



What's New in Chronic Lymphocytic Leukemia (CLL)?

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COH Multidisciplinary Approaches to Cancer Symposium

Las Vegas, NV

November 10-12, 2022

Disclosures

- Consultant for AstraZeneca, Beigene, Bristol Meyers-Squibb, Celgene, Abbvie, and Gilead.
- On the Speakers Bureau for AstraZeneca, Beigene, and Bristol Meyers-Squibb.

This presentation and/or comments will be free of any bias toward or promotion of the above referenced companies or their products and/or other business interests.

This presentation and/or comments will provide a balanced, non-promotional, and evidence-based approach to all diagnostic, therapeutic and/or research related content.

This presentation has been peer-reviewed and no conflicts were noted.

The off-label or investigational use of Pirtobrutinib, Lisoftoclax, Liso-Cel will be discussed.

Cultural Linguistic Competency (CLC) & Implicit Bias (IB)

STATE LAW:

The California legislature has passed Assembly Bill (AB) 1195, which states that as of July 1, 2006, all Category 1 CME activities that relate to patient care must include a cultural diversity/linguistics component. It has also passed AB 241, which states that as of January 1, 2022, all continuing education courses for a physician and surgeon **must** contain curriculum that includes specified instruction in the understanding of implicit bias in medical treatment.

The cultural and linguistic competency (CLC) and implicit bias (IB) definitions reiterate how patients' diverse backgrounds may impact their access to care.

EXEMPTION:

Business and Professions Code 2190.1 exempts activities which are dedicated solely to research or other issues that do not contain a direct patient care component.

The following CLC & IB components will be addressed in this presentation:

- Access to clinical trials among different community sites serving different populations.
- Non-English-speaking patients and their opportunities in participation in clinical trials.

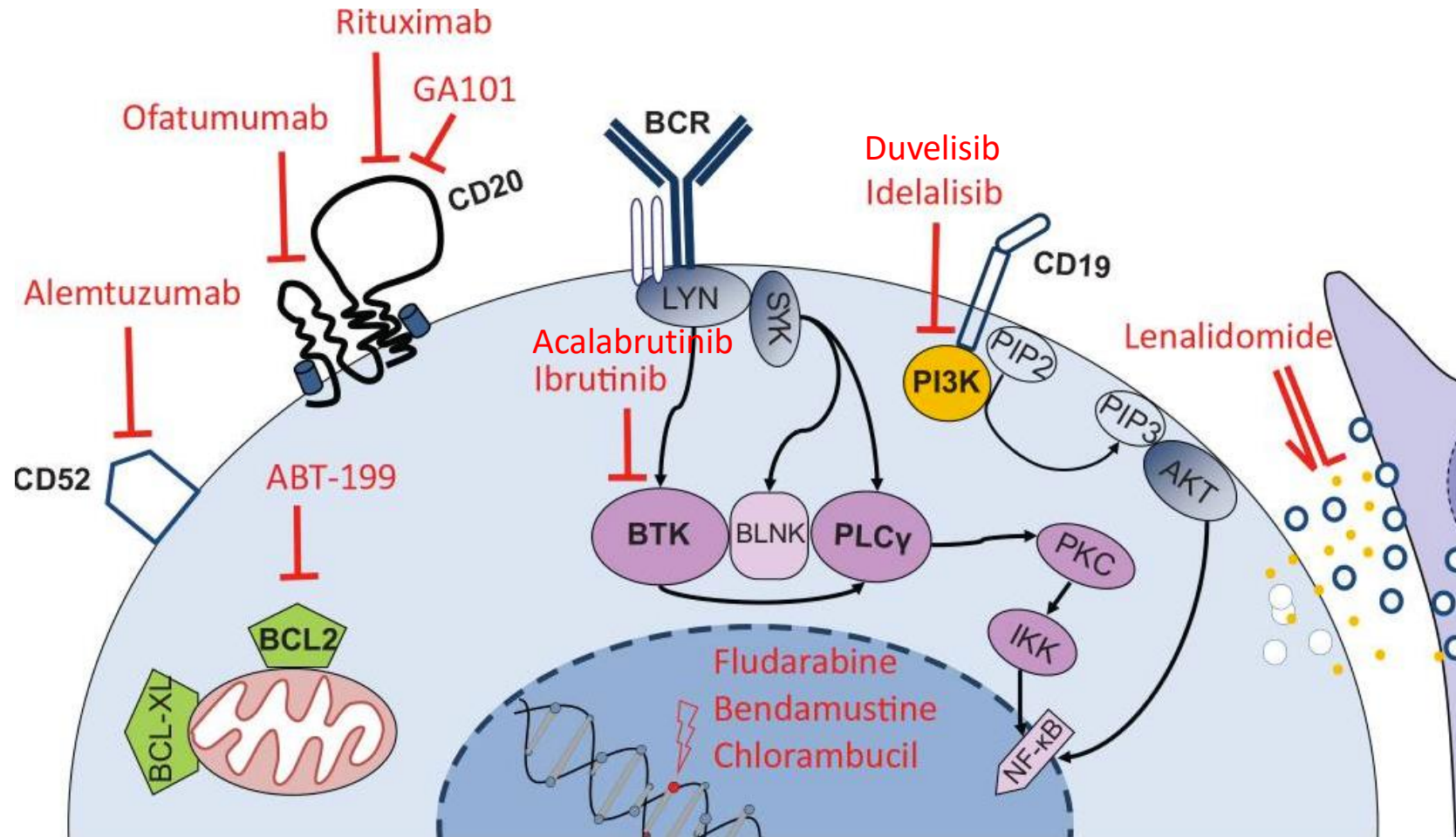
Agenda

- Current treatments
- Novel combinations
- Novel therapies in investigation
 - Non-covalent BTK inhibitors
 - BTK degraders
 - Novel BCL2 inhibitors
 - Novel antibodies, including bispecifics
- Cellular therapeutics
 - CAR-T cells
 - NK-CARs

Disclaimers

- I will not discuss chemotherapy options.
- I will show data from ASH annual meeting (Dec. 2021) on some therapies while only mentioning other treatments

Targeted therapy in CLL



Current treatments

- Typical frontline treatment algorithm nowadays (outside of clinical trials):
 - Venetoclax + Obinutuzumab (fixed duration) [CLL-14 trial]
 - Acalabrutinib +/- Obinutuzumab [ELEVATE-TN trial]
- What happened to chemotherapy in frontline CLL management??
 - FCR/BR/chlorambucil not used anymore based on results of phase 3 trials like E1912, Alliance A041202, RESONATE2, etc
- Typical relapsed/refractory treatment algorithm (if not on clinical trial):
 - Acalabrutinib +/- Obinutuzumab or rituximab [ELEVATE RR trial]
 - Venetoclax + rituximab (fixed duration) [MURANO trial]
 - Duvelisib +/- obinutuzumab or rituximab

Novel combinations

- Ibrutinib + venetoclax

Time-limited Venetoclax and Ibrutinib for Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia (RR CLL) who have Undetectable Minimal Residual Disease (uMRD) – Primary Analysis from the Randomized Phase 2 VISION HO141 Trial

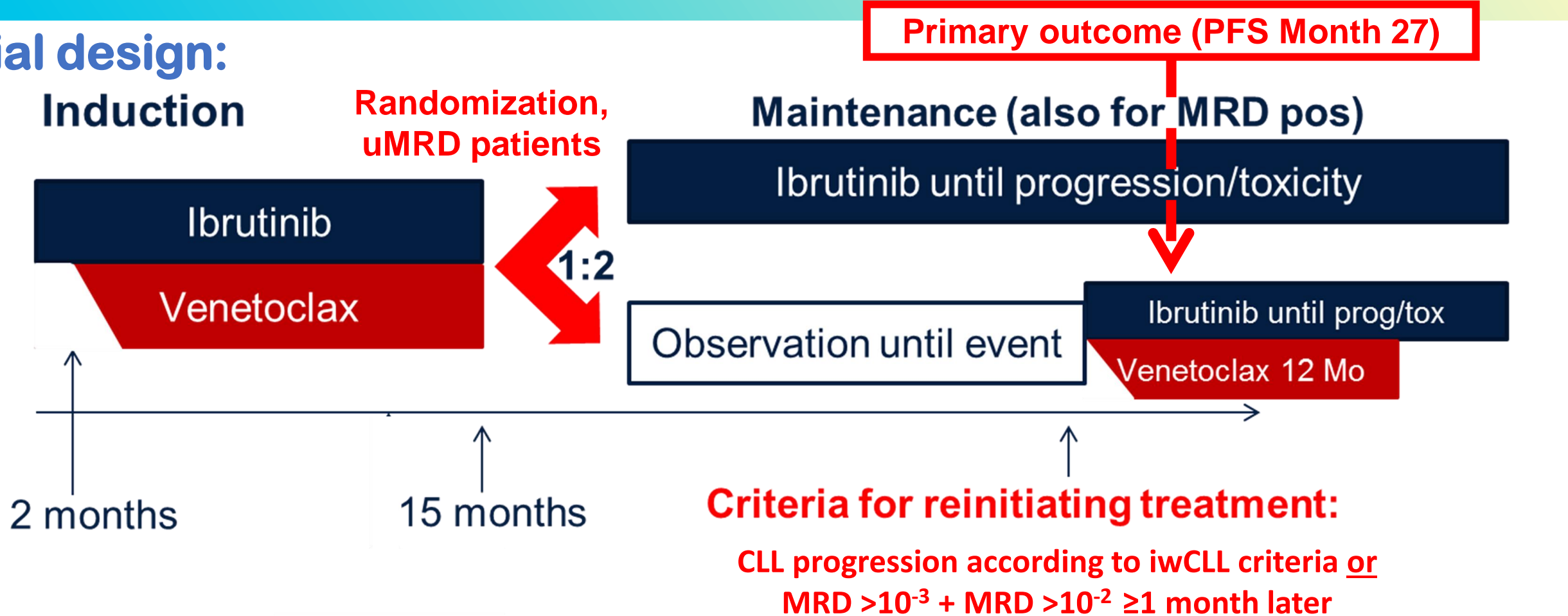
MRD guided Stop / Start in RR CLL

Carsten U Niemann, Julie Dubois, Christian Brieghel, Sabina Kersting, Lisbeth Enggaard, Gerrit J. Veldhuis, Rogier Mous, Clemens HM Mellink, Johan A Dobber, Christian B Poulsen, Henrik Frederiksen, Ann Janssens, Ida Schjødt, Ellen C Dompeling, Juha Ranti, Mattias Mattsson, Mar Bellido, Hoa TT Tran, Kazem Nasserinejad, Mark-David Levin, **Arnon P Kater**



ASH annual meeting 2021, Abstract #69, VISION HO141 – MRD guided Stop/Start in RR CLL

Trial design:



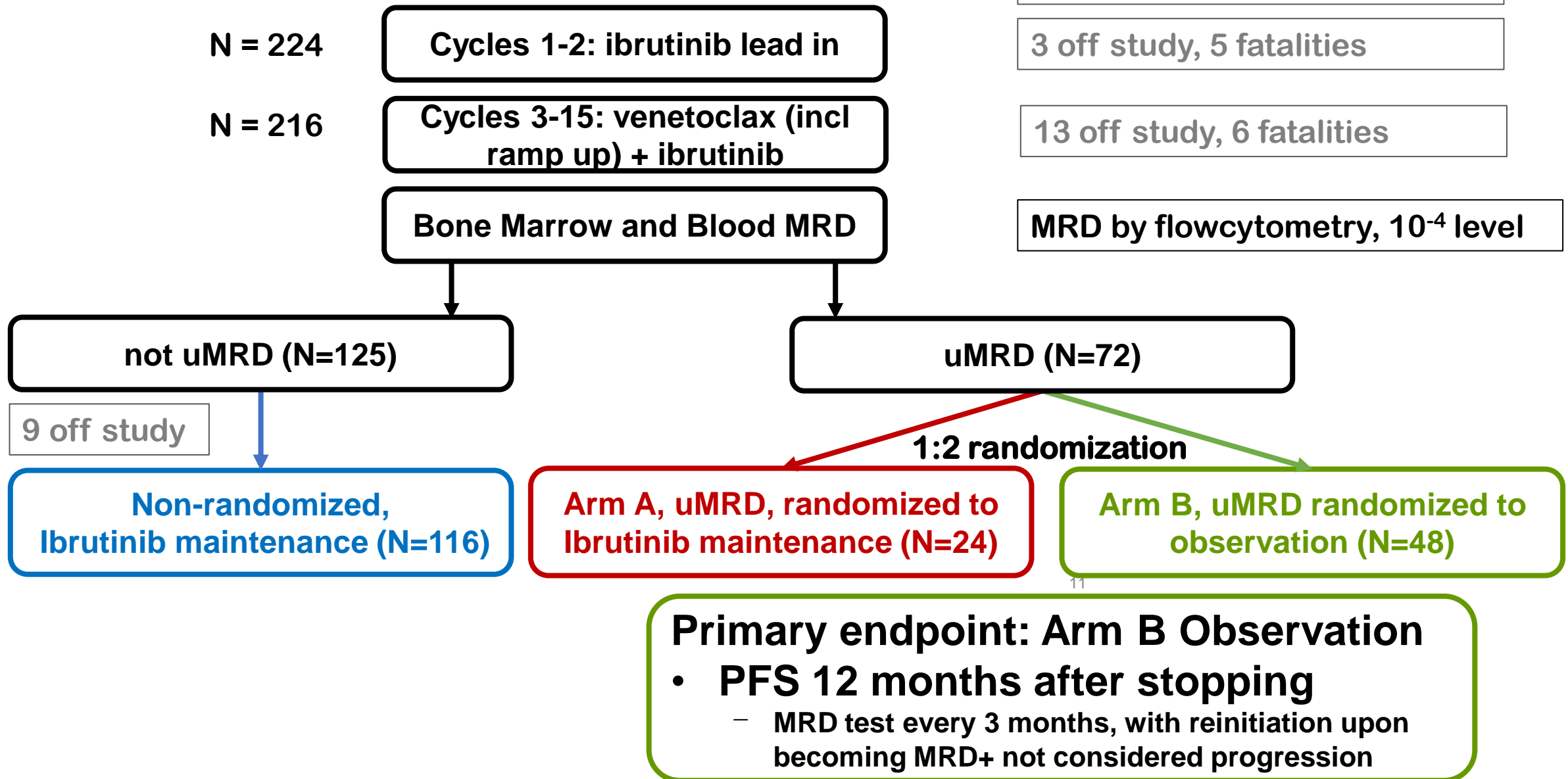
Main Inclusion / Exclusion Criteria:

- Relapsed or Refractory CLL or SLL
- Creatinine clearance ≥ 30 mL/min
- Performance status 0-3, all degrees of fitness / comorbidity allowed
- No prior venetoclax or ibrutinib

Trial organisation:

- 43 sites in the Netherlands, Belgium, Sweden, Norway, Denmark, Finland
- Sponsored by Hovon, funding from Janssen and Abbvie

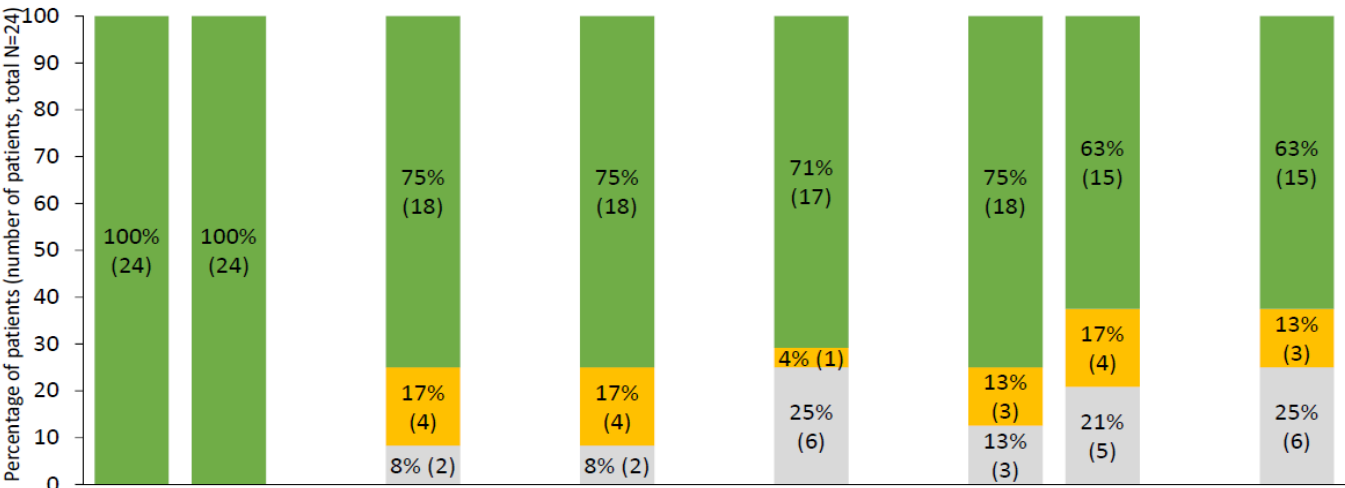
Trial Consort Diagram:



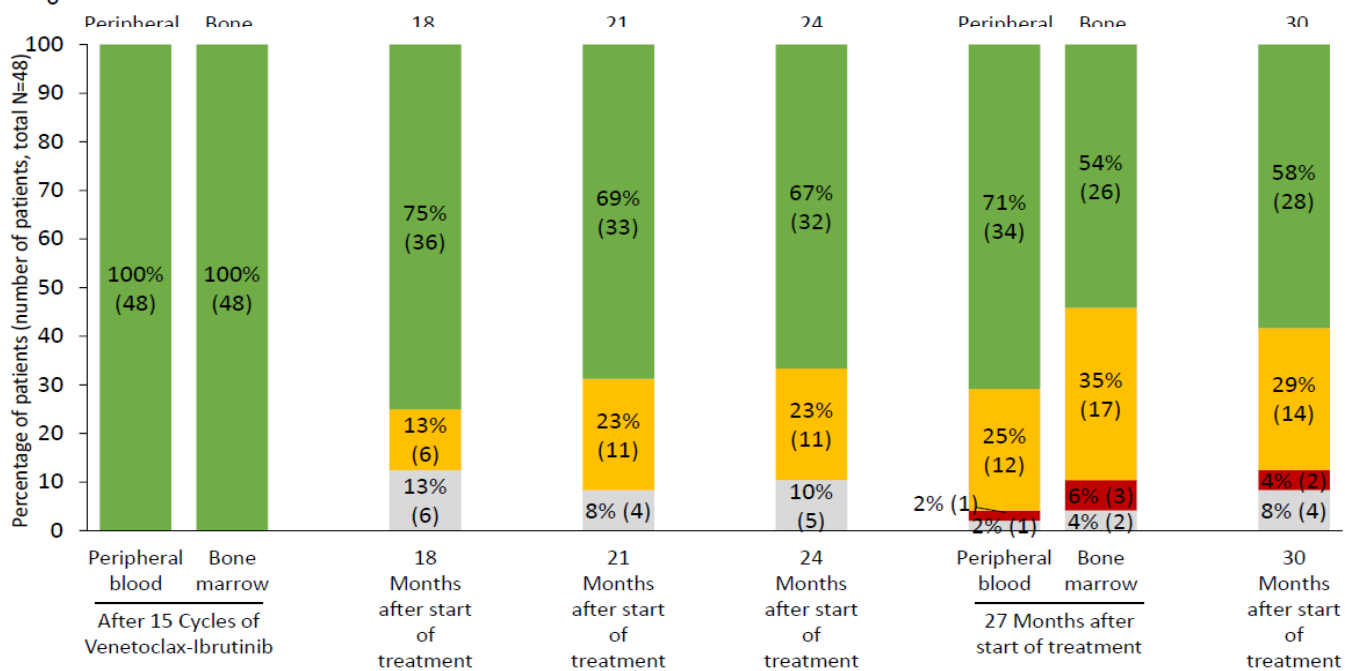
uMRD over time from C15, Arm A: ibrutinib and Arm B: observation:

■ Undetectable MRD ($<10^{-4}$) ■ Low MRD Positive ($\geq 10^{-4}$ and $<10^{-2}$) ■ High MRD Positive ($\geq 10^{-2}$) ■ Not available

Arm A, Ibrutinib
(N=24)

