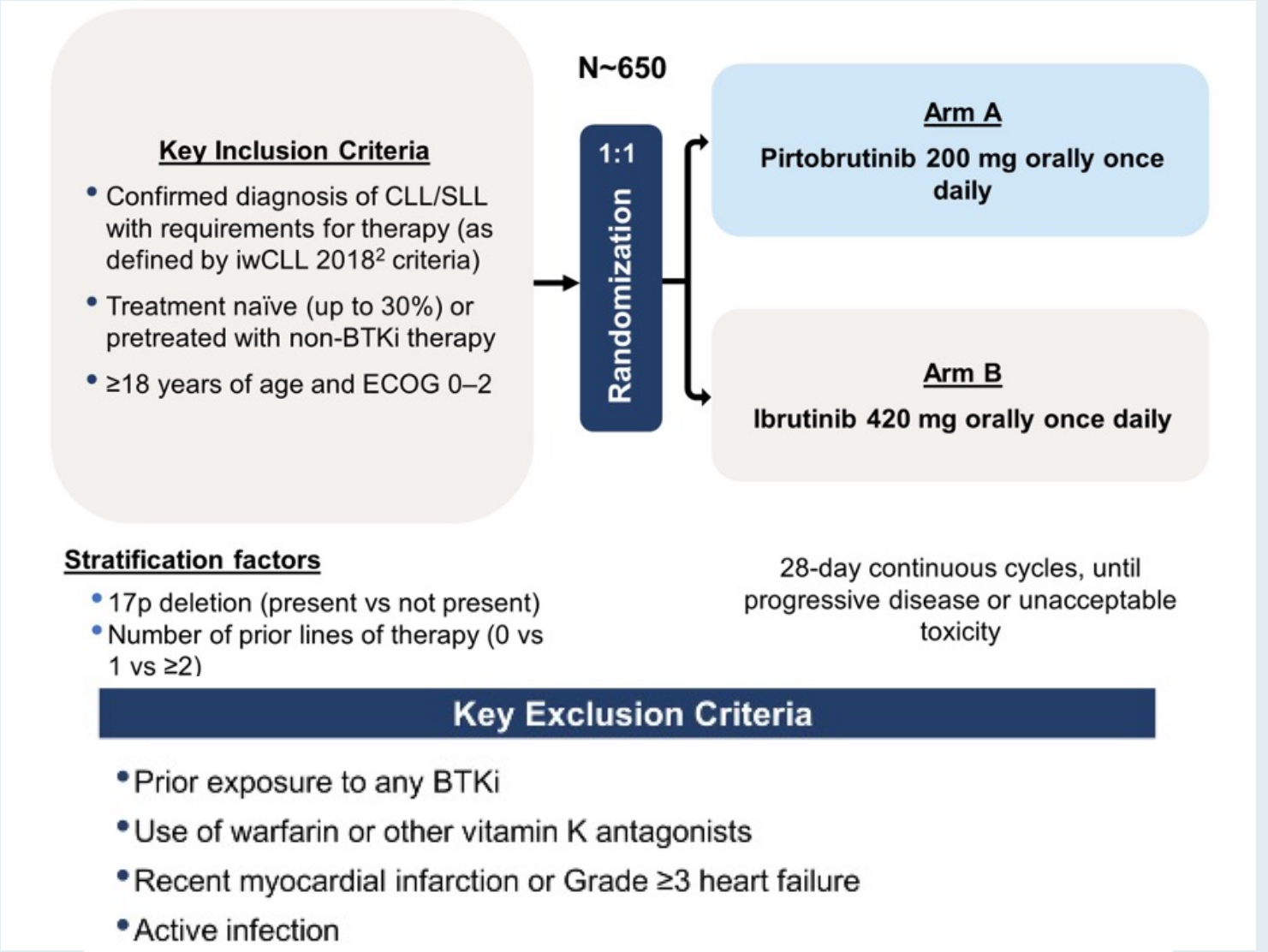
Pirtobrutinib reduced the risk of starting next treatment or death by 63% with a median TTNT of ~24 months

*nominal p-value. TTNT is defined as time from the date of randomization to the date of initiation of the subsequent anticancer therapy (including crossover) for CLL/SLL, or death due to any cause, whichever occurs first. Abbreviations: BR, bendamustine + rituximab; CI, confidence interval; mo, months; IdelaR, idelalisib + rituximab; TTNT, time to next treatment.

Sharman JP et al. ASH 2024;Abstract 886.

RTP RESEARCH TO PRACTICE

BRUIN CLL-314: A Phase III, Open-Label Study of Pirtobrutinib versus Ibrutinib for Patients with CLL/SLL



Woyach JA et al. ASCO 2023;Abstract TPS7584.

Pirtobrutinib in Richter Transformation: Updated Efficacy and Safety Results with 18-Month Median Survival Follow-Up from the Phase 1/2 BRUIN Study

Weirda WG et al.

