Year in Review:
Management of Chronic Lymphocytic Leukemia

A CME/MOC-Accredited Live Webinar

Tuesday, March 25, 2025
5:00 PM – 6:00 PM ET

Faculty

Jennifer R Brown, MD, PhD
Paolo Ghia, MD, PhD

Moderator

Neil Love, MD

RTP Year in Review 2025

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Jennifer R Brown, MD, PhD
Director, CLL Center and Institute Physician
Dana-Farber Cancer Institute
Worthington and Margaret Collette Professor of Medicine
in the Field of Hematologic Oncology
Harvard Medical School
Boston, Massachusetts

MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

Paolo Ghia, MD, PhD
Professor of Medical Oncology
Università Vita-Salute San Raffaele
Director, CLL Strategic Program
IRCCS Ospedale San Raffaele
Milano, Italy

Commercial Support

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

Dr Love — Disclosures

Dr Love is president and CEO of Research To Practice. Research To Practice receives funds in the form of educational grants to develop CME activities from the following companies: AbbVie Inc, ADC Therapeutics, Alexion Pharmaceuticals, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Arvinas, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, BeiGene Ltd, Black Diamond Therapeutics Inc, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol Myers Squibb, Clovis Oncology, Coherus BioSciences, CTI BioPharma, a Sobi Company, Daiichi Sankyo Inc, Eisai Inc, Elevation Oncology Inc, Exact Sciences Corporation, Exelixis Inc, Genentech, a member of the Roche Group, Genmab US Inc, Geron Corporation, Gilead Sciences Inc, GSK, Hologic Inc, ImmunoGen Inc, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Karyopharm Therapeutics, Kite, A Gilead Company, Legend Biotech, Lilly, MEI Pharma Inc, Merck, Mersana Therapeutics Inc, Mirati Therapeutics Inc, Mural Oncology Inc, Natera Inc, Novartis, Novartis Pharmaceuticals Corporation on behalf of Advanced Accelerator Applications, Novocure Inc, Nuvalent, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Rigel Pharmaceuticals Inc, R-Pharm US, Sanofi, Seagen Inc, Servier Pharmaceuticals LLC, SpringWorks Therapeutics Inc, Stemline Therapeutics Inc, Syndax Pharmaceuticals, Taiho Oncology Inc, Takeda Pharmaceuticals USA Inc, TerSera Therapeutics LLC, and Tesaro, A GSK Company.

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Prof Ghia — Disclosures

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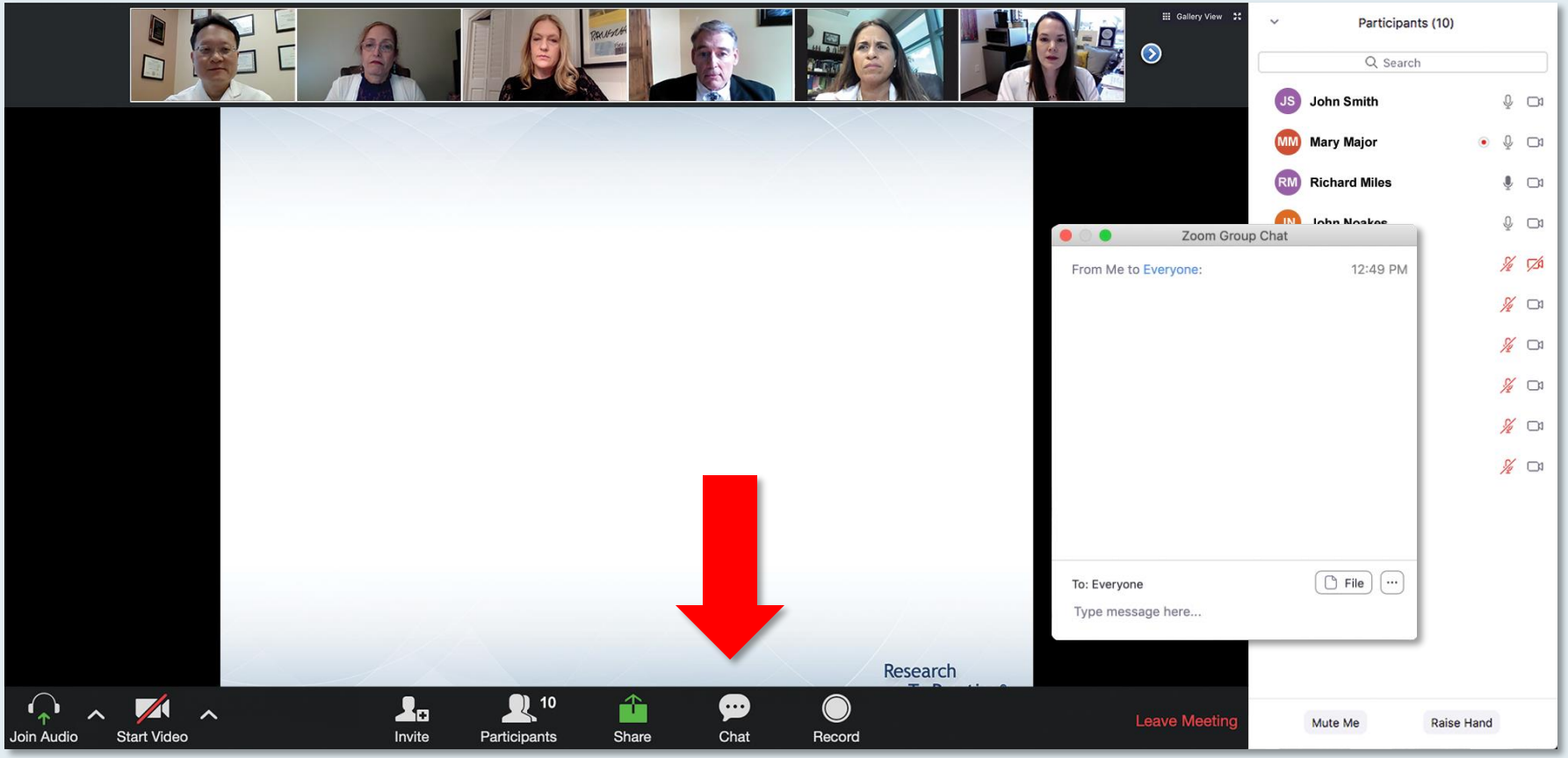
We Encourage Clinicians in Practice to Submit Questions



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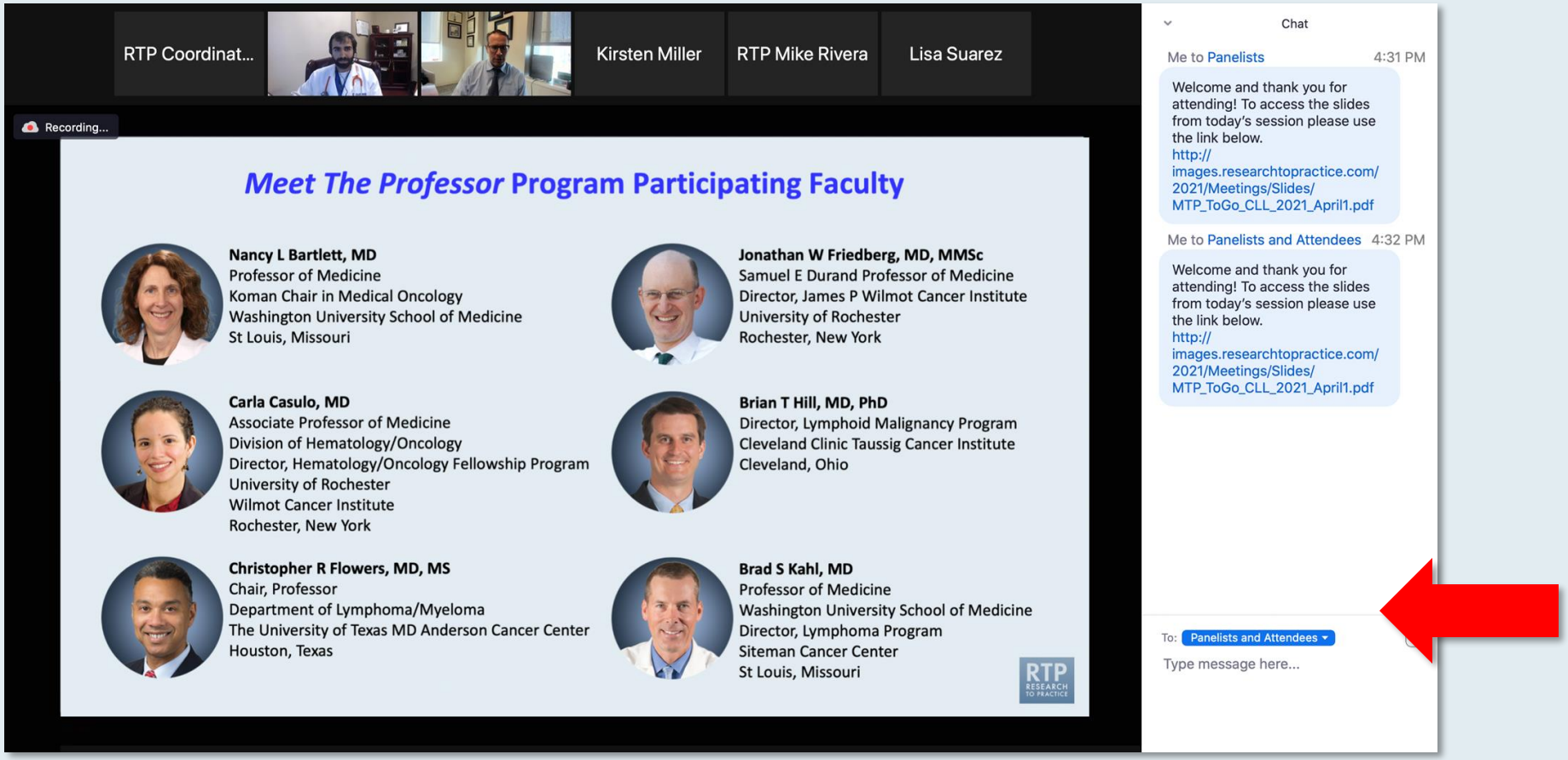

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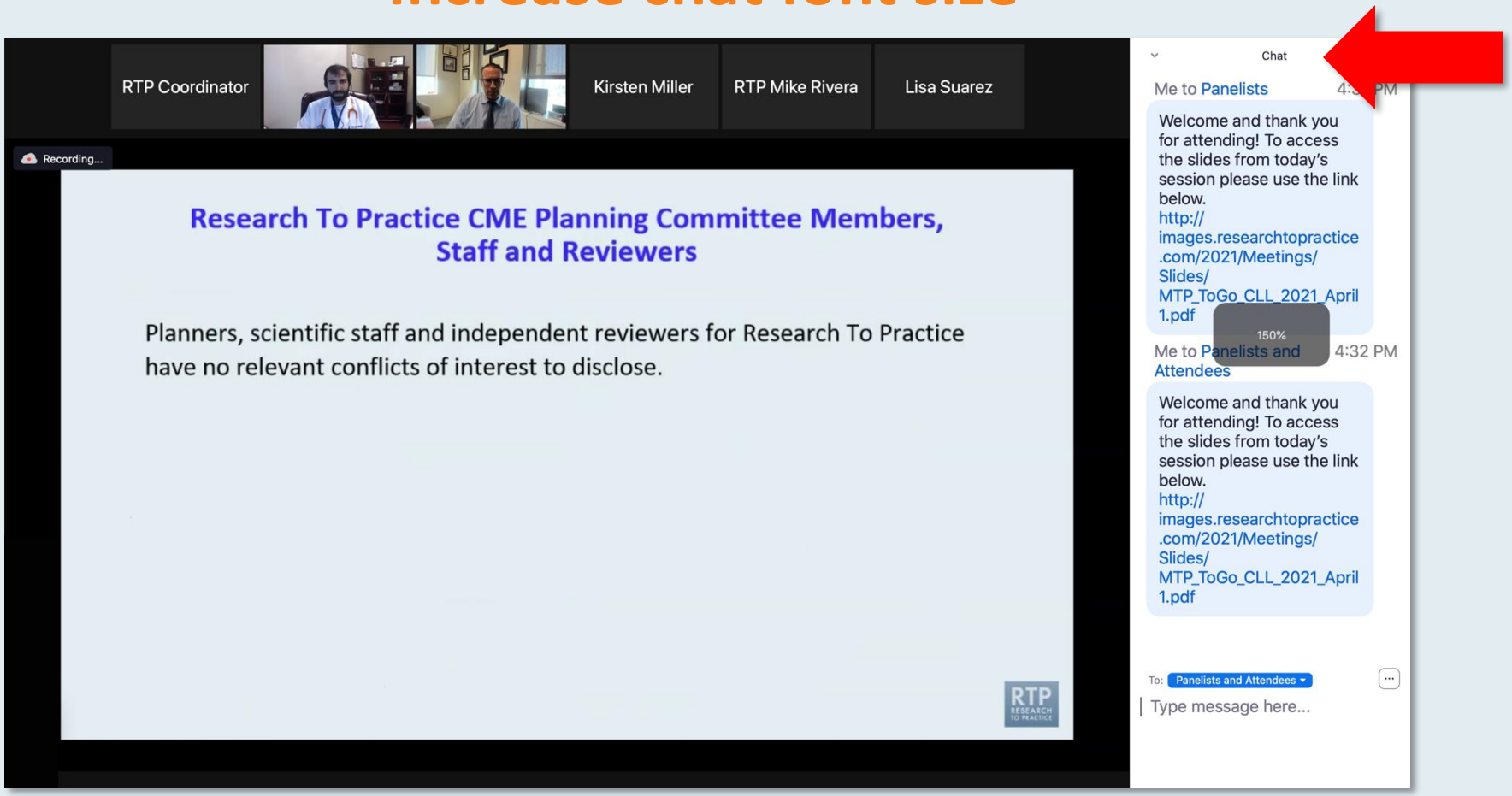

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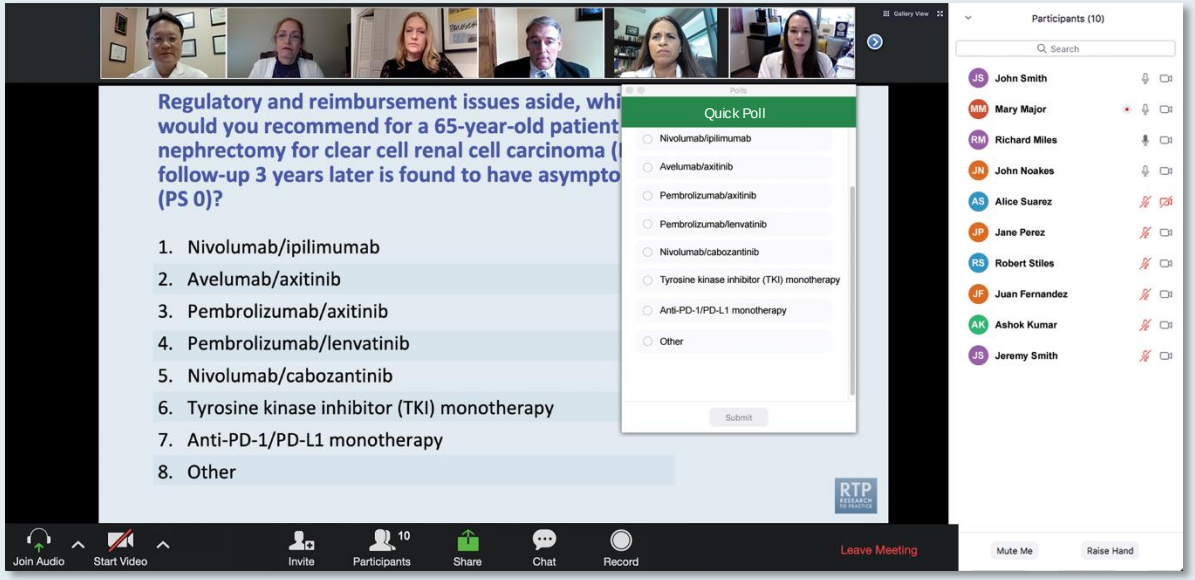

RTP RESEARCH TO PRACTICE

Data + Perspectives: Clinical Investigators Discuss the Role of CAR T-Cell Therapy for Patients with Non-Hodgkin Lymphoma and Chronic Lymphocytic Leukemia

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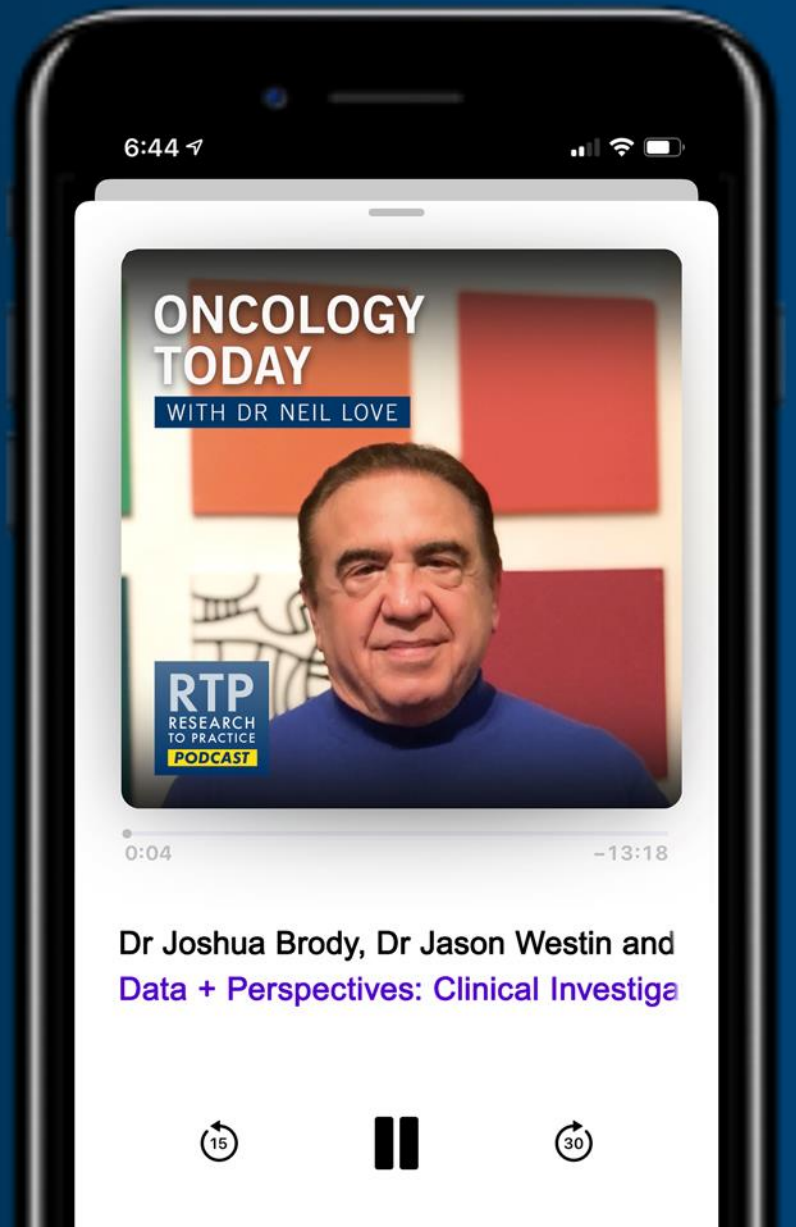

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RTP Year in Review 2025

AGENDA

Year in Review: Management of Chronic Lymphocytic Leukemia (CLL)

INTRODUCTION: The CLL Experience — 2000 to 2025

MODULE 1: Current Therapy Options with Covalent Bruton Tyrosine Kinase (BTK) Inhibitors

MODULE 2: Role of Venetoclax in the Treatment of CLL

MODULE 3: AMPLIFY Trial and Other Novel BTK Inhibitor and Bcl-2 Inhibitor Combination Strategies

MODULE 4: Noncovalent BTK Inhibitor Pirtobrutinib

MODULE 5: CAR T-Cell Therapy; Novel Agents

Thank you for joining us!

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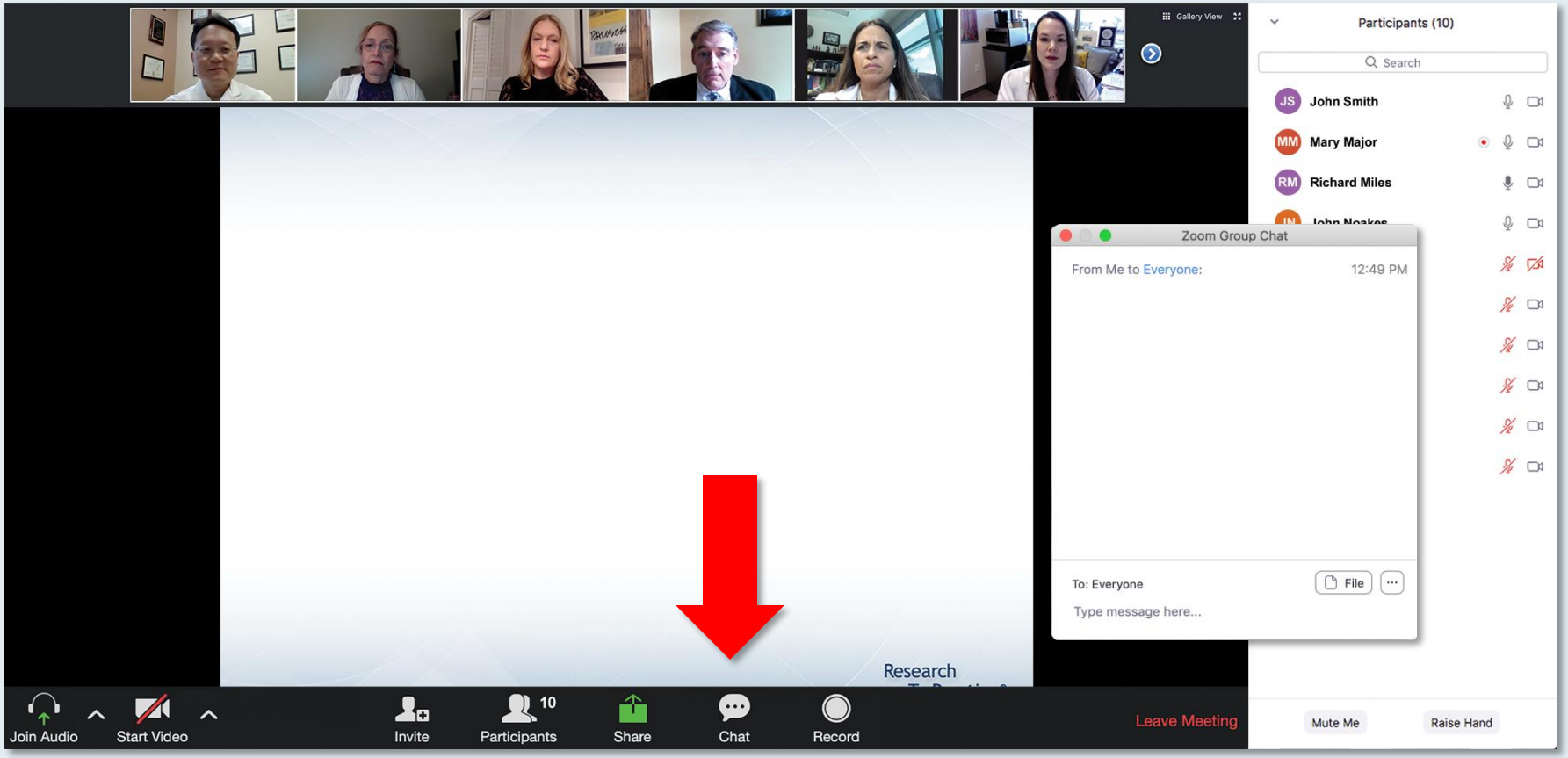

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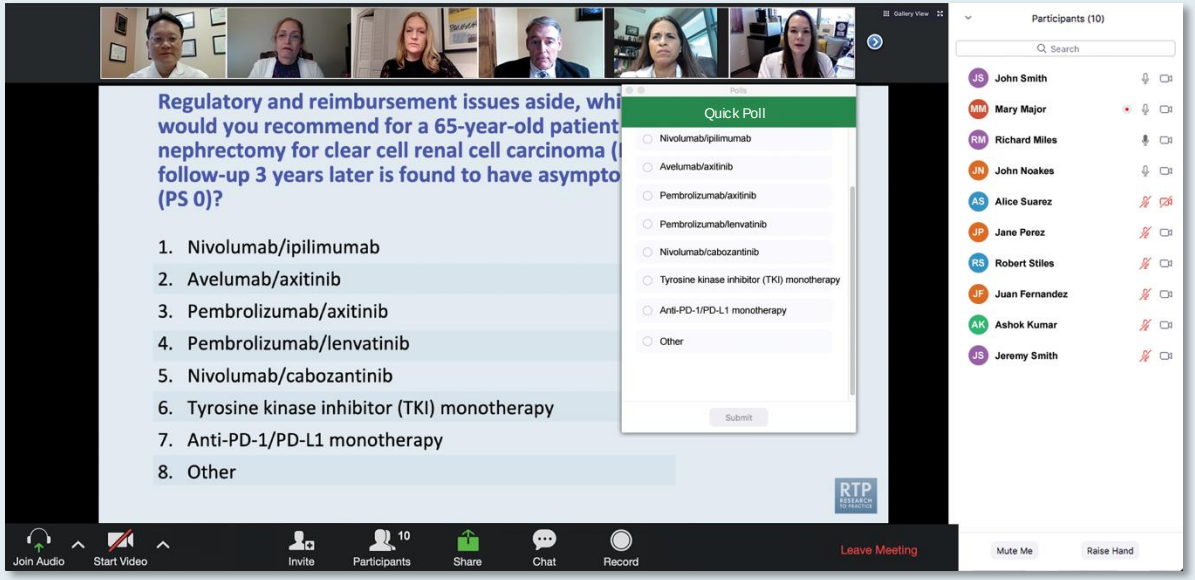