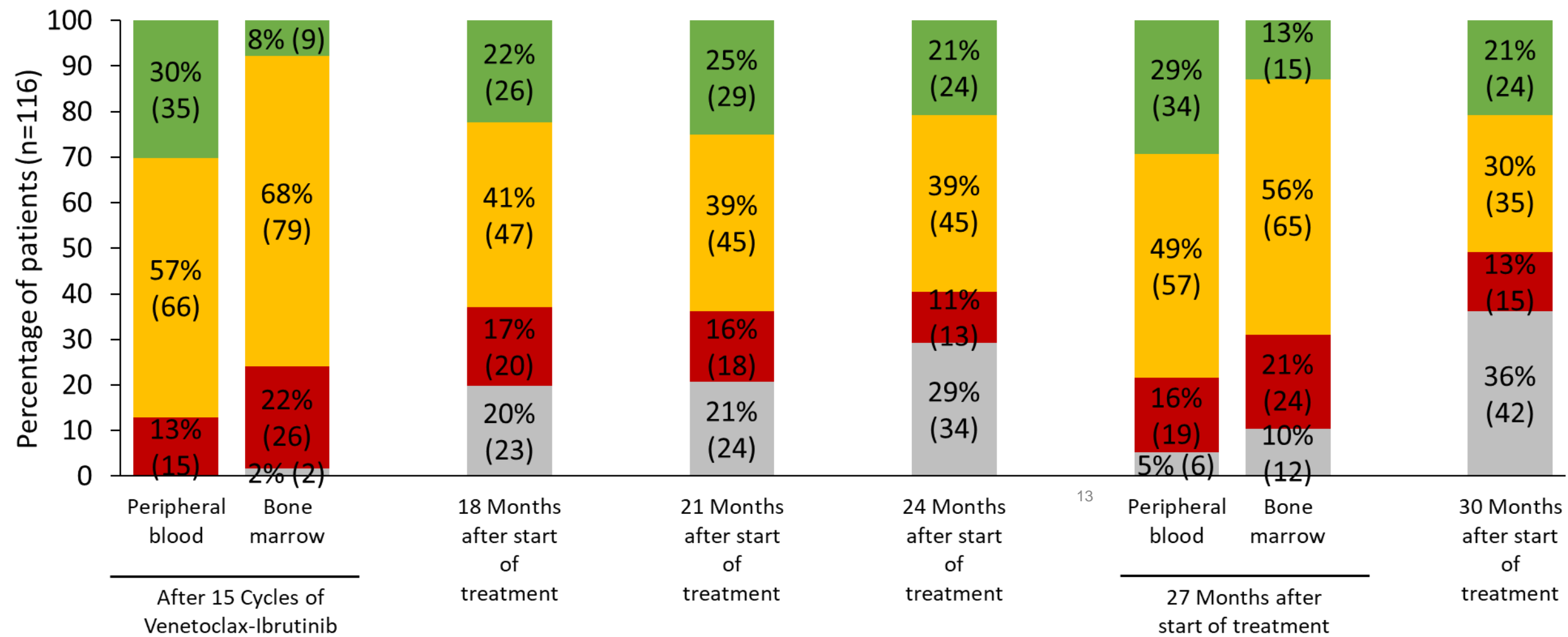


Arm B, Observation
(N=48): Primary Endpoint

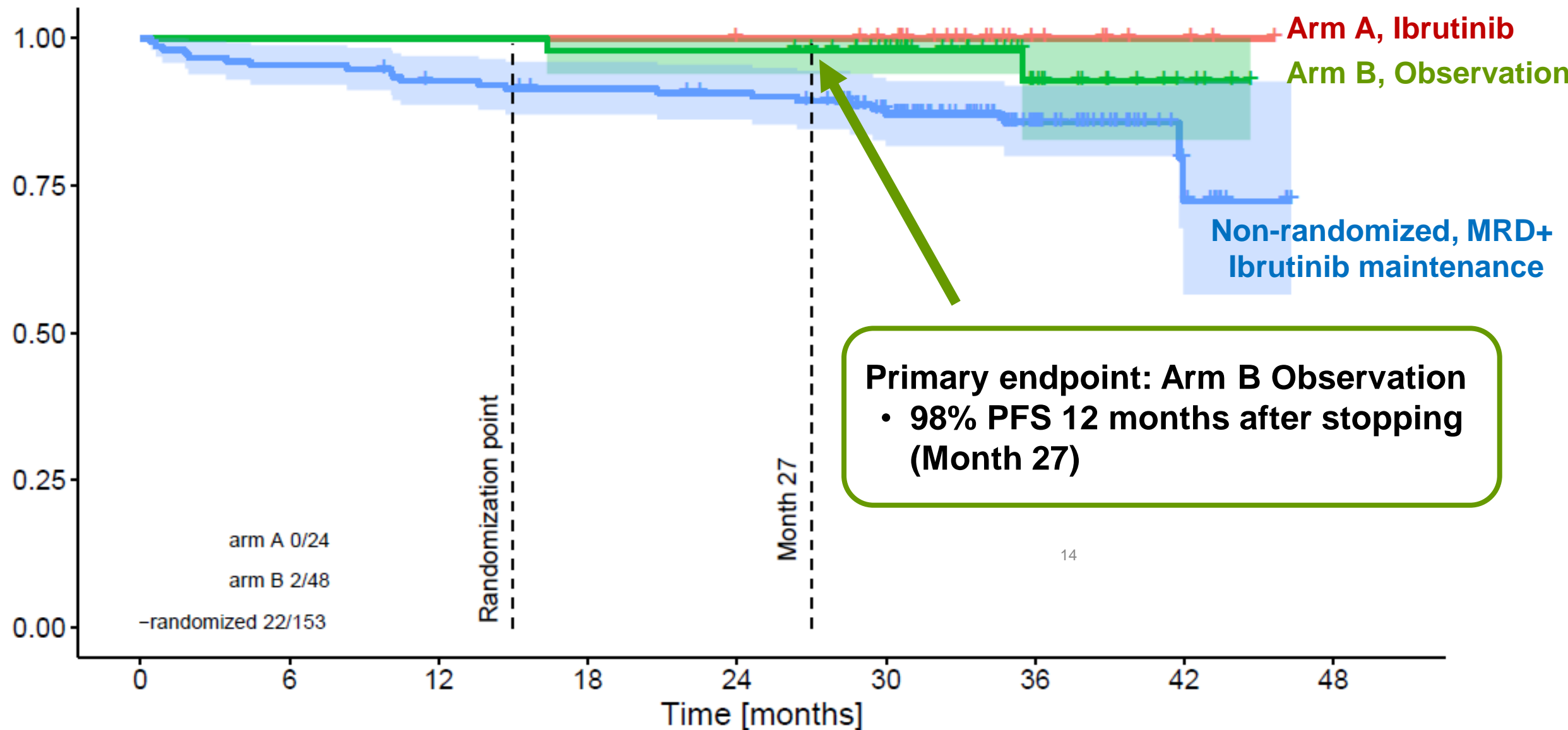


MRD over time from C15, non-randomized, ibrutinib maintenance:

■ Undetectable MRD ($<10^{-4}$) ■ Low MRD Positive ($\geq 10^{-4}$ and $<10^{-2}$) ■ High MRD Positive ($\geq 10^{-2}$) ■ Not available



Progression Free Survival (PFS)



Non-covalent BTK inhibitors

- Pirtobrutinib
- Nemtabrutinib

Non-covalent BTK inhibitors

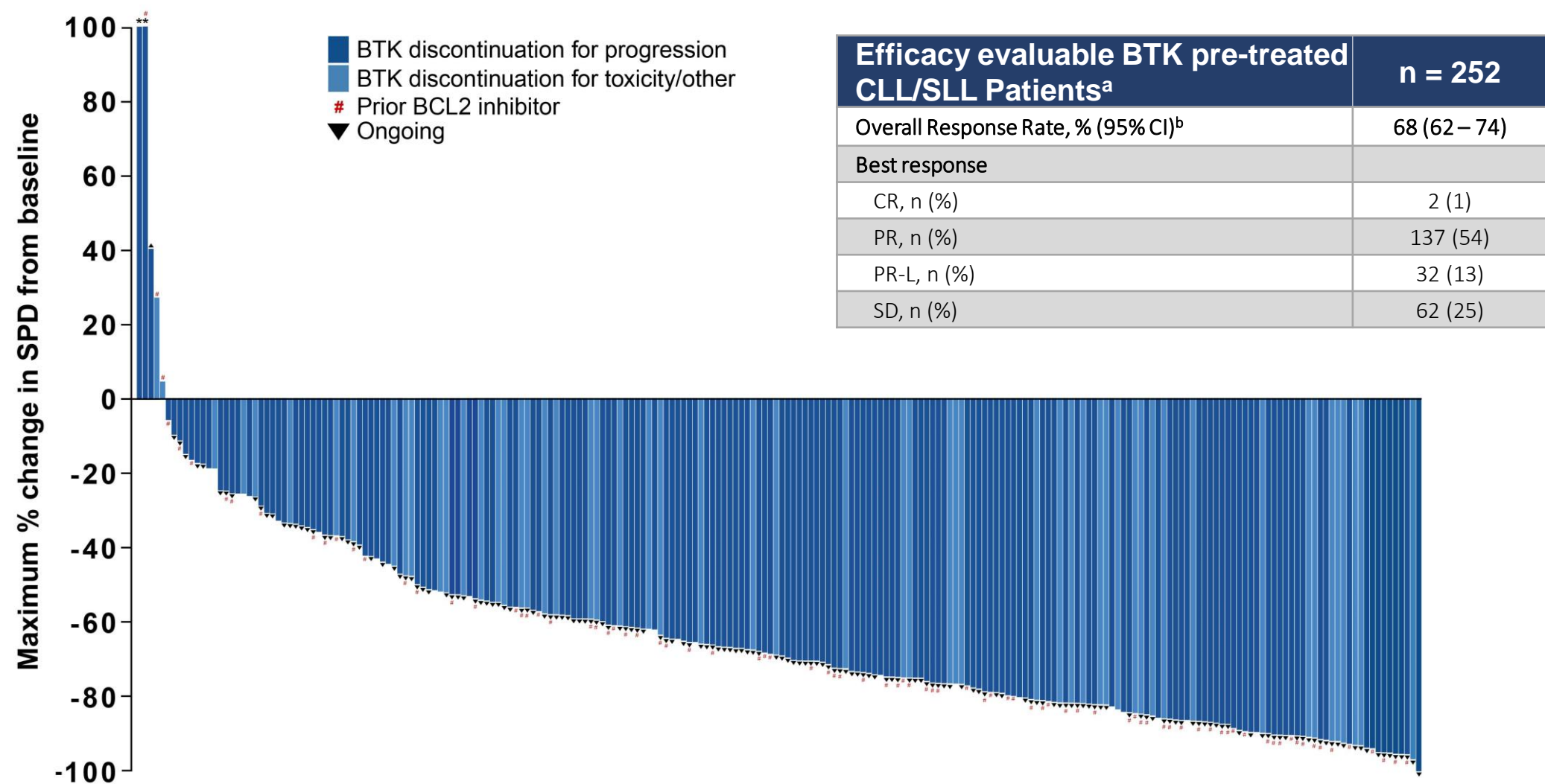
- Pirtobrutinib
- Nemtabrutinib

Pirtobrutinib, A Highly Selective, Non-covalent (Reversible) BTK Inhibitor In Previously Treated CLL/SLL: Updated Results From The Phase 1/2 BRUIN Study

Anthony R. Mato¹, John M. Pagel², Catherine C. Coombs³, Nirav N. Shah⁴, Nicole Lamanna⁵, Talha Munir⁶, Ewa Lech-Maranda⁷, Toby A. Eyre⁸, Jennifer A. Woyach⁹, William G. Wierda¹⁰, Chan Y. Cheah¹¹, Jonathan B. Cohen¹², Lindsey E. Roeker¹, Manish R. Patel¹³, Bita Fakhri¹⁴, Minal A. Barve¹⁵, Constantine S. Tam¹⁶, David J. Lewis¹⁷, James N. Gerson¹⁸, Alvaro J. Alencar¹⁹, Chaitra S. Ujjani²⁰, Ian W. Flinn²¹, Suchitra Sundaram²², Shuo Ma²³, Deepa Jagadeesh²⁴, Joanna M. Rhodes²⁵, Justin Taylor¹⁹, Omar Abdel-Wahab¹, Paolo Ghia²⁶, Stephen J. Schuster¹⁸, Denise Wang²⁷, Binoj Nair²⁷, Edward Zhu²⁷, Donald E. Tsai²⁷, Matthew S. Davids²⁸, Jennifer R. Brown²⁸, Wojciech Jurczak²⁹

