Summer Oncology Nursing Series

A Complimentary NCPD-Accredited Virtual Curriculum

Chronic Lymphocytic Leukemia: Session 1

Thursday, June 10, 2021
5:00 PM – 6:00 PM ET

Faculty

Jennifer Woyach, MD
Kristen E Battiato, AGNP-C

Moderator

Neil Love, MD

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Chronic Lymphocytic Leukemia Faculty

Jennifer Woyach, MD
Professor
Division of Hematology
Department of Internal Medicine
The Ohio State University Comprehensive Cancer Center
Columbus, Ohio

Kristen E Battiato, AGNP-C
Advanced Practice Providers
Memorial Sloan Kettering Cancer Center
New York, New York

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Commercial Support

This activity is supported by educational grants from AstraZeneca Pharmaceuticals LP, Genentech, a member of the Roche Group, and Pharmacyclics LLC, an AbbVie Company and Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC.

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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, Adaptive Biotechnologies Corporation, Agios Pharmaceuticals Inc, Alexion Pharmaceuticals, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, BeiGene Ltd, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Daiichi Sankyo Inc, Eisai Inc, Epizyme Inc, Exact Sciences Inc, Exelixis Inc, Five Prime Therapeutics Inc, Foundation Medicine, Genentech, a member of the Roche Group, Gilead Sciences Inc, GlaxoSmithKline, Grail Inc, Halozyme Inc, Helsinn Healthcare SA, 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, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, Merck, Novartis, Novocure Inc, Oncopeptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sanofi Genzyme, Seagen Inc, Sumitomo Dainippon Pharma Oncology Inc, Taiho Oncology Inc, Takeda Oncology, Tesaro, A GSK Company, TG Therapeutics Inc, Turning Point Therapeutics Inc and Verastem Inc.

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Dr Woyach — Disclosures

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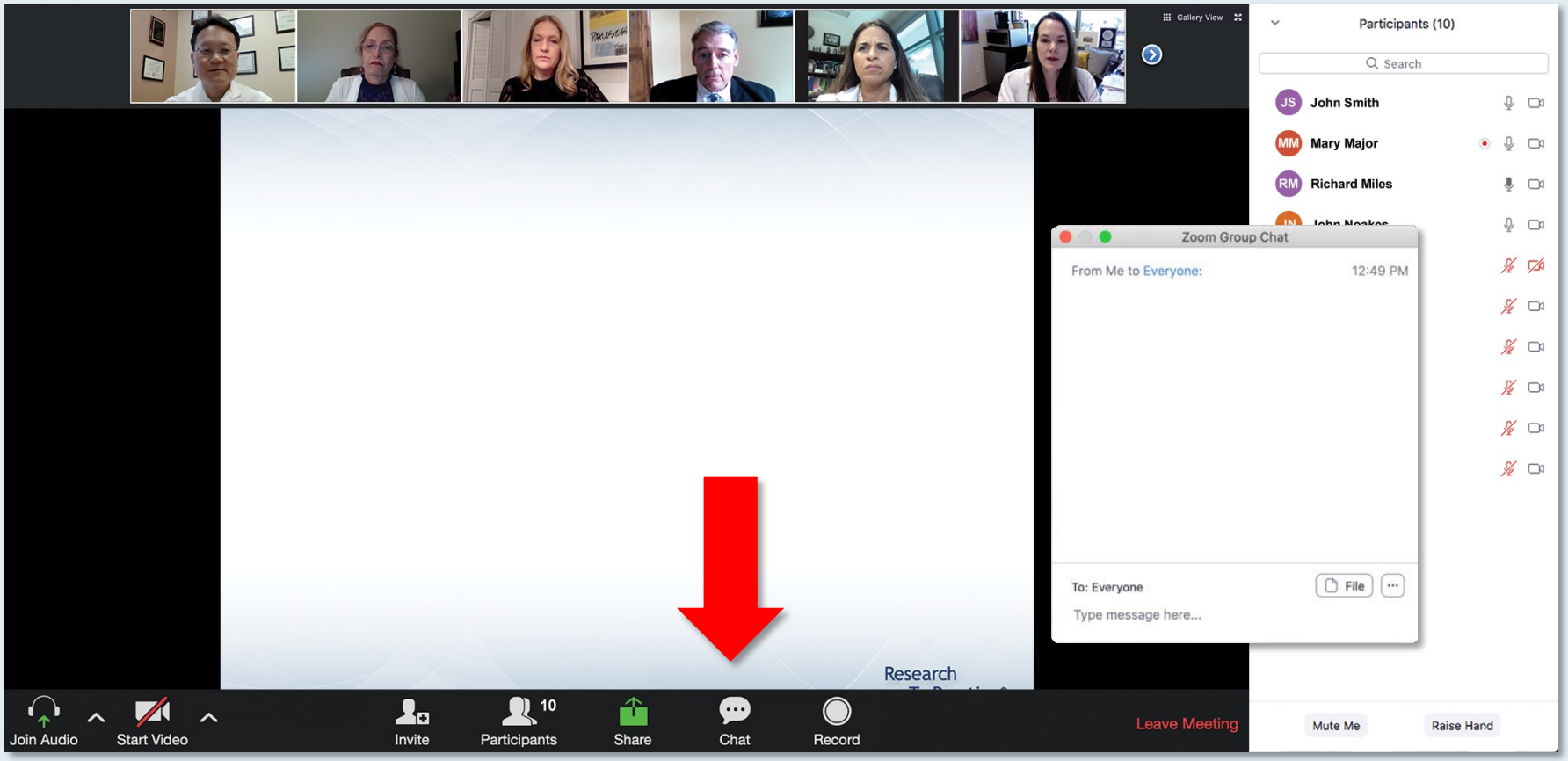
Ms Battiato — Disclosures

No relevant conflicts of interest to disclose.

We Encourage Clinicians in Practice to Submit Questions



Feel free to submit questions now before the program begins and throughout the program.

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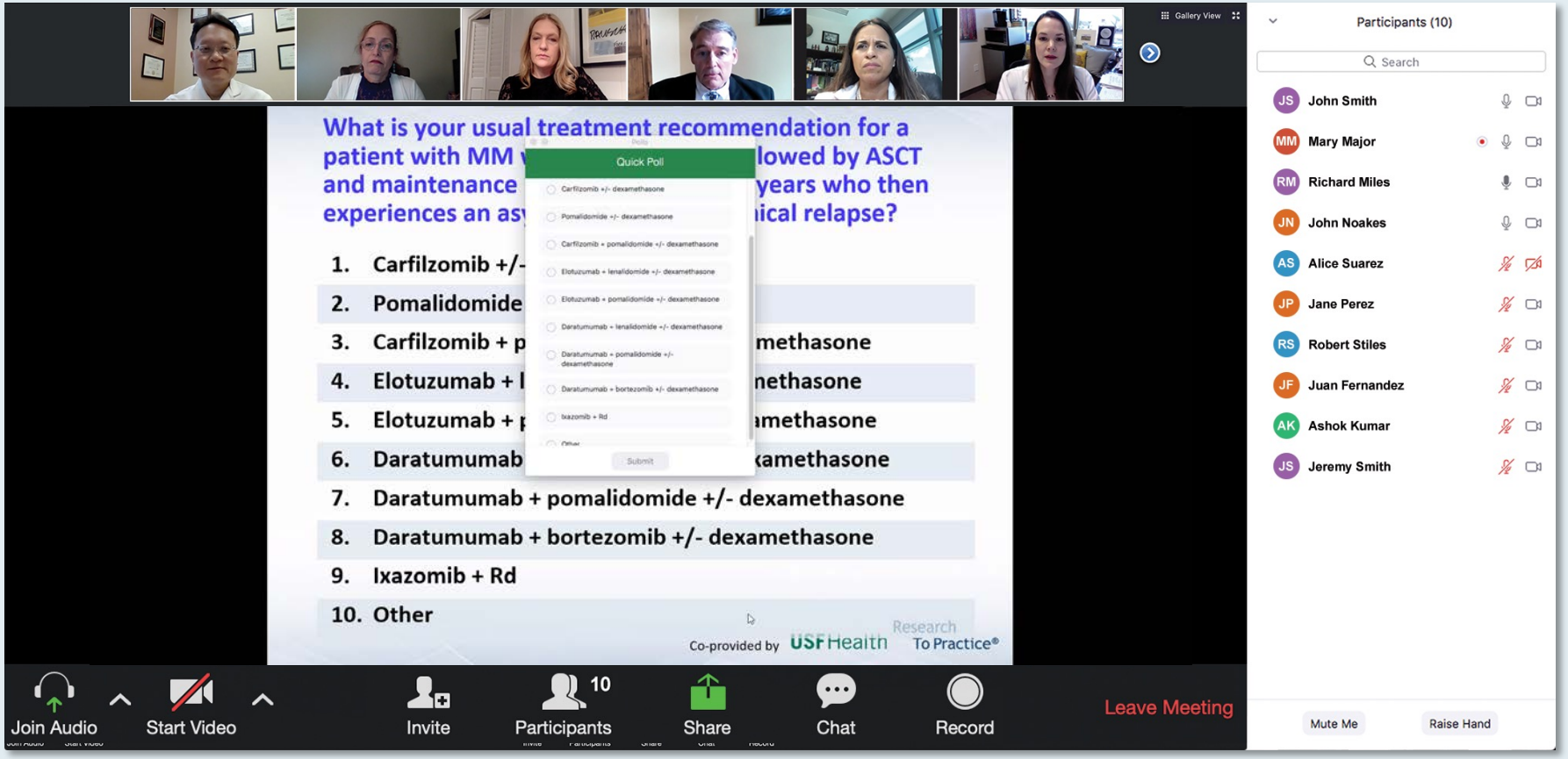
Familiarizing Yourself with the Zoom Interface

How to answer poll questions



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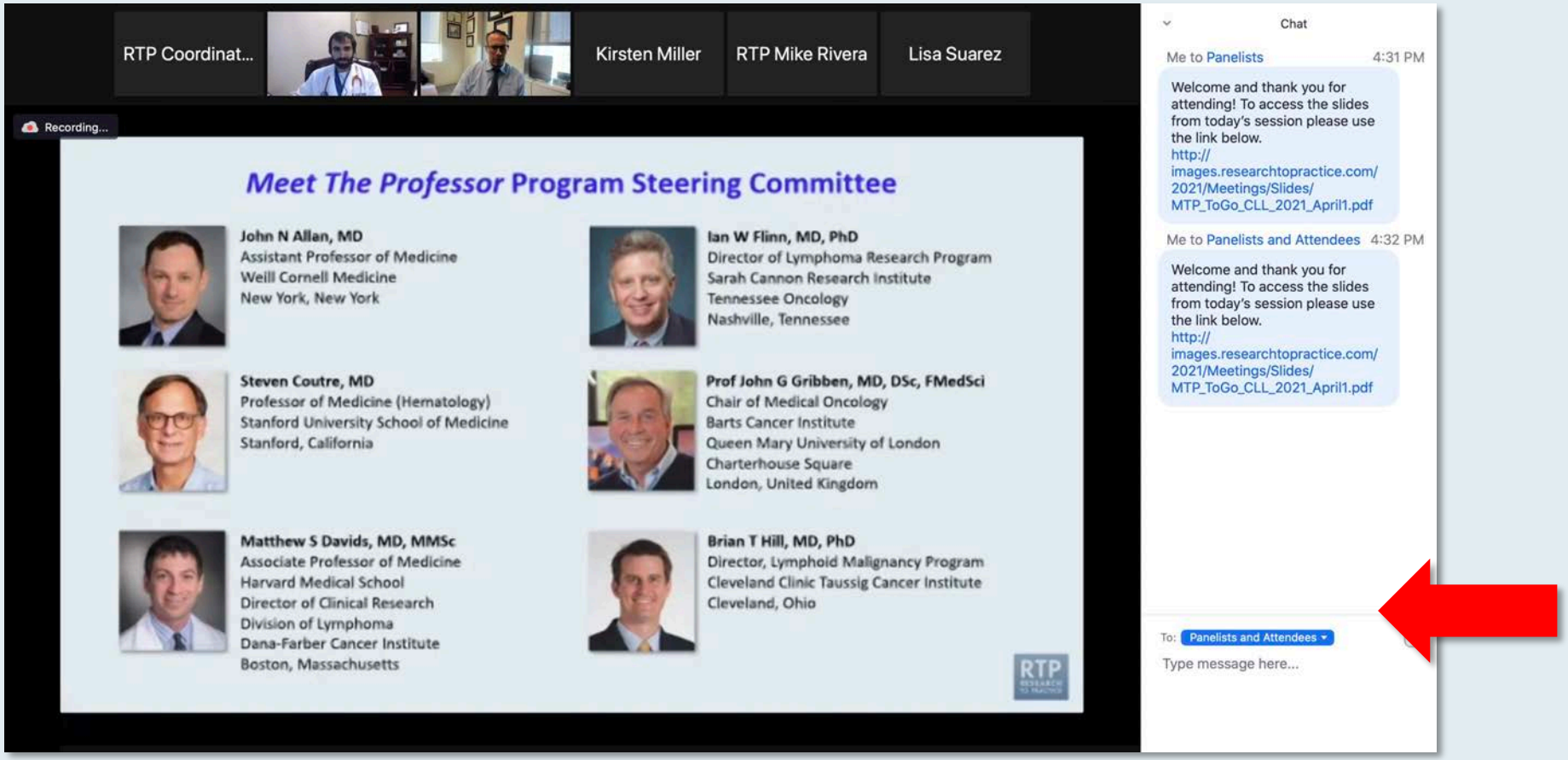
Familiarizing Yourself with the Zoom Interface

Expand chat submission box



Drag the white line above the submission box up to create more space for your message.