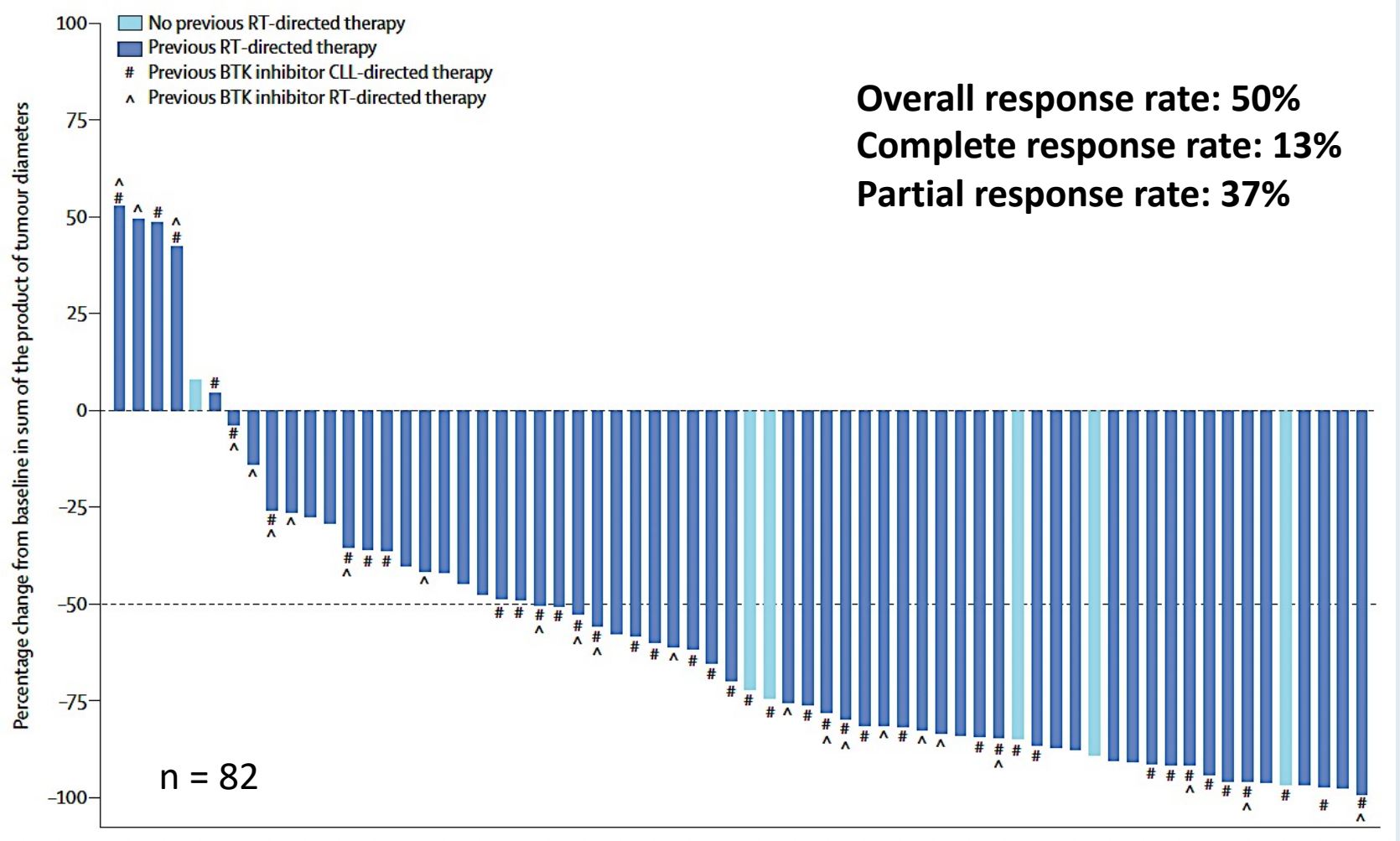
ASH 2023;Abstract 1737.

Pirtobrutinib, a highly selective, non-covalent (reversible) BTK inhibitor in patients with B-cell malignancies: analysis of the Richter transformation subgroup from the multicentre, open-label, phase 1/2 BRUIN study

William G Wierda, Nirav N Shah, Chan Y Cheah, David Lewis, Marc S Hoffmann, Catherine C Coombs, Nicole Lamanna, Shuo Ma, Deepa Jagadeesh, Talha Munir, Yucai Wang, Toby A Eyre, Joanna M Rhodes, Matthew McKinney, Ewa Lech-Maranda, Constantine S Tam, Wojciech Jurczak, Koji Izutsu, Alvaro J Alencar, Manish R Patel, John F Seymour, Jennifer A Woyach , Philip A Thompson, Paolo B Abada, Caleb Ho, Samuel C McNeely, Narasimha Marella, Bastien Nguyen, Chunxiao Wang, Amy S Ruppert, Binoj Nair, Hui Liu, Donald E Tsai, Lindsey E Roeker, Paolo Ghia

***Lancet Haematol* 2024 September;11(9):e682-92.**

BRUIN Subgroup Analysis: Activity of Pirtobrutinib in Patients with Richter's Transformation (RT)



- The most common Grade 3 or worse adverse event was neutropenia (n = 19).