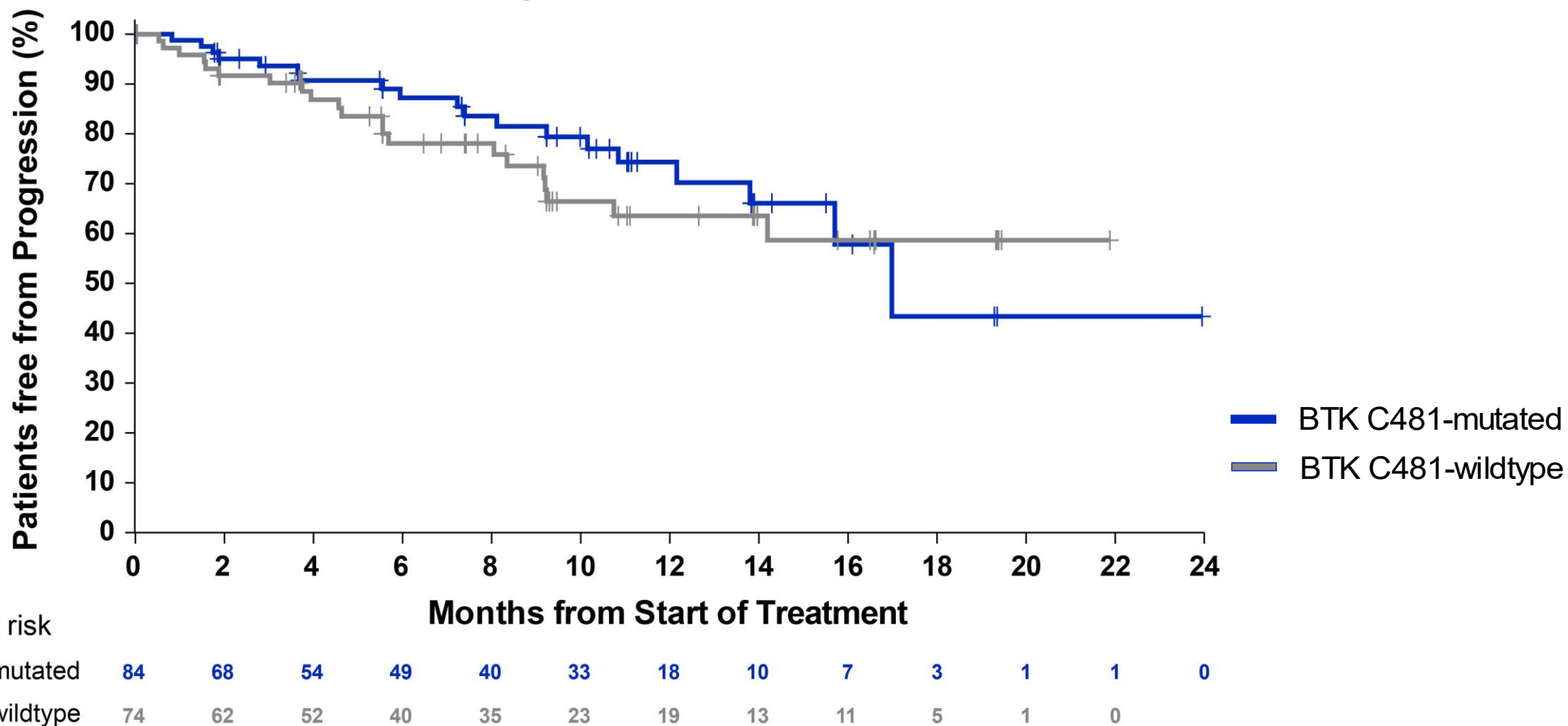
¹Memorial Sloan Kettering Cancer Center, New York, USA; ²Swedish Cancer Institute, Seattle, USA; ³University of North Carolina at Chapel Hill, Chapel Hill, USA; ⁴Medical College of Wisconsin, Milwaukee, USA; ⁵Herbert Irving Comprehensive Cancer Center, Columbia University, New York, USA; ⁶Department of Haematology, St. James's University Hospital, Leeds, UK; ⁷Institute of Hematology and Transfusion Medicine, Warsaw, Poland; ⁸Oxford University Hospitals NHS Foundation Trust, Churchill Cancer Center, Oxford, UK; ⁹The Ohio State University Comprehensive Cancer Center, Columbus, USA; ¹⁰MD Anderson Cancer Center, Houston, USA; ¹¹Linear Clinical Research and Sir Charles Gairdner Hospital, Perth, Australia; ¹²Winship Cancer Institute, Emory University, Atlanta, GA, USA; ¹³Florida Cancer Specialists/Sarah Cannon Research Institute, Sarasota, USA; ¹⁴University of California San Francisco, San Francisco, USA; ¹⁵Mary Crowley Cancer Research, Dallas, USA; ¹⁶Peter MacCallum Cancer Center, Royal Melbourne Hospital, and University of Melbourne, Melbourne, Australia; ¹⁷Plymouth Hospitals NHS Trust - Derriford Hospital, Plymouth, UK; ¹⁸Lymphoma Program, Abramson Cancer Center, University of Pennsylvania, Philadelphia, USA; ¹⁹University of Miami Miller School of Medicine, Miami, USA; ²⁰Fred Hutchinson Cancer Research Center, ²¹Sarah Cannon Research Institute, Nashville, USA; ²²Department of Hematology and Medical Oncology, Tisch Cancer Institute, Icahn School of Medicine at Mount Sinai, New York, NY; ²³Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Chicago, IL, USA; ²⁴Cleveland Clinic, Cleveland, OH, USA; ²⁵Northwell Health Cancer Institute, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell Health, New Hyde Park, NY; ²⁶Università Vita-Salute San Raffaele and IRCCS Ospedale San Raffaele, Milan, Italy; ²⁷Loxo Oncology at Lilly, Stamford, CT, USA; ²⁸Dana-Farber Cancer Institute and Harvard Medical School, Boston, USA; ²⁹Maria Skłodowska-Curie National Research Institute of Oncology, Krakow, Poland

Pirtobrutinib Efficacy in BTK Pre-treated CLL/SLL Patients



BTK C481 Mutation Status is not Predictive of Pirtobrutinib Benefit

Progression-free survival by BTK C481 mutation status^a in CLL/SLL patients with progression on a prior BTK inhibitor



Mato A, et al. ASH 2021 annual meeting

Data cutoff date of 16 July 2021. Response status per iwCLL 2018 according to investigator assessment. ^aBTK C481 mutation status was centrally determined and based on pre-treatment samples.

Pirtobrutinib Safety Profile

	All doses and patients (n=618)							
	Treatment-emergent AEs, (≥15%), %						Treatment-related AEs, %	
Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Any Grade		Grades 3/4	Any Grade
Fatigue	13%	8%	1%	-	23%		1%	9%
Diarrhea	15%	4%	<1%	<1%	19%		<1%	8%
Neutropenia ^a	1%	2%	8%	6%	18%		8%	10%
Contusion	15%	2%	-	-	17%		-	12%
AEs of special interest ^b								
Bruising ^c	20%	2%	-	-	22%		-	15%
Rash ^d	9%	2%	<1%	-	11%		<1%	5%
Arthralgia	8%	3%	<1%	-	11%		-	3%
Hemorrhage ^e	5%	2%	1% ^g	-	8%		<1%	2%
Hypertension	1%	4%	2%	-	7%		<1%	2%
Atrial fibrillation/flutter ^f	-	1%	<1%	<1%	2% ^h		-	<1%

No DLTs reported and MTD not reached

96% of patients received ≥1 pirtobrutinib dose at or above RP2D of 200 mg daily

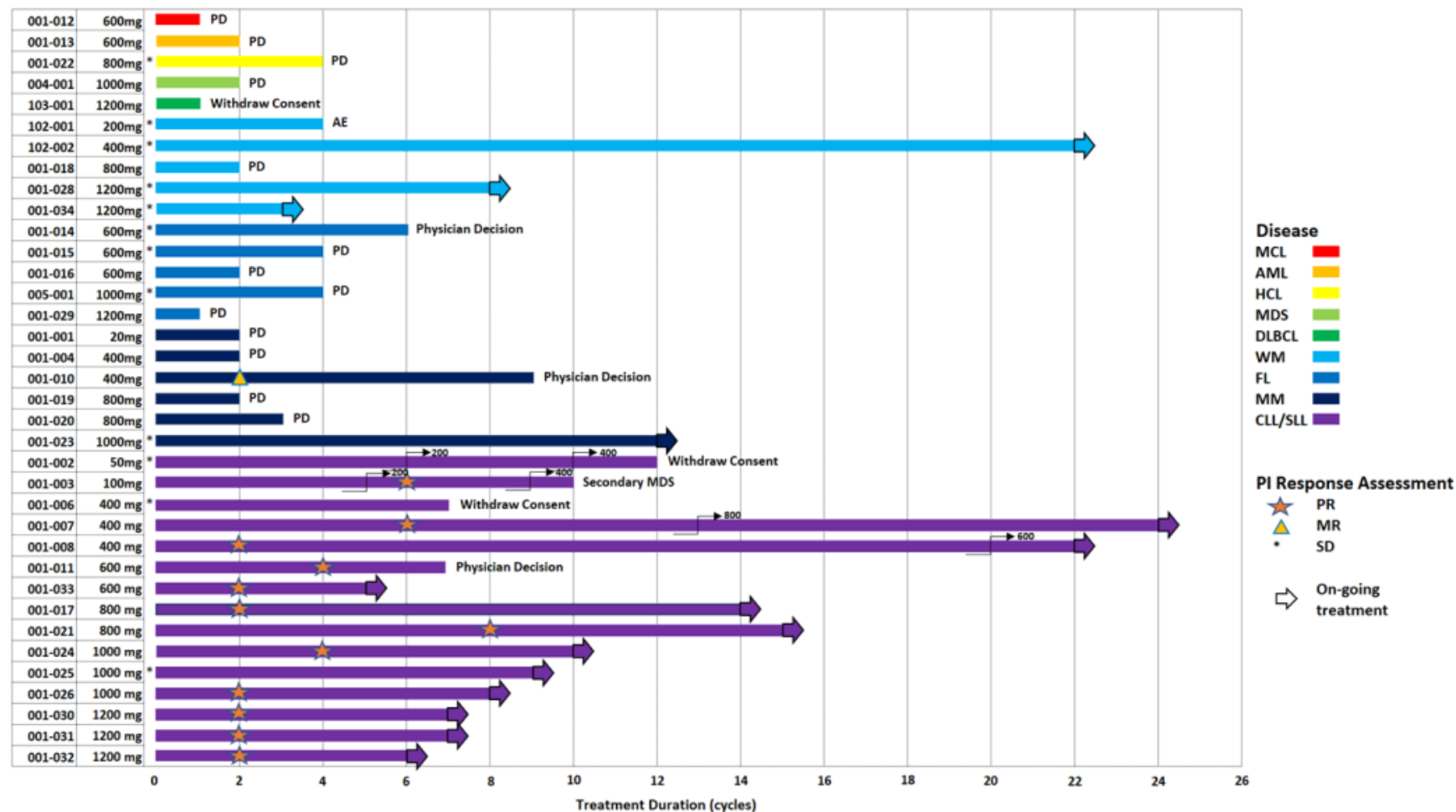
1% (n=6) of patients permanently discontinued due to treatment-related AEs

BTK degraders

- Nurix – trial in progress; first data to be presented at ASH annual meeting 12/2022

Novel BCL2 inhibitors

- Lisoftoclax (CLL trial in progress; first data to be presented at ASH annual meeting 12/2022)
- In an earlier trial, in pts with CLL/SLL (n=15) median of 9 cycles (range 5-24 cycles); 12 achieved partial response (PR) by 2008 iwCLL definition, for an objective response rate (ORR) of 80%; median time to response was 2 cycles (range 2-8 cycles)



Ailawadhi, et al. iwCLL 2021 virtual conference

Novel antibodies

- Tafasitamab (against CD19)
- Cirmtuzumab (against ROR1)
- Ianalumab/VAY-736 (against BAFF-R)
- Mosenutuzumab (against CD3 and CD20)
- Epcoritamab (against CD3 and CD20)

Novel antibodies

- Tafasitamab (against CD19)
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- Mosenutuzumab (against CD3 and CD20)
- Epcoritamab (against CD3 and CD20)

Ianalumab (VAY736) + ibrutinib in R/R CLL

- Included patients who developed ibrutinib resistance/BTK mutation
- High MRD rate with the combination