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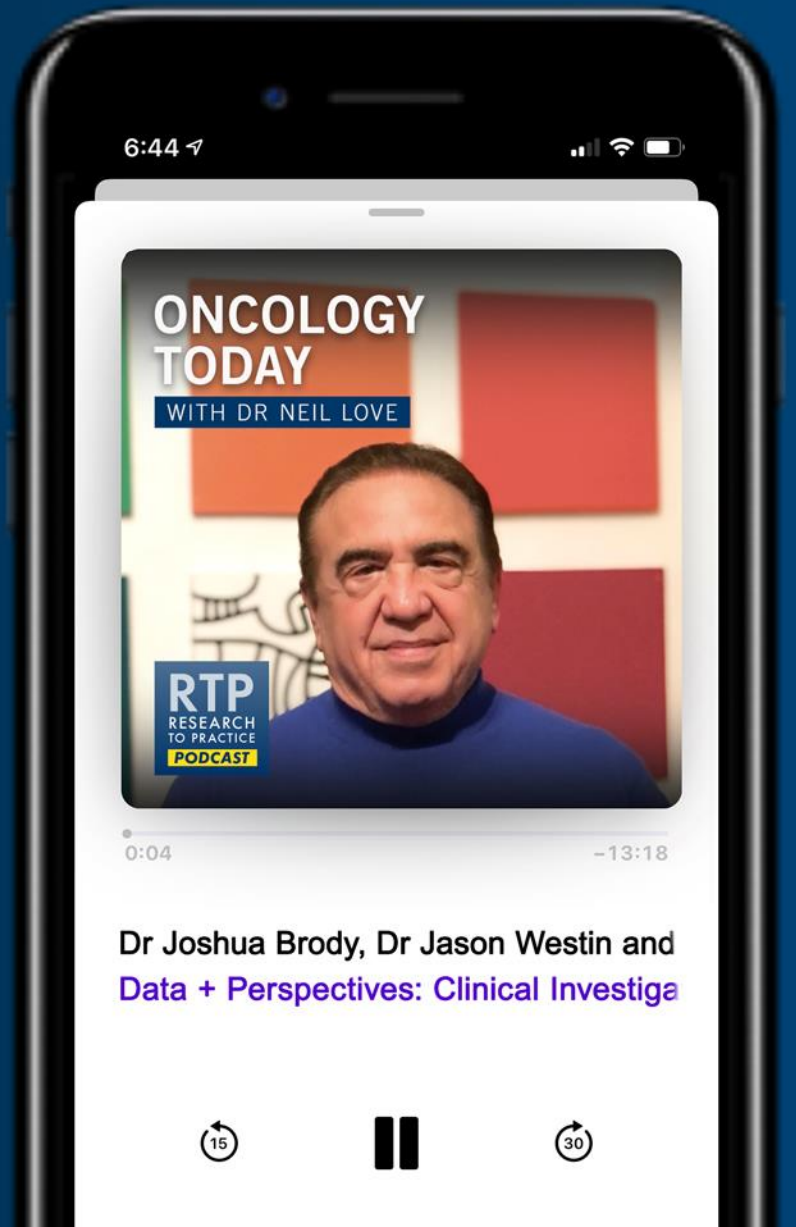

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Current Role of Covalent Bruton Tyrosine Kinase Inhibitors and Bcl-2 Inhibitors in the Treatment of Chronic Lymphocytic Leukemia

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Novel Agents and Combination Strategies

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Key Datasets

Paolo Ghia, MD, PhD

- Langerbeins P et al. **Ibrutinib** in early-stage chronic lymphocytic leukemia: The randomized, placebo-controlled, double-blind, **phase III CLL12 trial**. *J Clin Oncol* 2025 February;43(4):392-402.
- Davids MS et al. **Acalabrutinib-based regimens** in frontline or relapsed/refractory **higher-risk CLL**: **pooled analysis of 5 clinical trials**. *Blood Adv* 2024 July 9;8(13):3345-59.
- Ghia P et al. Impact of **acalabrutinib treatment by line of therapy** in patients with chronic lymphocytic leukemia: **Pooled analysis from ELEVATE-TN, ELEVATE-RR, and ASCEND**. EHA 2024;Abstract P703.
- Simon F et al. Efficacy and safety of **acalabrutinib** treatment in **very old (≥80y) and/or frail patients** with chronic lymphocytic leukemia (CLL) – Primary endpoint analysis of the **phase II CLL-Frail trial**. ASH 2024;Abstract 4618.
- Shadman M et al. Sustained superiority of **zanubrutinib vs bendamustine + rituximab** in **treatment-naive** chronic lymphocytic leukemia/small lymphocytic lymphoma (TN CLL): **5-year follow-up of cohort 1 from the SEQUOIA study**. ASH 2024;Abstract 3249.
- Brown JR et al. Sustained benefit of **zanubrutinib vs ibrutinib** in patients with **R/R CLL/SLL: Final comparative analysis of ALPINE**. *Blood* 2024 December 26;144(26):2706-17.

Key Datasets

Paolo Ghia, MD, PhD (continued)

- Kozarac S et al. **BTKi-induced cardiovascular toxicity** in CLL: **Risk mitigation and management** strategies. *Blood Rev* 2025 March;70:101268.
- Al-Sawaf O et al. **Venetoclax-obinutuzumab** for **previously untreated chronic lymphocytic leukemia**: **6-year results** of the randomized phase 3 CLL14 study. *Blood* 2024 October 31;144(18):1924-35.
- Fürstenau M et al. **First-line venetoclax combinations versus chemoimmunotherapy** in fit patients with chronic lymphocytic leukaemia **(GAIA/CLL13): 4-year follow-up** from a multicentre, open-label, randomised, phase 3 trial. *Lancet Oncol* 2024 June;25(6):744-59.
- Roeker L et al. **Minimal residual disease (MRD)-adapted duration of front-line venetoclax and obinutuzumab** treatment for fit patients with chronic lymphocytic leukemia (CLL). ASH 2024;Abstract 1010.
- Sharman JP et al. **CRISTALLO:** Results from a Phase III trial of **venetoclax-obinutuzumab versus fludarabine, cyclophosphamide and rituximab or bendamustine-rituximab** in patients with **untreated chronic lymphocytic leukemia without del(17p) or *TP53* mutations**. ASH 2024;Abstract 3237.
- Kater AP et al. Activity of **venetoclax in patients with relapsed or refractory chronic lymphocytic leukaemia**: Analysis of the **VENICE-1** multicentre, open-label, single-arm, phase 3b trial. *Lancet Oncol* 2024 April;25(4):463-73.

Key Datasets

Jennifer R Brown, MD, PhD

- Brown JR et al. **Fixed-duration acalabrutinib combinations** in **untreated chronic lymphocytic leukemia**. *N Engl J Med* 2025 February 20;392(8):748-62.
- Davids MS et al. Primary endpoint evaluation of a multicenter, phase 2 study of **acalabrutinib, venetoclax, obinutuzumab (AVO)** in a population of **previously untreated patients** with CLL enriched for high-risk disease. ASH 2024;Abstract 1865.
- Fürstenau M et al. **Acalabrutinib, venetoclax, and obinutuzumab** in **relapsed/refractory CLL**: Final efficacy and ctDNA analysis of the **CLL2-BAAG trial**. *Blood* 2024 July 18;144(3):272-82.
- Ma S et al. Combination of **zanubrutinib + venetoclax** for treatment-naïve (TN) CLL/SLL with del(17p) and/or TP53: **Preliminary results from SEQUOIA arm D**. EHA 2024;Abstract S160.
- Soumerai JD et al. **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. ASH 2024;Abstract 1012.
- Sharman JP et al. **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. ASH 2024;Abstract 886.

Key Datasets

Jennifer R Brown, MD, PhD (continued)

- Roeker LE et al. **Fixed-duration pirtobrutinib plus venetoclax with or without rituximab** in relapsed/refractory CLL: The **phase 1b BRUIN** trial. *Blood* 2024 September 26;144(13):1374-86.
- Wierda WG et al. **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. *Lancet Haematol* 2024 September;11(9):e682-92.
- Jain N et al. Combined **pirtobrutinib, venetoclax, and obinutuzumab as first-line treatment** of patients with chronic lymphocytic leukemia (CLL). ASH 2024;Abstract 1011.
- Siddiqi T et al. **Lisocabtagene maraleucel (liso-cel)** in patients (pts) with relapsed or refractory (R/R) chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL): **Updated follow-up of TRANSCEND CLL 004**. ASH 2024;Abstract 4633.
- Wierda WG et al. **Lisocabtagene maraleucel (liso-cel) combined with ibrutinib (ibr)** for patients (pts) with relapsed or refractory (R/R) chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL): **Primary results from the open-label, phase 1/2 TRANSCEND CLL 004 study**. ASH 2024;Abstract 887.
- Danilov A et al. **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**. ASH 2024;Abstract 883.

AGENDA

Year in Review: Management of Chronic Lymphocytic Leukemia (CLL)

INTRODUCTION: The CLL Experience — 2000 to 2025

MODULE 1: Current Therapy Options with Covalent Bruton Tyrosine Kinase (BTK) Inhibitors

MODULE 2: Role of Venetoclax in the Treatment of CLL

MODULE 3: AMPLIFY Trial and Other Novel BTK Inhibitor and Bcl-2 Inhibitor Combination Strategies

MODULE 4: Noncovalent BTK Inhibitor Pirtobrutinib

MODULE 5: CAR T-Cell Therapy; Novel Agents

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The CLL Experience: 2000 to 2025

- 2000-2013: Rituximab/BR/FCR
- 2013: Ibrutinib
- 2017: Acalabrutinib
- 2020: COVID-19 pandemic
- 2023: Zanubrutinib, pirtobrutinib
- 2024: Lisocabtagene maraleucel, AMPLIFY

AGENDA

Year in Review: Management of Chronic Lymphocytic Leukemia (CLL)

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MODULE 5: CAR T-Cell Therapy; Novel Agents

Current Therapy Options with Covalent BTK Inhibitors

- Langerbeins P et al. **Ibrutinib** in early-stage chronic lymphocytic leukemia: The randomized, placebo-controlled, double-blind, **phase III CLL12 trial**. *J Clin Oncol* 2025 February;43(4):392-402.
- Davids MS et al. **Acalabrutinib-based regimens** in frontline or relapsed/refractory **higher-risk CLL**: **pooled analysis of 5 clinical trials**. *Blood Adv* 2024 July 9;8(13):3345-59.
- Ghia P et al. Impact of **acalabrutinib treatment by line of therapy** in patients with chronic lymphocytic leukemia: **Pooled analysis from ELEVATE-TN, ELEVATE-RR, and ASCEND**. EHA 2024;Abstract P703.
- Simon F et al. Efficacy and safety of **acalabrutinib** treatment in **very old (≥80y) and/or frail patients** with chronic lymphocytic leukemia (CLL) – Primary endpoint analysis of the **phase II CLL-Frail trial**. ASH 2024;Abstract 4618.
- Shadman M et al. Sustained superiority of **zanubrutinib vs bendamustine + rituximab** in **treatment-naive** chronic lymphocytic leukemia/small lymphocytic lymphoma (TN CLL): **5-year follow-up of cohort 1 from the SEQUOIA study**. ASH 2024;Abstract 3249.
- Brown JR et al. Sustained benefit of **zanubrutinib vs ibrutinib** in patients with **R/R CLL/SLL: Final comparative analysis of ALPINE**. *Blood* 2024 December 26;144(26):2706-17.
- Kozarac S et al. **BTKi-induced cardiovascular toxicity** in CLL: **Risk mitigation and management** strategies. *Blood Rev* 2025 March;70:101268.

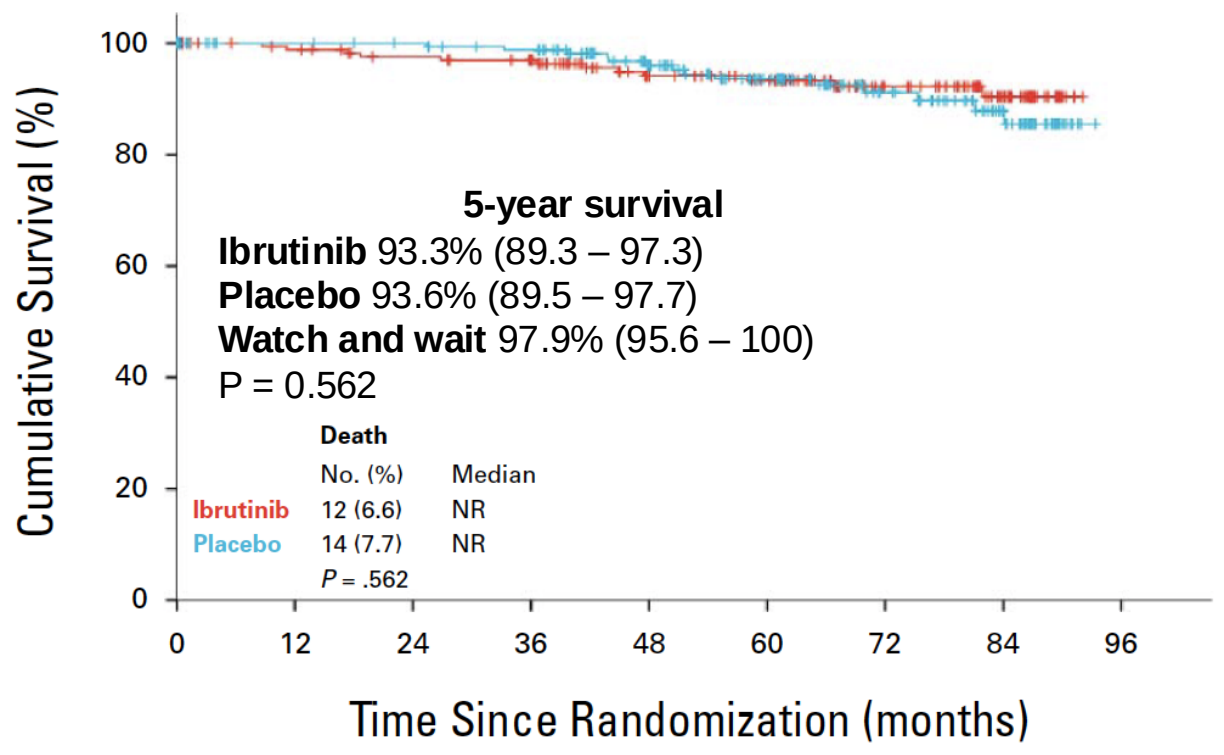
Ibrutinib in Early-Stage Chronic Lymphocytic Leukemia: The Randomized, Placebo-Controlled, Double-Blind, Phase III CLL12 Trial

Petra Langerbeins, MD[1]; Sandra Robrecht, PhD[1]; Pascal Nieper, MD[1]; Paula Cramer, MD[1]; Moritz Fürstenau, MD[1]; Othman Al-Sawaf, MD[1]; Florian Simon, MD[1]; Anna-Maria Fink, MD[1]; Karl-Anton Kreuzer, MD[1]; Ursula Vehling-Kaiser, MD[2]; Eugen Tausch, MD[3]; Christof Schneider, MD[3]; Lothar Müller, MD[4]; Michael Josef Eckart, MD[5]; Rudolf Schlag, MD[6]; Werner Freier, MD[7]; Tobias Gaska, MD[8]; Christina Balser, MD[9]; Marcel Reiser, MD[10]; Martina Stauch, MD[11]; Mark-Oliver Zahn, MD[12]; Steffen Dörfel, MD[13]; Peter Staib, MD[14]; Timo Behlendorf, MD[15]; Manfred Hensel, MD[16]; Holger Hebart, MD[17]; Holger Klaproth, MD[18]; Andreas Block, MD, MBA[19]; Rüdiger Liersch, MD[20]; Ulrich Hauch, MD[21]; Bernhard Heinrich, MD[22]; Clemens-Martin Wendtner, MD[23]; Kirsten Fischer, MD[1]; Stephan Stilgenbauer, MD[3]; Barbara Eichhorst, MD[1]; and Michael Hallek, MD[1]

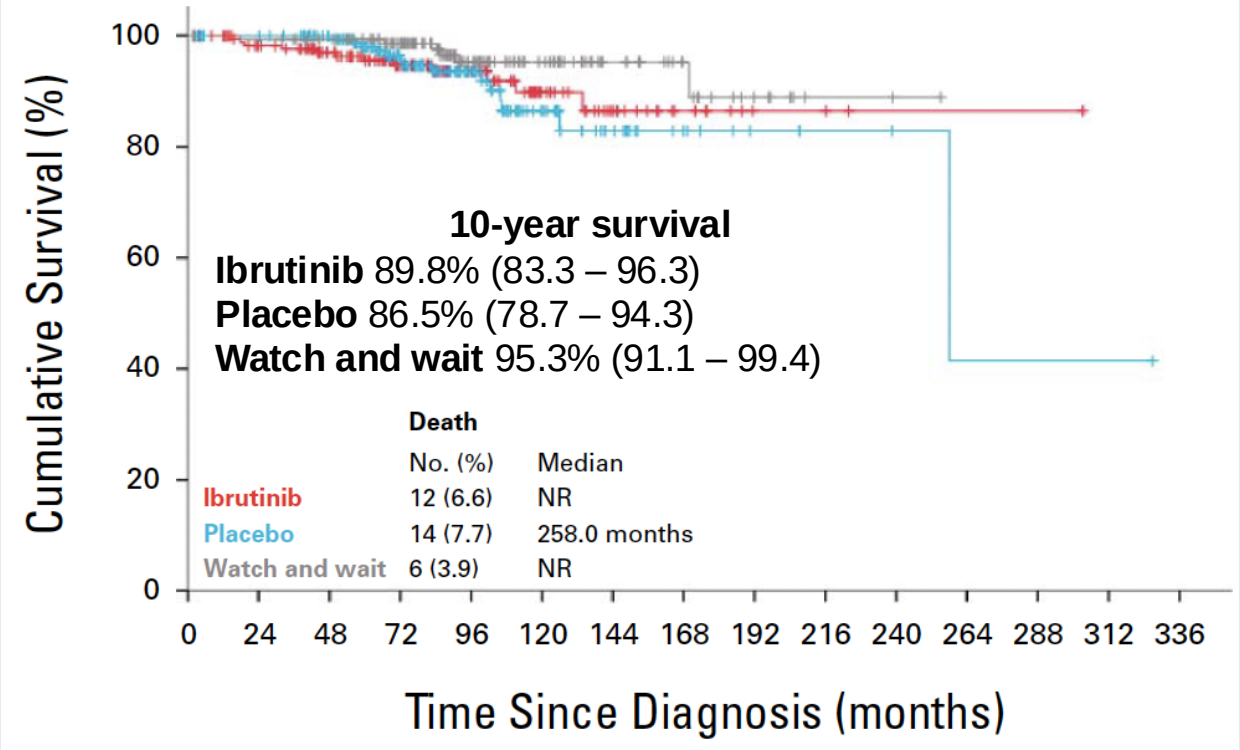
J Clin Oncol 2025 February;43(4):392-402.

Phase III CLL12 Study: Ibrutinib versus Placebo for Early-Stage Chronic Lymphocytic Leukemia (CLL)

5-year OS



10-year OS (from CLL diagnosis)



OS = overall survival

Langerbeins P et al. *J Clin Oncol* 2025 February;43(4):392-402.

RTP Year in Review 2025

Acalabrutinib-based regimens in frontline or relapsed/refractory higher-risk CLL: pooled analysis of 5 clinical trials

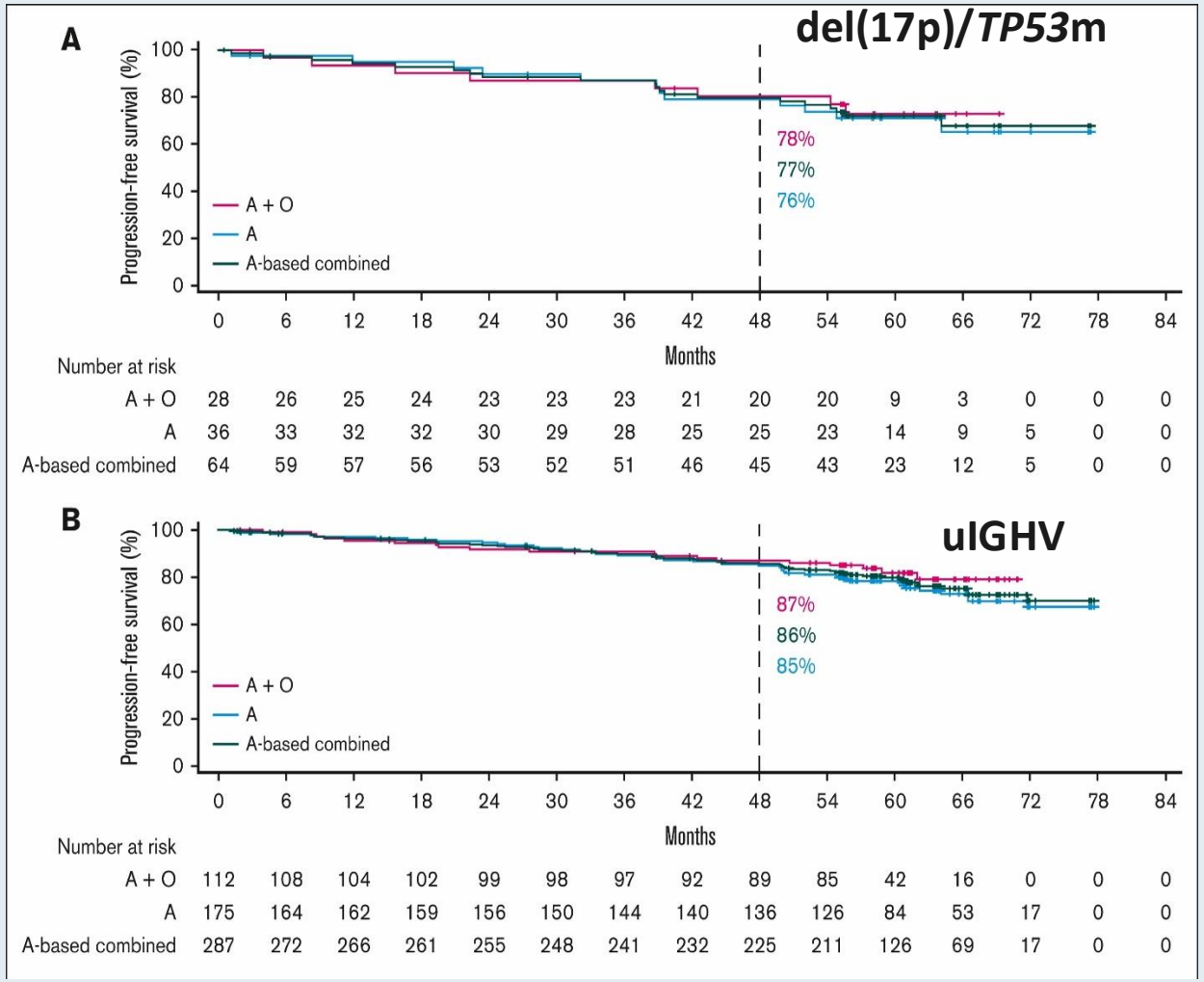
Matthew S. Davids,[1] Jeff P. Sharman,[2] Paolo Ghia,[3,4] Jennifer A. Woyach,[5] Toby A. Eyre,[6] Wojciech Jurczak,[7] Tanya Siddiqi,[8] Paulo Miranda,[9] Mina Shahkarami,[10] Anna Butturini,[10] Ugochinyere Emeribe,[9] and John C. Byrd[11]