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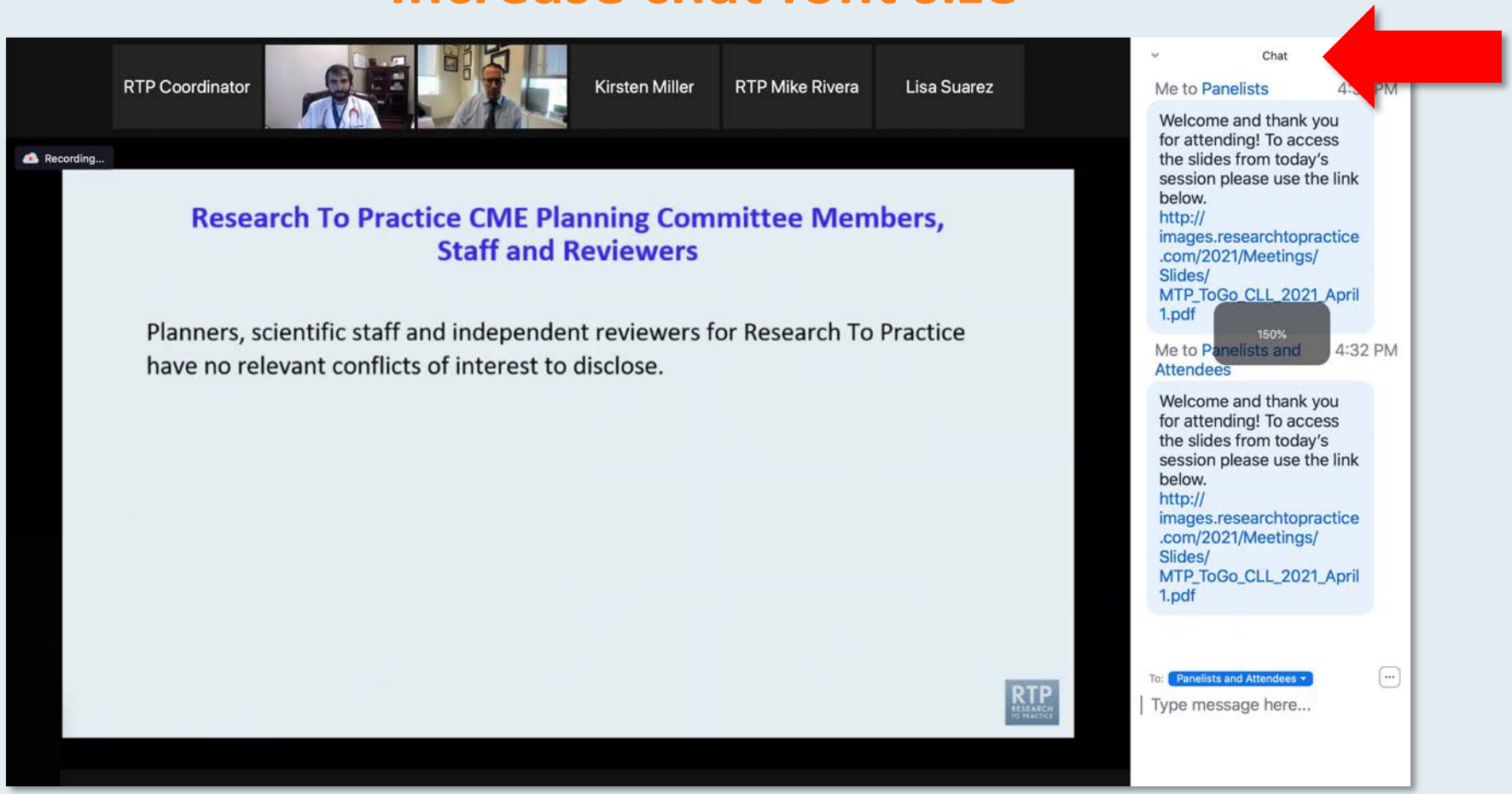
Increase chat font size



Press Command (for Mac) or Control (for PC) and the + symbol.
You may do this as many times as you need for readability.

ONCOLOGY TODAY

WITH DR NEIL LOVE

Key Presentations on Chronic Lymphocytic Leukemia and Follicular Lymphoma from the 2020 ASH Annual Meeting

DR ANN LACASCE

DANA-FARBER CANCER INSTITUTE

BOSTON, MASSACHUSETTS

Listen on Apple Podcasts

Spotify

Listen on Google Podcasts

Meet The Professor
Management of Ovarian Cancer

Tuesday, June 15, 2021
4:00 PM – 5:00 PM ET

Faculty
Susana Banerjee, MBBS, MA, PhD

Moderator
Neil Love, MD

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Meet The Professor

Optimizing the Selection and Sequencing of Therapy for Patients with Renal Cell Carcinoma

Wednesday, June 16, 2021
5:00 PM – 6:00 PM ET

Faculty

Thomas E Hutson, DO, PharmD

Moderator

Neil Love, MD

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Hodgkin and Non-Hodgkin Lymphomas

Thursday, June 17, 2021
5:00 PM – 6:00 PM ET

Faculty

Carla Casulo, MD
Jacklyn Gideon, MSN, AGPCNP-BC

Moderator

Neil Love, MD

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Chimeric Antigen Receptor T-Cell Therapy in Multiple Myeloma

Thursday, June 24, 2021
5:00 PM – 6:00 PM ET

Faculty

Noopur Raje, MD
Alli McClanahan, MSN, APRN, ANP-BC

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

ASCO Highlights and More: Investigators Review Recent Data Sets and Provide Perspectives on Current Oncology Care

A Daylong Multitumor Educational Webinar in Partnership with the Texas Society of Clinical Oncology (TxSCO)

Saturday, June 26, 2021
8:00 AM – 3:00 PM Central Time
(9:00 AM – 4:00 PM Eastern Time)

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17 Exciting CME/MOC Events You Do Not Want to Miss

A Live Webinar Series Held in Conjunction with the 2021 ASCO Annual Meeting

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Tuesday, June 22
5:00 PM – 6:00 PM ET

ER-Positive and Triple-Negative Breast Cancer
Wednesday, June 23
5:00 PM – 6:00 PM ET

Chronic Lymphocytic Leukemia and Follicular Lymphoma
Tuesday, June 29
5:00 PM – 6:00 PM ET

Multiple Myeloma
Wednesday, June 30
5:00 PM – 6:00 PM ET

Ovarian Cancer
Wednesday, July 7
5:00 PM – 6:00 PM ET

Hormonal Therapy for Prostate Cancer
Monday, July 12
5:00 PM – 6:00 PM ET

Chimeric Antigen Receptor T-Cell Therapy
Tuesday, July 13
5:00 PM – 6:00 PM ET

Acute Myeloid Leukemia and Myelodysplastic Syndromes
Wednesday, July 14
5:00 PM – 6:00 PM ET

Metastatic Castration-Resistant Prostate Cancer
Tuesday, July 20
5:00 PM – 6:00 PM ET

Bladder Cancer
Wednesday, July 21
5:00 PM – 6:00 PM ET

Endometrial and Cervical Cancers
Monday, July 26
5:00 PM – 6:00 PM ET

Targeted Therapy for Non-Small Cell Lung Cancer
Tuesday, July 27
5:00 PM – 6:00 PM ET

Immunotherapy and Other Nontargeted Approaches for Lung Cancer
Wednesday, July 28
5:00 PM – 6:00 PM ET

Mantle Cell, Diffuse Large B-Cell and Hodgkin Lymphoma
Monday, August 2
5:00 PM – 6:00 PM ET

Colorectal and Gastroesophageal Cancers
Tuesday, August 3
5:00 PM – 6:30 PM ET

Hepatocellular Carcinoma and Pancreatic Cancer
Wednesday, August 4
5:00 PM – 6:30 PM ET

Head and Neck Cancer
Wednesday, August 11
5:00 PM – 6:00 PM ET

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Ask the Expert: Clinical Investigators Provide Perspectives on the Management of Renal Cell Carcinoma

In Partnership with Project Echo® and Florida Cancer Specialists

Tuesday, July 6, 2021
5:00 PM – 6:00 PM ET

Faculty

David I Quinn, MBBS, PhD

Moderator

Neil Love, MD

Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.

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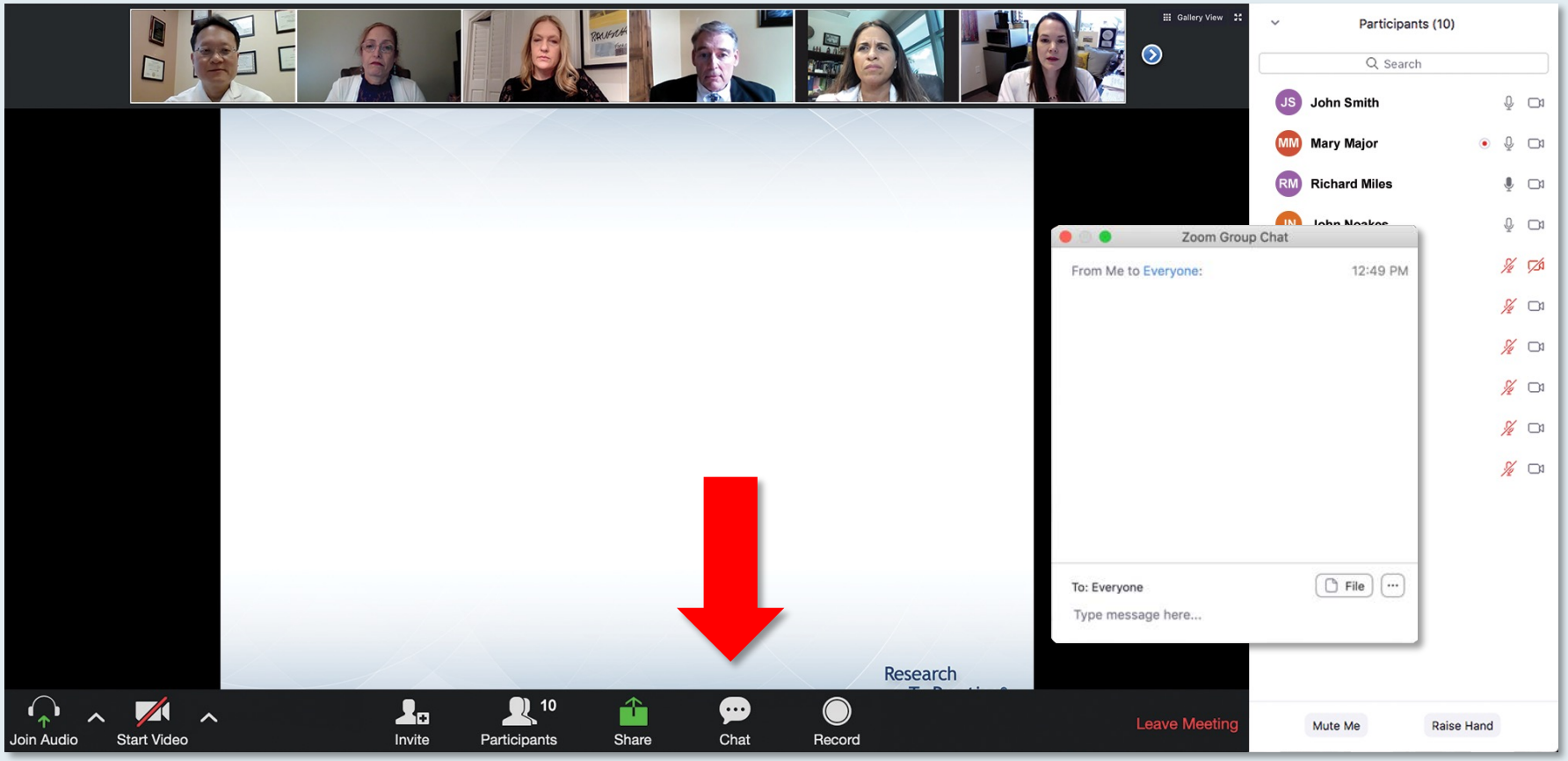