Wierda WG et al. *Lancet Haematol* 2024 September;11(9):e682-92.

CLINICAL TRIALS AND OBSERVATIONS

Fixed-duration pirtobrutinib plus venetoclax with or without rituximab in relapsed/refractory CLL: the phase 1b BRUIN trial

Lindsey E. Roeker,[1] Jennifer A. Woyach,[2] Chan Y. Cheah,[3] Catherine C. Coombs,[4] Nirav N. Shah,[5] William G. Wierda,[6] Manish R. Patel,[7] Nicole Lamanna,[8] Donald E. Tsai,[9] Binoj Nair,[9] Chunxiao Wang,[10] Xiang Zhao,[9] Dan Liu,[10] David Radtke,[10] Sonya Chapman,[10] Narasimha Marella,[9] Samuel C. McNeely,[9] and Jennifer R. Brown[11]

Blood **2024 September 26;144(13):1374-86.**

JC JOURNAL CLUB RTP RESEARCH TO PRACTICE

BRUIN CLL-322: A Phase 3 Open-Label, Randomized Study of Fixed Duration Pirtobrutinib plus Venetoclax and Rituximab versus Venetoclax and Rituximab in Previously Treated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

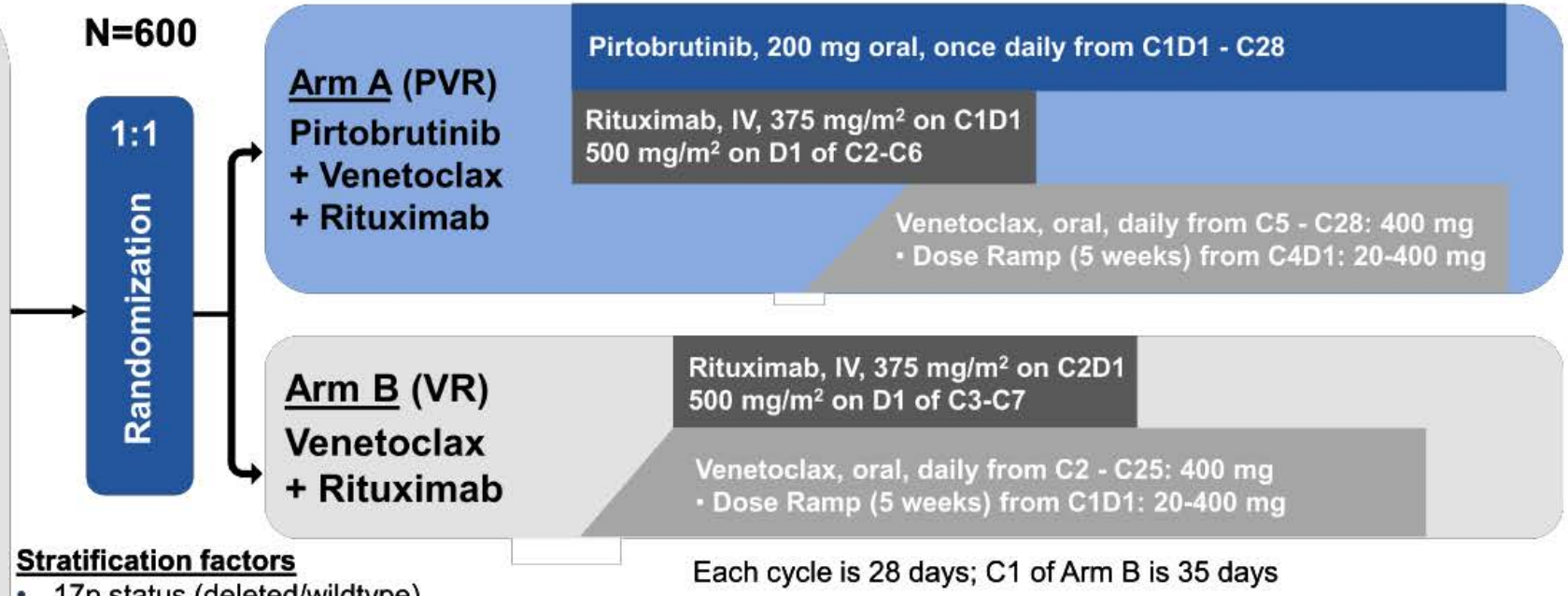
Eyre TA et al.

ASCO 2023;Abstract TPS7583.