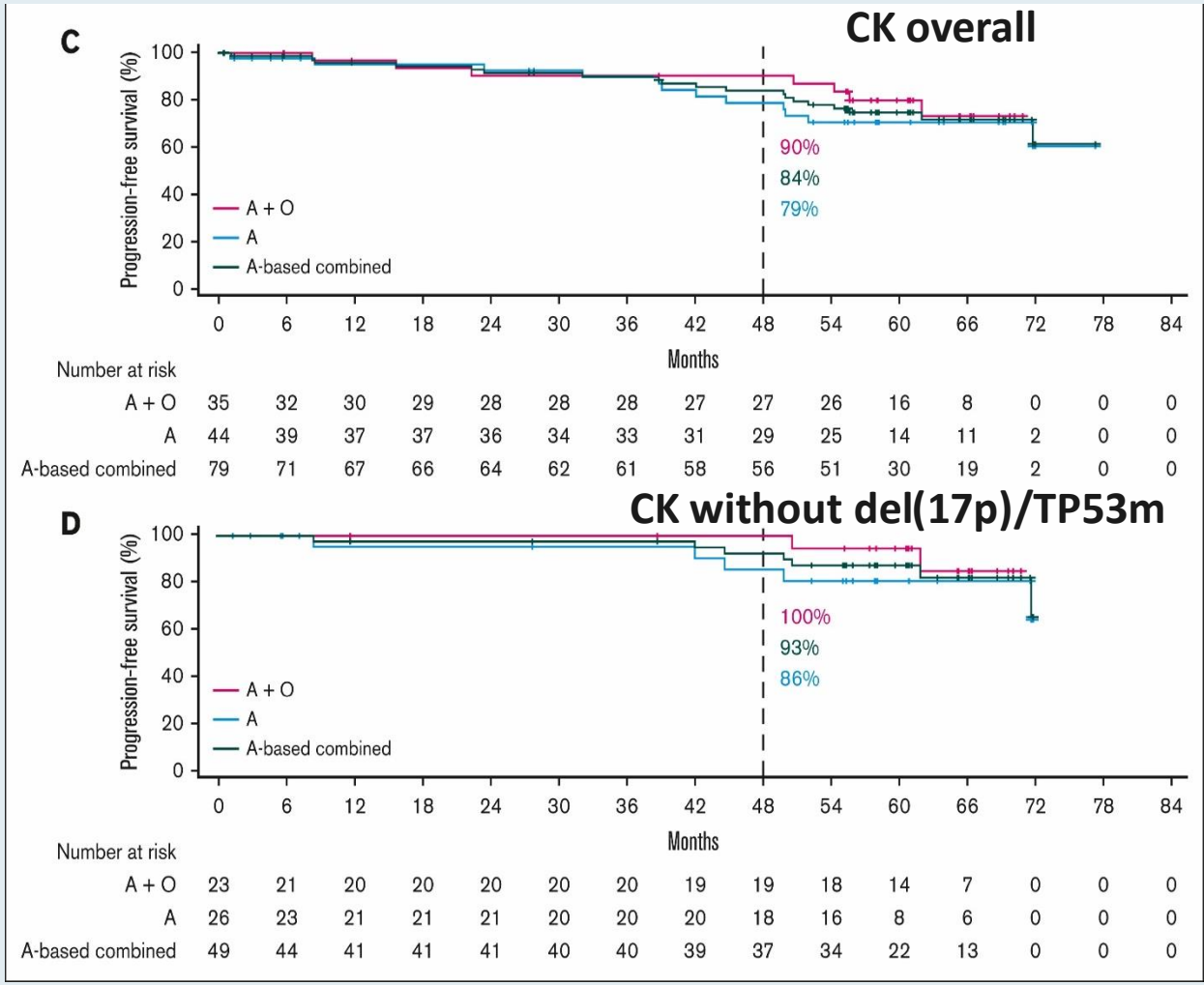
[1]Department of Medical Oncology, Dana-Farber Cancer Institute, Boston, MA; [2]Willamette Valley Cancer Institute and Research Center/US Oncology Research, Eugene, OR; [3]Division of Experimental Oncology, Università Vita-Salute San Raffaele, Milan, Italy; [4]Division of Experimental Oncology, IRCCS Ospedale San Raffaele, Milan, Italy; [5]The Ohio State University Comprehensive Cancer Center, Columbus, OH; [6]Cancer and Haematology Centre, Oxford University Hospitals NHS Foundation Trust, Oxford, United Kingdom; [7]Maria Skłodowska-Curie National Research Institute of Oncology, Krakow, Poland; [8]City of Hope Comprehensive Cancer Center, Duarte, CA; [9]AstraZeneca, Gaithersburg, MD; [10]AstraZeneca, South San Francisco, CA; and [11]Department of Internal Medicine, University of Cincinnati College of Medicine, Cincinnati, OH

***Blood Adv* 2024 July 9;8(13):3345-59.**

RTP Year in Review 2025

Pooled Analysis of 5 Clinical Trials of Acalabrutinib: Survival by Genetic Features in Patients with Treatment-Naïve Disease



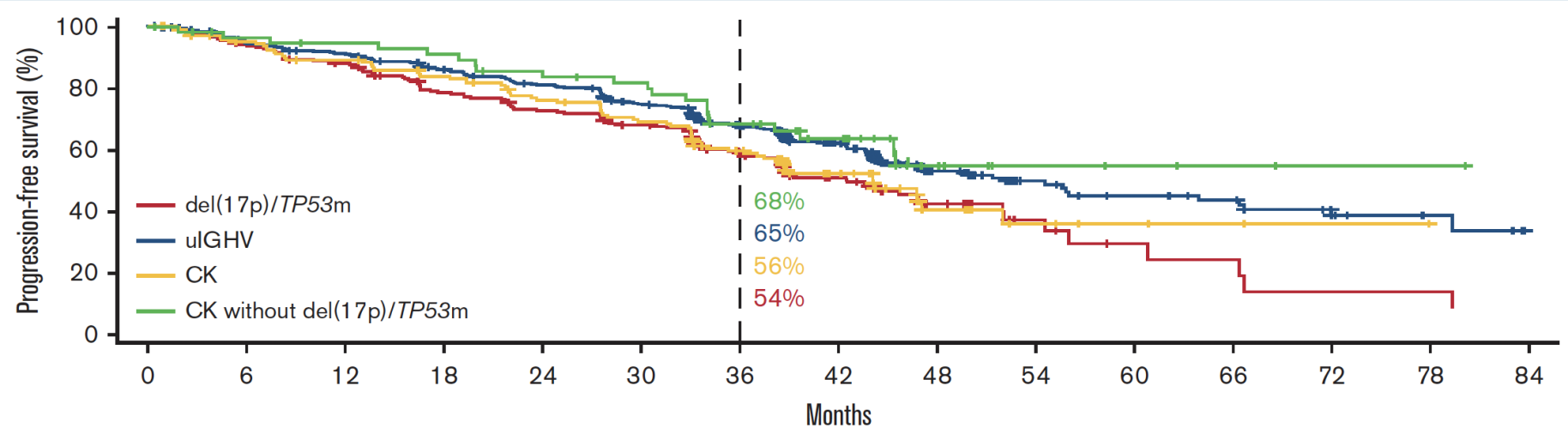


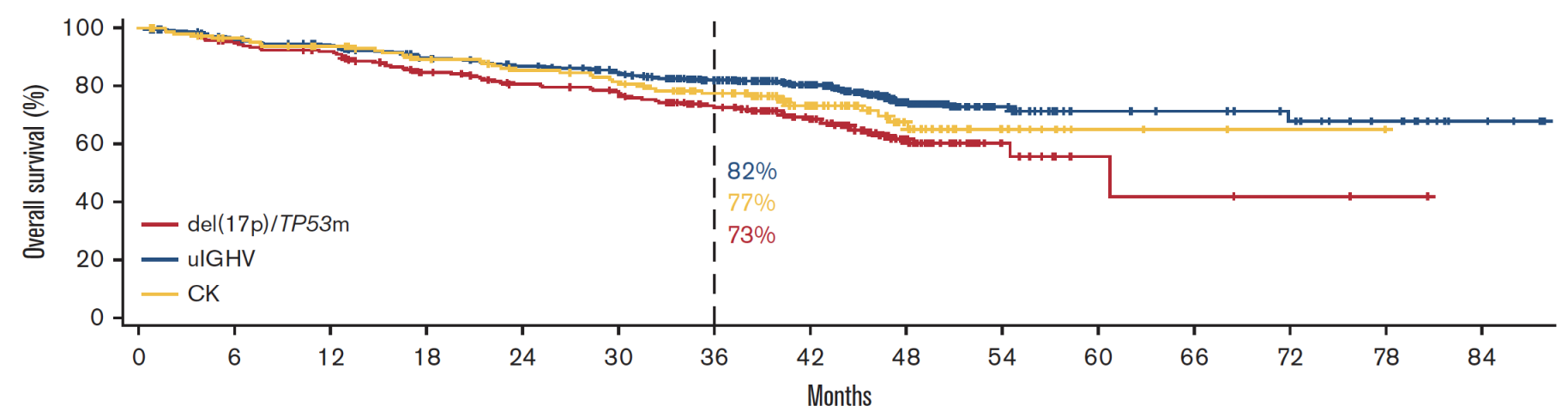
Davids MS et al. *Blood Adv* 2024 July 9;8(13):3345-59.

Courtesy of Paolo Ghia, MD, PhD

RTP Year in Review 2025

Pooled Analysis of 5 Clinical Trials of Acalabrutinib: Survival by Genetic Features in Patients with Relapsed/Refractory Disease





Davids MS et al. *Blood Adv* 2024 July 9;8(13):3345-59.

RTP Year in Review 2025

4618 Efficacy and Safety of Acalabrutinib Treatment in Very Old (≥80y) and/or Frail Patients with Chronic Lymphocytic Leukemia (CLL) – Primary Endpoint Analysis of the Phase II CLL-Frail Trial

Program: Oral and Poster Abstracts
Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Poster III
Hematology Disease Topics & Pathways:
Research, Clinical trials, Lymphoid Leukemias, CLL, Elderly, Clinical Research, Diseases, Lymphoid Malignancies, Adverse Events, Study Population, Human

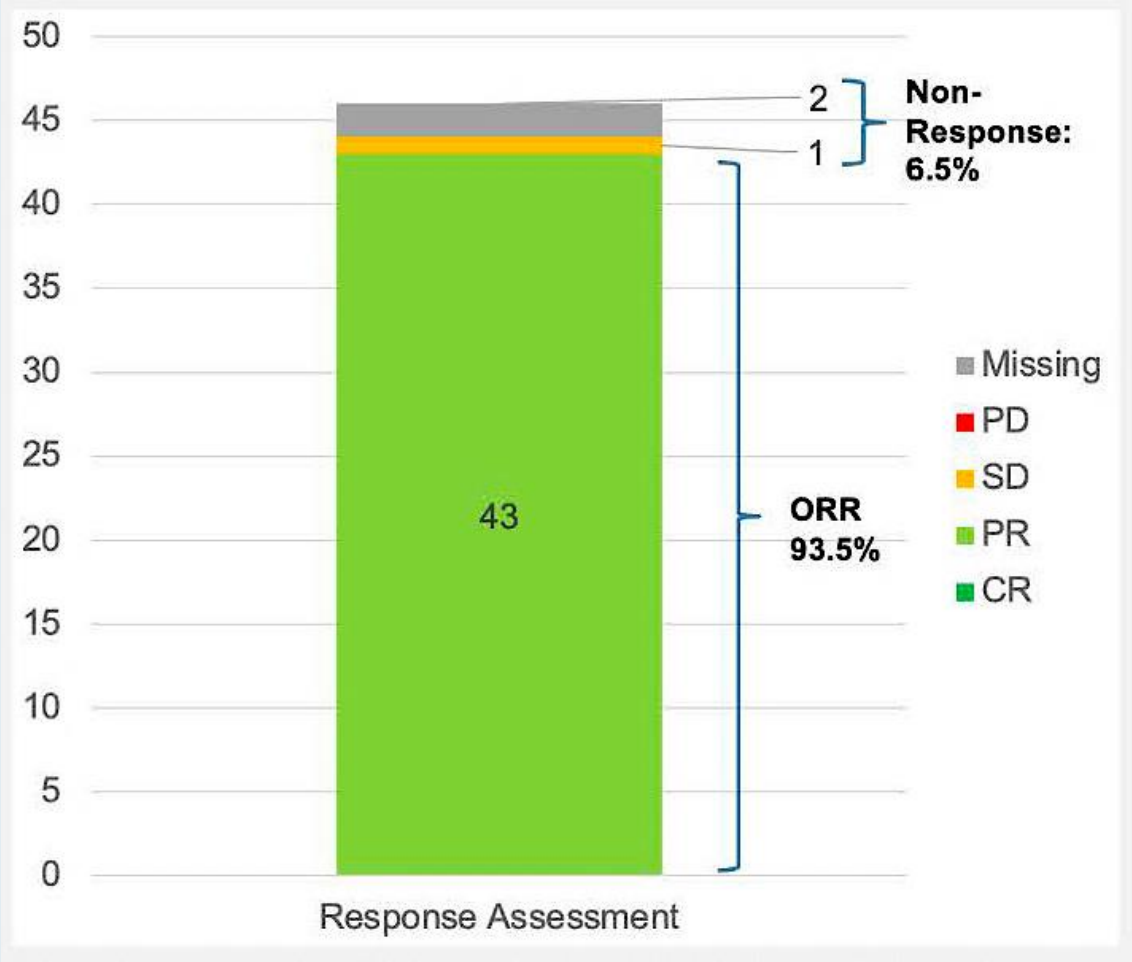
Monday, December 9, 2024, 6:00 PM-8:00 PM

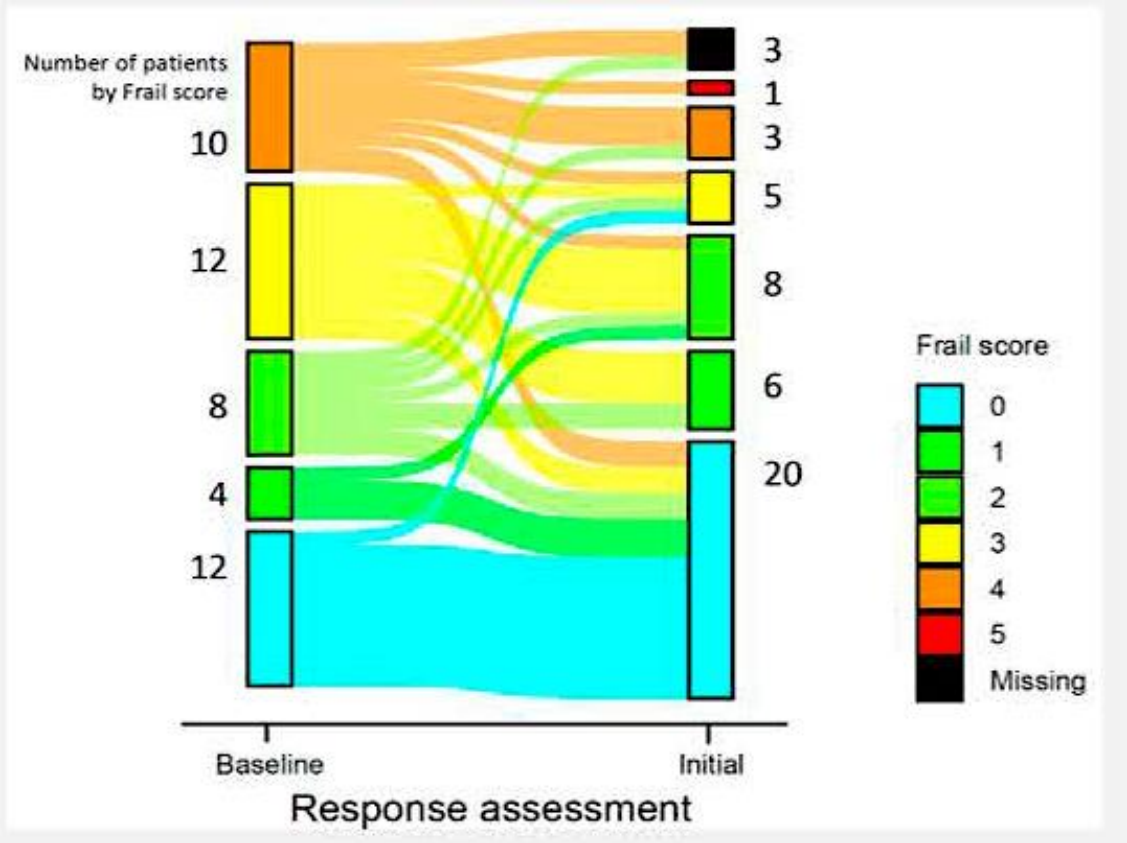
Florian Simon, MD[1*], *Rudy Ligtvoet, PhD*[1*], *Jan-Paul Bohn*[2*], *Thomas Noesslinger*[3*], *Julia Von Tresckow, MD*[4*], *Ruediger Liersch*[5*], *Tobias Gaska, MD*[6], *Kathleen Jentsch-Ullrich, MD*[7*], *Michael Gärtner, MD*[8*], *Thomas Wolff*[9*], *Ingo Schwaner*[10*], *Dominik Wolf, M.D.*[11*], *Christof Schneider, MD*[12*], *Ursula Vehling-Kaiser, MD*[13*], *Matthias Ritgen*[14*], *Christian Spoer*[15*], *Michael J. Eckart, MD*[16*], *Thomas Decker*[17*], *Geothy Chakupurakal, MBBS*[18], *Björn Schöttker*[19*], *Jens Kisro, MD, PhD*[20], *Janina Stumpf*[1*], *Eugen Tausch, MD*[12*], *Stephan Stilgenbauer, MD*[12], *Karl-Anton Kreuzer*[21*], *Sandra Robrecht, PhD*[22,23*], *Anna Maria Fink, MD*[22*], *Moritz Fürstenau, MD*[24*], *Kirsten Fischer, MD*[22*], *Valentin Goede, MD*[25*], *Michael Hallek, MD*[26*] *and Barbara F. Eichhorst, MD*[27]

ASH 2024

RTP Year in Review 2025

Phase II CLL-Frail Study of Acalabrutinib for Very Old (≥80 Years) and/or Frail Patients: ORR and Frailty Assessment





Simon F et al. ASH 2024;Abstract 4618.

RTP Year in Review 2025

Review

BTKi-induced cardiovascular toxicity in CLL: Risk mitigation and management strategies

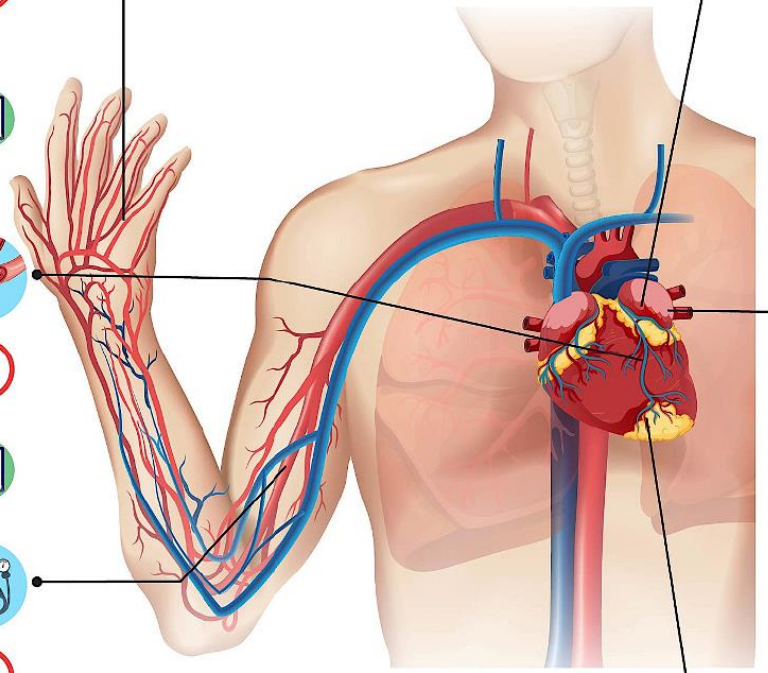
Sofija Kozarac [a,1], Vojin Vukovic [a,b,1], Michael Fradley [c], Darko Antic [a,b,*]

[a] *Clinic of Hematology, University Clinical Centre of Serbia, Serbia*
[b] *Faculty of Medicine, University of Belgrade, Serbia*
[c] *Thalheimer Center for Cardio-Oncology, Division of Cardiology, Hospital of the University of Pennsylvania*

***Blood Rev* 2025 March;70:101268.**

RTP Year in Review 2025

Cardiovascular Adverse Events Associated with BTK Inhibitors for CLL



Bleeding

Problem: Minor or major bleeding complications associated with Bruton tyrosine kinase inhibitor (BTKi) use

Solution:
1. For minor bleeding, monitor and adjust medication. For major bleeding, consider tranexamic acid or platelet transfusions and evaluate anticoagulation necessity
2. Prevention of periprocedural bleeding

Ischemic complications

Problem: Blockages in coronary arteries leading to conditions like stroke and myocardial infarction (MI)

Solution: Implement stroke and MI prevention strategies in BTKi patients, focusing on antiplatelet therapy and risk factor modification

Hypertension

Problem: Elevated blood pressure, exacerbating cardiovascular risks

Solution:
1. Antihypertensive medications, including angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), thiazide or thiazide-like diuretics, and calcium channel blockers, along with lifestyle interventions
2. Temporary BTKi discontinuation for grades 3 and 4

Atrial fibrillation

Problem: Irregular heartbeat in the atria causing increased stroke risk and symptomatic burden

Solution:
1. Stroke risk assessment with anticoagulation therapy
2. Heart rate control (medications or ablation)
3. Management of cardiovascular comorbidities (e.g., hypertension, diabetes)
4. BTKi dose reduction in case of grade <4 and BTKi discontinuation in case of grade 4

Heart failure

Problem: Impaired pumping function of the heart, leading to symptoms like shortness of breath and fatigue

Solution:
1. Utilize ACE inhibitors, ARBs, beta-blockers, sodium-glucose cotransporter-2 inhibitors, mineralocorticoid receptor antagonists, and loop diuretics for symptomatic relief and progression control
2. BTKi should be discontinued in cases of grades 3 and 4

Ventricular arrhythmia

Problem: Irregular heartbeats originating in the ventricles, potentially life-threatening

Solution: Withdrawal of BTKi, implantable cardioverter-defibrillator implantation in persistent cases, and rhythm management therapies

RTP Year in Review 2025

Kozarac S et al. *Blood Rev* 2025 March;70:101268.

Evaluation of Cardiovascular Risk and Action Thresholds with BTK Inhibitors

Evaluation of cardiovascular risk in patient on BTKi and required actions in case of abnormalities.

Parameter	Measurement tool	Frequency	Action thresholds	Level of evidence
Blood pressure	Sphygmomanometer	Monthly	>130/80 mmHg: initiate/adjust antihypertensive therapy. Grade 3/4: Temporary BTKi discontinuation	IIA
ECG	ECG machine	Every 3 months or in case of symptoms	Detection of AF or other significant rhythm abnormalities: Refer to cardiologist	IA
Holter Monitoring ECG	Holter device	As required based on initial risk stratification and in case of symptoms	Significant deviations in heart rate or rhythm: Immediate cardiologist evaluation	IIA
Echocardiography (Left Ventricular Ejection Fraction)	echocardiogram	Before treatment and in case of symptoms	<50 %: Consider alternative CLL therapy or dose reduction	IA
CHA_2DS_2VASc score	Clinical evaluation	In case of AF	≥2 (men), ≥3 (women): Initiate anticoagulation	IA
HAS-BLED score	Clinical evaluation	In case of AF	High score: Intensive bleeding risk management	IA
Platelet count	Blood tests	monthly	Low platelets count or significant deviation: modify BTKi dose or schedule	IIB

ECG – electrocardiography; BTKi – Bruton tyrosine kinase inhibitor; CLL - Chronic lymphocytic leukemia; AF – atrial fibrillation; CHA_2DS_2VASc score - congestive heart failure/left ventricular dysfunction, Hypertension, Age 75 – doubled, Diabetes, stroke-doubled, vascular disease, Sex category – female;

Kozarac S et al. *Blood Rev* 2025 March;70:101268.