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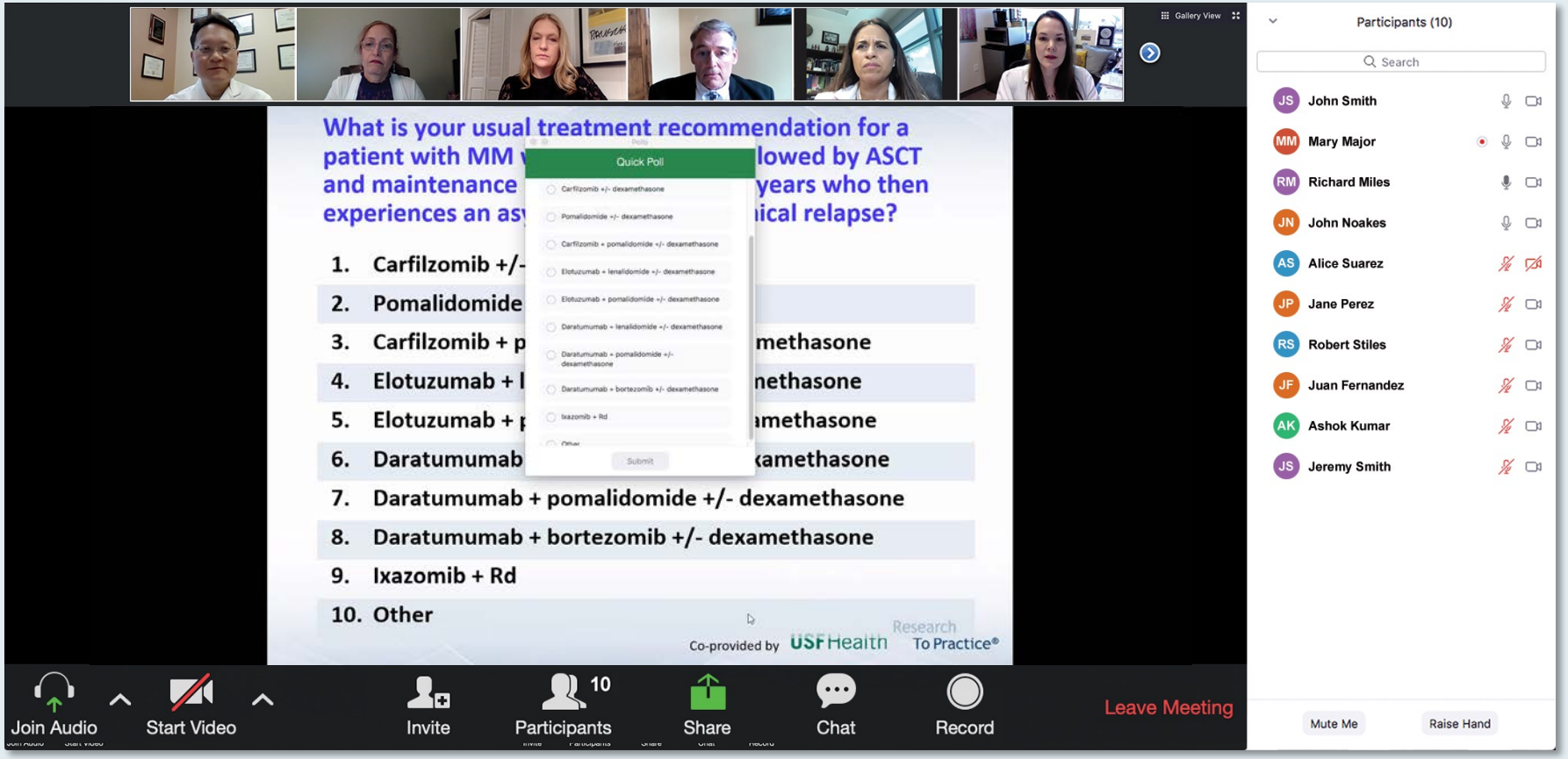

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Oncology Grand Rounds Nursing Webinar Series

April 2021

Monday	Tuesday	Wednesday	Thursday	Friday
19	20 Breast Ca 8:30 AM Lung Ca 5:00 PM	21 AML 12:00 PM CRC and GE Ca 4:45 PM	22 Prostate Ca 8:30 AM Lymphomas 5:00 PM	23
26	27 Multiple Myeloma 8:30 AM Gynecologic Ca 5:00 PM	28 Bladder Ca 12:00 PM	29 CLL 8:30 AM CAR-T 5:00 PM	30

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13th Annual Oncology Grand Rounds

A Complimentary NCPD Live Webinar Series
Held During the 46th Annual ONS Congress

Chronic Lymphocytic Leukemia

Thursday, April 29, 2021
8:30 AM – 10:00 AM ET

Medical Oncologists

Brian T Hill, MD, PhD
John M Pagel, MD, PhD
Jennifer Woyach, MD

Oncology Nurse Practitioners

Lesley Camille Ballance, MSN, FNP-BC
Kristen E Battiato, AGNP-C
Corinne Hoffman, MS, APRN-CNP, AOCNP

Moderator

Neil Love, MD

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Camille Ballance, MSN, FNP-BC
Kristen E Battiato, AGNP-C
Corinne Hoffman, MS, APRN-CNP, AOCNP

How was it different to take care of this patient versus another patient in the same oncologic setting? What unique biopsychosocial factors (eg, attitude, comorbidities, social support) were considered in the overall management of this case?

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Agenda

Module 1: Up-Front Treatment with a BTK (Bruton Tyrosine Kinase) Inhibitor

- **Dr Woyach: A 76-year-old man with IGHV-unmutated CLL**
- **Ms Battiato: A 50-year-old woman with IGHV-unmutated CLL/SLL and progressive lymphadenopathy**

Module 2: Up-Front Treatment with Obinutuzumab/Venetoclax

- **Dr Woyach: A 68-year-old woman with IGHV-mutated CLL – Trisomy 12**
- **Ms Battiato: A 57-year-old man with IGHV-unmutated CLL/SLL, multifocal adenopathy and splenomegaly**

Module 3: Future Directions in CLL (U2 Regimen, LOXO-305, CAR T-Cell Therapy)

- **Dr Woyach: An 86-year-old man with relapsed CLL and an acquired C418S BTK mutation associated with ibrutinib resistance**
- **Ms Battiato: An 89-year-old woman with relapsed CLL/SLL – 17p deletion, no IGHV mutation**

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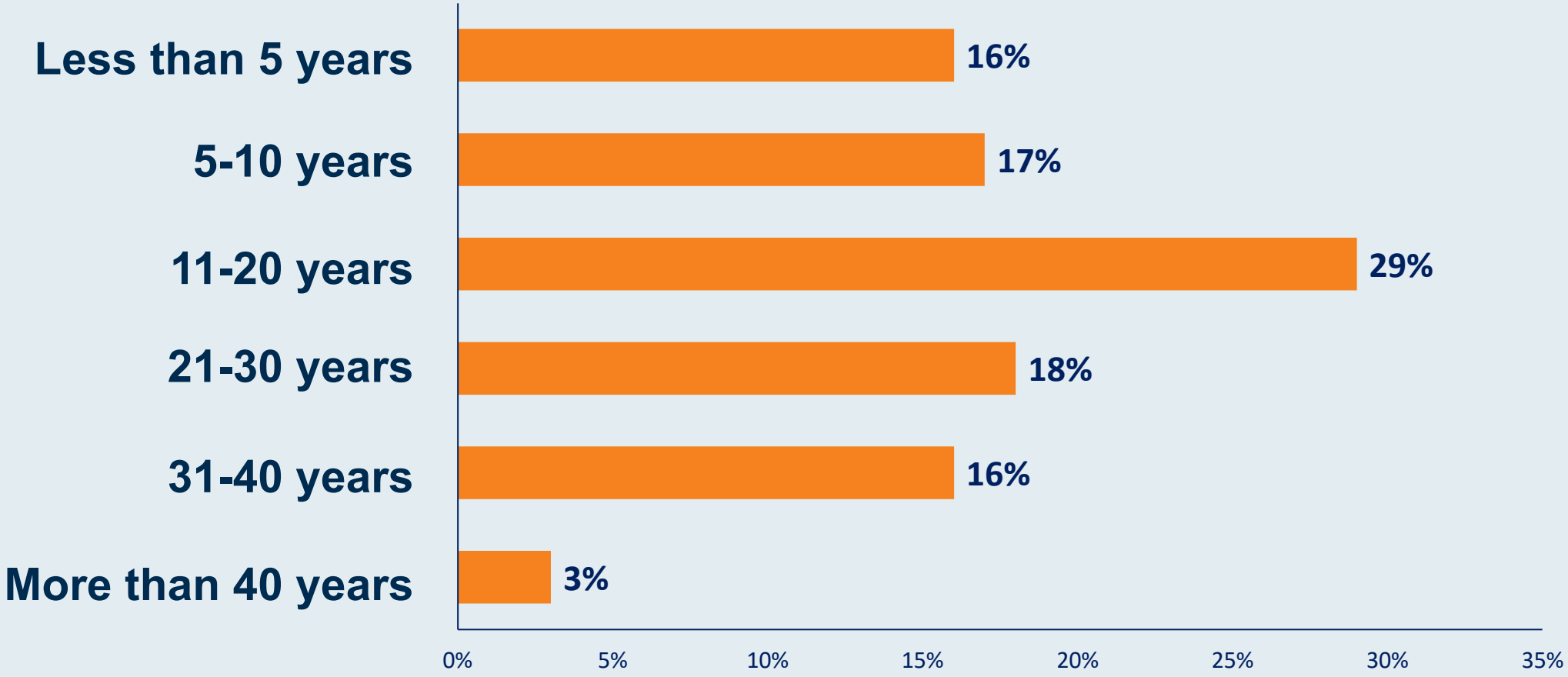
How long have you been in the field of oncology?



Survey of live webinar audience June 3, 2021

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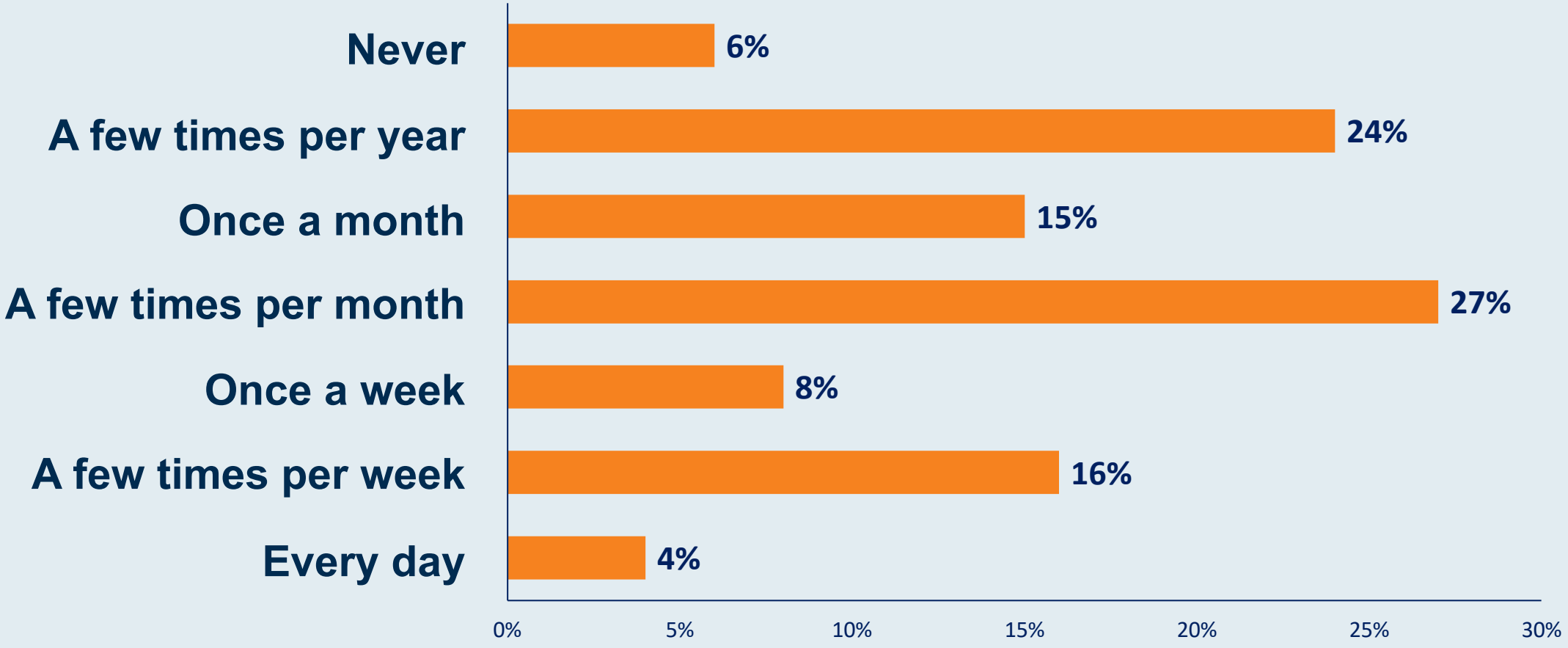
I feel frustrated by my work.