BRUIN CLL-322 Phase III Trial Design

Key Inclusion Criteria

- Confirmed CLL/SLL per iwCLL 2018[3]
- Previously treated CLL/SLL (including a covalent BTKi or covalent BTKi naïve [limited to 20% of total enrollment])
- Known 17p status
  - If 17p status is unknown, local or central FISH test results during screening can be used
- No prior venetoclax
- ≥18 years of age and ECOG 0-2



Each cycle is 28 days; C1 of Arm B is 35 days

Stratification factors

- 17p status (deleted/wildtype)
- Prior experience of BTKi (discontinuation due to PD or other vs no prior BTKi)

Primary endpoint: Progression-free survival per iwCLL 2018 by IRC

Eyre TA et al. ASCO 2023;Abstract TPS7583.

Evaluation of bleeding risk in patients who received pirtobrutinib in the presence or absence of antithrombotic therapy

Nicole Lamanna[1] | Constantine S. Tam[2,3] | Jennifer A. Woyach[4] | Alvaro J. Alencar[5] | M. Lia Palomba[6] | Pier Luigi Zinzani[7,8] | Ian W. Flinn[9] | Bita Fakhri[10] | Jonathon B. Cohen[11] | Arrin Kontos[12] | Heiko Konig[12] | Amy S. Ruppert[13] | Anindya Chatterjee[12] | Richard Sizelove[13] | Livia Compte[13] | Donald E. Tsai[12] | Wojciech Jurczak[14]

EJHaem 2024 September 27;5(5):929-39.

Meet The Professor with Dr Woyach

Module 1: AMPLIFY — First-Line Trials of BTKi/Venetoclax

Module 2: Pirtobrutinib

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Module 4: Cardiotoxicity of BTKi

Module 5: CLL and COVID-19 Vaccinations; Role of MRD Testing; Anti-CD20 Antibodies

Module 6: Transformed CLL

Case Presentation: 86-year-old woman diagnosed with CLL over 30 years ago now has relapsed/refractory, ibrutinib-intolerant disease

Dr Warren Brenner (Boca Raton, Florida)

Regulatory and reimbursement issues aside and assuming equal access to acalabrutinib and zanubrutinib, in general which BTK inhibitor do you prefer to administer as first-line treatment for CLL?

 Dr Coombs	Zanubrutinib as monotherapy due to overall favorable experience with drug, superiority data over ibrutinib, and dose flexibility
 Dr Davids	Acalabrutinib given longer-term follow-up data, personal experience prescribing, and availability of combination data with venetoclax in this setting
 Dr Kittai	Acalabrutinib for most patients as I believe it has a better side-effect profile and there is no head-to-head data to suggest zanubrutinib is more effective
 Dr Lamanna	Zanubrutinib given its ability to dose-reduce easily and convenient administration
 Dr Ujjani	Zanubrutinib due to its better tolerability and easier dosing
 Dr Woyach	Acalabrutinib for most patients due to longer-term data, safety profile; zanubrutinib for del(17p)/TP53 abnormalities due to large experience in front-line TP53-altered CLL

RTP RESEARCH TO PRACTICE

Regulatory and reimbursement issues aside and assuming equal access to acalabrutinib and zanubrutinib, are there specific clinical situations for which you prefer one BTK inhibitor versus the other?

 Dr Coombs	Prefer acalabrutinib for patients with difficult-to-treat HTN
 Dr Davids	I prefer zanubrutinib for patients with preexisting issues with headaches and I tend to use it more now in the TP53-aberrant population given the favorable PK/PD of the drug; for patients with preexisting HTN, I prefer acalabrutinib
 Dr Kittai	I might prefer zanubrutinib for someone with severe headaches, and I prefer acalabrutinib overall, especially for patients who struggle with HTN
 Dr Lamanna	Zanubrutinib given its ability to dose-reduce easily and convenient administration
 Dr Ujjani	Zanubrutinib due to its better tolerability and easier dosing
 Dr Woyach	Acalabrutinib for patients with HTN; zanubrutinib for patients with headaches