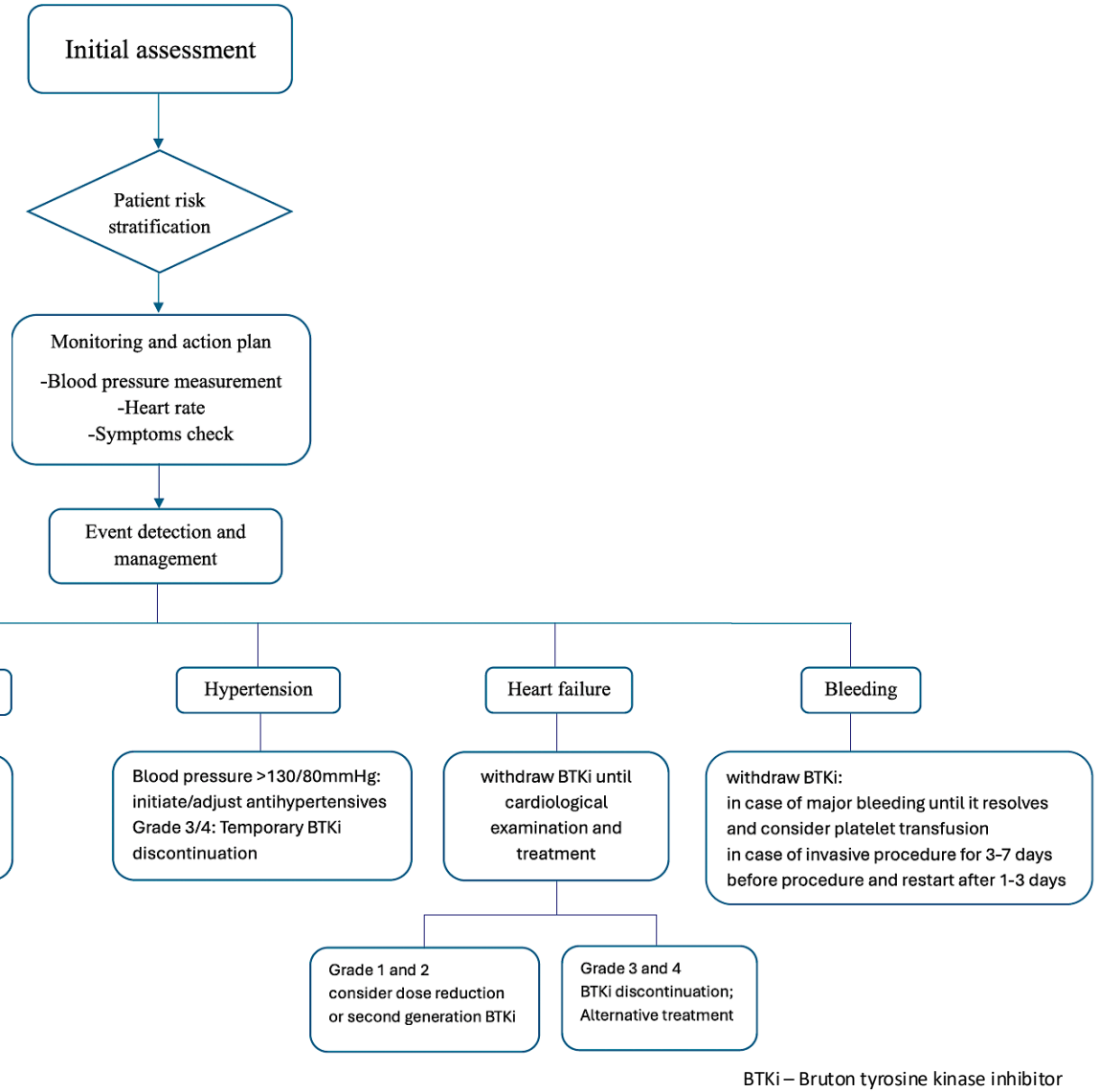
RTP Year in Review 2025

Algorithm for Managing Cardiovascular Toxicity During CLL Treatment

CLL treatment modifications in case of cardiotoxicity.

Adverse effect	Grade 1	Grade 2	Grade3	Grade 4	Level of evidence
AF	BTKi dose reduction after achieving heart rate control			Permanent BTKi discontinuation and alternative CLL treatment	
HTN	/		Temporarily BTKi discontinuation; Permanent discontinuation in case of persistent HTN or inadequate BP control		IIA
VA	Temporarily BTKi discontinuation and immediate cardiologist evaluation				
HF	Dose reduction or second generation BTKi		Permanent BTKi discontinuation and alternative treatment		
Bleeding	/		Temporarily BTKi discontinuation		

AF – atrial fibrillation; HTN – hypertension; VA – ventricular arrhythmia; HF – heart failure; BTKi - Bruton tyrosine kinase inhibitor; CLL - Chronic lymphocytic leukemia; BP – blood pressure;



BTKi – Bruton tyrosine kinase inhibitor

Kozarac S et al. *Blood Rev* 2025 March;70:101268.

RTP Year in Review 2025

AGENDA

Year in Review: Management of Chronic Lymphocytic Leukemia (CLL)

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Role of Venetoclax in the Treatment of CLL

- Al-Sawaf O et al. **Venetoclax-obinutuzumab** for **previously untreated chronic lymphocytic leukemia**: **6-year results** of the randomized phase 3 CLL14 study. *Blood* 2024 October 31;144(18):1924-35.
- Fürstenau M et al. **First-line venetoclax combinations versus chemoimmunotherapy** in fit patients with chronic lymphocytic leukaemia **(GAIA/CLL13): 4-year follow-up** from a multicentre, open-label, randomised, phase 3 trial. *Lancet Oncol* 2024 June;25(6):744-59.
- Roeker L et al. **Minimal residual disease (MRD)-adapted duration of front-line venetoclax and obinutuzumab** treatment for fit patients with chronic lymphocytic leukemia (CLL). ASH 2024;Abstract 1010.
- Sharman JP et al. **CRISTALLO:** Results from a Phase III trial of **venetoclax-obinutuzumab versus fludarabine, cyclophosphamide and rituximab or bendamustine-rituximab** in patients with **untreated chronic lymphocytic leukemia without del(17p) or TP53 mutations**. ASH 2024;Abstract 3237.
- Kater AP et al. Activity of **venetoclax in patients with relapsed or refractory chronic lymphocytic leukaemia**: Analysis of the **VENICE-1** multicentre, open-label, single-arm, phase 3b trial. *Lancet Oncol* 2024 April;25(4):463-73.

CLINICAL TRIALS AND OBSERVATIONS

Venetoclax-obinutuzumab for previously untreated chronic lymphocytic leukemia: 6-year results of the randomized phase 3 CLL14 study

Othman Al-Sawaf,[1] Sandra Robrecht,[1] Can Zhang,[1] Stefano Olivieri,[2] Yi Meng Chang,[3] Anna Maria Fink,[1] Eugen Tausch,[4] Christof Schneider,[4] Matthias Ritgen,[5] Karl-Anton Kreuzer,[1] Liliya Sivchev,[6] Carsten Utoft Niemann,[7] Anthony Schwarer,[8] Javier Loscertales,[9] Robert Weinkove,[10,11] Dirk Strumberg,[12] Allanah Kilfoyle,[13] Beenish S. Manzoor,[14] Dureshahwar Jawaid,[14] Nnadozie Emechebe,[14] Jacob Devine,[15] Michelle Boyer,[16] Eva D. Runkel,[14] Barbara Eichhorst,[1] Stephan Stilgenbauer,[4] Yanwen Jiang,[15] Michael Hallek,[1] and Kirsten Fischer[1]

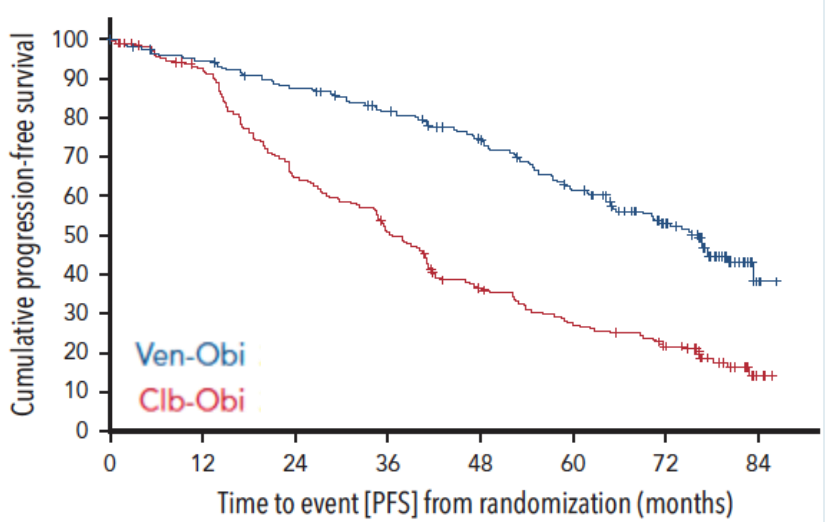
[1]Department I of Internal Medicine, Faculty of Medicine and University Hospital of Cologne, Center for Integrated Oncology Aachen Bonn Cologne Duesseldorf, German Chronic Lymphocytic Leukemia Study Group, University of Cologne, Cologne, Germany; [2]F. Hoffmann-La Roche Ltd, Basel, Switzerland; [3]F. Hoffmann-La Roche Ltd, Mississauga, ON, Canada; [4]Division of CLL, Department III of Internal Medicine, University Hospital Ulm, Ulm, Germany; [5]Universitätsklinikum Schleswig Holstein, Kiel, Germany; [6]Multiprofile Hospital for Active Treatment Pazardjik, Pazardzhik, Bulgaria; [7]Rigshospitalet, Copenhagen, Denmark; [8]Box Hill Hospital, Box Hill, VIC, Australia; [9]Hospital De La Princesa, Madrid, Spain; [10]Te Rerenga Ora Wellington Blood and Cancer Centre, Te Whatu Ora Health New Zealand Capital, Wellington, New Zealand; [11]Cancer Immunotherapy Program, Malaghan Institute of Medical Research, Wellington, New Zealand; [12]Evangelisches Krankenhaus Herne, Herne, Germany; [13]Palmerston North Hospital, Palmerston North, New Zealand; [14]AbbVie Inc, Chicago, IL; [15]Genentech Inc, South San Francisco, CA; and [16]F. Hoffmann-La Roche Ltd, Welwyn, United Kingdom

***Blood* 2024 October 31;144(18):1924-35.**

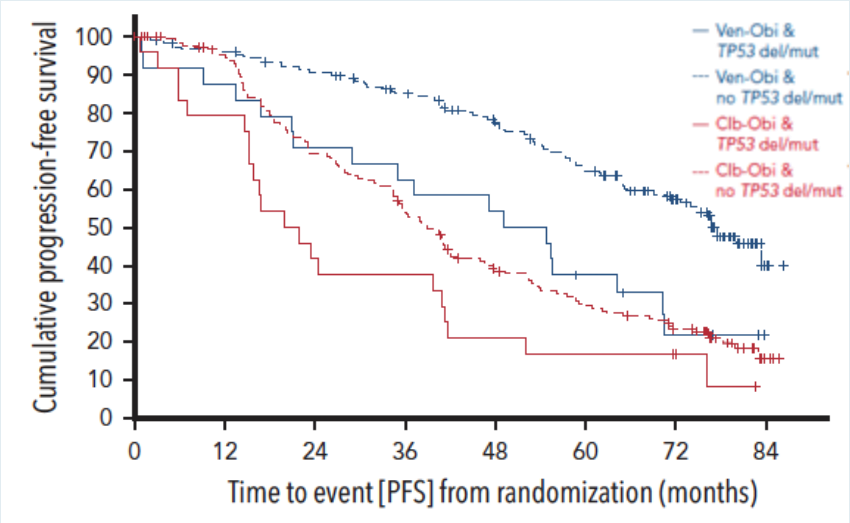
RTP Year in Review 2025

Venetoclax/Obinutuzumab for Previously Untreated CLL: 6-Year Results of the Phase III CLL14 Study – PFS

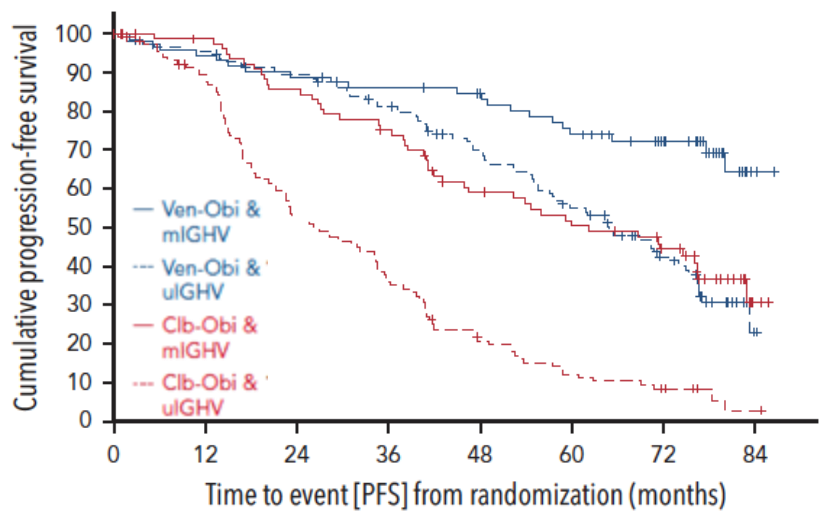
All patients



TP53 del/mut



IGHV status



	Median PFS	6-year PFS rate
Ven-Obi	76.2 months	53.1%
Clb-Obi	36.4 months	21.7%
	HR 0.40, 95% CI [0.31-0.52] P<0.0001	

mPFS, mo	Venetoclax + obinutuzumab	Chlorambucil + obinutuzumab
No *TP53* del/mut	76.6	38.9
TP53 del/mut	51.9	20.8
IGHV mutated	NR	62.2
IGHV no mutation	64.8	26.9

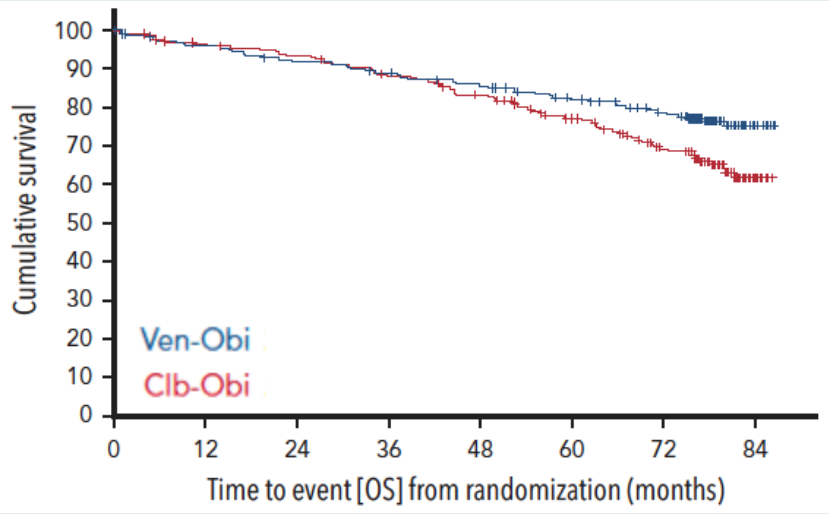
Al-Sawaf O et al. *Blood* 2024 October 31;144(18):1924-35.

Courtesy of Paolo Ghia, MD, PhD

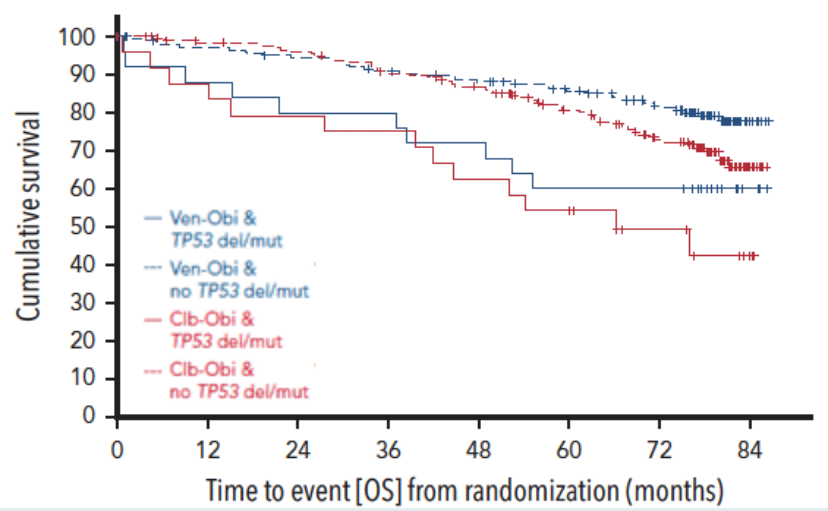
RTP Year in Review 2025

Venetoclax/Obinutuzumab for Previously Untreated CLL: 6-Year Results of the Phase III CLL14 Study – OS

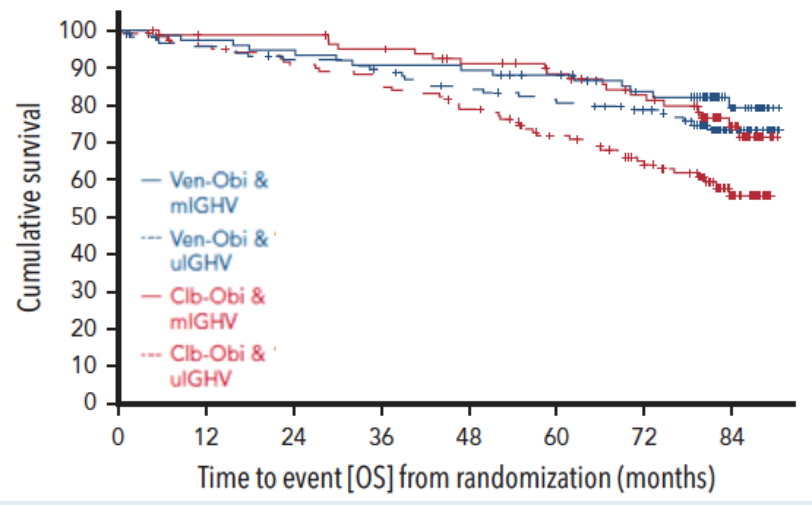
All patients



TP53 del/mut



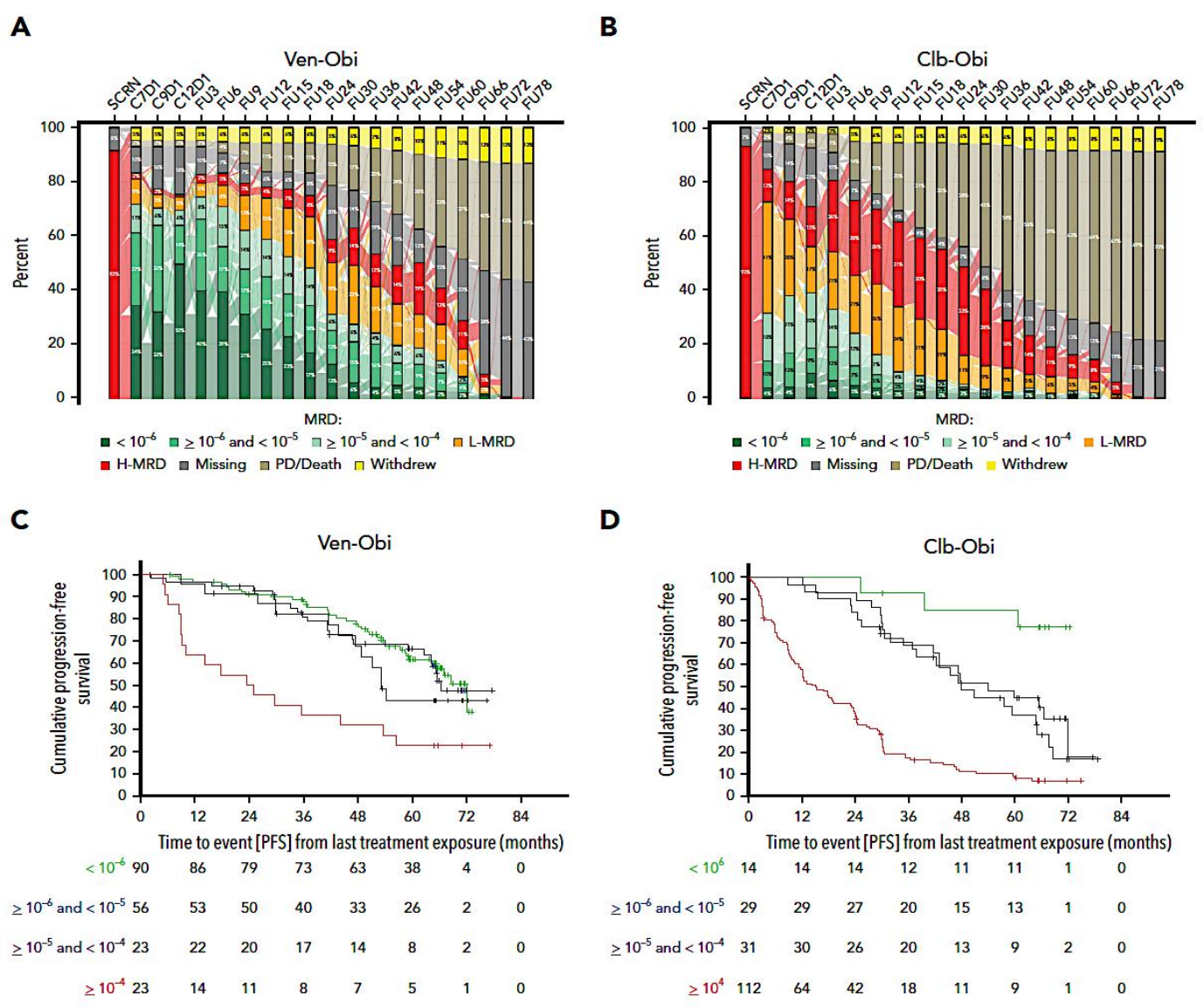
IGHV status



Al-Sawaf O et al. *Blood* 2024 October 31;144(18):1924-35.

RTP Year in Review 2025

Venetoclax/Obinutuzumab for Previously Untreated CLL: 6-Year Results of the Phase III CLL14 Study – Minimal Residual Disease (MRD)



Al-Sawaf O et al. *Blood* 2024 October 31;144(18):1924-35.

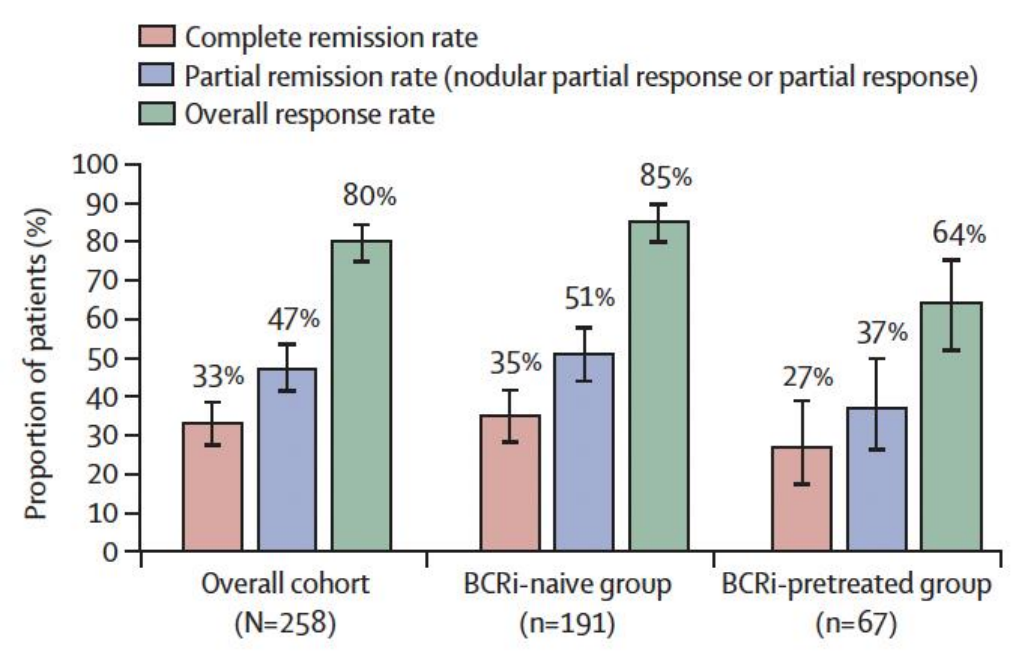
RTP Year in Review 2025

Activity of venetoclax in patients with relapsed or refractory chronic lymphocytic leukaemia: analysis of the VENICE-1 multicentre, open-label, single-arm, phase 3b trial

Arnon P Kater, Önder Arslan, Fatih Demirkan, Yair Herishanu, Burhan Ferhanoglu, Marcos Gonzalez Diaz, Brian Leber, Marco Montillo, Panayiotis Panayiotidis, Davide Rossi, Alan Skarbnik, Adrian Tempescul, Mehmet Turgut, Clemens H Mellink, Anne-Marie F van der Kevie-Kersemaekers, Stuart Lanham, Ben Sale, Luis Del Rio, Relja Popovic, Brenda J Chyla, Todd Busman, Viktor Komlosi, Xifeng Wang, Kavita Sail, German E Pena, Tamas Vizkelety, Francesco Forconi

***Lancet Oncol* 2024 April;25(4):463-73.**

Venetoclax Monotherapy for Relapsed or Refractory CLL: The Single-Arm Phase IIIb VENICE-1 Trial – Response



	All patients (N=258)	BCRi-naive group (n=191)	BCRi-pretreated group (n=67)
Best response			
Complete remission	76 (29%)	59 (31%)	17 (25%)
Complete remission with incomplete marrow recovery	8 (3%)	7 (4%)	1 (1%)
Nodular partial remission	5 (2%)	5 (3%)	0
Partial remission	117 (45%)	92 (48%)	25 (37%)
Stable disease	17 (7%)	11 (6%)	6 (9%)
Progressive disease	9 (3%)	3 (2%)	6 (9%)
No post-baseline disease assessment	26 (10%)	14 (7%)	12 (18%)
Complete remission rate (complete remission or complete remission with incomplete marrow recovery), n (%; 95% CI)	84 (33%; 26·9–38·6)	66 (35%; 27·8–41·8)	18 (27%; 16·8–39·1)
Partial remission rate (nodular partial remission or partial remission), n (%; 95% CI)	122 (47%; 41·1–53·6)	97 (51%; 43·5–58·1)	25 (37%; 25·8–50·0)
Overall response rate (complete remission or complete remission with incomplete marrow recovery, nodular partial remission, or partial remission),* n (%; 95% CI)	206 (80%; 74·4–84·6)	163 (85%; 79·5–90·0)	43 (64%; 51·5–75·5)

Data are n (%) unless otherwise stated. BCRi=B-cell receptor inhibitor. *Partial remission was confirmed later than 7 weeks or more for objective response.