Survey of live webinar audience June 3, 2021

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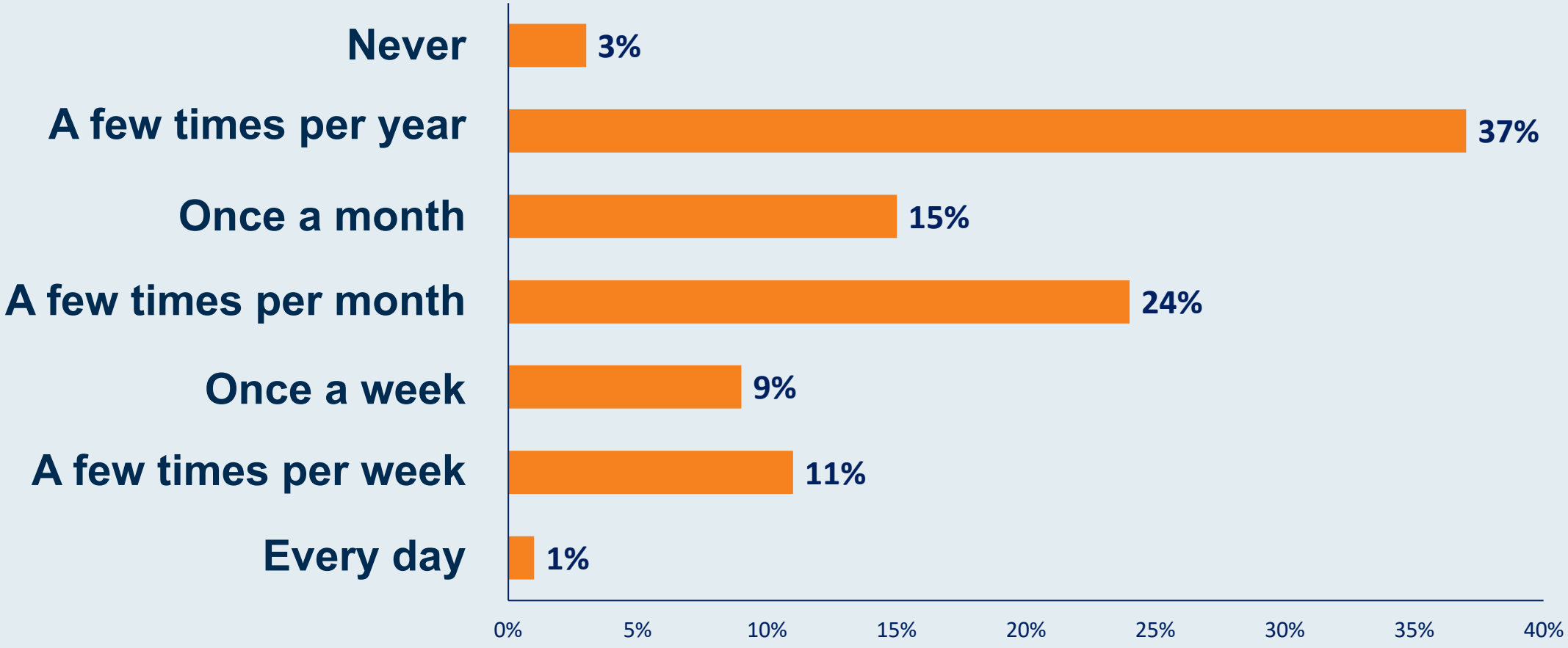
I feel emotionally drained by my work.



Survey of live webinar audience June 3, 2021

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How do you manage the stress associated with working in the field of oncology?

- Yoga and Meditation
- Gardening, making jam. Lots of jam...
- Long weekend getaways
- Horseback riding
- Exercise
- Buy myself flowers every week
- Relax and watch some TV which takes me away
- I run 3x/week and stay outside as much as possible
- Church, travel, movies
- Family, music, prayers
- Walking and exercise
- Family time
- Hiking and biking
- Traveling and reading about Native American history
- Walking
- Running
- The gym 4x/week
- Biking
- Facials & massage
- Exercise and laughing!!!! Humor is a necessity
- Getting outdoors
- Praying daily
- Biking; travel
- Prayer is vital!
- I don't answer emails when I am scheduled off. It is really important to set limits and to be present with your family when you are off

Chat room comments from live webinar audience June 3, 2021

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I feel very satisfied with my work.

1. Never
2. A few times per year
3. Once a month
4. A few times per month
5. Once a week
6. A few times per week
7. Every day

I wish I were in another line of work.

1. Never
2. A few times per year
3. Once a month
4. A few times per month
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7. Every day

Agenda

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Case Presentation – Dr Woyach: A 76-year-old man with IGHV-unmutated CLL

- 2017: Initial diagnosis of CLL
- 2020: Presented with increasing fatigue and decreasing hemoglobin and platelet counts
  - IGHV unmutated, FISH normal, no TP53 mutation
  - Patient is not interested in clinical trial participation
- Acalabrutinib 100 mg BID initiated
  - Fatigue began to improve and lymph nodes were no longer palpable within 2 weeks after starting therapy
  - Hemoglobin normalized within 4 months and platelet counts normalized within 5 months after starting therapy
- He remains on therapy 1 year into treatment and is feeling well; intermittent neutropenia

Case Presentation – Dr Woyach: A 76-year-old man with IGHV-unmutated CLL (continued)

What important factors did you consider in managing this case?

1. Patient's genomic risk (intermediate) given unmutated IGHV status and no TP53 abnormalities
2. Age of patient and risk of adverse events (AEs) with different therapies
3. Patient preference for fixed duration vs indefinite therapy
4. COVID-19 pandemic and ease of administration with BTKi
5. Long term outcomes with frontline BTKi in CLL

How was it different to take care of this patient versus another patient in the same oncologic setting? What unique biopsychosocial factors (eg, attitude, comorbidities, social support) were considered in the overall management of this case?

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Case Presentation – Ms Battiato: A 50-year-old woman with IGHV-unmutated CLL/SLL and progressive lymphadenopathy

- 11/2007: Initial diagnosis of CLL/SLL
  - IGHV unmutated, del(14q32), trisomy 12
- Progressive lymphadenopathy
- 8/2017: Ibrutinib initiated
- She remains on ibrutinib with ongoing disease response and is tolerating treatment well

Case Presentation – Ms Battiato: A 50-year-old woman with IGHV-unmutated CLL/SLL and progressive lymphadenopathy (continued)

What are the 5 most important things that you discussed with this patient prior to starting treatment?

1. Adverse events are common and are often managed by briefly holding for 7 days or less or with supportive care. These include cutaneous toxicities, increased risk for infection (fungal infections), headaches, and myalgias and arthralgias.
2. During the first 4-6 weeks patients tend to feel fatigued. It is usually better tolerated after the first month.
3. Weekly labs for the first month to monitor for tumor lysis and organ function. Peripheralization is common in the first weeks to months. Patients should not be alarmed if WBC count increases.
4. There is an increased bleeding risk. Will have to hold ibrutinib at least 3-7 days prior to procedures and inform the medical team.
5. Hypertension and atrial fibrillation can occur at any time. New medications should be reported to avoid drug interactions, especially antiplatelet medications.

How was it different to take care of this patient versus another patient in the same oncologic setting? What unique biopsychosocial factors (eg, attitude, comorbidities, social support) were considered in the overall management of this case?

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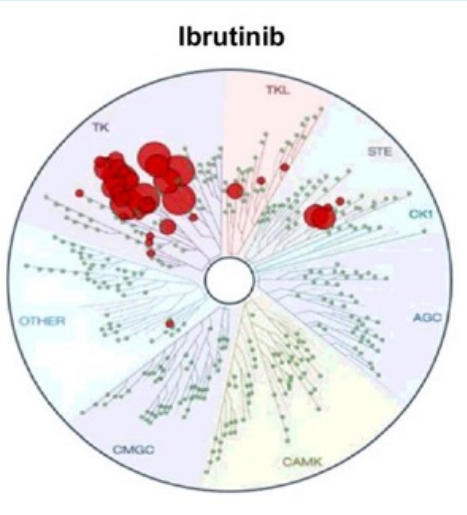
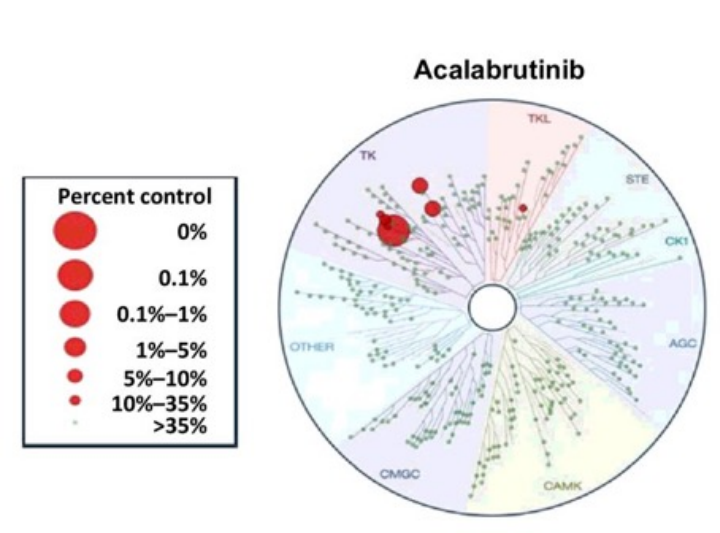
Overview of BTK Inhibitors in CLL

Irreversible

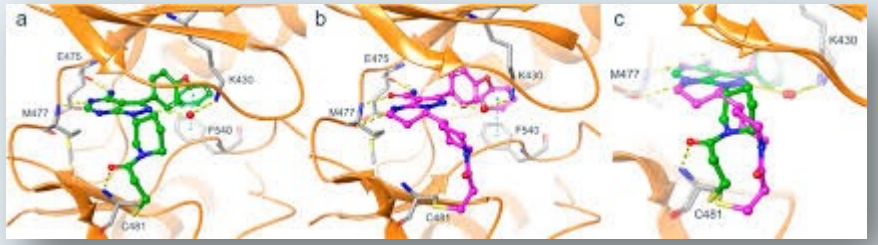
Ibrutinib



Acalabrutinib

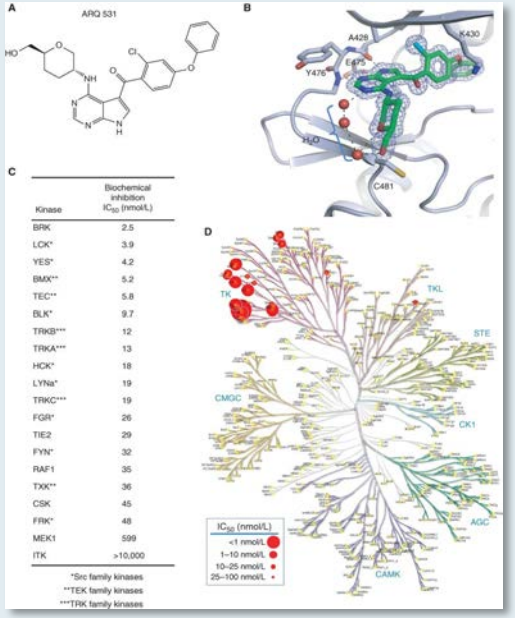


Zanubrutinib

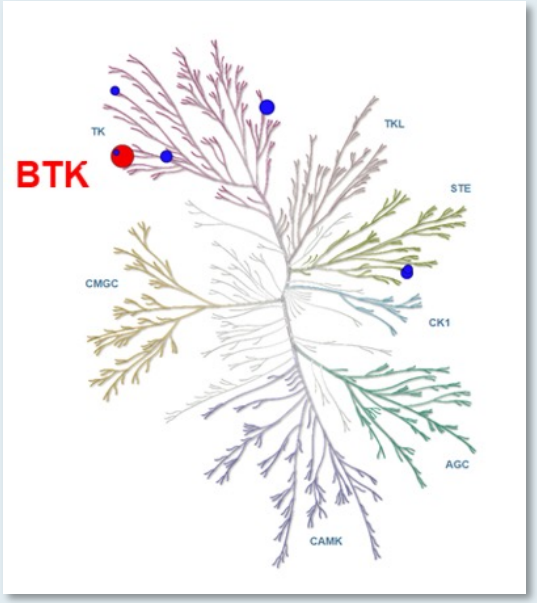


Reversible

ARQ-531 (MK-1026)



Pirtobrutinib (LOXO-305)