Figure 1A: Best percentage change from baseline in blood MRD

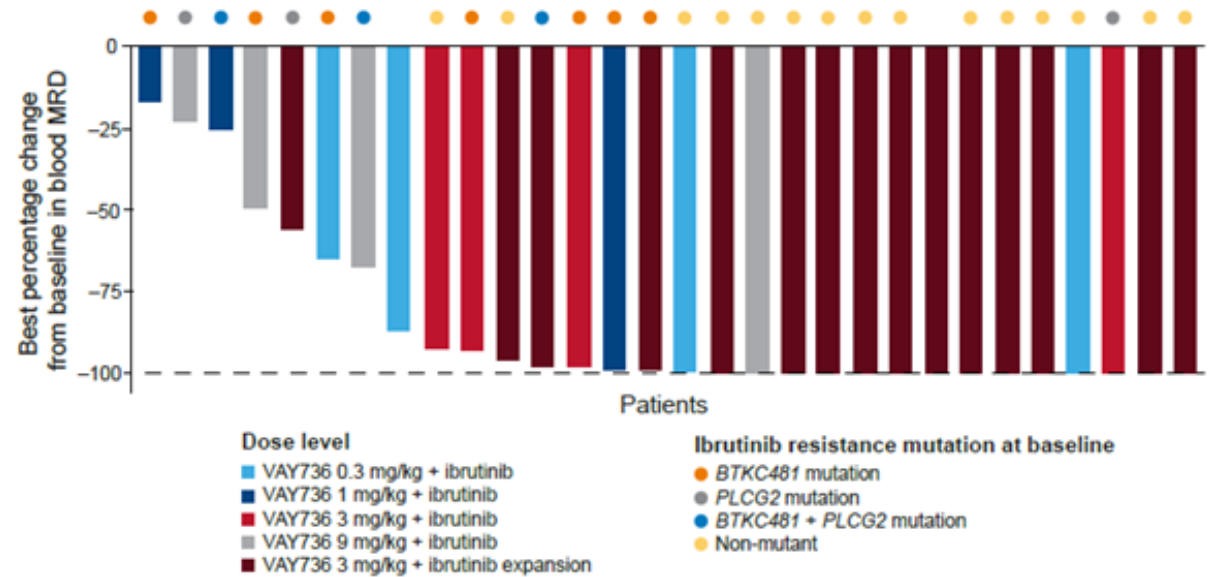
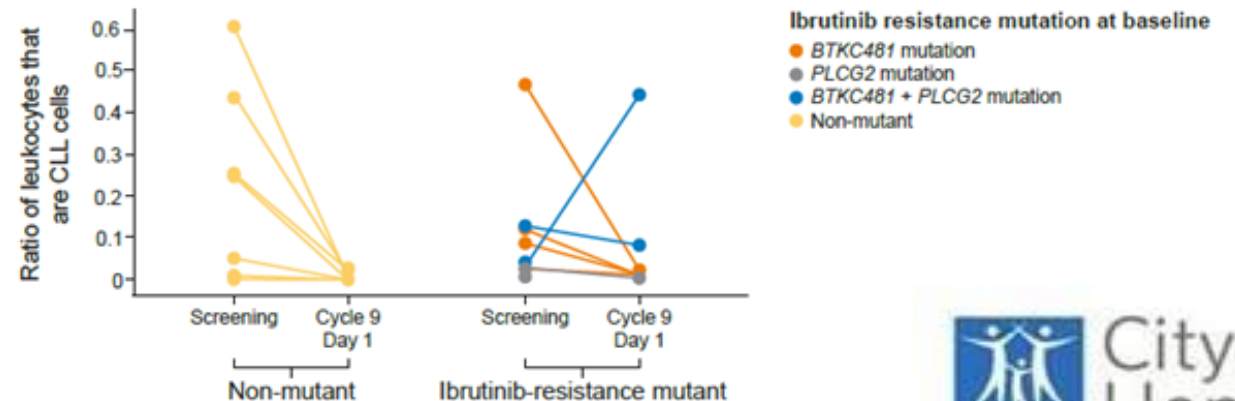


Figure 1B: Change in CLL cells in bone marrow measured by flow cytometry at baseline and C9D1 by ibrutinib resistant mutation status



Subcutaneous Epcoritamab in Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia: Preliminary Results from the EPCORE CLL-1 Trial

Arnon P Kater, MD, PhD¹, Jacob Haaber Christensen, MD, PhD², Hans Herluf Bentzen, MD³, Carsten Utoft Niemann, MD, PhD⁴, Martin Hutchings, MD, PhD⁴, Jenny Chen, MD, PhD⁵, Marcia Rios, MBA⁵, Tammy Palenski, PhD⁶, Tommy Li, PhD⁵, Anthony Mato, MD, MSCE⁷

¹Amsterdam UMC, Cancer Center Amsterdam, University of Amsterdam, Amsterdam, Netherlands; ²Odense University Hospital, Odense, Denmark; ³Aarhus University Hospital, Aarhus, Denmark; ⁴Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark; ⁵Genmab, Princeton, NJ, USA; ⁶AbbVie, North Chicago, IL, USA; ⁷Memorial Sloan Kettering Cancer Center, Chronic Lymphocytic Leukemia Program, New York, NY, USA

Presented at the 63rd American Society of Hematology Annual Meeting and Exposition; December 11–14, 2021; Atlanta, GA, and virtual (Poster number: 2627)

Study Design: EPCORE CLL-1

Open-label, multicenter, phase 1b/2 trial of single-agent epcoritamab in adults with R/R CLL

Key inclusion criteria

- Diagnosis of CLL with evidence of CD20⁺
- Previously treated with ≥2 prior lines of systemic therapy, including treatment with (or intolerance to) a BTK inhibitor
- Measurable disease with ≥5×10⁹/L B lymphocytes *or* measurable lymphadenopathy, *and/or* organomegaly
- ECOG PS 0–2
- Acceptable laboratory parameters

Epcoritamab^a in 4-wk (28-d) cycles

QW C1–3, Q2W C4–9, Q4W C10+ until progression or unacceptable toxicity

Phase 1b: Dose escalation

- 2 full-dose levels
24 mg → 48 mg

Phase 2: Expansion

- 2 arms at RP2D (48 mg)
– Cohort 1: R/R CLL

Primary objectives:
DLT/Safety and tolerability

Key secondary objective:
Antitumor activity^b

Primary objective:
Antitumor activity^b

Data cutoff: October 1, 2021

	BTK inhibitor	11 (100)
Prior treatment, n (%)	Ibrutinib	9 (82)
	Venetoclax	7 (64)
	CAR-T therapy	2 (18)

Patients were heavily pretreated (median of 6 prior lines of therapy), and the majority had poor-risk features of del(17p) and/or *TP53* mutations

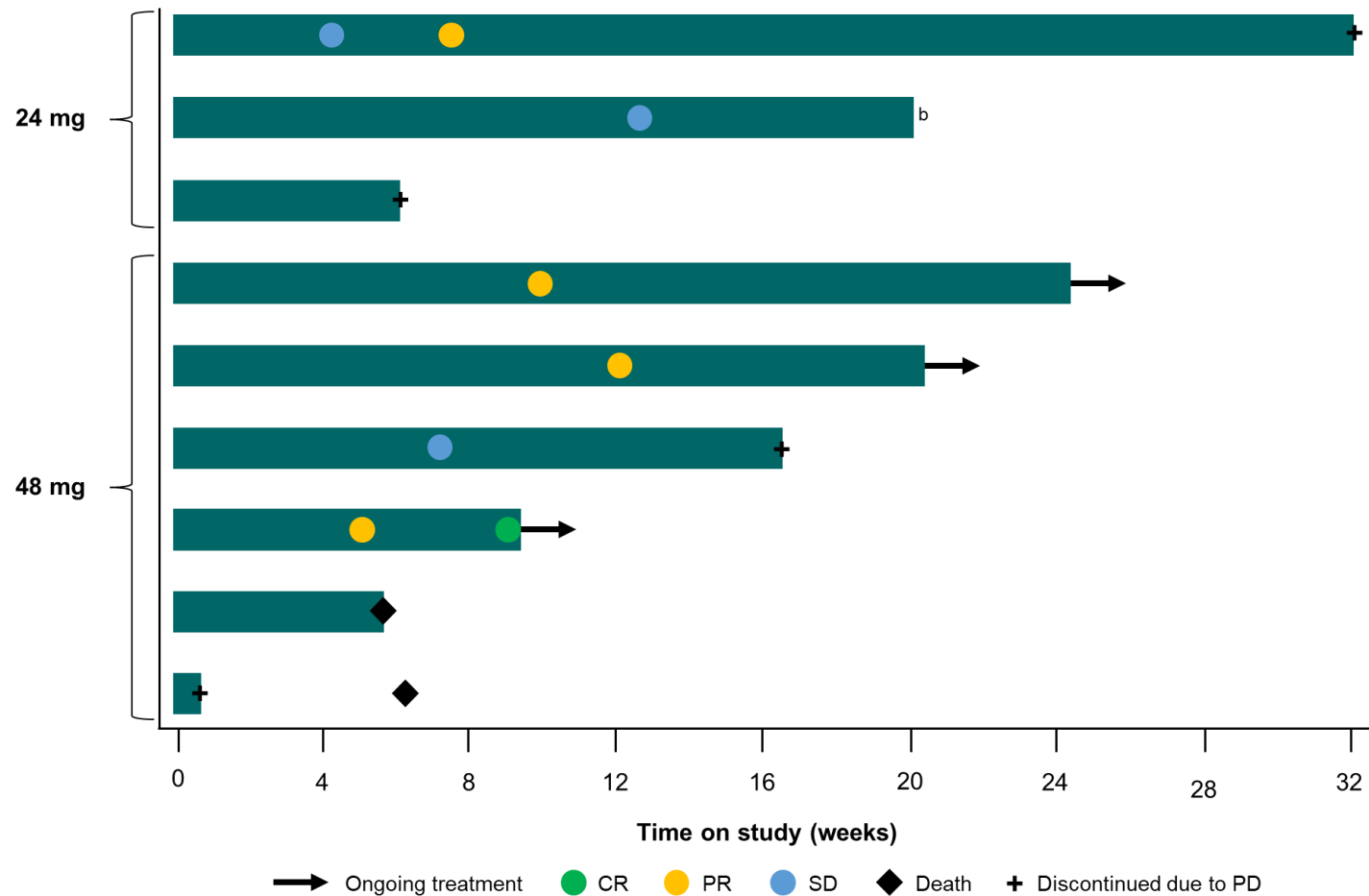
Adverse Events of Special Interest

	Total N=11
CRS, ^a n (%)	8 (73)
Grade 1	2 (18)
Grade 2	6 (55)
CRS leading to dose delay	3 (27)
Median time to onset, d (range)	9 (2–23)

Data cutoff: October 1, 2021. ^aCRS graded by Lee et al¹ criteria.

- CRS events occurred early in treatment and resolved
- No patient discontinued epcoritamab due to CRS
- No cases of ICANS or tumor lysis syndrome were observed

Response-Evaluable Population^a (n=9)



- Responses were observed in 4 patients, including 1 CR and 3 PRs
- Responders had high-risk disease; 3 of 4 responders had *TP53* aberrations

Data cutoff: October 1, 2021. ^aThe response-evaluable population includes patients who had evaluable disease at baseline and ≥ 1 postbaseline response evaluation or died within 60 d of first dose. ^bPatient discontinued due to physician decision.