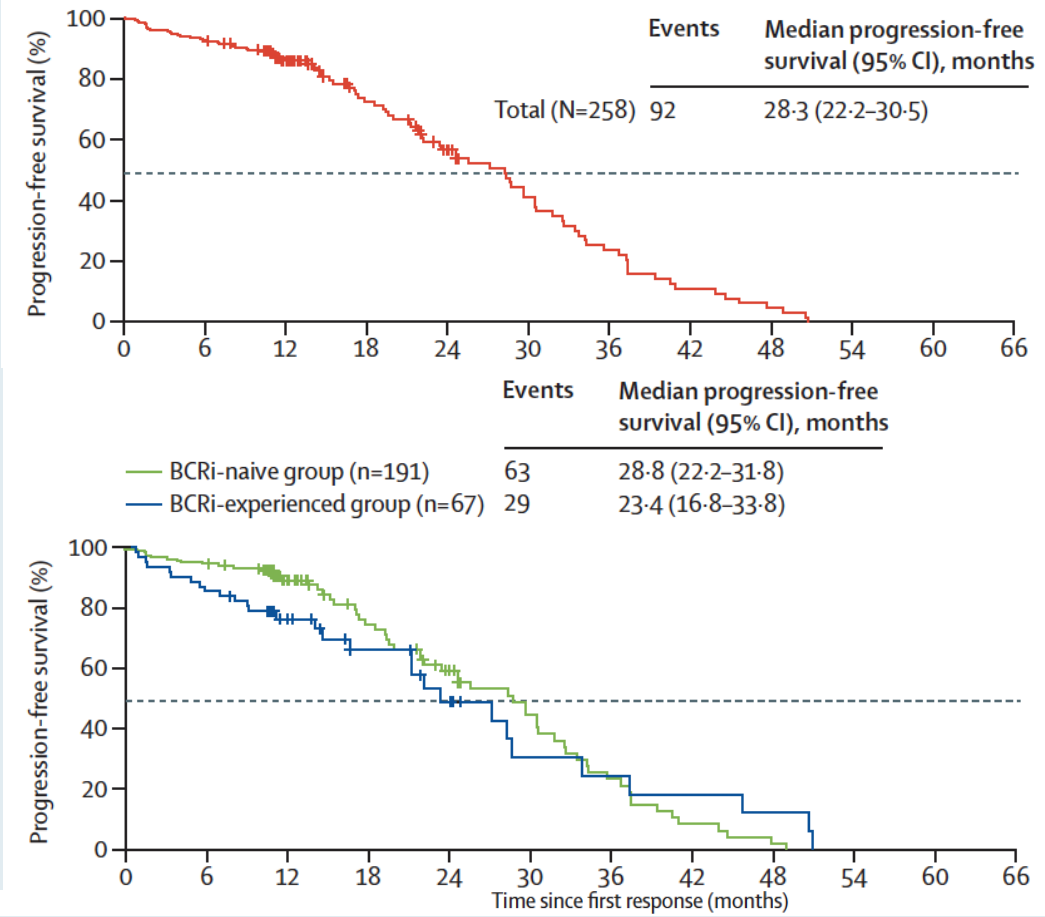
Median follow-up in the overall cohort was 49·5 months (IQR 47·2-54·1)

Kater AP et al. *Lancet Oncol* 2024 April;25(4):463-73.

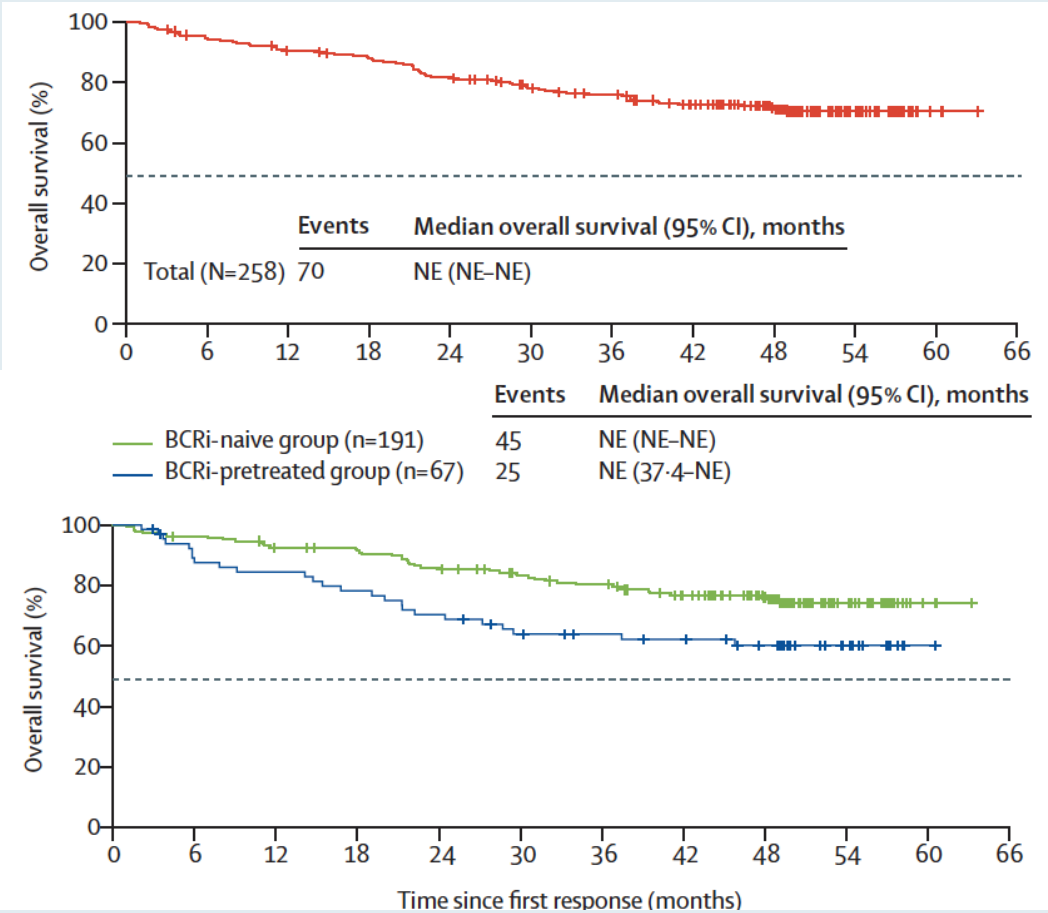
RTP Year in Review 2025

Phase IIIb VENICE-1: Survival by B-Cell Receptor-Associated Kinase Inhibitor (BCRi) Exposure

PFS



OS



Kater AP et al. *Lancet Oncol* 2024 April;25(4):463-73.

RTP Year in Review 2025

Phase IIIb VENICE-1: Summary

- Venetoclax monotherapy demonstrated deep and durable responses and prolonged overall survival, irrespective of previous BCRi treatment.
  - With dose modifications, the safety profile of venetoclax was manageable even given this extended period of follow-up, and many patients transitioned to an extension study to continue receiving venetoclax therapy.
- The safety profile reported here was consistent with previously published venetoclax data with relapsed or refractory CLL.
  - Although common, neutropenia was managed with brief interruptions or reductions in venetoclax dosing.

Kater AP et al. *Lancet Oncol* 2024 April;25(4):463-73.

RTP Year in Review 2025

AGENDA

Year in Review: Management of Chronic Lymphocytic Leukemia (CLL)

INTRODUCTION: The CLL Experience — 2000 to 2025

MODULE 1: Current Therapy Options with Covalent Bruton Tyrosine Kinase (BTK) Inhibitors

MODULE 2: Role of Venetoclax in the Treatment of CLL

MODULE 3: AMPLIFY Trial and Other Novel BTK Inhibitor and Bcl-2 Inhibitor Combination Strategies

MODULE 4: Noncovalent BTK Inhibitor Pirtobrutinib

MODULE 5: CAR T-Cell Therapy; Novel Agents

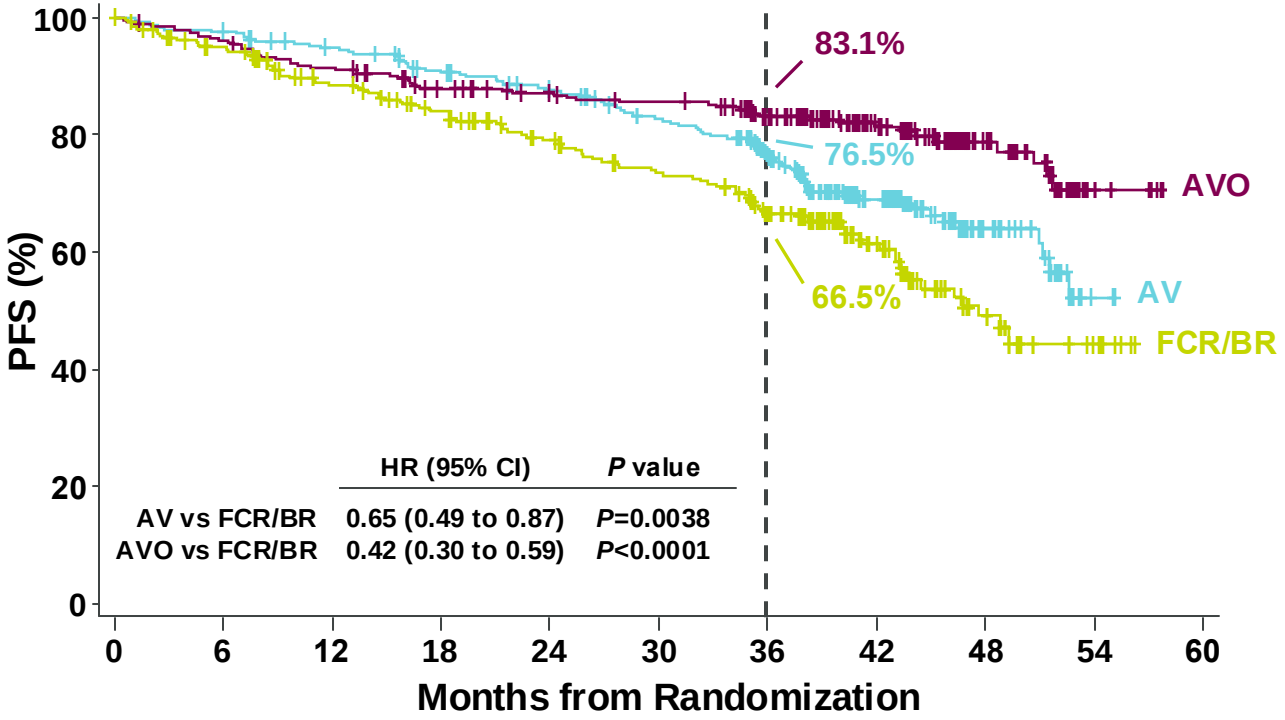
AMPLIFY and Other Novel BTK Inhibitor and Bcl-2 Inhibitor Combination Strategies

- Brown JR et al. **Fixed-duration acalabrutinib combinations** in **untreated chronic lymphocytic leukemia**. *N Engl J Med* 2025 February 20;392(8):748-62.
- Davids MS et al. Primary endpoint evaluation of a multicenter, phase 2 study of **acalabrutinib, venetoclax, obinutuzumab (AVO)** in a population of **previously untreated patients** with CLL enriched for high-risk disease. ASH 2024;Abstract 1865.
- Fürstenau M et al. **Acalabrutinib, venetoclax, and obinutuzumab** in **relapsed/refractory CLL**: Final efficacy and ctDNA analysis of the **CLL2-BAAG trial**. *Blood* 2024 July 18;144(3):272-82.
- Ma S et al. Combination of **zanubrutinib + venetoclax** for treatment-naïve (TN) CLL/SLL with del(17p) and/or TP53: **Preliminary results from SEQUOIA arm D**. EHA 2024;Abstract S160.
- Soumerai JD et al. **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. ASH 2024;Abstract 1012.

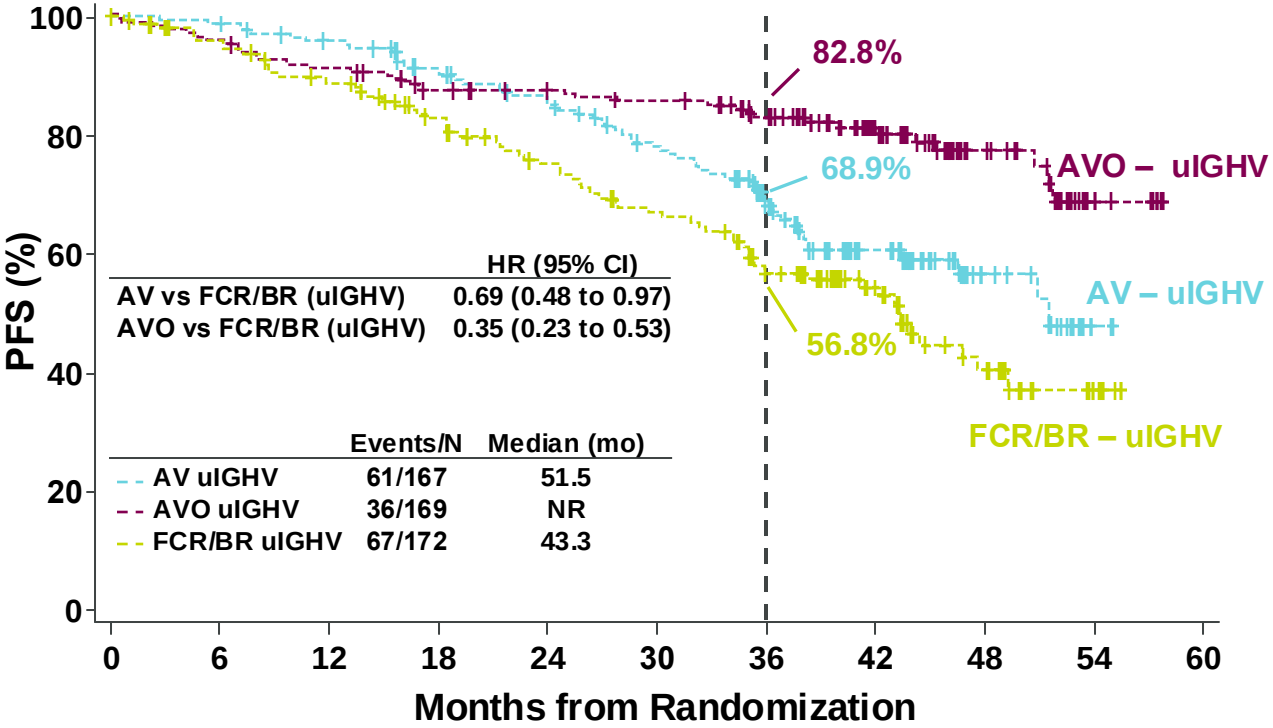
AMPLIFY: AV and AVO vs FCR/BR

Progression-Free Survival

PFS Significantly Improved With AV and AVO vs FCR/BR



PFS in the uIGHV Subgroup



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

uMRD rates ($<10^{-4}$) in peripheral blood at EOT (evaluable patients): 45.0% (AV), 95.0% (AVO), 72.9% (FCR/BR)

Courtesy of Jennifer R Brown, MD, PhD

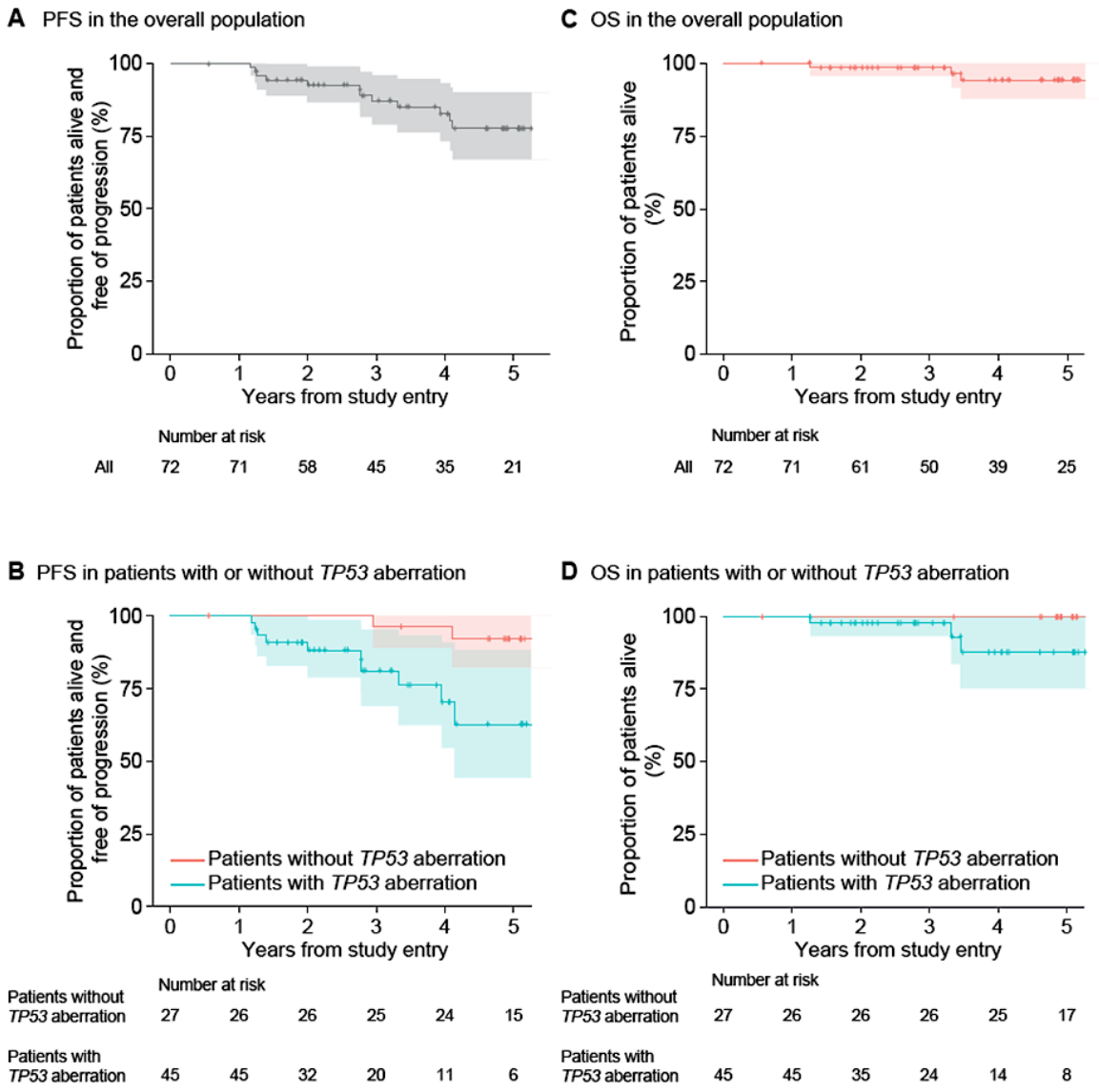
Brown JR et al. ASH 2024; Abstract 1009
Brown JR NEJM 2025

What about AMPLIFY results?

- **First potential registration trial for a BTKi-BCL2i combination**
- **AV is very safe and very easy: potentially applicable to most any CLL patient**
- **AVO is very effective, equalizing outcome in UM and M IGHV patients at 3 yrs: good for young fit higher risk patients**

Courtesy of Jennifer R Brown, MD, PhD

AVO for 16-25 Months for High Risk Del17p Disease: Survival & Recurrence



- 35 pts (51%) had MRD recurrence
  - Median time to MRD recurrence was 32.2 months
- **70% 4-year PFS in pts with *TP53* aberration; 96% in pts without *TP53* aberration**
- 88% 4-year OS in pts with *TP53* aberration; 100% in pts without *TP53* aberration
- 10 pts have had clinical progression, 4 of these 10 progressions were transformation events, including Richter's DLBCL (n=2) and Hodgkin lymphoma (n=2)
- 3 pts have died in total, one each due to gr 5 COVID-19 infection during treatment, complications from polysubstance abuse, and progression of Richter's

Courtesy of Jennifer R Brown, MD, PhD

Davids M et al. ASH 2024; Abstract 1865

AVO for 15-25 Months for High Risk Del17p Disease

- **Longer, MRD guided AVO regimen for patients with del17p disease**
- **Highly effective in inducing uMRD remission**
- **Durability is somewhat reduced compared to the 17p wild type population – but nonetheless looks better compared to ven obin**
- **Ongoing head to head trial comparing AVO to VO in high risk del17p disease (GCLLSG)**

Courtesy of Jennifer R Brown, MD, PhD

Author's slide

Acalabrutinib, Venetoclax, and Obinutuzumab in Relapsed CLL: Final Efficacy and Circulating Tumor DNA (ctDNA) Analysis of the CLL2-BAAG Trial

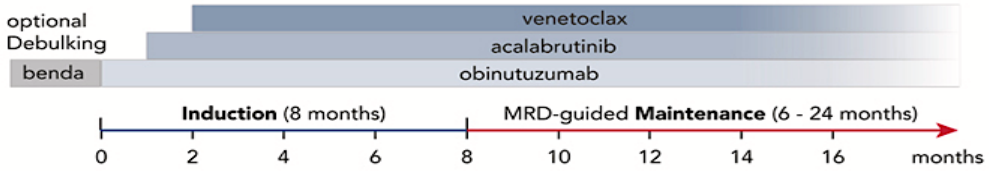
Study Design and Exposure (ClinicalTrials.gov Identifier: NCT03787264)

Phase 2 CLL2-BAAG study

46 patients with r/r CLL
- Unmutated IGHV: 75.6%
- TP53 aberration(s): 31.8%
- Prior BTKi/venetoclax: 40.0%

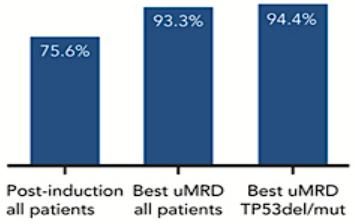
Median time to uMRD: **5.4 months**

Median treatment duration: **14.7 months**

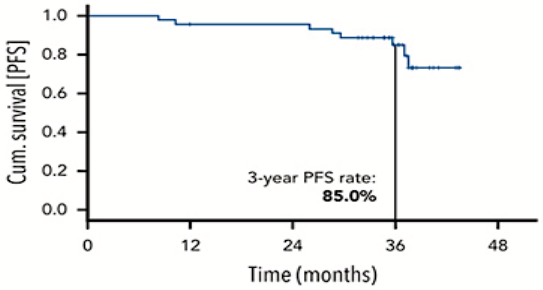


Main Findings (median follow-up 36.3 months)

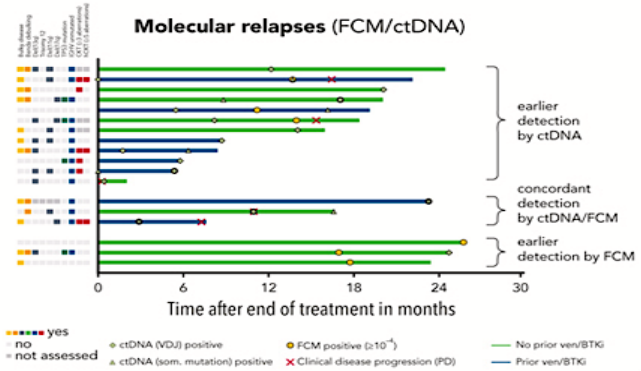
PB undetectable MRD rates



Progression-free survival



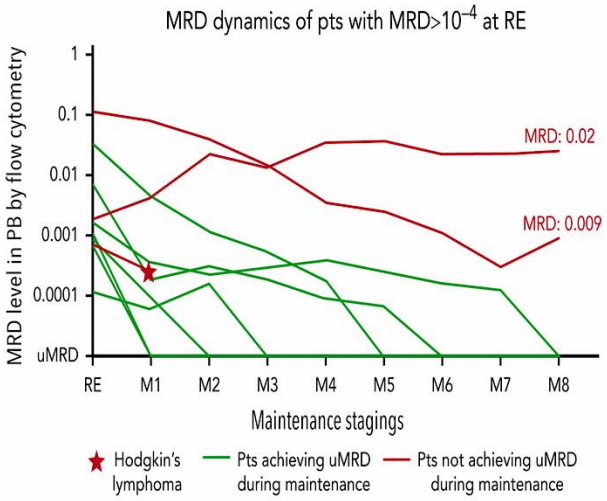
Molecular relapses (FCM/ctDNA)

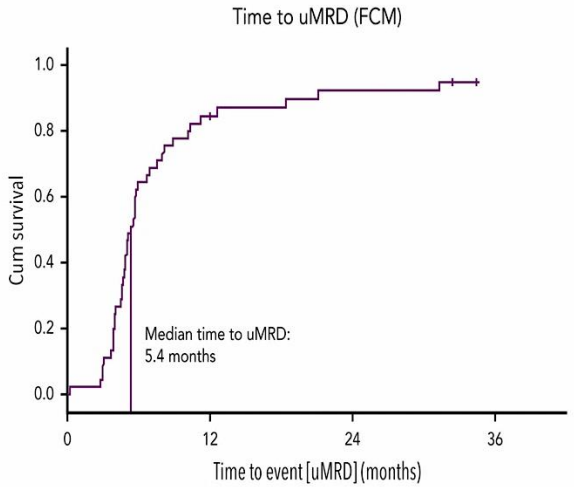


Conclusion: Time-limited acalabrutinib, venetoclax, and obinutuzumab induced deep and ongoing remissions in patients with relapsed/refractory CLL, including those with *TP53* aberrations and prior BTKi/venetoclax exposure.