HTN = hypertension; PK/PD = pharmacokinetics/pharmacodynamics

RTP RESEARCH TO PRACTICE

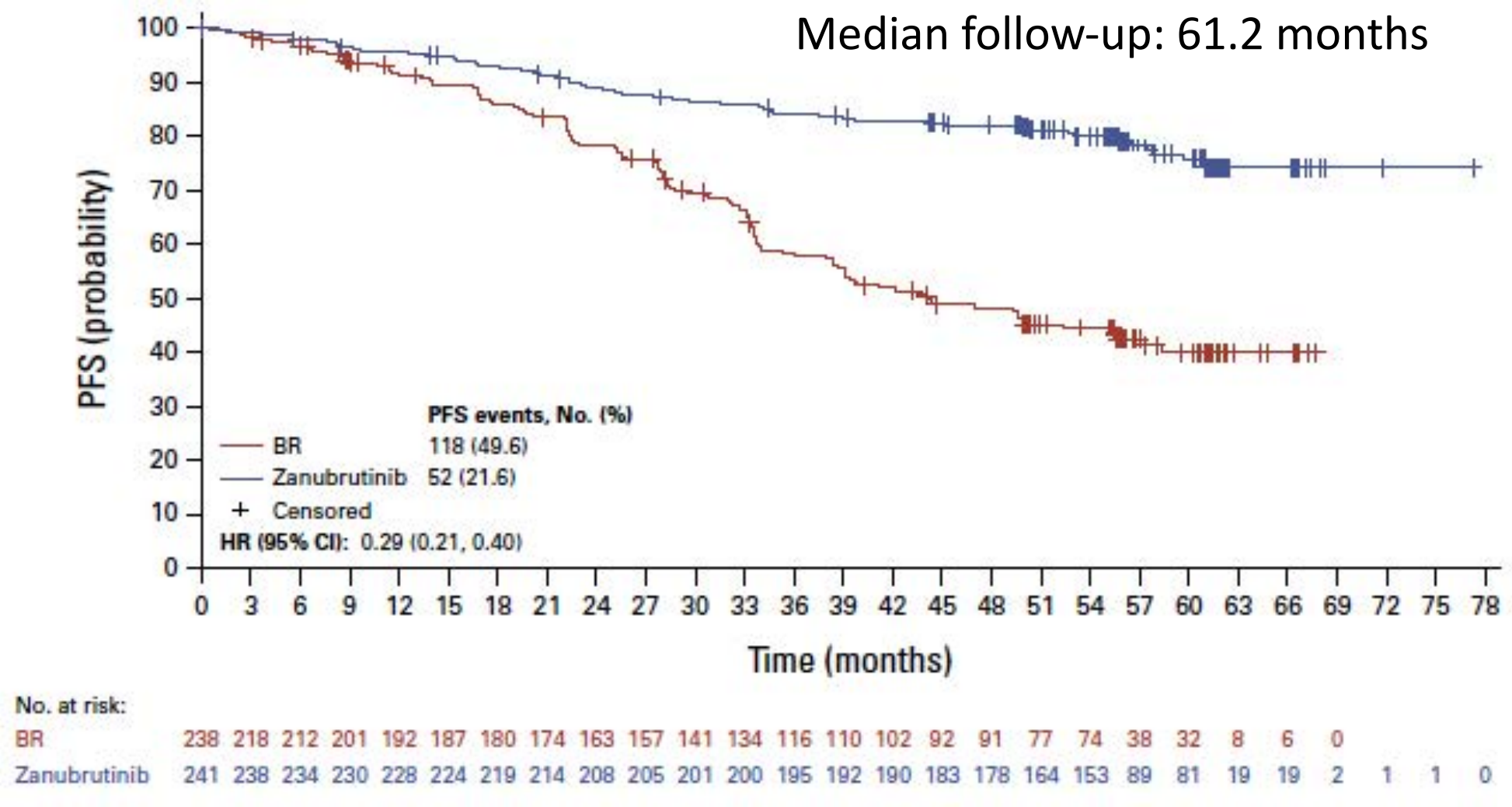
Clinical Trial Updates

Zanubrutinib Versus Bendamustine and Rituximab in Patients With Treatment-Naïve Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma: Median 5-Year Follow-Up of SEQUOIA

Mazyar Shadman, MD, MPH[1]; Talha Munir, PhD, MBBS, MRCP, FRCPath[2]; Tadeusz Robak, MD, PhD[3]; Jennifer R. Brown, MD, PhD[4]; Brad S. Kahl, MD[5]; Paolo Ghia, MD, PhD[6,7]; Krzysztof Giannopoulos, MD, PhD, DSc[8,9]; Martin Šimkovič, MD, PhD[10]; Anders Österborg, MD, PhD[11]; Luca Laurenti, MD[12]; Patricia A. Walker, MD[13]; Stephen S. Opat, MD, MBBS, FRACP, FRCPA[14]; Hanna Ciepluch, PhD[15]; Richard Greil, MD[16,17,18]; Merit Hanna, MD[19]; Monica Tani, MD, PhD[20]; Marek Trněný, MD, CSc[21]; Danielle Brander, MD[22]; Ian W. Flinn, MD, PhD[23]; Sebastian Grosicki, MD, PhD[24]; Emma Verner, MBBS, BMedSci, FRACP, FRCPA[25,26]; Alessandra Tedeschi, MD[27]; Sophie de Guibert, MD[28]; Gayane Tumyan, MD[29]; Kamel Laribi, MD[30]; José A. García-Marco, MD, PhD[31]; Jian-Yong Li, MD, PhD[32]; Tian Tian, PhD[33]; Yu Liu, PhD[33]; Roman Korolkiewicz, MD, PhD[33]; Andy Szeto, PharmD[33]; Constantine S. Tam, MD, MB, BS (Hons), FRACP, FRCPA[34]; and Wojciech Jurczak, MD, PhD[35]

J Clin Oncol December 8 2024;[Online ahead of print].