Courtesy of Matthew S Davids, MD, MMSc

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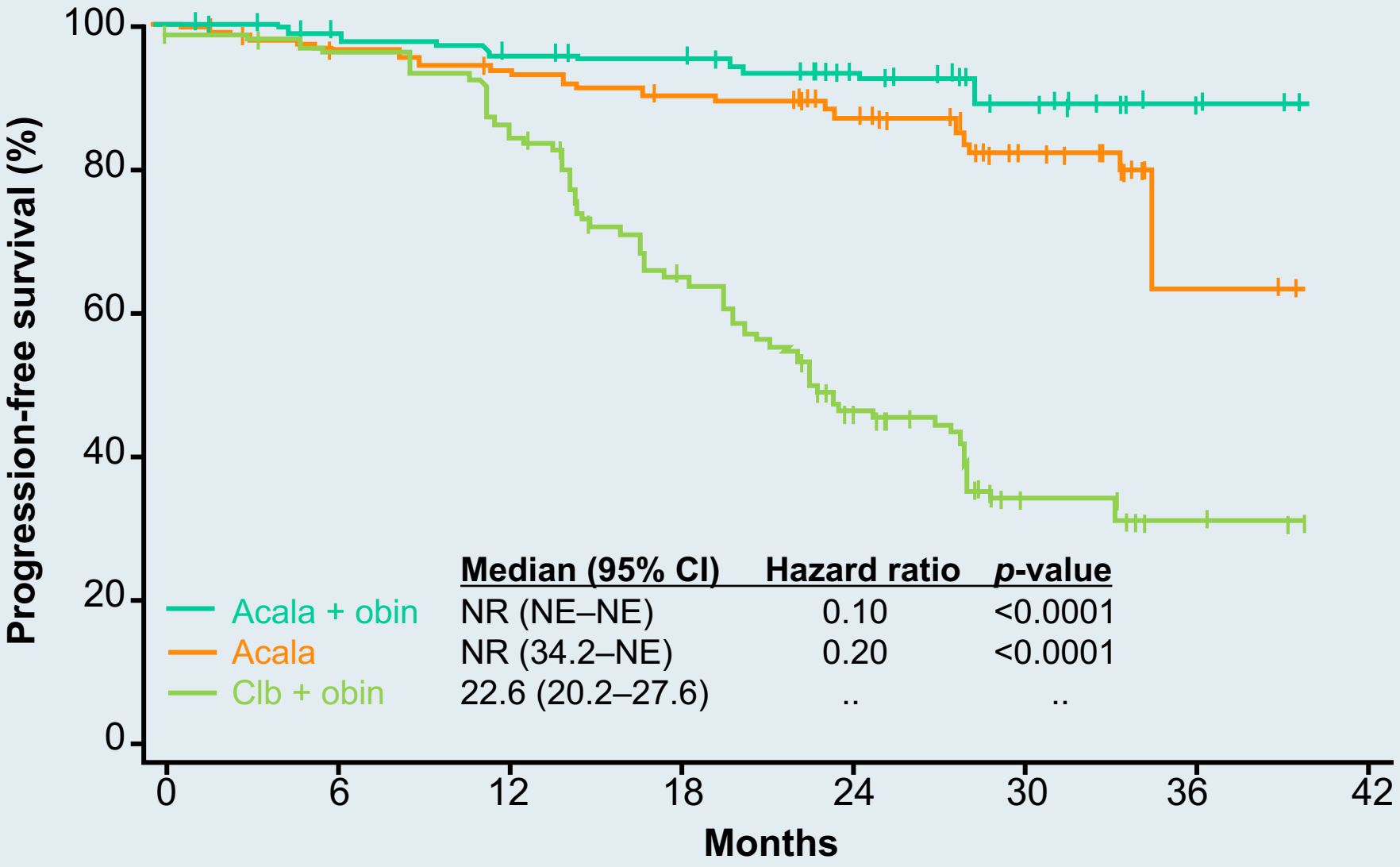
Articles

Acalabrutinib with or without obinutuzumab versus chlorambucil and obinutuzumab for treatment-naive chronic lymphocytic leukaemia (ELEVATE-TN): a randomised, controlled, phase 3 trial

Jeff P Sharman, Miklos Egyed, Wojciech Jurczak, Alan Skarbnik, John M Pagel, Ian W Flinn, Manali Kamdar, Talha Munir, Renata Walewska, Gillian Corbett, Laura Maria Fogliatto, Yair Herishanu, Versha Banerji, Steven Coutre, George Follows, Patricia Walker, Karin Karlsson, Paolo Ghia, Ann Janssens, Florence Cymbalista, Jennifer A Woyach, Gilles Salles, William G Wierda, Raquel Izumi, Veerendra Munugalavadla, Priti Patel, Min Hui Wang, Sofia Wong, John C Byrd

Lancet 2020;395(10232):1278-91.

ELEVATE-TN: PFS (IRC)



Sharman JP et al. *Lancet* 2020;395:1278-91.

2021 ASCO ANNUAL MEETING

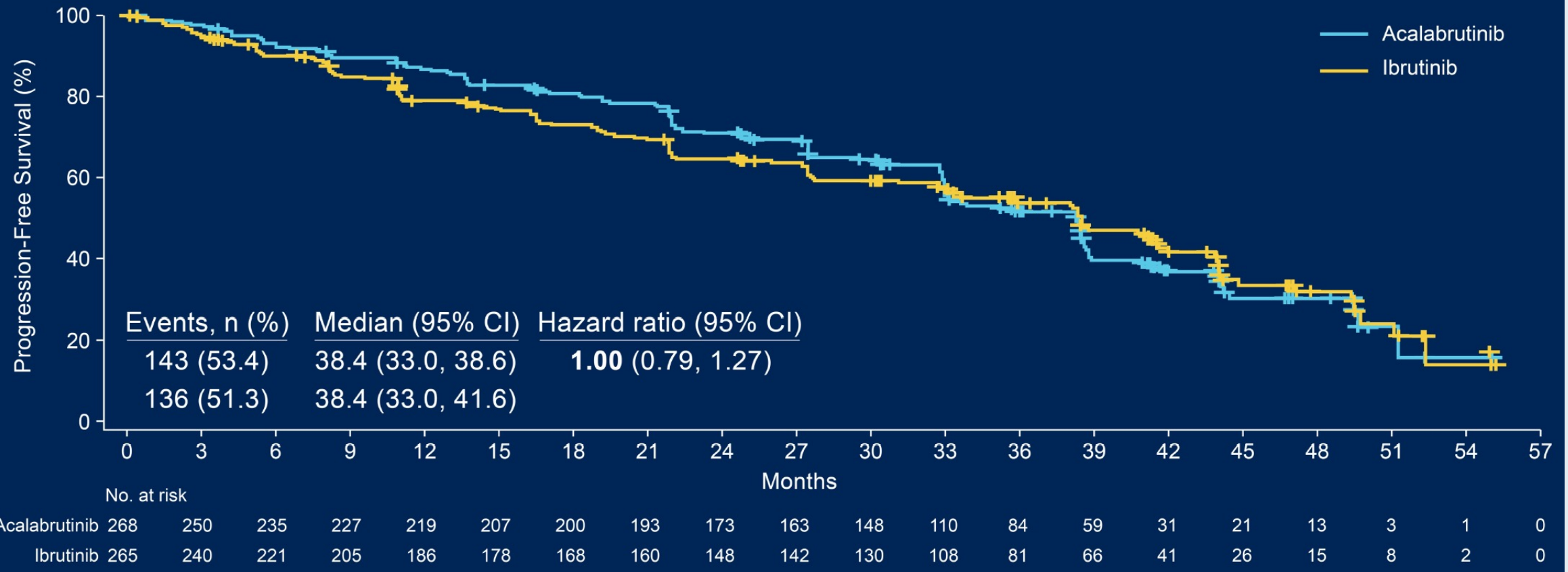
7500

FIRST RESULTS OF A HEAD-TO-HEAD TRIAL OF ACALABRUTINIB VERSUS IBRUTINIB IN PREVIOUSLY TREATED CHRONIC LYMPHOCYTIC LEUKEMIA

John C. Byrd[1]; Peter Hillmen[2]; Paolo Ghia[3]; Arnon P. Kater[4]; Asher Chanan-Khan[5]; Richard R. Furman[6]; Susan O'Brien[7]; Mustafa Nuri Yenerel[8]; Arpad Illes[9]; Neil Kay[10]; Jose A. Garcia-Marco[11]; Anthony Mato[12]; John F. Seymour[13]; Stephane Lepretre[14]; Stephan Stilgenbauer[15]; Tadeusz Robak[16]; Priti Patel[17]; Kara Higgins[17]; Sophia Sohoni[17]; Wojciech Jurczak[18]

[1]The Ohio State University Comprehensive Cancer Center, Columbus, OH, USA; [2]St. James's University Hospital, Leeds, UK; [3]Università Vita-Salute San Raffaele and IRCCS Ospedale San Raffaele, Milano, Italy; [4]Amsterdam University Medical Centers, Amsterdam, on behalf of Hovon, Netherlands; [5]Mayo Clinic Jacksonville, Jacksonville, FL, USA; [6]Weill Cornell Medicine, New York Presbyterian Hospital, New York, NY, USA; [7]Chao Family Comprehensive Cancer Center, University of California-Irvine, Irvine, CA, USA; [8]Istanbul University, Istanbul, Turkey; [9]University of Debrecen, Debrecen, Hungary; [10]Mayo Clinic Rochester, Rochester, MN, USA; [11]Hospital Universitario Puerta de Hierro-Majadahonda, Madrid, Spain; [12]University of Pennsylvania, Philadelphia, PA, USA; [13]Peter MacCallum Cancer Centre, Royal Melbourne Hospital and University of Melbourne, Victoria, Australia; [14]Centre Henri Becquerel and Normandie University UNIROUEN, Rouen, France; [15]University of Ulm, Ulm, Germany; [16]Medical University of Lodz, Lodz, Poland; [17]AstraZeneca, South San Francisco, CA, USA; [18]Maria Sklodowska-Curie National Research Institute of Oncology, Krakow, Poland

Primary Endpoint: Non-inferiority Met on IRC-Assessed PFS

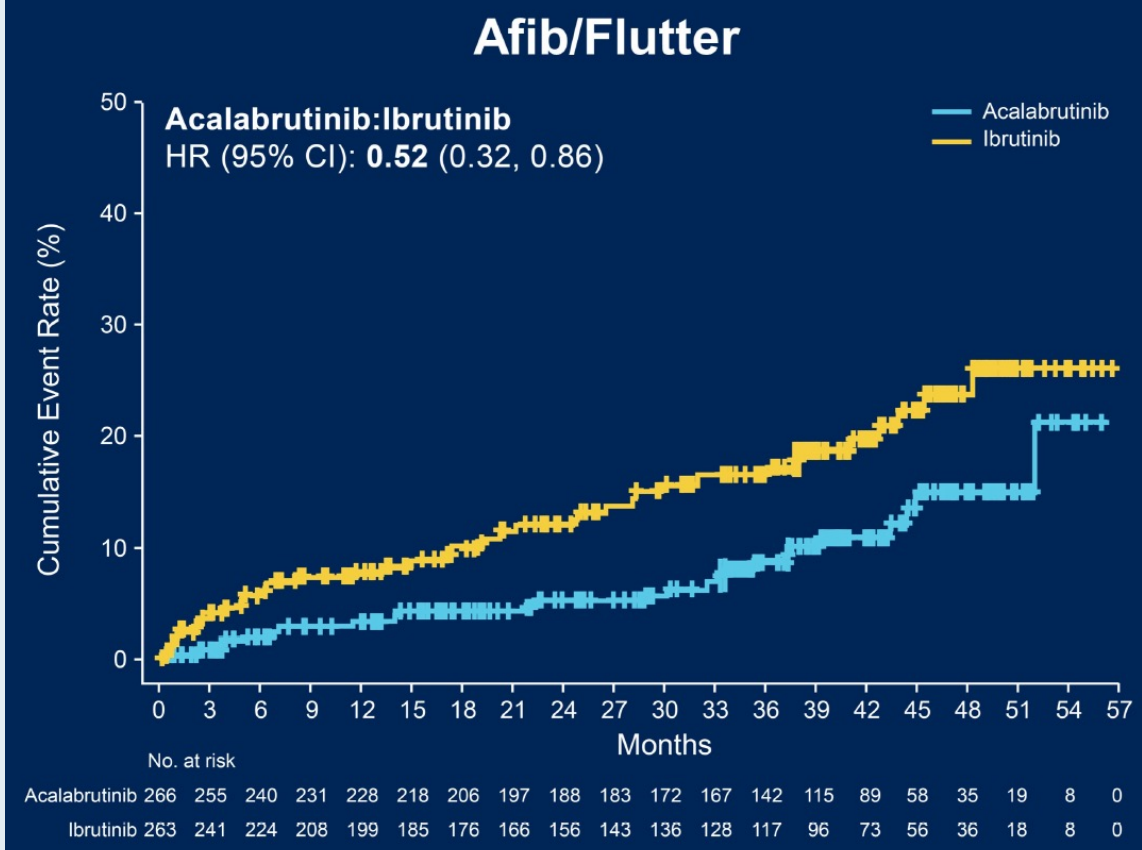


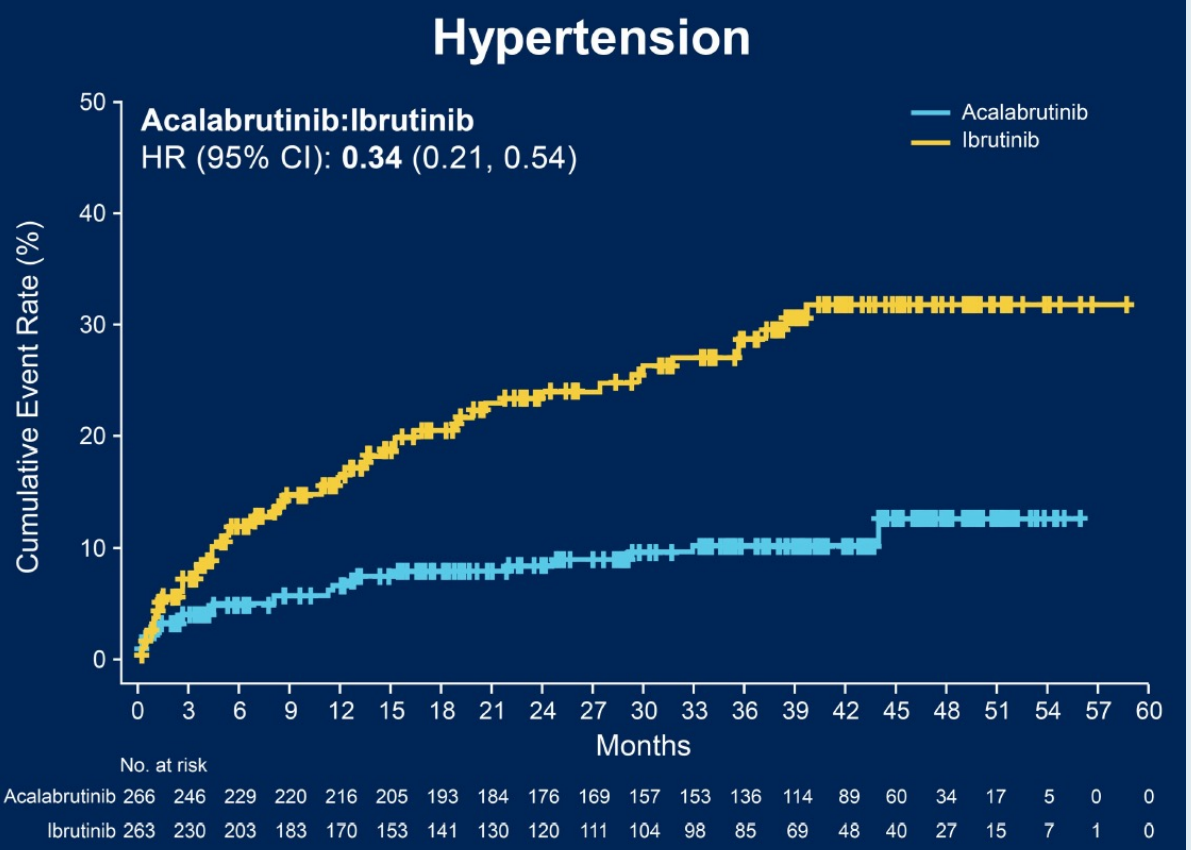
Median follow-up: 40.9 months (range, 0.0–59.1).