*Fürstenau et al. DOI: 10.1182/**blood**.2023022730*

blood Visual Abstract





Fürstenau M et al. Blood 2024
Courtesy of Jennifer R Brown, MD, PhD

What about AVO in Relapsed Disease?

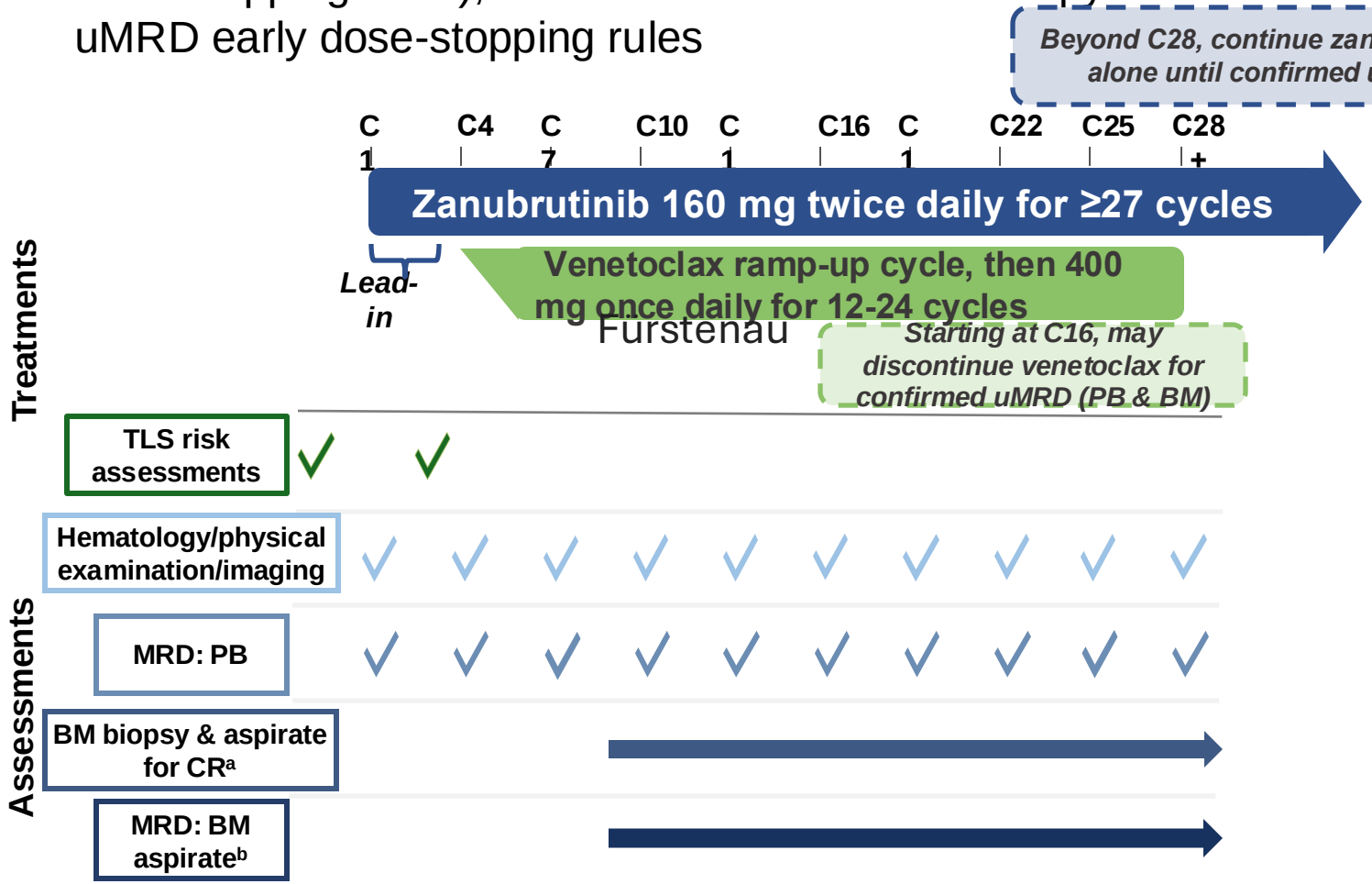
- **Heterogeneous group of heavily pretreated patients**
- **Surprisingly effective – 3 yr PFS 85%**
- **Some patients may not get to uMRD: should they just continue?**
- **Underscores the importance of avoiding development of resistance – but maybe combination will still work….**

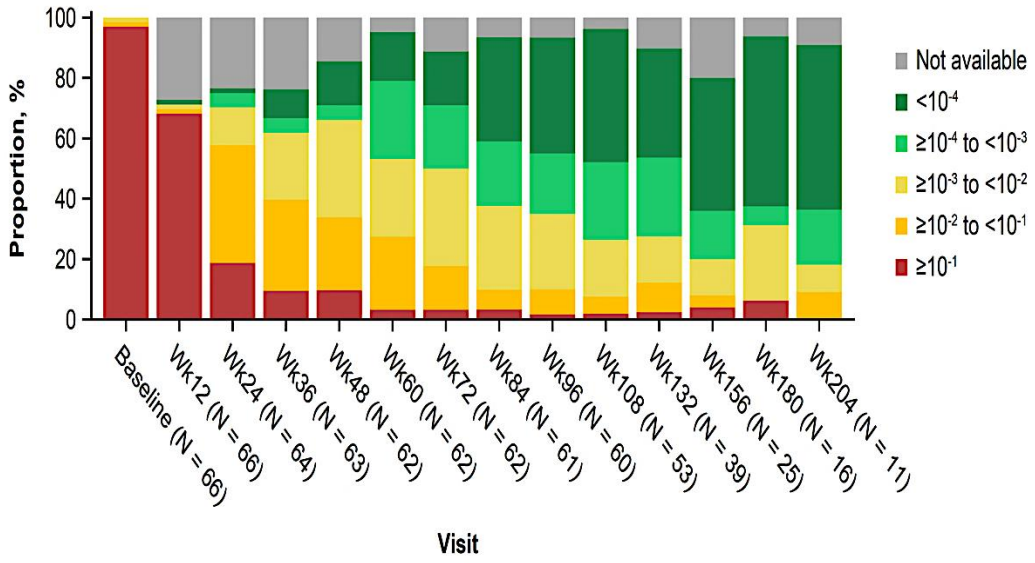
Courtesy of Jennifer R Brown, MD, PhD

Author's slide

SEQUOIA Arm D Treatment Regimen and MRD

- Zanubrutinib lead-in (3 cycles) followed by zanubrutinib + venetoclax (12-24 cycles dependent on uMRD early dose-stopping rules), then zanubrutinib monotherapy until disease progression, unacceptable toxicity, or meeting uMRD early dose-stopping rules





[a] BM biopsy and aspirate are required to confirm a suspected CR/CRi (BM collection timepoint not defined per protocol), starting after cycle 9 and then annually if needed.
[b] Patients with confirmed CR/CRi and 2 consecutive PB uMRD ≥12 weeks apart.

Courtesy of Jennifer R Brown, MD, PhD

Shuo MA et al. EHA 2024;Abstract S160

SEQUOIA Arm D: Zanu Ven in Del17p

- **Relatively slow achievement of uMRD:? Due to 17p**

- **Very strict stopping criteria: Most patients continue on therapy**
  --?Is this really a time limited regimen

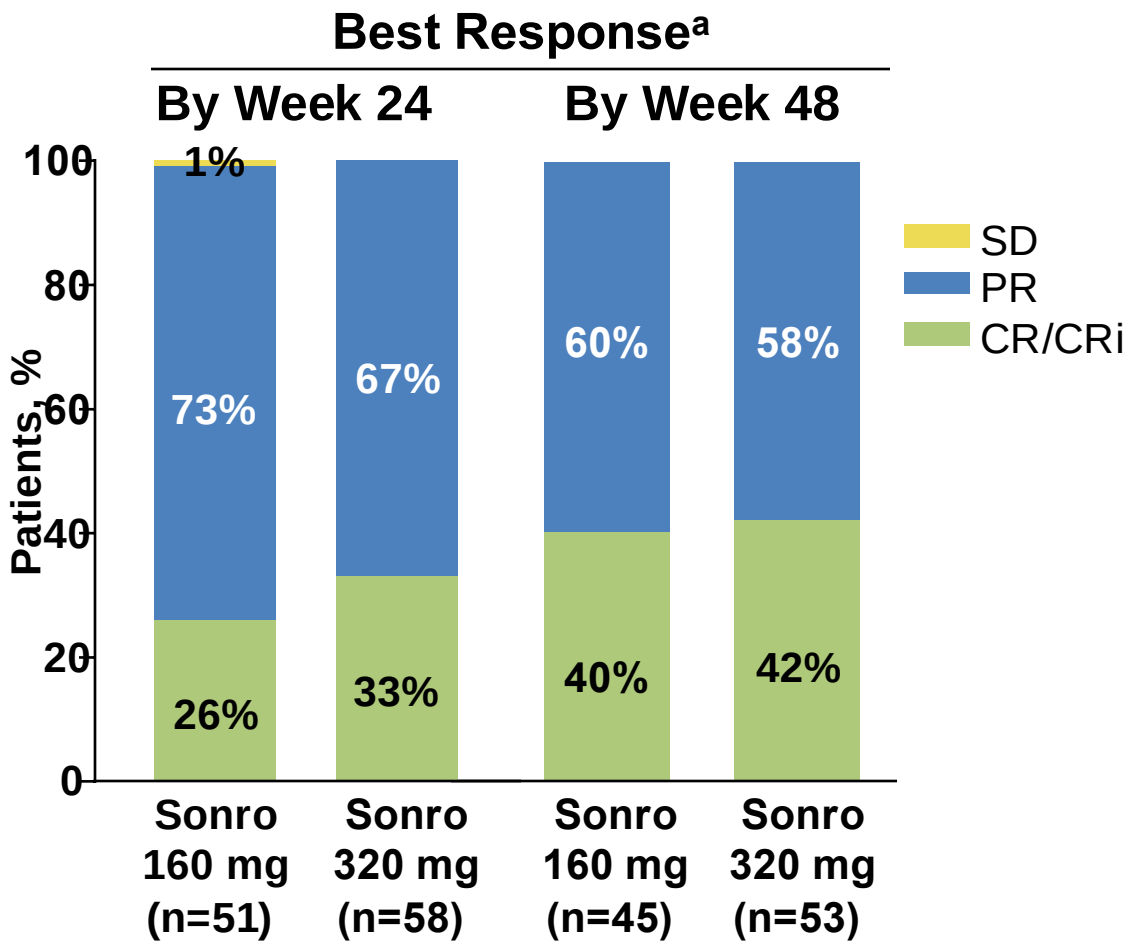
BUT: maybe a longer treatment duration is preferred in this patient subgroup –

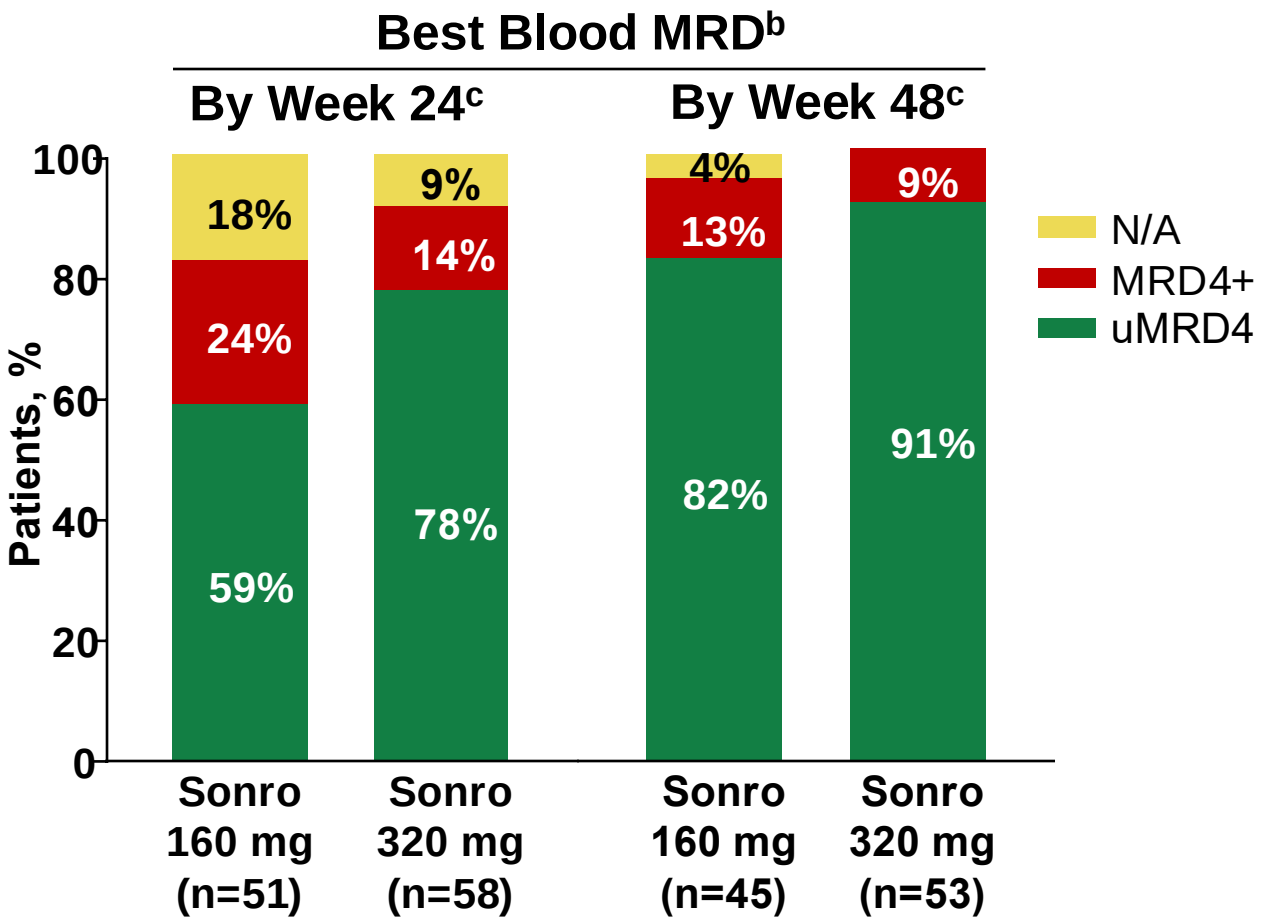
Longer follow-up is required

Courtesy of Jennifer R Brown, MD, PhD

Author's slide

Sonrotoclax + Zanubrutinib Demonstrates Substantial Antitumor Activity in TN CLL





[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
[b] As measured by ERIC flow cytometry panel; uMRD4 is defined as less than 1 CLL cell per 10,000 leukocytes (<10-4). c Number of weeks at target dose, following zanu monotherapy and sonro ramp-up to target dose.

Courtesy of Jennifer R Brown, MD, PhD

Soumerai JD et al. ASH 2024;Abstract 1012

Sonrotoclax + Zanubrutinib Demonstrates Substantial Antitumor Activity in TN CLL

- **Sonrotoclax more potent in vitro and so far very limited TLS, although ramp-up schedule has been as complicated as venetoclax**
- **Highest uMRD rates of any BTKi-BCL2i combination (without an antibody)**
- **Selected phase 1 population, needs longer follow-up and broadly multicenter trials**

Courtesy of Jennifer R Brown, MD, PhD

AGENDA

Year in Review: Management of Chronic Lymphocytic Leukemia (CLL)

INTRODUCTION: The CLL Experience — 2000 to 2025

MODULE 1: Current Therapy Options with Covalent Bruton Tyrosine Kinase (BTK) Inhibitors

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MODULE 4: Noncovalent BTK Inhibitor Pirtobrutinib

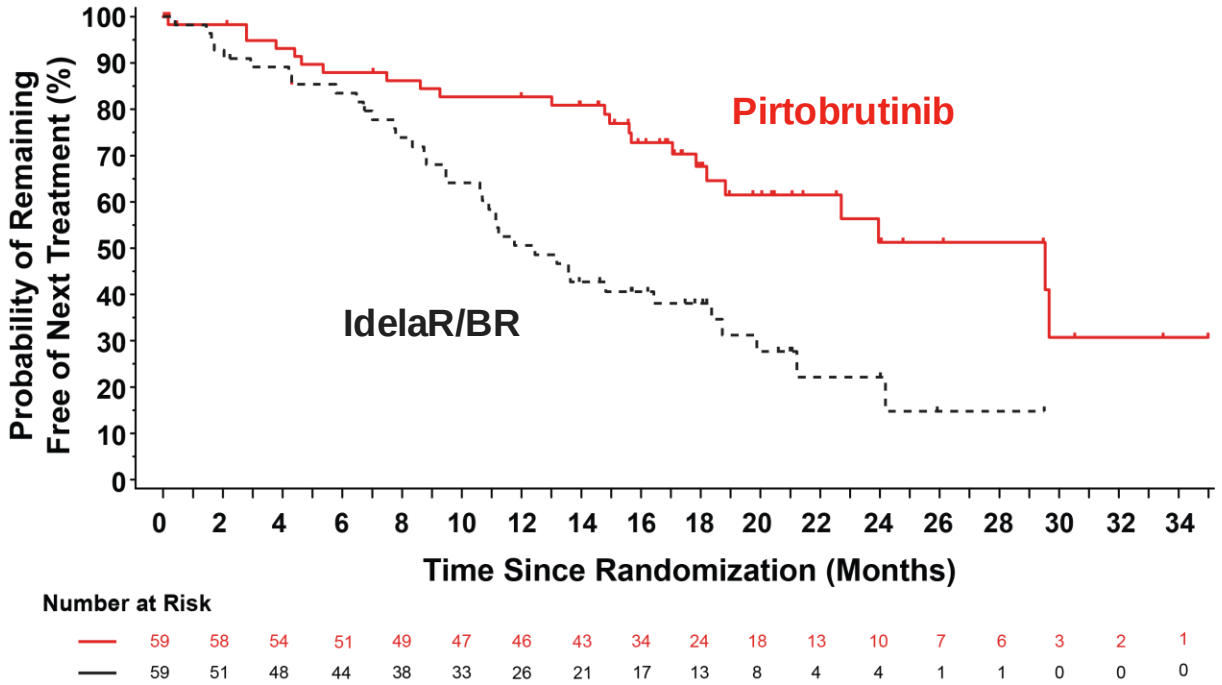
MODULE 5: CAR T-Cell Therapy; Novel Agents

Noncovalent BTK Inhibitor Pirtobrutinib

- Sharman JP et al. **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. ASH 2024;Abstract 886.
- Roeker LE et al. **Fixed-duration pirtobrutinib plus venetoclax with or without rituximab** in relapsed/refractory CLL: The **phase 1b BRUIN** trial. *Blood* 2024 September 26;144(13):1374-86.
- Wierda WG et al. **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. *Lancet Haematol* 2024 September;11(9):e682-92.
- Jain N et al. Combined **pirtobrutinib, venetoclax, and obinutuzumab as first-line treatment** of patients with chronic lymphocytic leukemia (CLL). ASH 2024;Abstract 1011.

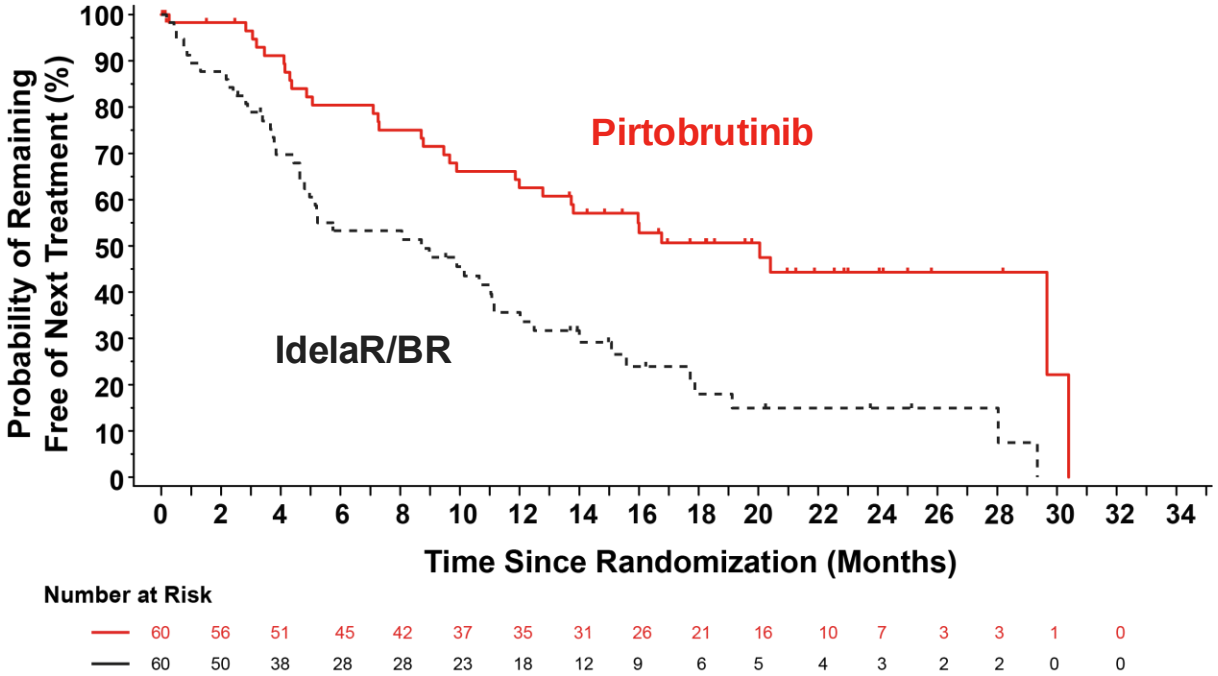
BRUIN 321: Time to Next Treatment or Death in Venetoclax Naïve and Treated Patients

Venetoclax Naïve n=59/arm



	Pirtobrutinib n=119	IdelaR/BR n=119
Median TTNT, mo (95% CI)	29.5	12.5
Hazard ratio (95% CI)	0.36 (0.21- 0.61)	
Stratified log-rank 2-sided p-value	0.0001*	

Venetoclax Treated n=60/arm



	Pirtobrutinib n=119	IdelaR/BR n=119
Median TTNT, mo (95% CI)	20.0	8.7
Hazard ratio (95% CI)	0.37 (0.23- 0.60)	
Stratified log-rank 2-sided p-value	<0.0001*	

Courtesy of Jennifer R Brown, MD, PhD

Sharman J et al ASH 2024;Abstract 866

BRUIN 321

- First phase 3 registration trial in patients with prior cBTKi treatment
- Pirtobrutinib improved PFS compared to IdelaR/BR
- Outcomes are poor overall, underscoring the high risk nature of this group
- Idela-R has activity, with about one year of clinical benefit

Courtesy of Jennifer R Brown, MD, PhD

Pirtobrutinib + Venetoclax +/- Rituximab

Fixed-Duration Pirtobrutinib Plus Venetoclax With or Without Rituximab in R/R Chronic Lymphocytic Leukemia (CLL): Phase 1b BRUIN Trial

Background

Fixed-duration treatments with venetoclax and covalent Bruton tyrosine kinase inhibitors (cBTKi) have achieved deep remissions in patients with CLL.

Non-covalent (reversible) BTKi pirtobrutinib shows efficacy in patients with CLL, including those previously treated with cBTKi.

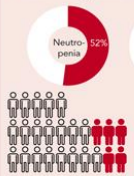
We tested fixed-duration pirtobrutinib plus venetoclax with or without rituximab (PV or PVR) in pretreated patients with CLL, including those who had received a cBTKi.