SEQUOIA: Progression-Free Survival (PFS) for Patients without Del(17p)

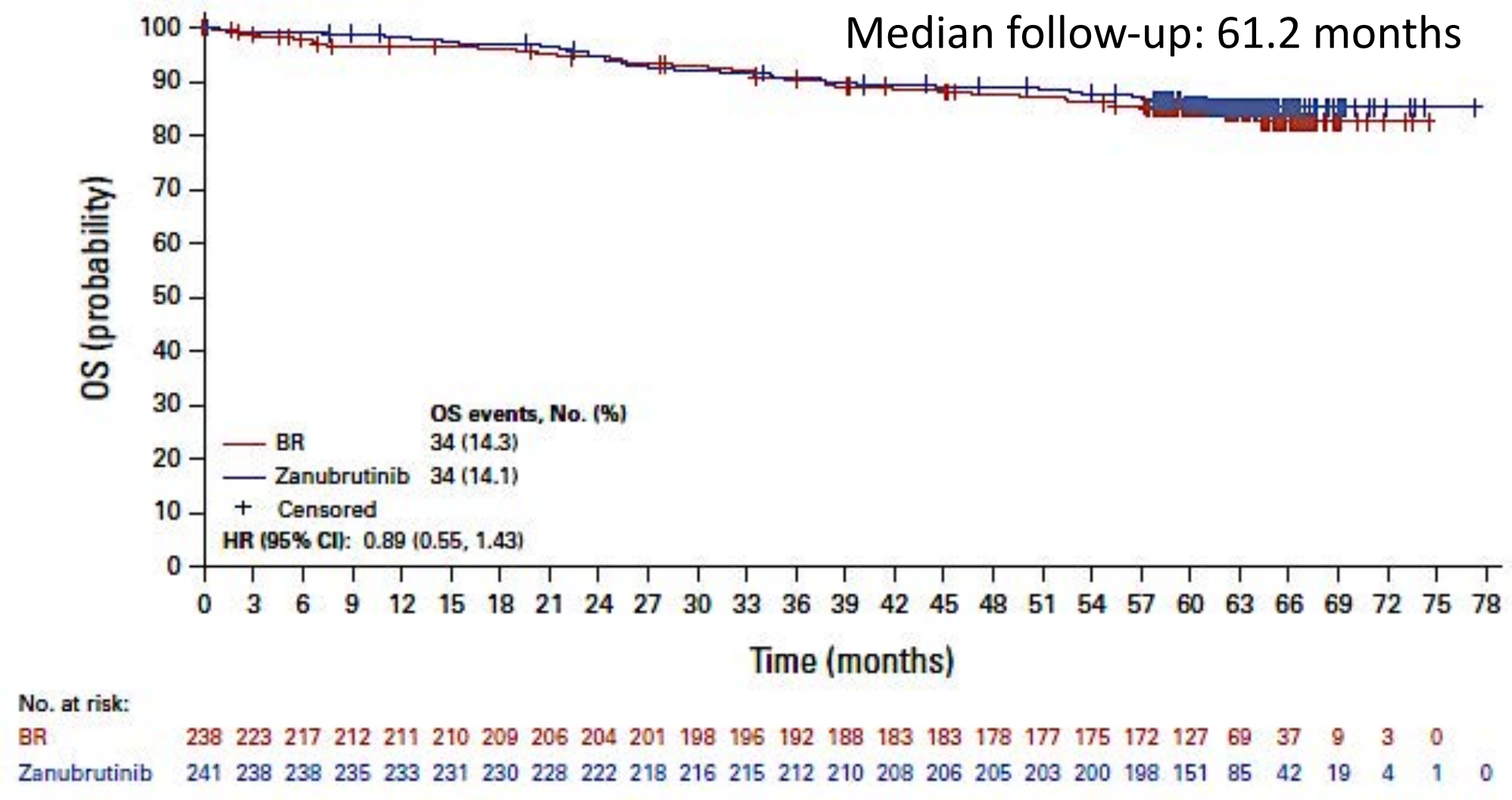


BR = bendamustine/ritixumab

Shadman M et al. *J Clin Oncol* December 8 2024;[Online ahead of print].

RTP RESEARCH TO PRACTICE

SEQUOIA: Overall Survival (OS) for Patients without Del(17p)



Shadman M et al. *J Clin Oncol* December 8 2024;[Online ahead of print].