Cellular therapeutics

- CAR-T cells (against CD19 or ROR1)
- NK-CARs

Cellular therapeutics

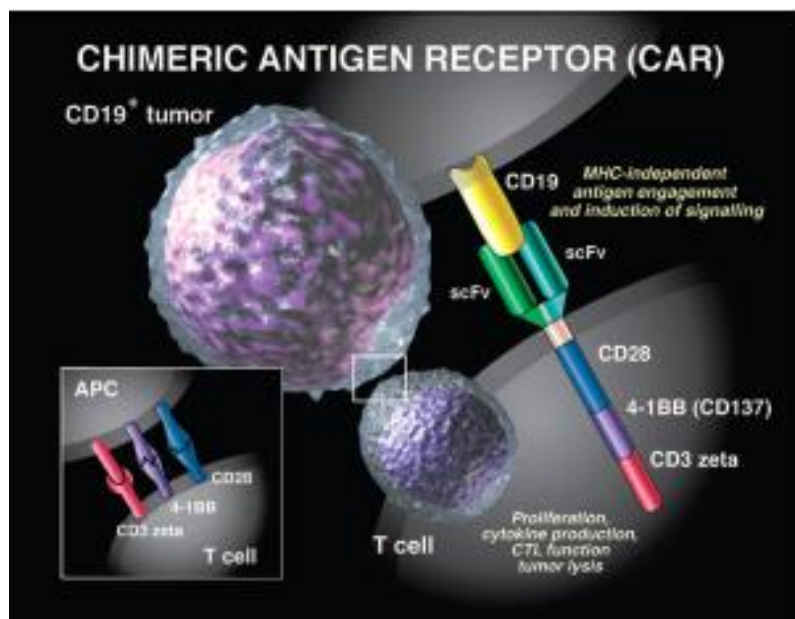
- CAR-T cells (against CD19 or ROR1)
- NK-CARs

Long-Term Remission of CLL

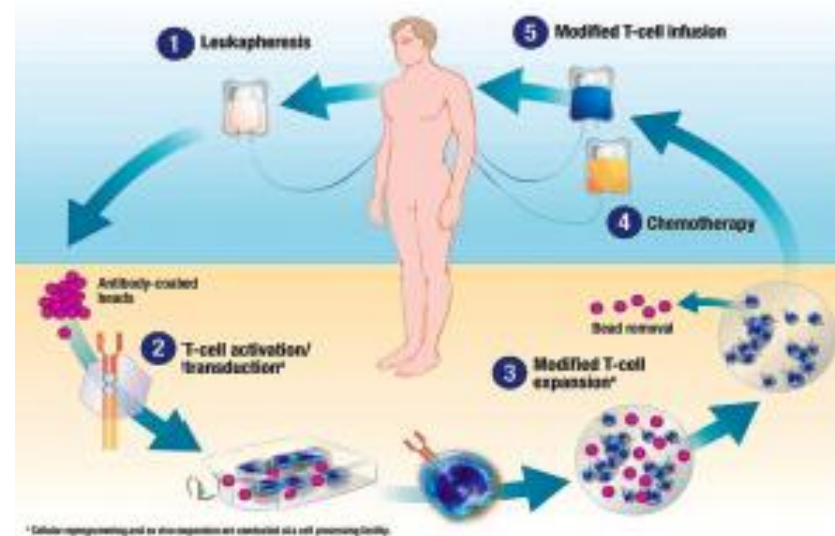
- 2 advanced, chemotherapy-resistant CLL patients with the longest (10+ years) follow-up on any trial of CART19 cells
- Both patients had received five therapies before being treated at the University of Pennsylvania with autologous CART19 cells (tisagenlecleucel) cells in 2010
- Both patients have persistence of CAR-engineered T cells and both patients are still in remission as determined by flow cytometry and deep sequencing of IgH rearrangements for over 10 years

Melenhorst JJ, et al. Nature 2022; 602: 503-9

CD19 Specific CAR-T Cells



Overview of CTL019 Therapy



- N = 14; median prior rx = 5 [1-11]; median cell dose = 1.6×10^8 cells
- 4 CRs (29%), 4 (29%) PRs, ORR 57%
- CAR-T cells detectable 4 yrs later in some
- Expected toxicities: B cell aplasia, delayed TLS and cytokine release syndrome
- MRD undetectable in CR pts

Porter D, et al. Blood 2013; ASH abs. 4162

Porter D, et al. Blood 2013; ASH abs. 873

Porter D, et al. Sci Transl Med 2015; 7(303):303ra139.

doi: 10.1126/scitranslmed.aac5415

CAR-T cells with concurrent ibrutinib after ibrutinib failure

- Pilot cohort of JCAR014 with concurrent ibrutinib on a Ph1/2 study
- R/R CLL pts; med age 65 [56-69] yrs; med prior rx = 5 [4-7]
- N = 19; 89% (17/19) with high risk cytogenetics
- Ibrutinib began ≥ 2 weeks prior to leuk and continued for ≥ 3 months after JCAR014
- 2×10^6 CD19 CAR-T cells/kg
- Flu/Cy lymphodepletion
- Ibrutinib effects:
 - Mobilize lymphocytes
 - Improve CAR-T cell function
 - Decrease CRS
 - Prevent tumor flare

CAR-T cells with ibrutinib

- Well tolerated; 13 patients (68%) received ibrutinib as planned without dose reduction
- 1 sudden death from probably cardiac arrhythmia in the setting of gr2 CRS not requiring vasopressors
- 4-week ORR was 83% (15/18); 61% achieved MRD-negative marrow response by *IGH* sequencing (13/18)
- In this subset, the 1-year OS and PFS probabilities were 86% and 59%, respectively
- JCAR014 plus ibrutinib led to lower CRS severity and lower serum concentrations of CRS-associated cytokines despite equivalent in vivo CAR-T cell expansion

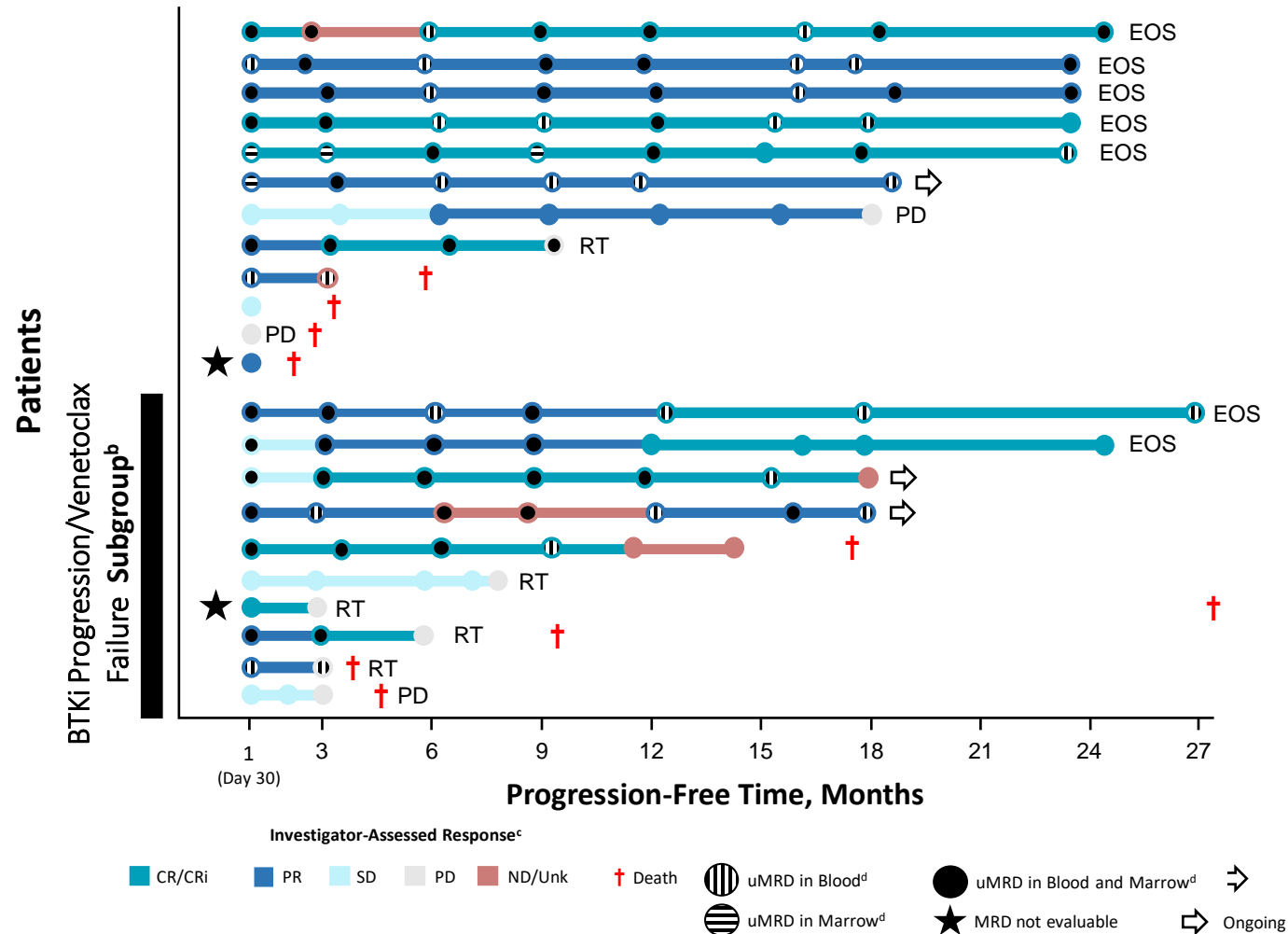
Updated Follow-Up of Patients with Relapsed/Refractory CLL/SLL Treated with Lisocabtagene Maraleucel in the Phase 1 Monotherapy Cohort of TRANSCEND CLL 004, Including High-Risk and Ibrutinib-Treated Patients

Tanya Siddiqi,¹ Jacob D. Soumerai,² Kathleen A. Dorritie,³ Deborah M. Stephens,⁴
Peter A. Riedell,⁵ Jon Arnason,⁶ Thomas J. Kipps,⁷ Heidi H. Gillenwater,⁸ Lucy Gong,⁸ Lin Yang,⁸ Ken Ogasawara,⁹
William G. Wierda¹⁰

¹City of Hope National Medical Center, Duarte, CA, USA; ²Center for Lymphoma, Massachusetts General Hospital Cancer Center, Boston, MA, USA; ³UPMC Hillman Cancer Center, University of Pittsburgh, Pittsburgh, PA, USA; ⁴Huntsman Cancer Institute, University of Utah, Salt Lake City, UT, USA; ⁵University of Chicago Medical Center, Chicago, IL, USA; ⁶Beth Israel Deaconess Medical Center, Boston, MA, USA; ⁷Moore's Cancer Center, University of California San Diego Health, San Diego, CA, USA; ⁸Bristol Myers Squibb, Seattle, WA, USA; ⁹Bristol Myers Squibb, Princeton, NJ, USA; ¹⁰The University of Texas MD Anderson Cancer Center, Houston, TX, USA