CI, confidence interval; IRC, independent review committee; PFS, progression-free survival.

Byrd JC et al. ASCO 2021;Abstract 7500.

Lower Cumulative Incidences of Any Grade Atrial Fibrillation/Flutter and Hypertension With Acalabrutinib





CI, confidence interval; HR, hazard ratio.

Byrd JC et al. ASCO 2021;Abstract 7500.

RTP RESEARCH TO PRACTICE

ELEVATE-RR: Acalabrutinib versus Ibrutinib for Previously Treated CLL

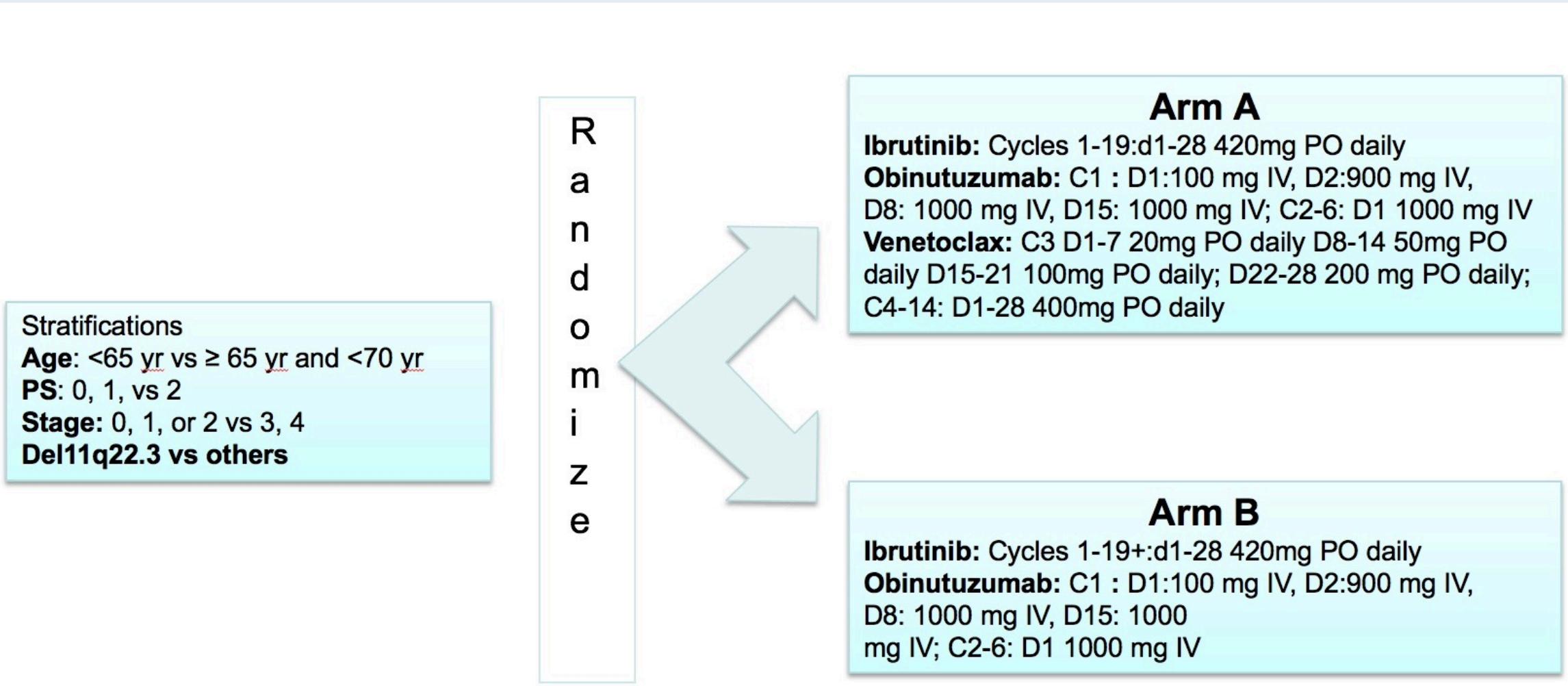
Adverse events (AEs)	Acalabrutinib (n = 266)		Ibrutinib (n = 263)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Cardiac events	24.1%	8.6%	30.0%	9.5%
Atrial fibrillation	9.4%	4.9%	16.0%	3.8%
Ventricular tachyarrhythmias	0	0	0.4%	0.4%
Hypertension	9.4%	4.1%	23.2%	9.1%
Bleeding events	38.0%	3.8%	51.3%	4.6%
Major bleeding events	4.5%	3.8%	5.3%	4.6%
Infections	78.2%	30.8%	81.4%	30.0%
SPMs	9.0%	6.0%	7.6%	5.3%
Headache	34.6%		20.2%	
AEs leading to treatment discontinuation	14.7%		21.3%	

SPMs = Second primary malignancies, excluding nonmelanoma skin cancers

- Median PFS: 38.4 months for both arms (HR 1.00)
- Median OS: Not reached in either arm (HR 0.82)

Byrd JC et al. ASCO 2021;Abstract 7500.

Phase III EA9161 Schema



Clinicaltrials.gov/ct2/show/NCT03701282?term=EA9161&draw=2&rank=1, Accessed March 1, 2021

Zanubrutinib Demonstrates Superior ORR and Reduced Rates of Atrial Fibrillation or Flutter in Head-to-Head Trial Against Ibrutinib for CLL

Press Release: April 28, 2021

"Positive results from a planned interim analysis of the Phase 3 ALPINE trial comparing zanubrutinib against ibrutinib in adults with relapsed or refractory CLL or SLL.

Zanubrutinib met the primary endpoint of the trial, demonstrating non-inferiority in objective response rate (ORR) by both investigator and independent review committee (IRC) assessments ($p < 0.0001$). The interim analysis from this fully-enrolled, ongoing trial is based on 415 of 652 patients followed for a minimum of 12 months.

The trial also met a pre-specified secondary endpoint related to safety. Compared to ibrutinib, zanubrutinib demonstrated a statistically significant lower risk of atrial fibrillation or flutter…"

https://www.businesswire.com/news/home/20210428005360/en/BRUKINSA%C2%AE-Zanubrutinib-Demonstrates-Superior-Objective-Response-Rate-by-Investigator-Assessment-and-Reduced-Rates-of-Atrial-Fibrillation-or-Flutter-at-Interim-Analysis-in-Head-to-Head-Trial-Against-Ibrutinib-in-Chronic-Lymphocytic-Leukemia

First Interim Analysis of ALPINE Study: Results of a Phase 3 Randomized Study of Zanubrutinib versus Ibrutinib in Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia

Hillmen P et al.

EHA 2021;Abstract LB1900.

Presidential Symposium: Friday, June 11, 2021

Agenda

Module 1: Up-Front Treatment with a BTK (Bruton Tyrosine Kinase) Inhibitor

- Dr Woyach: A 76-year-old man with IGHV-unmutated CLL
- Ms Battiato: A 50-year-old woman with IGHV-unmutated CLL/SLL and progressive lymphadenopathy

Module 2: Up-Front Treatment with Obinutuzumab/Venetoclax

- Dr Woyach: A 68-year-old woman with IGHV-mutated CLL – Trisomy 12
- Ms Battiato: A 57-year-old man with IGHV-unmutated CLL/SLL, multifocal adenopathy and splenomegaly

Module 3: Future Directions in CLL (U2 Regimen, LOXO-305, CAR T-Cell Therapy)

- Dr Woyach: An 86-year-old man with relapsed CLL and an acquired C418S BTK mutation associated with ibrutinib resistance
- Ms Battiato: An 89-year-old woman with relapsed CLL/SLL – 17p deletion, no IGHV mutation

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Case Presentation – Dr Woyach: A 68-year-old woman with IGHV-mutated CLL – Trisomy 12

- Diagnosed with CLL and symptomatic lymphadenopathy and splenomegaly
  - IGHV mutated, trisomy 12, and TP53 mutation-negative
  - She desired fixed duration therapy
- Venetoclax/obinutuzumab → MRD-negative, CR
- She is in remission about 8 months following completion of therapy

Case Presentation – Dr Woyach: A 68-year-old woman with IGHV-mutated CLL – Trisomy 12 (continued)

What important factors did you consider in managing this case?

1. Patient's genomic risk (good) given mutated IGHV status and no TP53 abnormalities
2. Age of patient and risk of AEs with different therapies
3. Patient preference for fixed duration vs indefinite therapy
4. Long term outcomes with venetoclax/obinutuzumab

How was it different to take care of this patient versus another patient in the same oncologic setting? What unique biopsychosocial factors (eg, attitude, comorbidities, social support) were considered in the overall management of this case?

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Case Presentation – Ms Battiato: A 57-year-old man with IGHV-unmutated CLL/SLL, multifocal adenopathy and splenomegaly

- 6/2018: Initial diagnosis of Rai Stage IV CLL/SLL, multifocal adenopathy and splenomegaly
  - IGHV unmutated, trisomy 12
- Obinutuzumab/venetoclax → venetoclax x 12 mos
  - Treatment course notable for infusion reaction on day 1 of first cycle consisting of diaphoresis, nausea, brief disorientation, brief hypotension; resolved with stopping the infusion and giving corticosteroids
  - Intermittent neutropenia
- 5/2019: MRD-negative by peripheral flow
- 8/2020: Re-staging shows non-pathological lymphadenopathy
- Remains in deep remission with undetectable disease by flow cytometry

Case Presentation – Ms Battiato: A 57-year-old man with IGHV-unmutated CLL/SLL, multifocal adenopathy and splenomegaly (continued)

What are the 5 most important things that you discussed with this patient prior to starting treatment?

1. Most patients (60%) will experience some form of an infusion reaction during week of C1D1 of obinutuzumab. This can be managed with pre-medications in advance, stopping the infusion during the reaction, and administering supportive medications in addition to careful monitoring by the medical team.
2. Patients often feel fatigued the month or two of therapy but then symptoms improve with time.
3. The venetoclax ramp-up requires time-sensitive labs which are reviewed in real time. Patients must adhere to the demanding schedule during these 5 weeks.
4. Neutropenia, thrombocytopenia, and transient transaminitis (often the first week of therapy) are often seen. Both are managed with holding drug, depending on the severity, and using growth factors for the neutropenia.
5. Patients most often will report nausea or diarrhea with the higher doses of venetoclax. This can be treated with the use of antiemetics and anti-diarrheal medications such as loperamide. Sometimes changing the venetoclax dosing to the evenings has helped so patients sleep during the time in which they are nauseated.

How was it different to take care of this patient versus another patient in the same oncologic setting? What unique biopsychosocial factors (eg, attitude, comorbidities, social support) were considered in the overall management of this case?