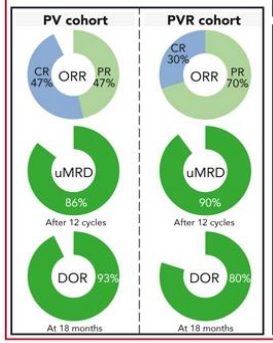
Patients and methods

- ClinicalTrials.gov ID: NCT03740529
- Study design: Phase 1b clinical trial
- Participants: 25 adults with R/R CLL
  - PV (n = 15)
  - PVR (n = 10)
- Dosing regimen: Fixed duration, 25 cycles (1 cycle = 28 days)
- Primary endpoint: Safety
- Secondary endpoints:
  - Overall response rate (ORR) including complete & partial response (CR; PR)
  - Undetectable minimal residual disease (uMRD)
  - Progression-free survival (PFS)
  - Duration of response (DOR)

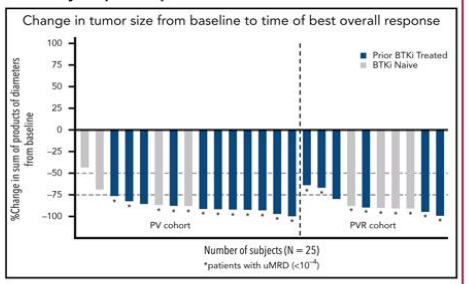
Primary endpoint - both cohorts

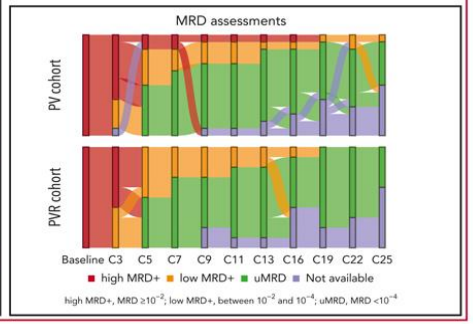
- No dose-limiting toxicities
- Most common all-cause AEs: Neutropenia, diarrhea, fatigue, nausea
- Common grade ≥3 AEs:





Secondary endpoints – per cohort

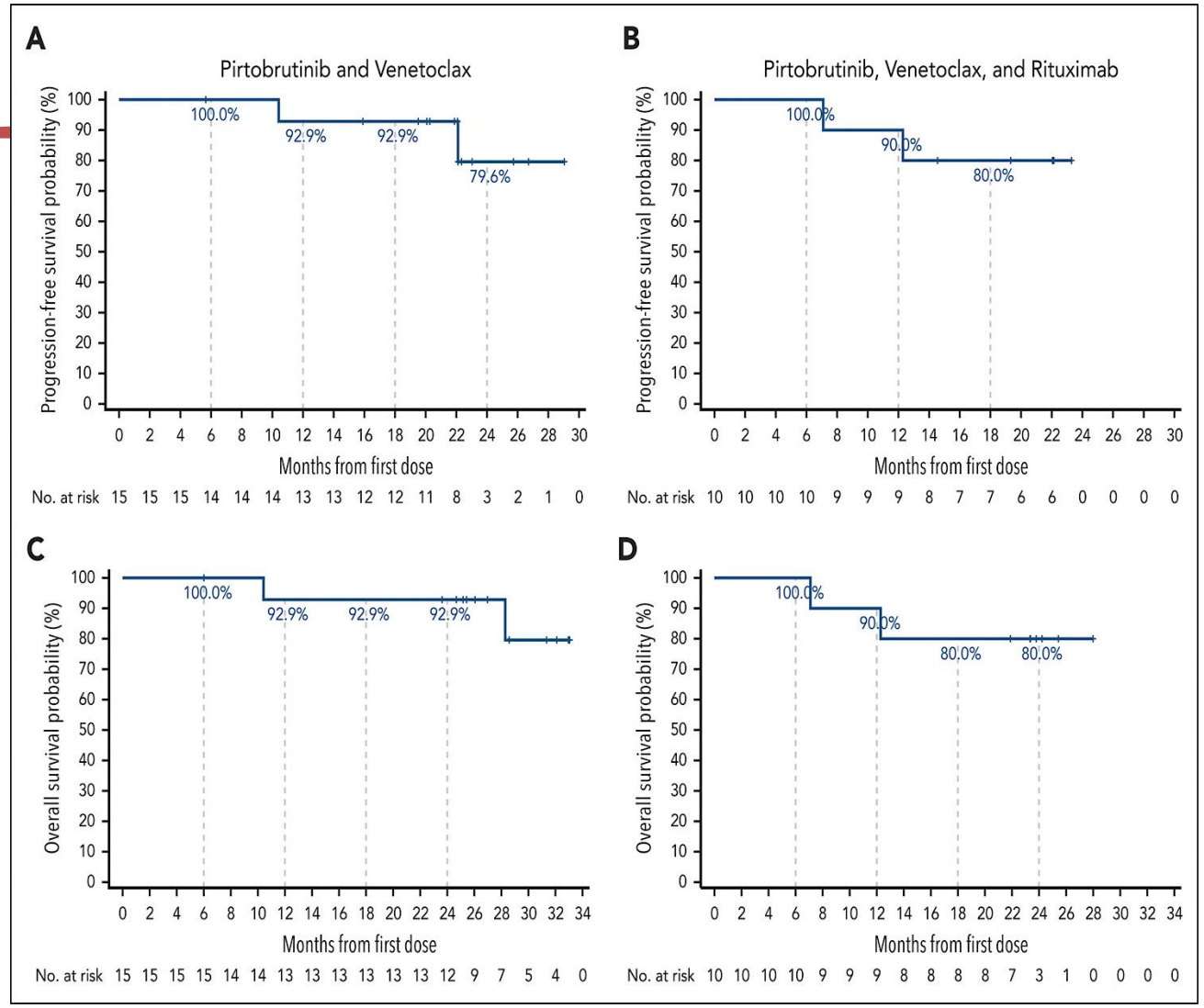




Conclusion: **In both covalent BTK-naïve and BTK-exposed patients, fixed-duration PV and PVR regimens were well tolerated and demonstrated sufficiently encouraging efficacy to warrant further investigation in patients with R/R CLL.**

*Roeker et al. DOI: 10.1182/**blood**.2024024510*

blood Visual Abstract



Courtesy of Jennifer R Brown, MD, PhD

Roeker LE et al Blood 2024

Pirtobrutinib Ven +/- R in R/R CLL

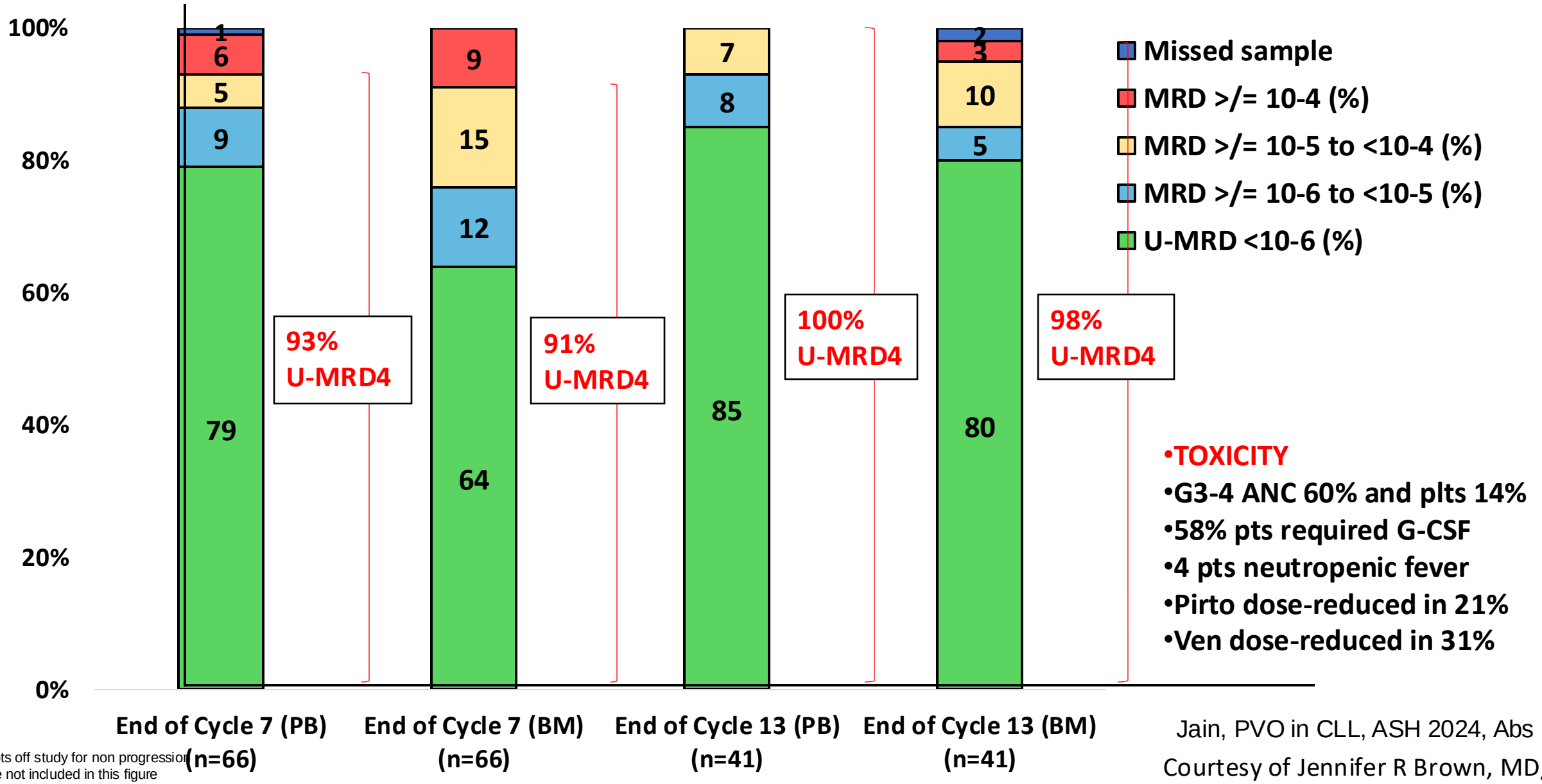
- Phase 1 study – well tolerated
- High ORR and uMRD
- About 20% progression during the two years of therapy
- Need longer follow-up after discontinuation of therapy at 2 yrs

- Basis of fully accrued phase 3 registration trial

Courtesy of Jennifer R Brown, MD, PhD

Pirtobrutinib, Venetoclax, Obinutuzumab Frontline

MRD at Serial Time-Points in Blood and Bone Marrow



- **TOXICITY**
- G3-4 ANC 60% and plts 14%
- 58% pts required G-CSF
- 4 pts neutropenic fever
- Pirto dose-reduced in 21%
- Ven dose-reduced in 31%

3 pts off study for non progression are not included in this figure

Jain, PVO in CLL, ASH 2024, Abs 1011

Courtesy of Jennifer R Brown, MD, PhD

Pirto Ven Obin

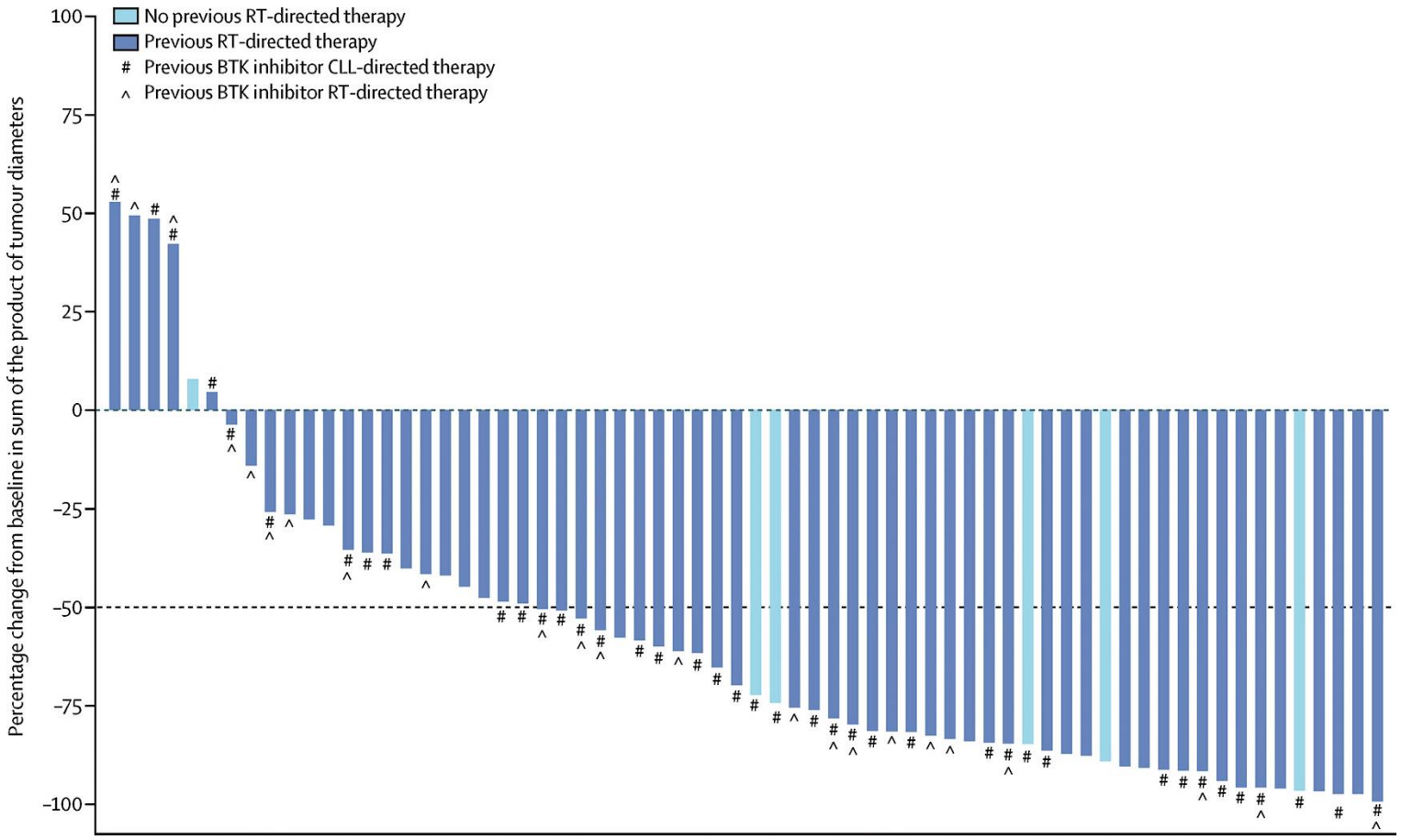
- MDACC trial
- Very high rates of uMRD
- BUT: very high rates of heme tox and dose reductions

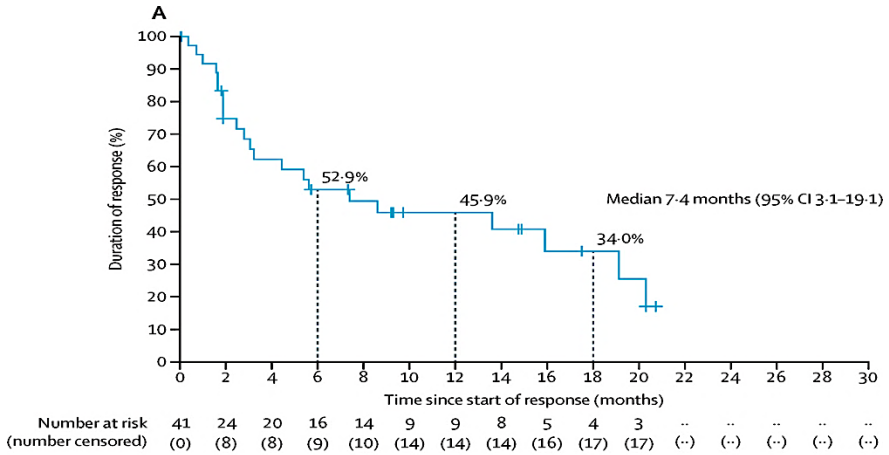
- Needs confirmation in multicenter setting
- Risk of using pirto before cBTKi

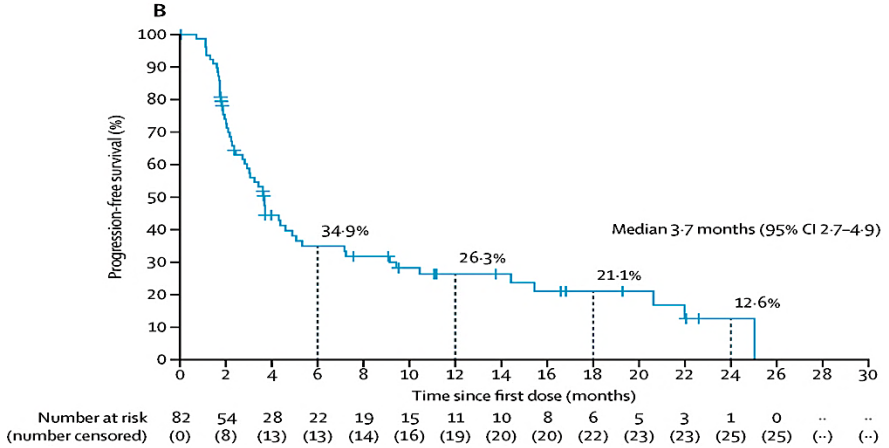
Courtesy of Jennifer R Brown, MD, PhD

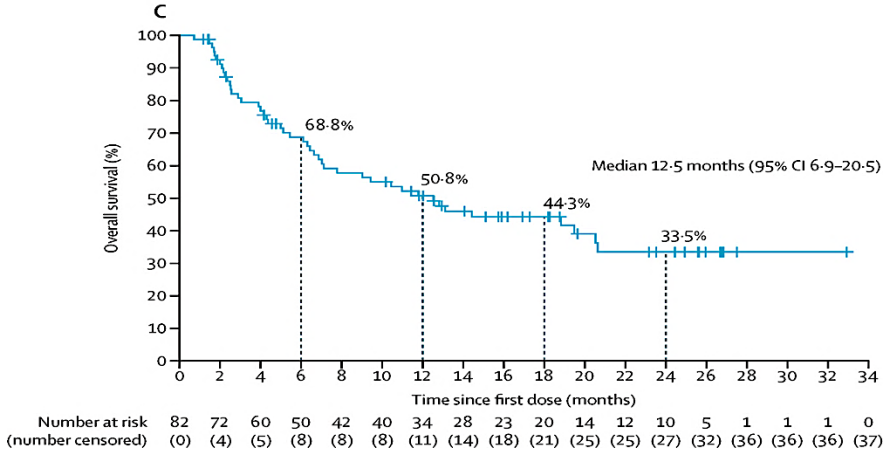
Author's slide

Pirtobrutinib in RT









Wierda WG et al Lancet Haematol 2024

Courtesy of Jennifer R Brown, MD, PhD

What about Pirtobrutinib in RT?

- Largest prospective trial (82 patients)
- ORR 50%, CR 13%
- DOR 7.4 mos, PFS 3.7 mos

- High response but short durability
- Basis for combination therapies?

Courtesy of Jennifer R Brown, MD, PhD

AGENDA

Year in Review: Management of Chronic Lymphocytic Leukemia (CLL)

INTRODUCTION: The CLL Experience — 2000 to 2025

MODULE 1: Current Therapy Options with Covalent Bruton Tyrosine Kinase (BTK) Inhibitors

MODULE 2: Role of Venetoclax in the Treatment of CLL

MODULE 3: AMPLIFY Trial and Other Novel BTK Inhibitor and Bcl-2 Inhibitor Combination Strategies

MODULE 4: Noncovalent BTK Inhibitor Pirtobrutinib

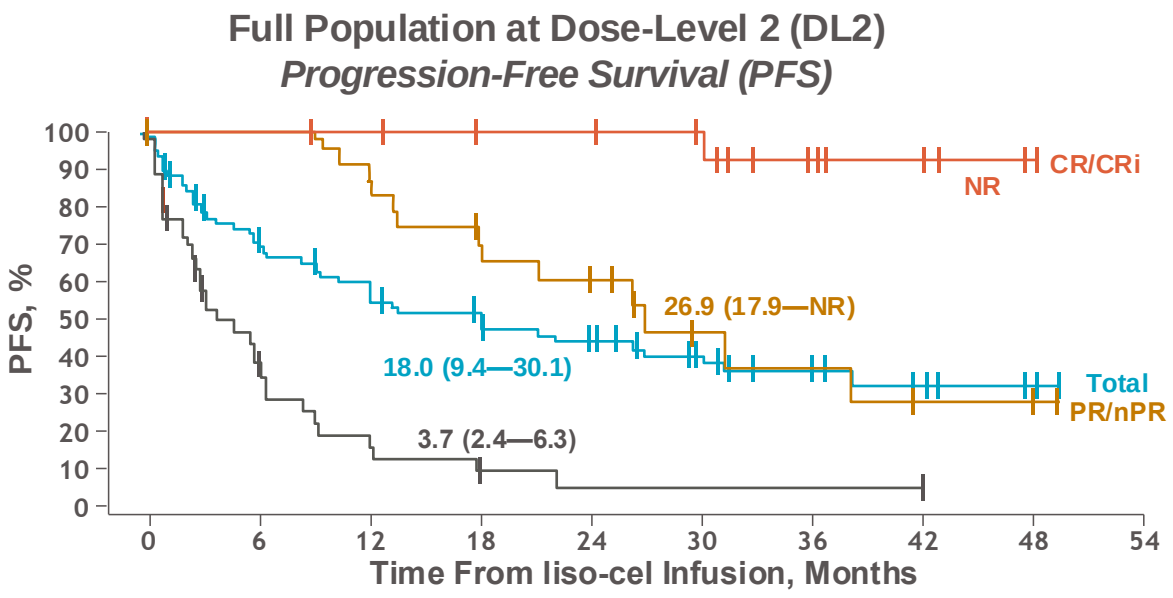
MODULE 5: CAR T-Cell Therapy; Novel Agents

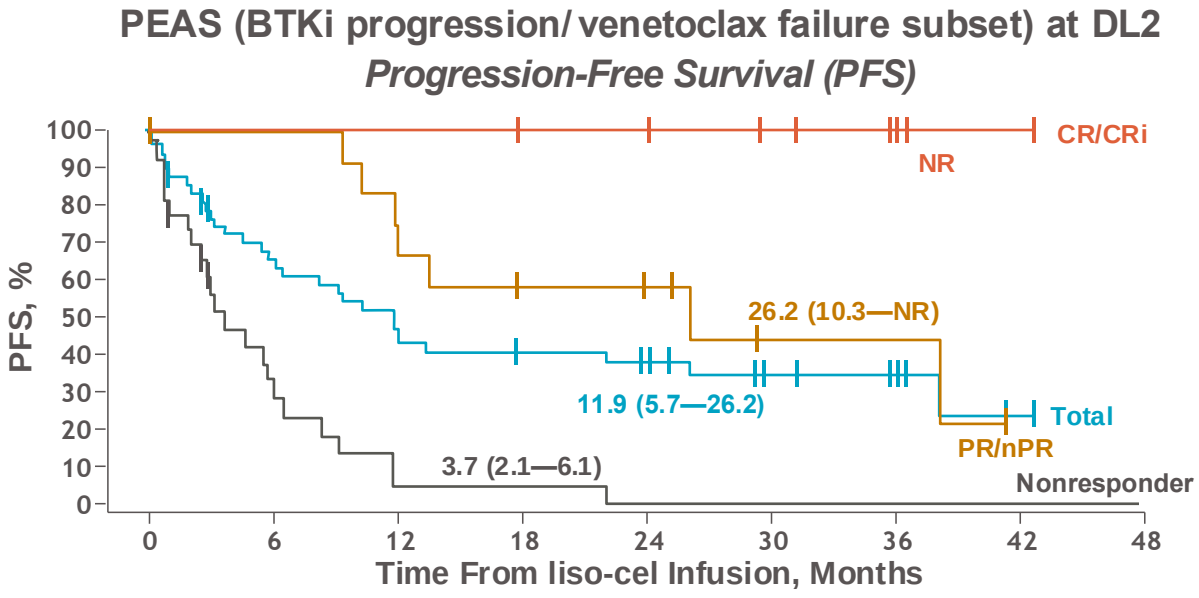
RTP Year in Review 2025

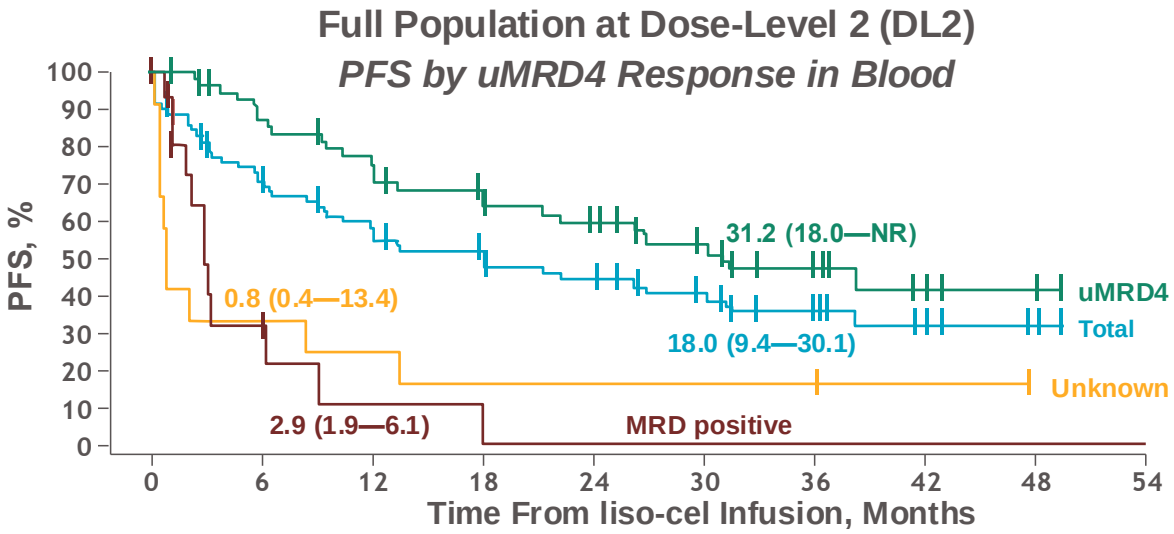
CAR (Chimeric Antigen Receptor) T-Cell Therapy; Novel Agents

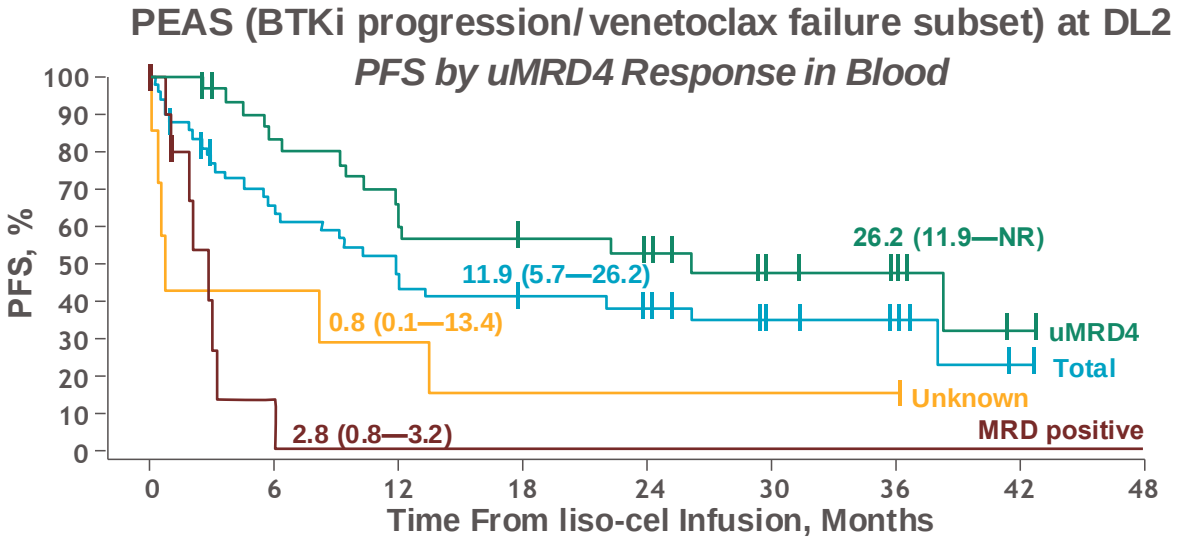
- Siddiqi T et al. **Lisocabtagene maraleucel (liso-cel)** in patients (pts) with relapsed or refractory (R/R) chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL): **Updated follow-up of TRANSCEND CLL 004**. ASH 2024;Abstract 4633.
- Wierda WG et al. **Lisocabtagene maraleucel (liso-cel) combined with ibrutinib (ibr)** for patients (pts) with relapsed or refractory (R/R) chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL): **Primary results from the open-label, phase 1/2 transcend CLL 004 study**. ASH 2024;Abstract 887.
- Danilov A et al. **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**. ASH 2024;Abstract 883.