Meet The Professor with Dr Woyach

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Module 6: Transformed CLL

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Case Presentation: 72-year-old man with chronic atrial fibrillation requiring long-term anticoagulation is diagnosed with IGHV-unmutated CLL (del[13q], del[17p], XPO1 mutation)

Dr Tina Bhatnagar (Wheeling, West Virginia)

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Case Presentation: 74-year-old man with CLL (trisomy 12, IGHV unmutated) has a history of CHF (EF 20%-25%) resulting in multiple admissions

Dr Laurie Matt-Amaral (Akron, Ohio)

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STATE-OF-THE-ART REVIEW

Cardiovascular Toxicities of BTK Inhibitors in Chronic Lymphocytic Leukemia

JACC: CardioOncology State-of-the-Art Review

Cooper Quartermaine, MD,[a] Sanam M. Ghazi, MD,[a] Aneeq Yasin, MD,[a] Farrukh T. Awan, MD, MS,[b] Michael Fradley, MD,[c] Tracy Wiczer, PharmD,[d] Sujay Kalathoor, MD,[a] Mussammat Ferdousi, MD,[a] Satyam Krishan, MD,[e] Alma Habib, MD,[f] Adnan Shaaban, MD,[a] Onaopepo Kola-Kehinde, BS,[a] Adam S. Kittai, MD,[f] Kerry A. Rogers, MD,[f] Michael Grever, MD,[f] Patrick Ruz, BS,[a] Seema Bhat, MD,[f] Tyler Dickerson, PharmD,[d] John C. Byrd, MD,[g] Jennifer Woyach, MD,[f] Daniel Addison, MD[a,h]

JACC Cardio Oncol 2023 October 17;5(5):570-90.

Cardiovascular Toxicities Associated with BTK Inhibitors and Other Therapies for Patients with CLL

Drug	Atrial Fibrillation	Ventricular Arrhythmias	Hypertension	Heart Failure	Bleeding	Stroke
FDA-approved drugs						
Ibrutinib	+++	++	+++	+	+++	+
Acalabrutinib	++	++	++	?	++	–
Zanubrutinib	++	?	++	?	++	–
Pirtobrutinib	+	?	?	?	++	–
Other BTK inhibitors in early phase testing						
Other (reversible) BTK inhibitors	+	?	?	?	++	?
Other drug therapies[a]						
Venetoclax	–	–	–	–	+	–
Idelalisib	+	–	++	+	–	–
Rituximab	–	–	–	–	–	–

? indicates areas where systematic cardiac data are not widely available. *More emphasis placed on comprehensive cardiovascular studies where adjudication methodology is well known. [a] More common drug therapies.

Quartermaine C et al. *JACC Cardio Oncol* 2023 Oct 17;5(5):570-90.

Atrial fibrillation burden and clinical outcomes following BTK inhibitor initiation

John Alan Gambril[1,2✉], Sanam M. Ghazi[2], Stephen Sansoterra[2], Mussammat Ferdousi[1], Onaopepo Kola-Kehinde[1], Patrick Ruz[1], Adam S. Kittai[3], Kerry Rogers[3], Michael Grever[3], Seema Bhat[3], Tracy Wiczer[4], John C. Byrd[5], Jennifer Woyach[3] and Daniel Addison[2,6✉]

Leukemia **2024 October;38(10):2141-9.**

JC JOURNAL CLUB RTP RESEARCH TO PRACTICE

LETTER TO THE EDITOR

BJHaem
BRITISH JOURNAL OF HAEMATOLOGY

Pericardial events associated with ibrutinib-based therapies for chronic lymphocytic leukaemia in two landmark trials

Fakhri B et al. *Br J Haematol* 2024 October;205(4):1645-8.

JC JOURNAL CLUB
RTP RESEARCH TO PRACTICE

Meet The Professor with Dr Woyach

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Case Presentation: 61-year-old man with CLL receives first-line obinutuzumab/venetoclax and has moderate infusion reaction to obinutuzumab

Dr Erik Rupard (St George, Utah)

RTP
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Case Presentation: 63-year-old man with CLL and well controlled autoimmune hemolytic anemia on ibrutinib is switched to zanubrutinib

Dr Zanetta Lamar (Naples, Florida)

RTP
RESEARCH
TO PRACTICE

Questions for the Faculty: CLL and COVID-19 vaccinations; role of MRD testing; anti-CD20 antibodies

Dr Warren Brenner (Boca Raton, Florida)

RTP
RESEARCH
TO PRACTICE

Efficacy of COVID Vaccinations in Patients with Chronic Lymphocytic Leukemia

Annunzio K et al.

ASCO 2023;Abstract 7532.

JC JOURNAL CLUB RTP RESEARCH TO PRACTICE

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Epcoritamab Monotherapy in Patients (Pts) with Relapsed or Refractory (R/R) Chronic Lymphocytic Leukemia (CLL): Results from CLL Expansion and Optimization Cohorts of EPCORE CLL-1

Alexey Danilov, MD, PhD,[1] Bita Fakhri, MD, MPH,[2] Farrukh Awan, MD,[3] Hans Herluf Bentzen, MD,[4] Herbert Eradat, MD,[5] Carsten Utoft Niemann, MD, PhD,[6] Fritz Offner, MD, PhD,[7] Christian Bjørn Poulsen, MD,[8] Thor Høyer, MD,[9] Mar Bellido, MD, PhD,[10] Damien Roos-Weil, MD, PhD,[11] Alessandra Ferrajoli, MD,[12] Meghan C. Thompson, MD,[13] Jacob Haaber Christensen, MD, PhD,[14] Ann Janssens, MD, PhD,[15] Tamar Tadmor, MD,[16] Mazyar Shadman, MD, MPH,[17] Pegah Jafarinasabian, MD, PhD,[18] Jimin Zhang, PhD,[19] Marcia Rios, MBA,[19] Alexandra Kuznetsova, PhD,[20] Rebecca Valentin, MD, PhD,[20] Arnon P. Kater, MD, PhD[21]