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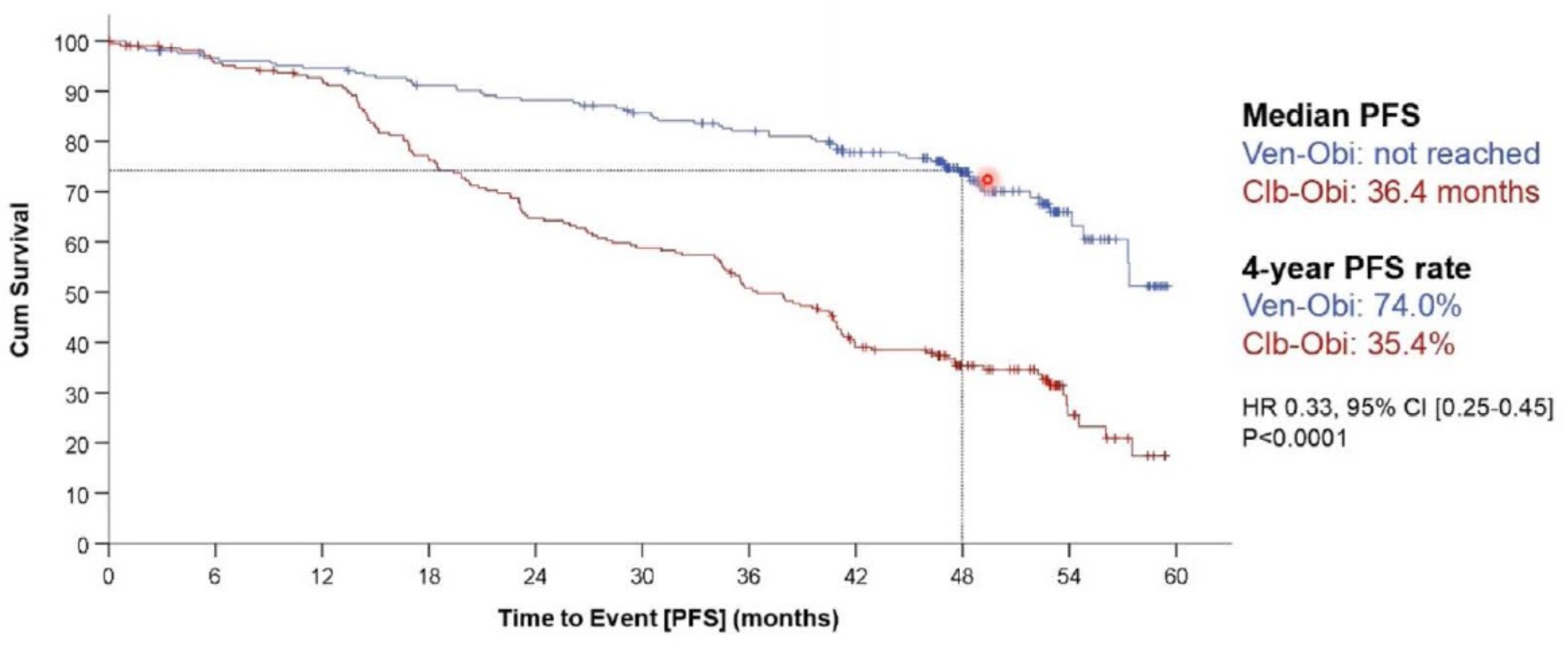
Articles

Venetoclax plus obinutuzumab versus chlorambucil plus obinutuzumab for previously untreated chronic lymphocytic leukaemia (CLL14): follow-up results from a multicentre, open-label, randomised, phase 3 trial

Othman Al-Sawaf, Can Zhang, Maneesh Tandon, Arijit Sinha, Anna-Maria Fink, Sandra Robrecht, Olga Samoylova, Anna M Liberati, Javier Pinilla-Ibarz, Stephen Opat, Liliya Sivcheva, Katell Le Dû, Laura M Fogliatto, Carsten U Niemann, Robert Weinkove, Sue Robinson, Thomas J Kipps, Eugen Tausch, William Schary, Matthias Ritgen, Clemens-Martin Wendtner, Karl-Anton Kreuzer, Barbara Eichhorst, Stephan Stilgenbauer, Michael Hallek, Kirsten Fischer**

Lancet Oncol 2020;21(9):1188-200.

CLL14: Updated 4-Year PFS



Median observation time: 52.4 months

Al-Sawaf O et al. ASH 2020;Abstract 127 .

RTP RESEARCH TO PRACTICE

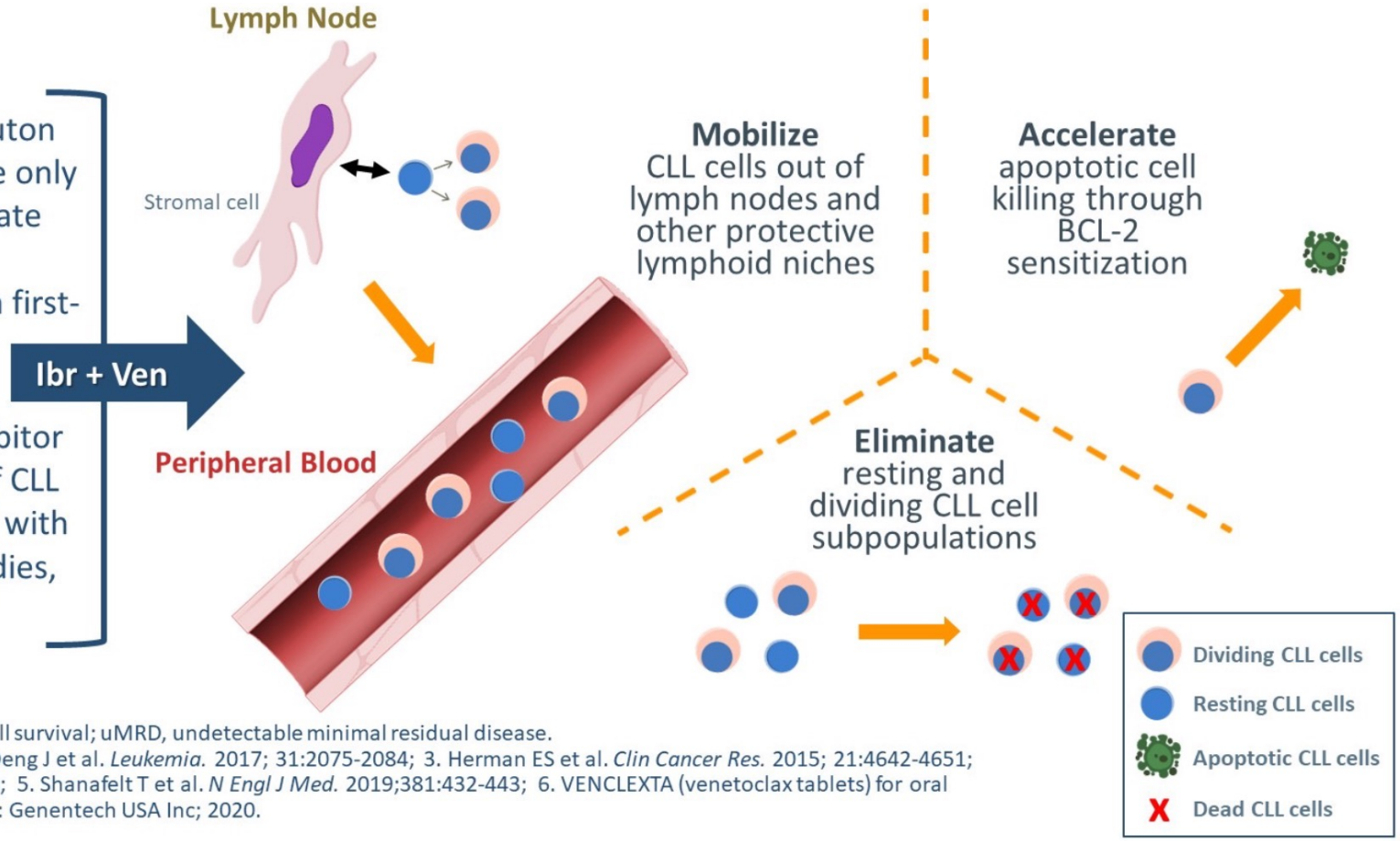
Fixed-Duration (FD) First-Line Treatment With Ibrutinib Plus Venetoclax for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma: Primary Analysis of the FD Cohort of the Phase 2 CAPTIVATE Study

Paolo Ghia, MD, PhD[1]; John N. Allan, MD[2]; Tanya Siddiqi, MD[3]; Thomas J. Kipps, MD, PhD[4]; Ryan Jacobs, MD[5]; Stephen Opat, FRACP, FRCPA, MBBS[6]; Paul M. Barr, MD[7]; Alessandra Tedeschi, MD[8]; Livio Trentin, MD[9]; Rajat Bannerji, MD, PhD[10]; Sharon Jackson, MD[11]; Bryone Kuss, MBBS, PhD, FRACP, FRCPA[12]; Carol Moreno, MD, PhD[13]; Edith Szafer-Glusman, PhD[14]; Kristin Russell, BS[14]; Cathy Zhou, MS[14]; Joi Ninomoto, PharmD[14]; James P. Dean, MD, PhD[14]; William G. Wierda, MD, PhD[15]; Constantine Tam, MBBS, MD[16]

[1]Division of Experimental Oncology, Università Vita-Salute San Raffaele and IRCCS Ospedale San Raffaele, Milan, Italy; [2]Weill Cornell Medicine, New York, NY, USA; [3]City of Hope National Medical Center, Duarte, CA, USA; [4]UCSD Moores Cancer Center, San Diego, CA, USA; [5]Levine Cancer Institute, Charlotte, NC, USA; [6]Monash University, Clayton, VIC, Australia; [7]Wilmot Cancer Institute, University of Rochester Medical Center, Rochester, NY, USA; [8]ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy; [9]Hematology and Clinical Immunology Unit, Department of Medicine, University of Padova, Padova, Italy; [10]Rutgers Cancer Institute of New Jersey, New Brunswick, NJ, USA; [11]Middlemore Hospital, Auckland, New Zealand; [12]Flinders University and Medical Centre, Bedford Park, SA, Australia; [13]Hospital de la Santa Creu i Sant Pau, Autonomous University of Barcelona, Barcelona, Spain; [14]Pharmacyclics LLC, an AbbVie Company, Sunnyvale, CA, USA; [15]Department of Leukemia, University of Texas MD Anderson Cancer Center, Houston, TX, USA; [16]Peter MacCallum Cancer Center & St. Vincent's Hospital and the University of Melbourne, Melbourne, VIC, Australia

Rationale: Ibrutinib and Venetoclax Have Distinct and Complementary Modes of Action That Work Synergistically[1-3]

- Ibrutinib, a once-daily oral Bruton tyrosine kinase inhibitor, is the only targeted therapy to demonstrate significant OS benefit in randomized phase 3 studies in first-line CLL[4,5]
- Venetoclax, an oral BCL-2 inhibitor approved for the treatment of CLL as a single agent or combined with anti-CD20 monoclonal antibodies, achieves high rates of uMRD[6]

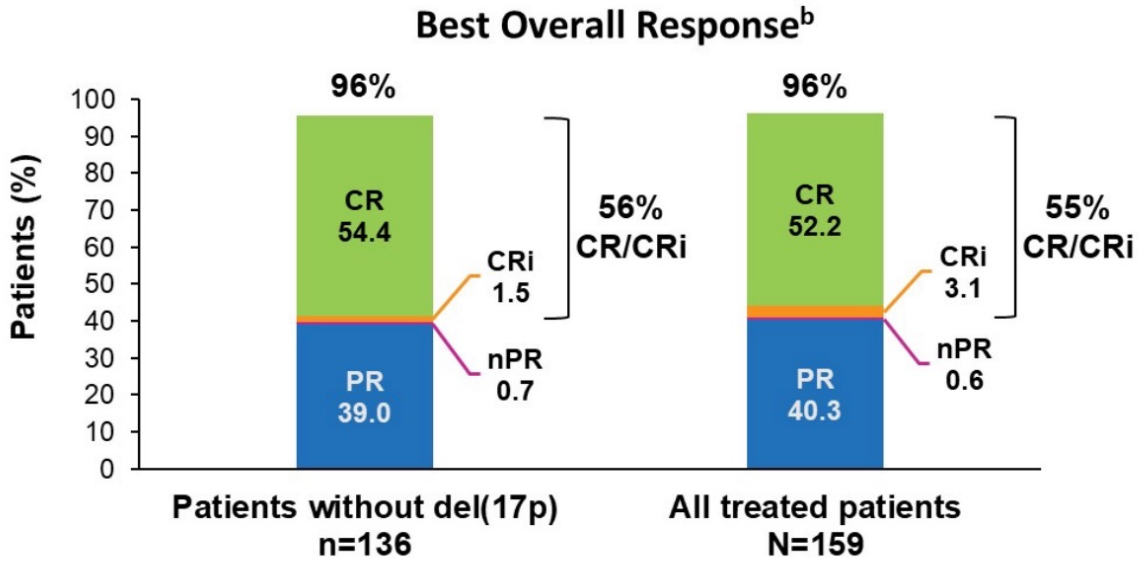


CLL, chronic lymphocytic leukemia; OS, overall survival; uMRD, undetectable minimal residual disease.

1. Lu P et al. *Blood Cancer J.* 2021; 11:39; 2. Deng J et al. *Leukemia.* 2017; 31:2075-2084; 3. Herman ES et al. *Clin Cancer Res.* 2015; 21:4642-4651; 4. Burger JA et al. *Leukemia.* 2020;34:787-798; 5. Shanafelt T et al. *N Engl J Med.* 2019;381:432-443; 6. VENCLEXTA (venetoclax tablets) for oral use [package insert]. South San Francisco, CA: Genentech USA Inc; 2020.

Ghia P et al. ASCO 2021;Abstract 7501.