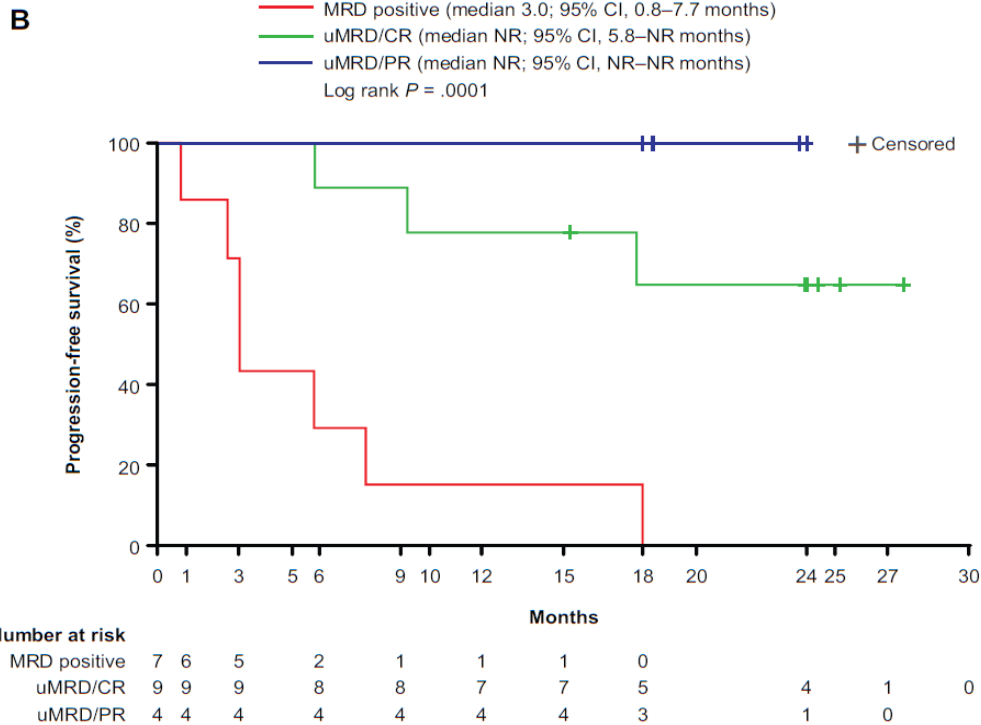
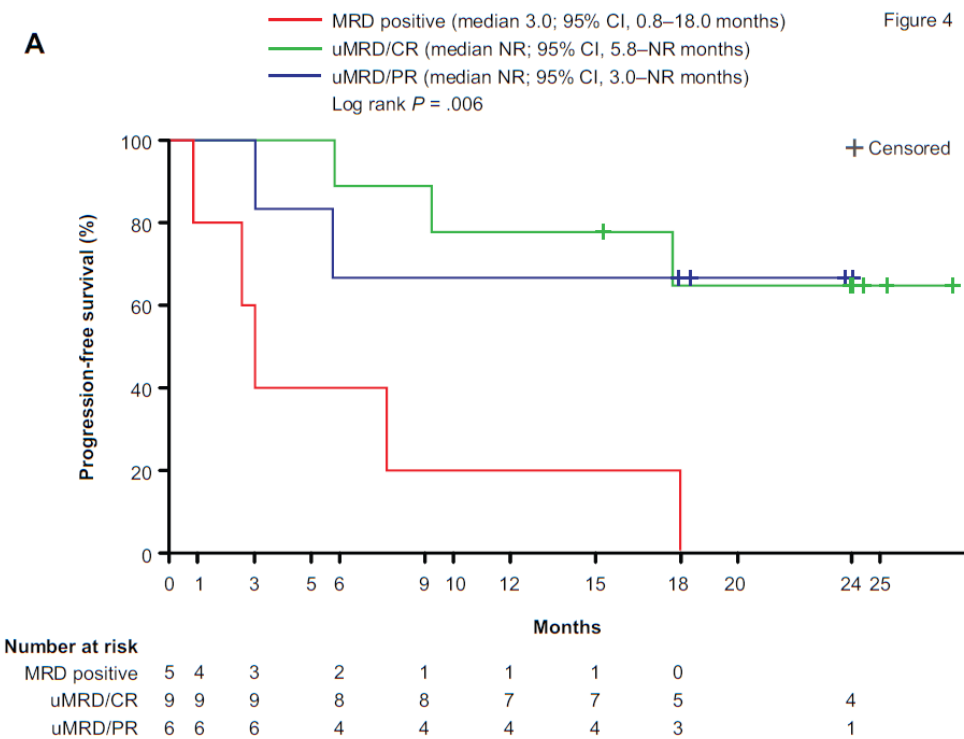
Virtual ASH annual meeting 2020: Presentation 546

Patient Responses at 24-Month Median Follow-Up

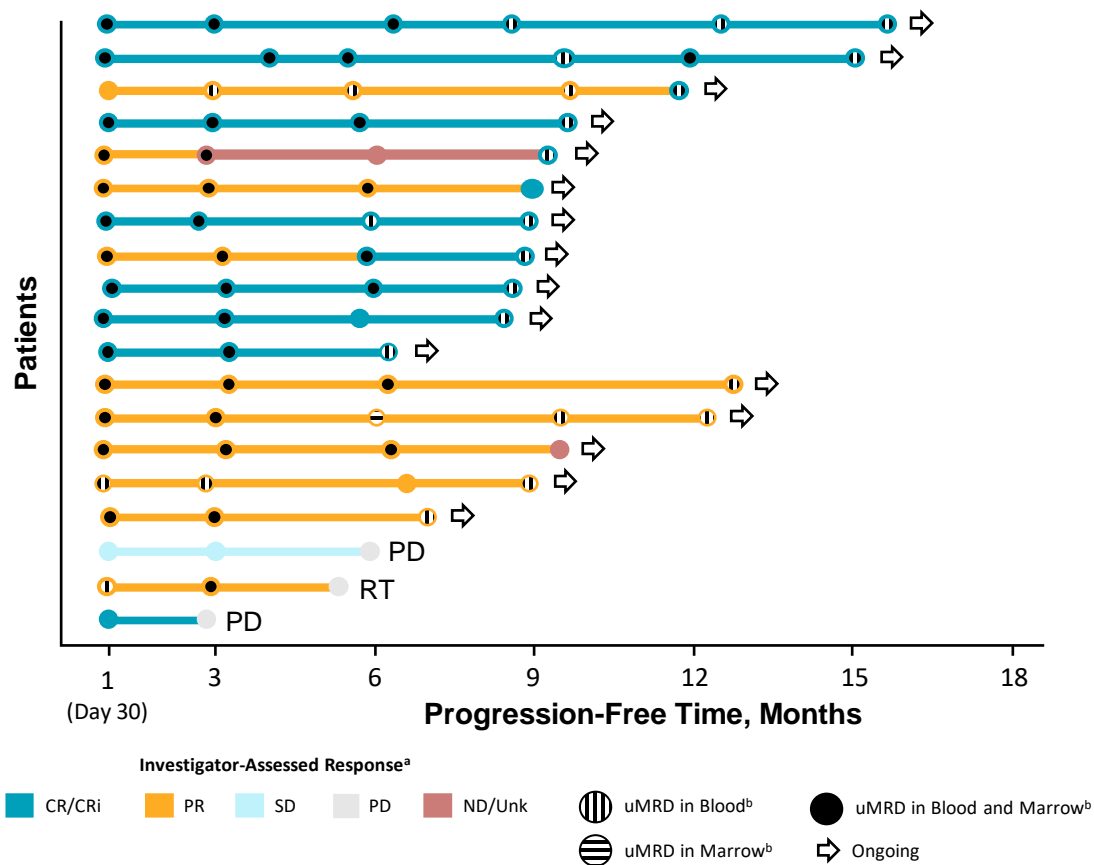


- ORR was 82% (CR/CRi, 46%; PR, 36%), with 68% (n = 15/22)^a of patients achieving a rapid response within 30 days
- 27% (n = 6/22) of patients had a deepening of response
- Response was durable. At 12 months, 50% (n = 11/22) were in response and only 2 of these responders progressed beyond 12 months
- The subgroup also demonstrated rapid and durable responses
- Four of the 15 patients with uMRD (blood) response (CR or PR) have progressed, with 3 due to Richter transformation (RT)
- Four of 6 progression events in the subgroup were due to RT