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Presented at the American Society of Hematology Annual Meeting; December 7–10, 2024; San Diego, CA

ASH 2024;Abstract 883

RTP RESEARCH TO PRACTICE

Case Presentation: 65-year-old Amish man requires treatment for CLL but is paying for treatment “out of pocket”

Dr Erik Rupard (St George, Utah)

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Case Presentation: 93-year-old man with del(13q) CLL receives acalabrutinib

Dr Tina Bhatnagar (Wheeling, West Virginia)

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TO PRACTICE

Meet The Professor with Dr Woyach

Module 1: AMPLIFY — First-Line Trials of BTKi/Venetoclax

Module 2: Pirtobrutinib

Module 3: Choice of First-Line BTKi

Module 4: Cardiotoxicity of BTKi

Module 5: CLL and COVID-19 Vaccinations; Role of MRD Testing; Anti-CD20 Antibodies

Module 6: Transformed CLL

RTP RESEARCH TO PRACTICE

Questions for the Faculty: Care of patients with Richter's transformation

Dr Erik Rupard
(St George, Utah)

Dr Tina Bhatnagar
(Wheeling, West Virginia)

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Regulatory and reimbursement issues aside, what treatment would you recommend for a 75-year-old patient with IGHV-unmutated CLL and a TP53 mutation who developed Richter's transformation?

 Dr Coombs	R-CHOP + venetoclax
 Dr Davids	R-CHOP + venetoclax
 Dr Kittai	R-CHOP + venetoclax
 Dr Lamanna	Pirtobrutinib
 Dr Ujjani	R-CHOP
 Dr Woyach	R-CHOP + venetoclax

Patient characteristics that predict Richter's transformation in patients with chronic lymphocytic leukemia treated with ibrutinib

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Am J Hematol 2023 January;98(1):56-65.

Single-Agent Epcoritamab Leads to Deep Responses in Patients With Richter's Transformation (RT): Primary Results From the EPCORE CLL-1 Trial

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Presented at the European Hematology Association Annual Congress; June 13–16, 2024; Madrid, Spain

EHA 2024;Abstract S163

EPCORE CLL-1: Best Overall Response with Epcoritamab in RT Cohort

Response, n (%)[a]	Total Efficacy Evaluable n=38[b]	1L RT n=20	2L+ RT n=18
Overall response	**20 (53)**	**12 (60)**	**8 (44)**
Complete response	16 (42)	10 (50)	6 (33)
Partial response	4 (11)	2 (10)	2 (11)
Stable disease	1 (3)	0	1 (6)
Progressive disease	14 (37)	6 (30)	8 (44)

Median follow-up: 12.9 mo (range, 0.5+ to 28.6). [a]Based on modified response-evaluable population, defined as patients with ≥1 target lesion at baseline and ≥1 postbaseline response evaluation and/or patients who died within 60 d of first dose. Response assessment according to Lugano 2014 criteria. [b]Three patients died without postbaseline assessment (2 in the 1L RT population and 1 in the 2L+ RT population).

High response rates observed, particularly in 1L RT patients

1L, previously untreated; 2L+, second line or later.

Kater AP et al. EHA 2024;Abstract S163.

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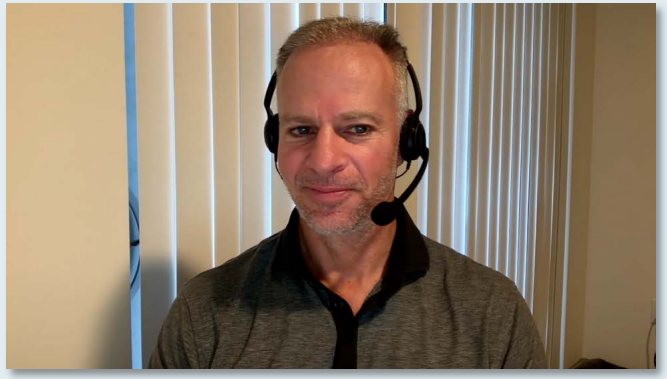

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Year in Review: Clinical Investigator Perspectives on the Most Relevant New Datasets and Advances in Oncology

EGFR-Mutant Non-Small Cell Lung Cancer

A CME/MOC-Accredited Live Webinar

Wednesday, January 15, 2025
5:00 PM – 6:00 PM ET

Faculty

Enriqueta Felip, MD, PhD
Helena Yu, MD

Moderator

Neil Love, MD

RTP Year in Review 2025

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