TRANSCEND CLL 004: lisocabtagene maraleucel (liso-cel)









Courtesy of Jennifer R Brown, MD, PhD

Median (95% CI) follow-up: 31.4 mo (24.3—36.2)

Siddiqi et al *Blood* (2024) 144 (Supplement 1): 4633.

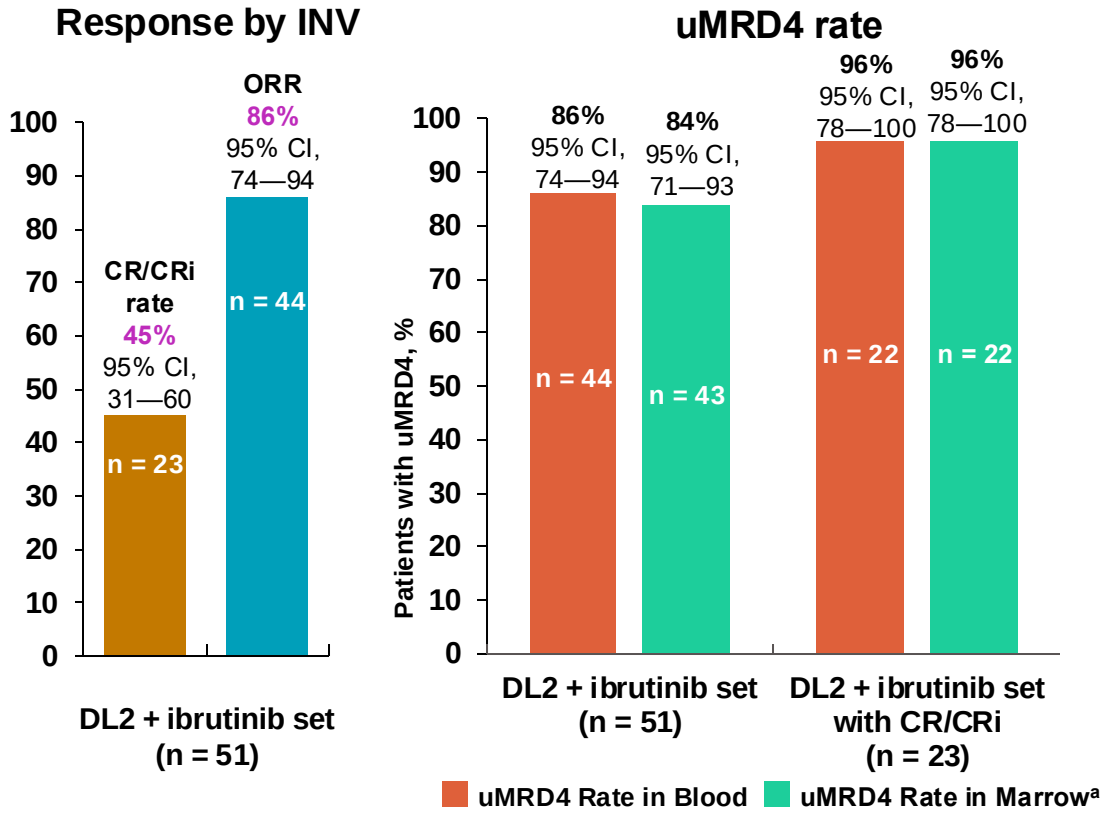
Update on Liso-cel in CLL

- CR is more predictive than uMRD (unlike every other situation)
- CR rate only 20%
- Double refractory population has worse outcome than full population (similar to pirtobrutinib)
- <=3 prior regimens and absence of bulky disease associated with response (PR or CR)

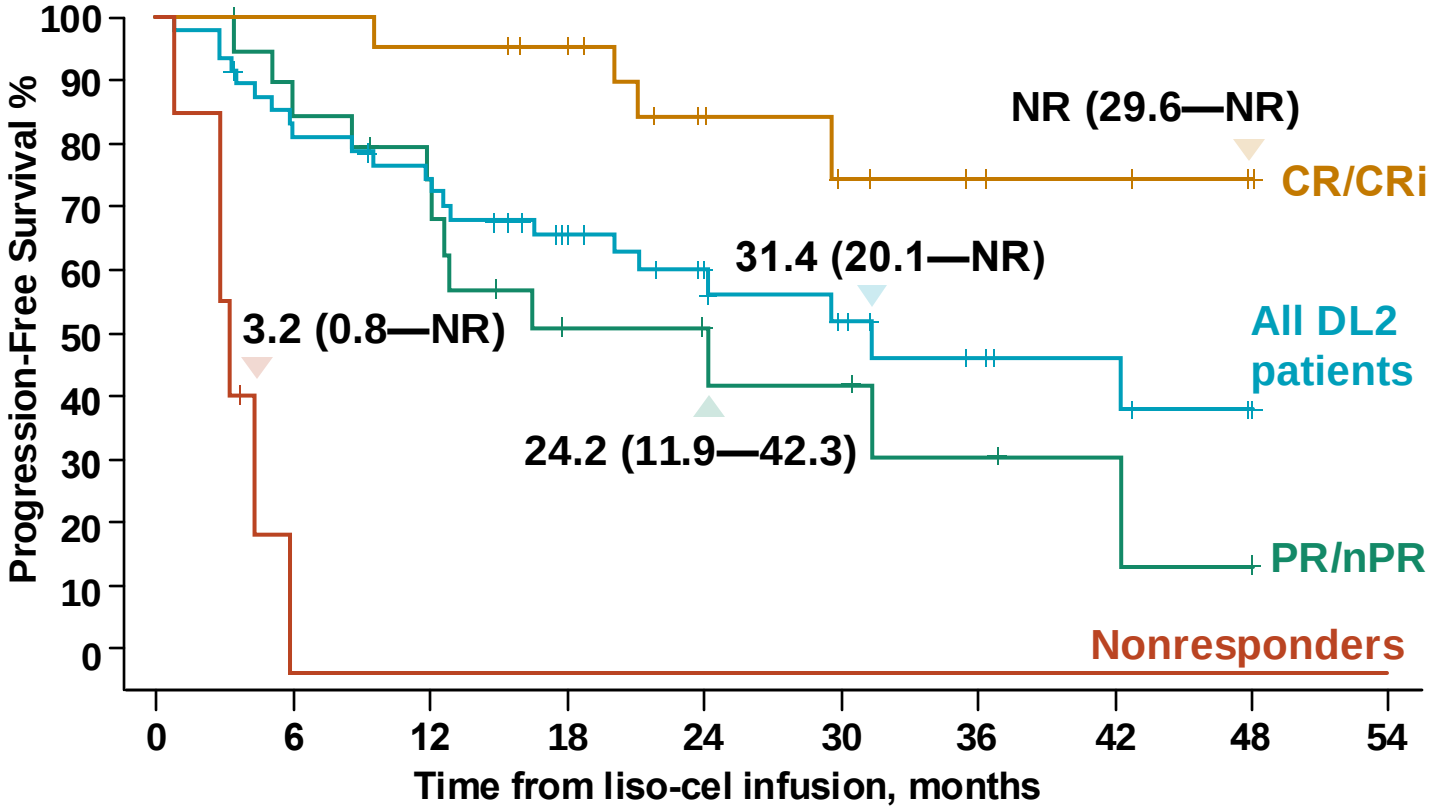
Courtesy of Jennifer R Brown, MD, PhD

Liso-cel + Ibrutinib Outcomes

Efficacy Outcomes: Response by Investigator and uMRD4



Progression-Free Survival by Best Overall Response at DL2



- Median (IQR) on-study follow-up (including LTFU): 24.8 months (14.2—34.6)
- Median (range) time to first response: 1 month (0.9—6.0)
- Median (range) time to first CR/CRi: 3 months (0.9—12.1)

Median (95% CI) follow-up for PFS: 24.3 months (23.7—35.5)

Courtesy of Jennifer R Brown, MD, PhD

Wierda W, et al. ASH 2024 TRANSCEND CLL 004: Liso-cel + Ibrutinib Cohort [Abstract #887]

What about Liso-cel + Ibrutinib?

Also heavily pretreated

CR rate higher at 45% - but hard to compare patient populations across studies

Ibrutinib side effects (brain hemorrhage, cardiac arrests on prior studies) plus still 59% needed steroids or toci for CRS

Consider studies with second generation BTKis

Courtesy of Jennifer R Brown, MD, PhD

EPCORE

Study Design: EPCORE® CLL-1 Expansion and C1 Optimization

Key inclusion criteria

- CD20+ R/R CLL
- ≥2 prior lines of systemic therapy
- ECOG PS 0–2
- Measurable disease with ≥5×10⁹/L B lymphocytes (expansion only)
- No prior allogeneic HSCT

Expansion (EXP; N=23)

CRS prophylaxis
- *Prednisone*

Step-up dose 1 (C1D1): 0.16 mg → Step-up dose 2 (C1D8): 0.8 mg → First full dose (C1D15): 48 mg

Data cutoff: May 28, 2024
Median follow-up: 22.8 months

Cycle 1 Optimization (C1 OPT; N=17)

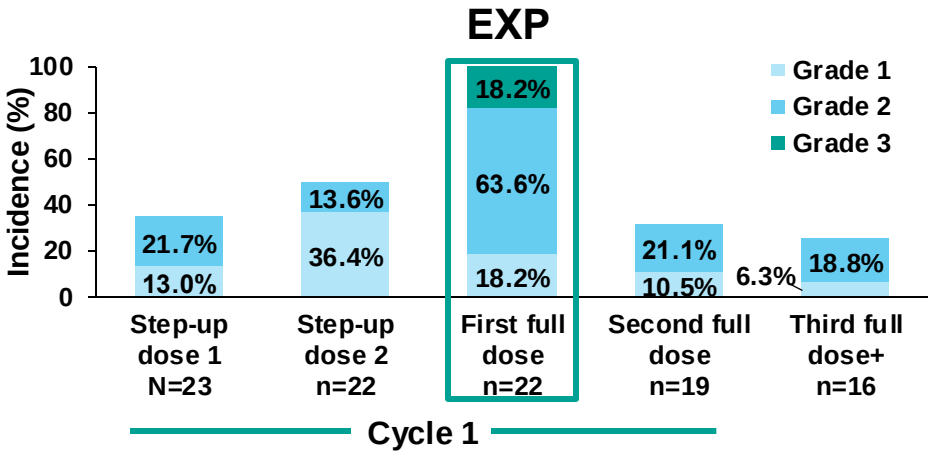
CRS prophylaxis
- *Dexamethasone*
- *Adequate hydration*

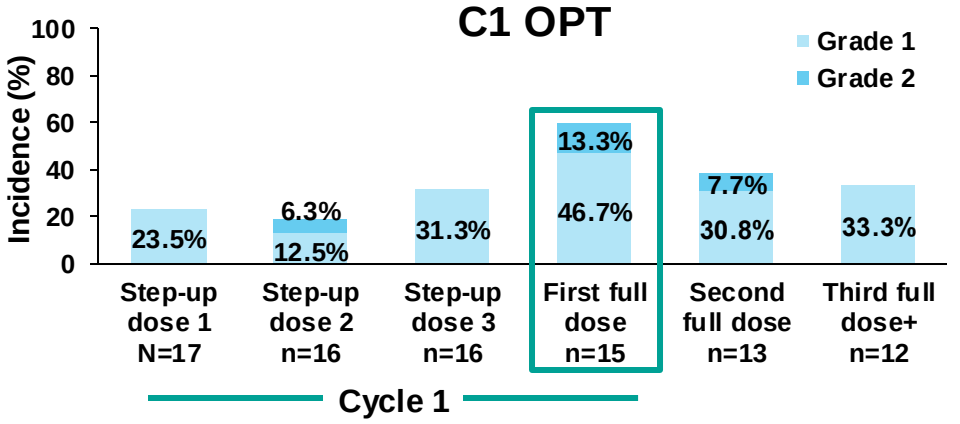
Step-up dose 1 (C1D1): 0.16 mg → Step-up dose 2 (C1D8): 0.8 mg → Step-up dose 3 (C1D15): 3 mg → First full dose (C1D22): 48 mg

Data cutoff: May 28, 2024
Median follow-up: 2.9 months

C1 OPT Mitigated Adverse Events of Interest Including ICANS and Clinical TLS

CRS Events by Dosing Period





ClinicalTrials.gov: NCT04623541; EudraCT: 2023-504828-25.

Courtesy of Jennifer R Brown, MD, PhD

Danilov A et al ASH 2024; Abstract 883

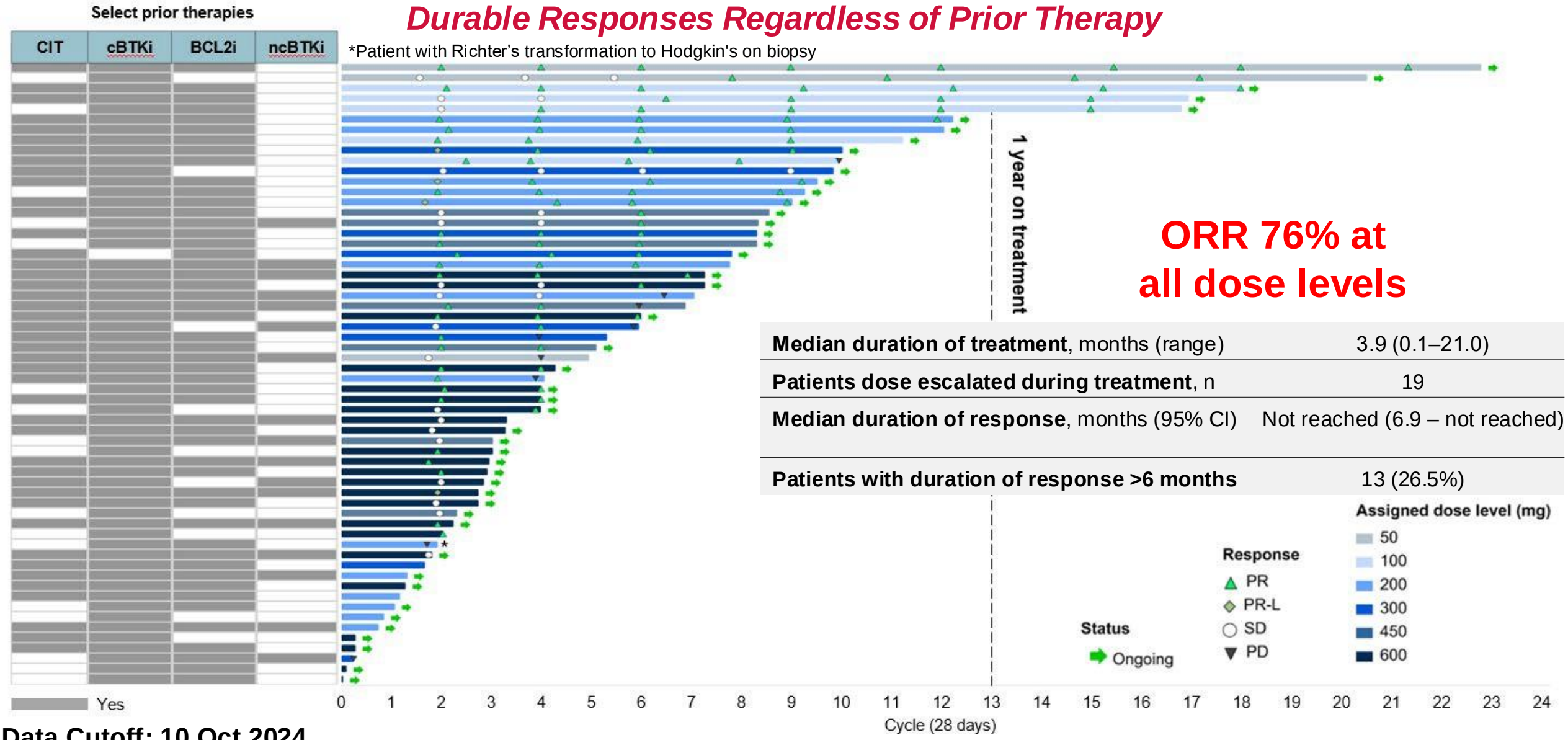
Epcoritamab in R/R CLL

- Optimization cohort to reduce CRS risk
  - CRS still most common at the first full dose but now no grade 3 and mostly grade 1
- Heavily pretreated patients, ORR 61% and CR 39% are encouraging
  - uMRD 75% in responders
- Median PFS about one year at present
- Ongoing enrollment: plan combinations, or consolidation

Courtesy of Jennifer R Brown, MD, PhD

NX-5948 Duration of Treatment

Durable Responses Regardless of Prior Therapy



ORR 76% at all dose levels

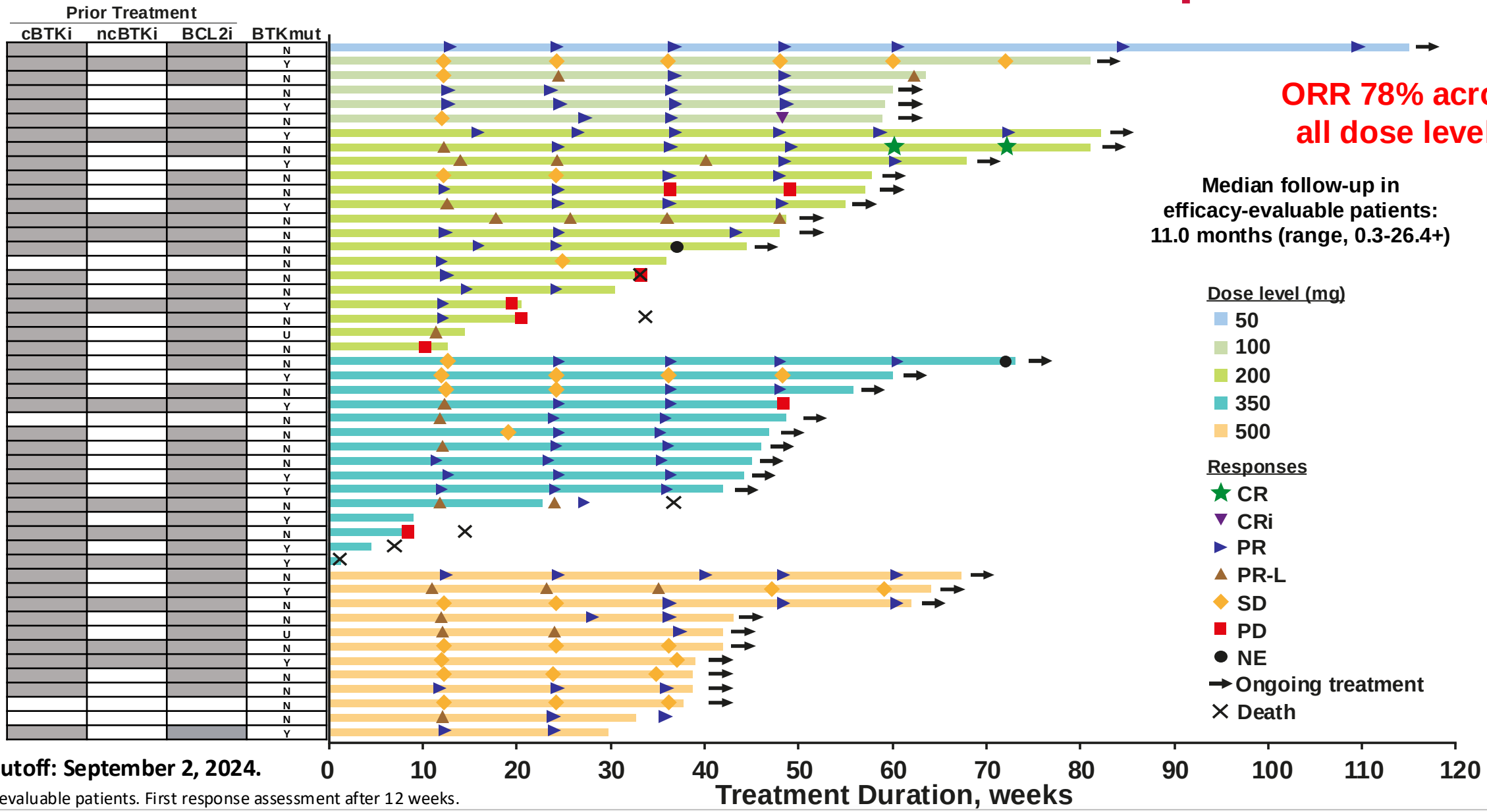
Median duration of treatment, months (range)	3.9 (0.1–21.0)
Patients dose escalated during treatment, n	19
Median duration of response, months (95% CI)	Not reached (6.9 – not reached)
Patients with duration of response >6 months	13 (26.5%)

Data Cutoff: 10 Oct 2024

Courtesy of Jennifer R Brown, MD, PhD

Shah et. al. ASH 2024 - *Blood* 2024;144(Supplement 1):884.

BGB-16673 Treatment Duration & Response



Data Cutoff: September 2, 2024.

Efficacy-evaluable patients. First response assessment after 12 weeks.

Courtesy of Jennifer R Brown, MD, PhD

Thompson MC et al ASH 2024; Abstract 885

BTK Degraders

- Two phase 1 studies of distinct molecules, in heavily pretreated patients most with prior BTKi and BCL-2i exposure, both with very nice ORR approximately 76%
- Follow-up short but very encouraging
- Mechanisms of resistance still to emerge but important

Courtesy of Jennifer R Brown, MD, PhD

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

Management of Breast Cancer

A CME/MOC-Accredited Live Webinar

Wednesday, March 26, 2025
5:00 PM – 6:00 PM ET

Faculty

Rebecca A Dent, MD, MSc
Nancy U Lin, MD

Moderator

Neil Love, MD

RTP Year in Review 2025

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