Duration of Response and PFS at 24-Month Median Follow-Up

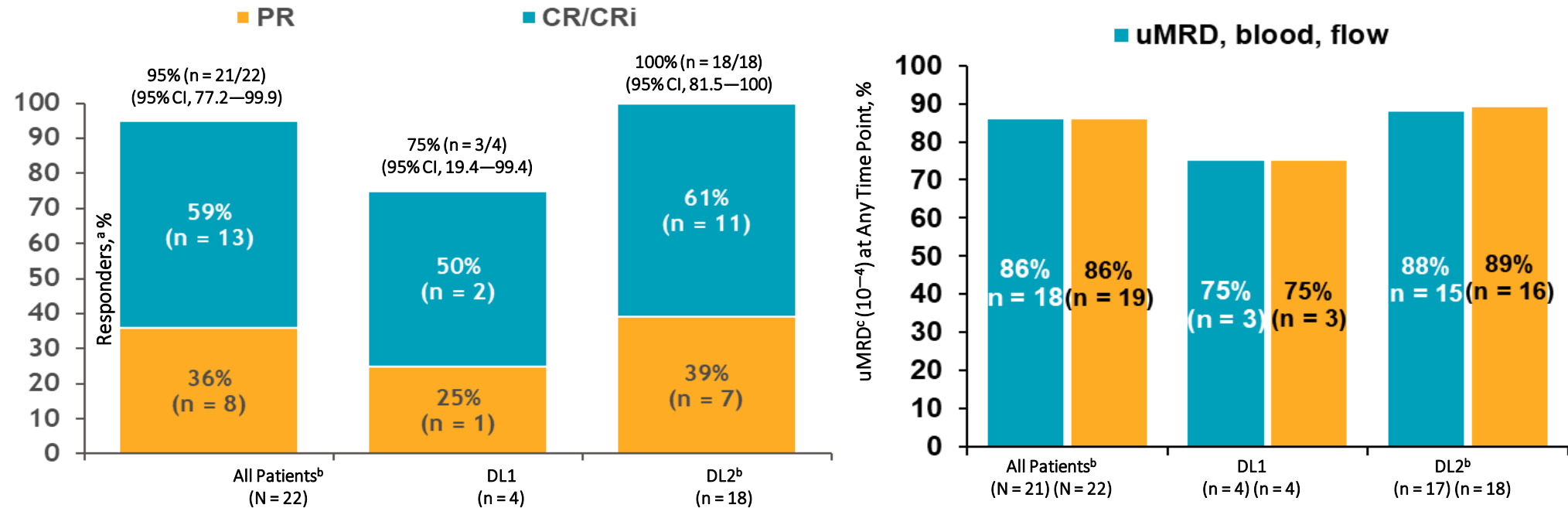


Patient Responses at 10-month median followup – liso-cel + ibrutinib cohort



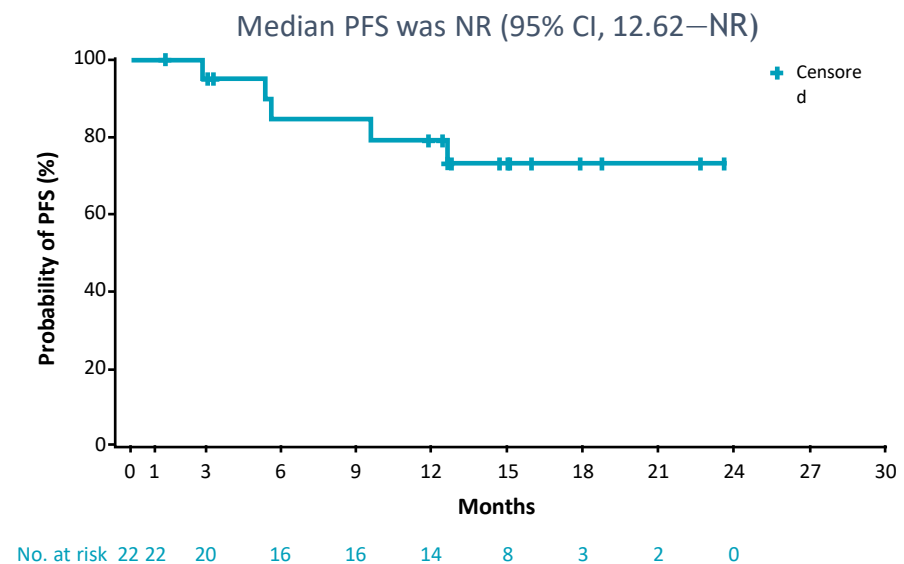
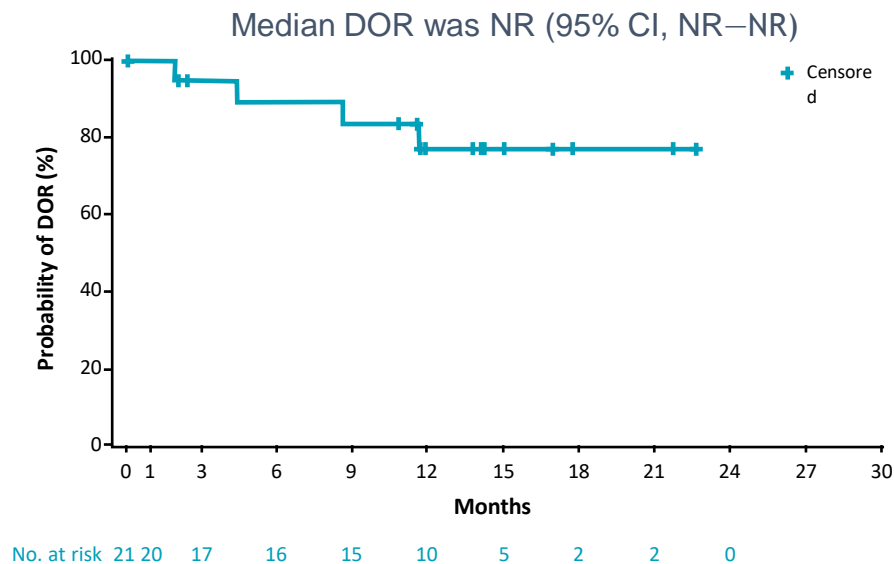
- All responders (n = 18/19) achieved a response by Day 30 after liso-cel
- Among 18 patients with ≥6 months of follow-up, 89% (n = 16/18) maintained or improved response from Day 30
- Of 17 patients who achieved uMRD in blood:
 - All achieved this response by Day 30
 - Only 1 later progressed due to Richter transformation (RT)

Best Objective Response by iwCLL and uMRD ($<10^{-4}$) – liso-cel + ibrutinib cohort



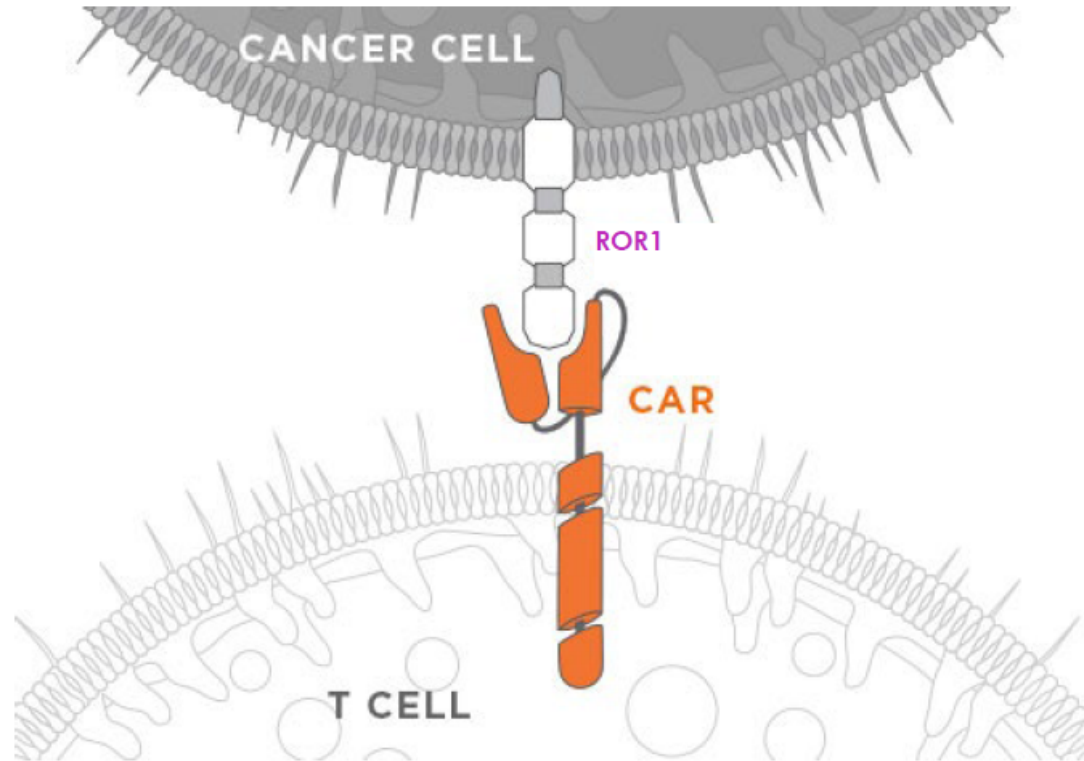
- No patients had PD during the first month after liso-cel
- One patient at DL1 had SD for 6 months but later progressed

Progression-Free Survival and Duration of Response at 17-month median followup – liso-cel + ibrutinib cohort



ROR1 CAR T

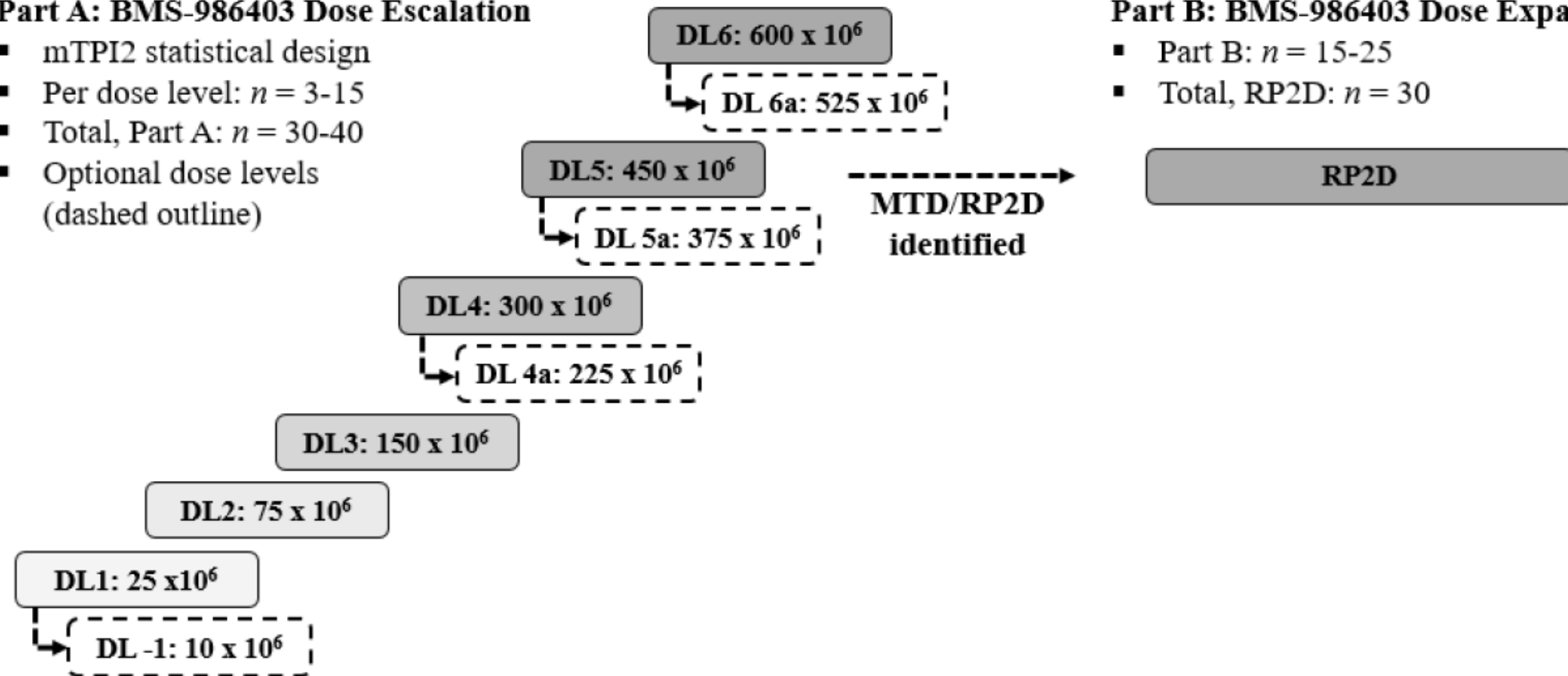
- BMS-986403 is an investigational ROR1-targeted CAR T cell product.
- ROR1 CAR T cell generation and initial preclinical testing of BMS-986403 reveals comparable cytotoxicity, proliferation and cytokine production to CD19 CAR T cells in primary CLL PBMCs
- BMS-986403 shows enhanced anti-tumor activity and survival in ROR1 expressing MCL cell line in vivo (JeKo-1)
- Autologous T cells are collected from subjects by leukapheresis, engineered to express the anti-ROR1 CAR via viral vector transduction, and administered to the subject by intravenous infusion to therapeutically target the tumor-specific antigen ROR1



Study Design/Schematic

Part A: BMS-986403 Dose Escalation

- mTPI2 statistical design
- Per dose level: $n = 3-15$
- Total, Part A: $n = 30-40$
- Optional dose levels (dashed outline)



Part B: BMS-986403 Dose Expansion

- Part B: $n = 15-25$
- Total, RP2D: $n = 30$

RP2D

DL = dose level; mTPI-2 = the modified toxicity probability interval method 2; n = number of subjects; MTD = maximum tolerated dose; RP2D = recommended Phase 2 dose. For Part B, total $n=30$ results from total number treated at the RP2D in Part A ($n=5-15$) plus those treated in Part B (15-25)

City of Hope: trials for CLL

- APG2575CU101 Therapeutic Single Agent or in Combination Study in Patients with R/R CLL/SLL [\[novel BCL2 inhibitor\]](#)
- A Phase 1 Study of Oral LOXO-338, a Selective BCL-2 Inhibitor, in Patients with Advanced Hematologic Malignancies [\[novel BCL2 inhibitor\]](#)
- S1925 - Randomized, Phase III Study of Venetoclax + Obinutuzumab in Pts. with CLL/SLL [\[early treatment vs. watch and wait\]](#)
- BMS-986403 in Subjects with Relapsed and/or Refractory CLL or SLL [\[ROR1 CAR T cells\]](#)
- Acalabrutinib for the treatment of relapsed/refractory autoimmune hemolytic anemia [\[BTK inhibitor\]](#)
- NX-2127-001: NX-2127, a BTK Degradar, in Adults with R/R B-cell Malignancies [\[BTK degrader\]](#)
- AZD4573 in Novel Combinations with Anti-cancer Agents in Patients with Advanced Haematological Malignancies [\[CDK9 inhibitor\]](#)
- A Phase 2 study with a safety lead-in of the anti-CD19 antibody tafasitamab with the BTK inhibitor zanubrutinib in newly diagnosed chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) - TaZa CLL Study [\[coming soon\]](#)
- Subcutaneous epcoritamab in CLL [\[coming soon\]](#)

Thank you for your attention!