Primary Endpoint of CR Rate[a]: Fixed-Duration Treatment with Ibrutinib + Venetoclax Provides Deep, Durable Responses



DOCR ≥12 cycles n/N (%)	66/76 (87)	78/88 (89)*

- Primary endpoint was met: 56% (95% CI, 48–64) CR rate[a] in patients without del(17p)
  - Significantly excludes 37% minimum rate (P<0.0001)
  - Meaningful improvement over 40% rate of historical comparator of FCR in CLL10[1]

*After achieving CR[a], 9 patients with <1 year of follow-up were not evaluable; 1 patient died 7 months after CR and completion of therapy.

nPR, nodular partial response; PR, partial response; DOCR, duration of complete response.
[a]Proportion of patients with CR or CRi. [b]Overall response was assessed at the end of Cycle 3, on Day 1 of Cycles 7, 10, 13, 19, 25, 28, and 31, and every 6 months thereafter.

1. Eichhorst B et al. *Lancet Oncol.* 2016;17:928-942.

ASCO 2021, CAPTIVATE-FD; Ghia et al.

Ghia P et al. ASCO 2021;Abstract 7501.

Fixed-Duration Ibrutinib and Venetoclax (I + V) versus Chlorambucil plus Obinutuzumab (CLB + O) for First-line (1L) Chronic Lymphocytic Leukemia (CLL): Primary Analysis of the Phase 3 GLOW Study

Kater A et al.

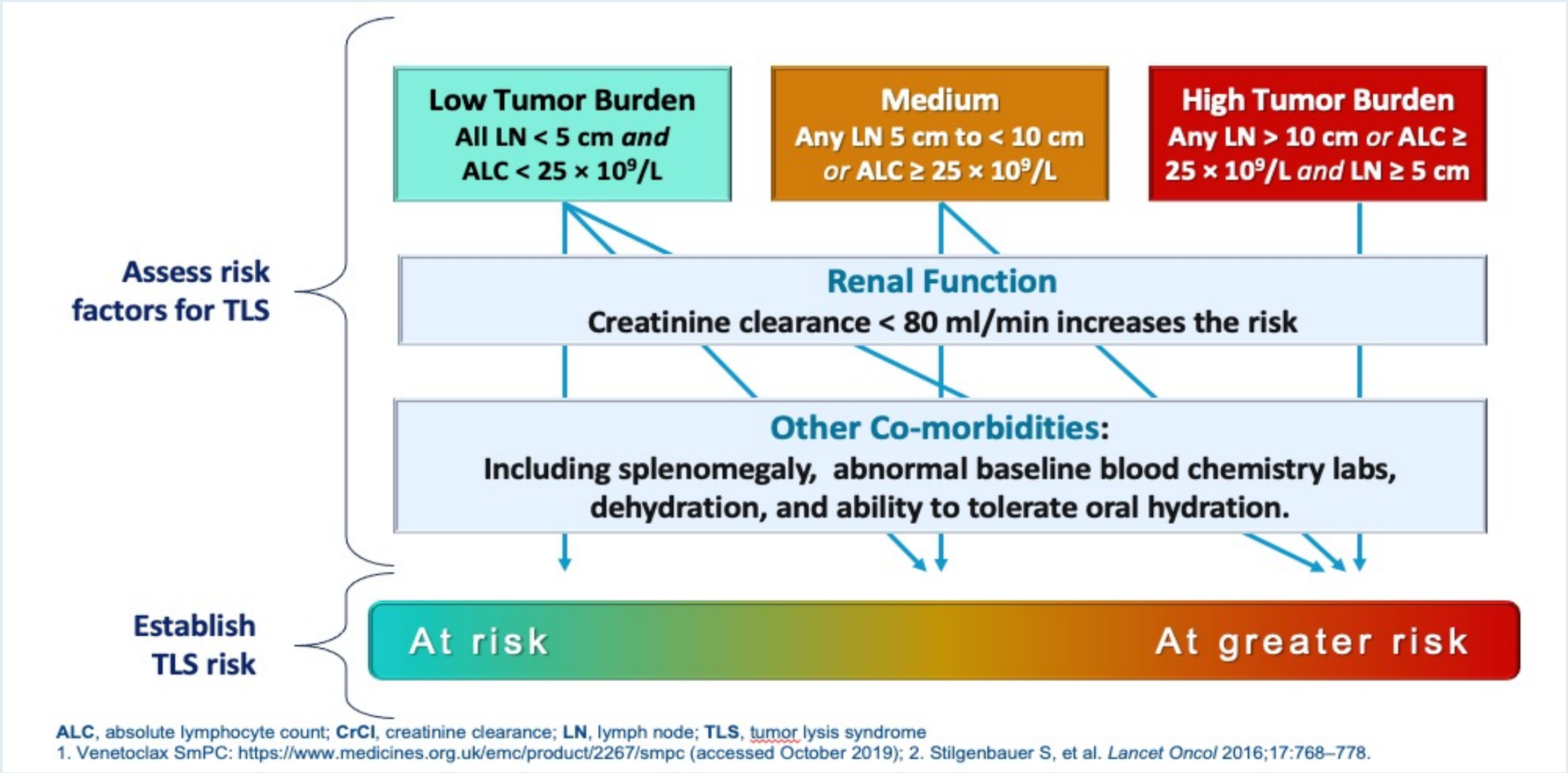
EHA 2021;Abstract LB1902.

Late-Breaking Oral Session: Saturday, June 12, 2021

Which of the following disease-related factors is critical in attempting to determine an individual's risk of developing tumor lysis syndrome from treatment with venetoclax for CLL?

1. White blood cell count
2. Size of lymph nodes
3. Tumor grade
4. All of the above
5. Only 1 and 2
6. Only 1 and 3
7. Only 2 and 3
8. I don't know

TLS Risk with Venetoclax Is a Continuum Based on Multiple Factors

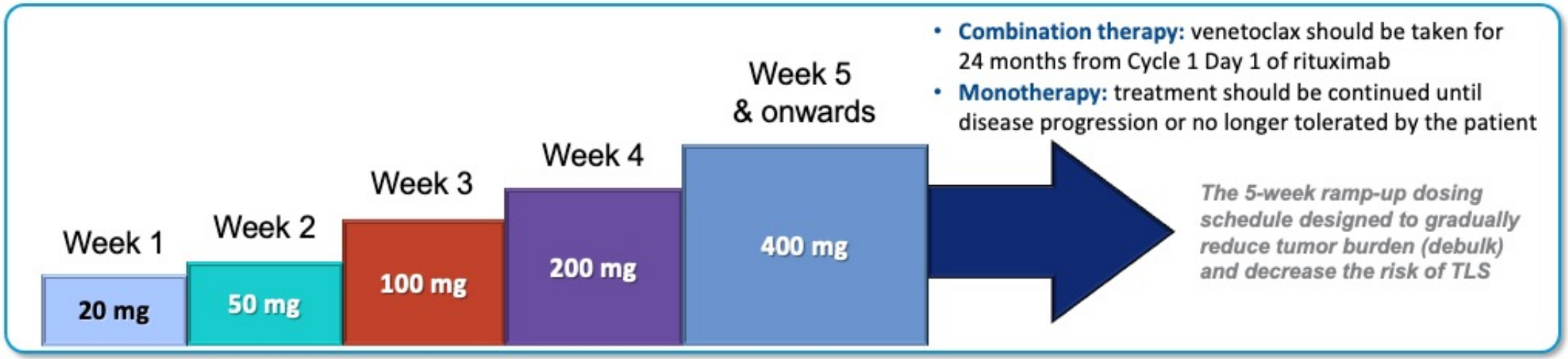


ALC, absolute lymphocyte count; **CrCl**, creatinine clearance; **LN**, lymph node; **TLS**, tumor lysis syndrome

1. Venetoclax SmPC: https://www.medicines.org.uk/emc/product/2267/smpc (accessed October 2019); 2. Stilgenbauer S, et al. *Lancet Oncol* 2016;17:768–778.

Courtesy of Matthew S Davids, MD, MMSc

Venetoclax Dose Initiation



The 5-week dose-titration schedule is designed to gradually reduce tumour burden and decrease the risk of TLS

Combination therapy: recommended dose of venetoclax in combination with rituximab is 400 mg once daily; rituximab should be administered after the patient has completed the dose-titration schedule and has received the recommended daily dose of 400 mg venetoclax for 7 days.

Monotherapy: the recommended dose of venetoclax is 400 mg once daily.

Venetoclax SmPC: https://www.medicines.org.uk/emc/product/2267/smpc (accessed October 2019).

Courtesy of Matthew S Davids, MD, MMSc

Venetoclax: TLS Prophylaxis and Monitoring

[a] **HYDRATION**	**Oral** (1.5 – 2 L); start 2 days prior to treatment start.	**IV** if needed due to higher TLS risk
ANTI-HYPER-URICAEMIC AGENTS	Patients with high uric acid or TLS risk should be administered with anti-hyperuricaemic agents **2 to 3 days prior** to treatment start	
[b,c] **LABORATORY MONITORING**	• **Pre-dose, 6–8, 24 hours** (at 1st dose of 20 mg and 50 mg, and for patients who continue to be at risk • Pre-dose at subsequent ramp-up doses	Evaluate blood chemistries and review in real time
HOSPITALIZATION	Based on physician assessment, some patients consider hospitalisation on first dose of venetoclax for more intensive prophylaxis and monitoring during the first 24 hours.	

[a]Administer intravenous hydration for any patient who cannot tolerate oral hydration; [b]Evaluate blood chemistries (potassium, uric acid, phosphorus, calcium, and creatinine); review in real time; [c]For patients at risk of TLS, monitor blood chemistries at 6–8 hours and at 24 hours at each subsequent ramp-up dose. Changes in blood chemistries consistent with TLS that require prompt management can occur as early as 6-8 hours following the first dose of venetoclax, and at each dose increase. **LN,** lymph node; **ALC**, absolute lymphocyte count; **TLS**, tumour lysis syndrome; **VEN**, venetoclax

1. Venetoclax SPC https://www.medicines.org.uk/emc/product/2267/smpc (accessed October 2019); 2. Stilgenbauer S, et al. *Lancet Oncol*. 2016; 17:768–778

Courtesy of Matthew S Davids, MD, MMSc

Agenda

Module 1: Up-Front Treatment with a BTK (Bruton Tyrosine Kinase) Inhibitor

- Dr Woyach: A 76-year-old man with IGHV-unmutated CLL
- Ms Battiato: A 50-year-old woman with IGHV-unmutated CLL/SLL and progressive lymphadenopathy

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Module 3: Future Directions in CLL (U2 Regimen, LOXO-305, CAR T-Cell Therapy)

- Dr Woyach: An 86-year-old man with relapsed CLL and an acquired C418S BTK mutation associated with ibrutinib resistance
- Ms Battiato: An 89-year-old woman with relapsed CLL/SLL – 17p deletion, no IGHV mutation

Case Presentation – Dr Woyach: An 86-year-old man with relapsed CLL and an acquired C418S BTK mutation associated with ibrutinib resistance

- 2008: Initial diagnosis with CLL
  - Unmutated IGHV, del(17p), complex karyotype
- 2013: BR → PD → lenalidomide/ofatumumab → PD
- 2013 – 2020: Ibrutinib → PD with C481S BTK mutation
- Pirtobrutinib (LOXO-305) initiated, and 16 cycles of therapy have been completed
- Excellent response to therapy

Case Presentation – Dr Woyach: An 86-year-old man with relapsed CLL and an acquired C418S BTK mutation associated with ibrutinib resistance (continued)

What important factors did you consider in managing this case?

1. High genomic risk CLL
2. Reversible BTKi as an investigational therapy for BTKi resistant CLL
3. Clinical trials
4. Potential AEs with BTK directed therapy

How was it different to take care of this patient versus another patient in the same oncologic setting? What unique biopsychosocial factors (eg, attitude, comorbidities, social support) were considered in the overall management of this case?

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Case Presentation – Ms Battiato: An 89-year-old woman with relapsed CLL/SLL – Del(17p), no IGHV mutation

- 1/2016: Initial diagnosis of CLL
  - IGHV unmutated, del(17p), trisomy 12, del(13q)
- 4/2016 - 9/2018: Ibrutinib (held in 9/2018 in preparation for meningioma resection)
- 9/2019: After being on observation, disease progression noted in the setting of leukocytosis and cytopenias
  - Monthly rituximab initiated, but complicated by recurrent infusion reactions following 4 cycles
- Venetoclax initiated → disease progression; IR biopsy negative for Richter's transformation
- 1/2021: Pirtobrutinib (LOXO-305) monotherapy on protocol, 200 mg dosing
- Remains on therapy with ongoing response

Case Presentation – Ms Battiato: An 89-year-old woman with relapsed CLL/SLL – Del(17p), no IGHV mutation (continued)

What are the 5 most important things that you discussed with this patient prior to starting treatment?

1. LOXO-305 is generally well tolerated, though common AEs include fatigue, diarrhea, neutropenia, and easy bruising.
2. The expectations of participating in a clinical trial and the importance of compliance.
3. LOXO-305 is effective in overcoming BTK resistance.
4. We had to reassure her that she is not a “guinea pig” and encourage her to participate.
5. Unsure of response timeline. Report all new medication and supplements.

How was it different to take care of this patient versus another patient in the same oncologic setting? What unique biopsychosocial factors (eg, attitude, comorbidities, social support) were considered in the overall management of this case?

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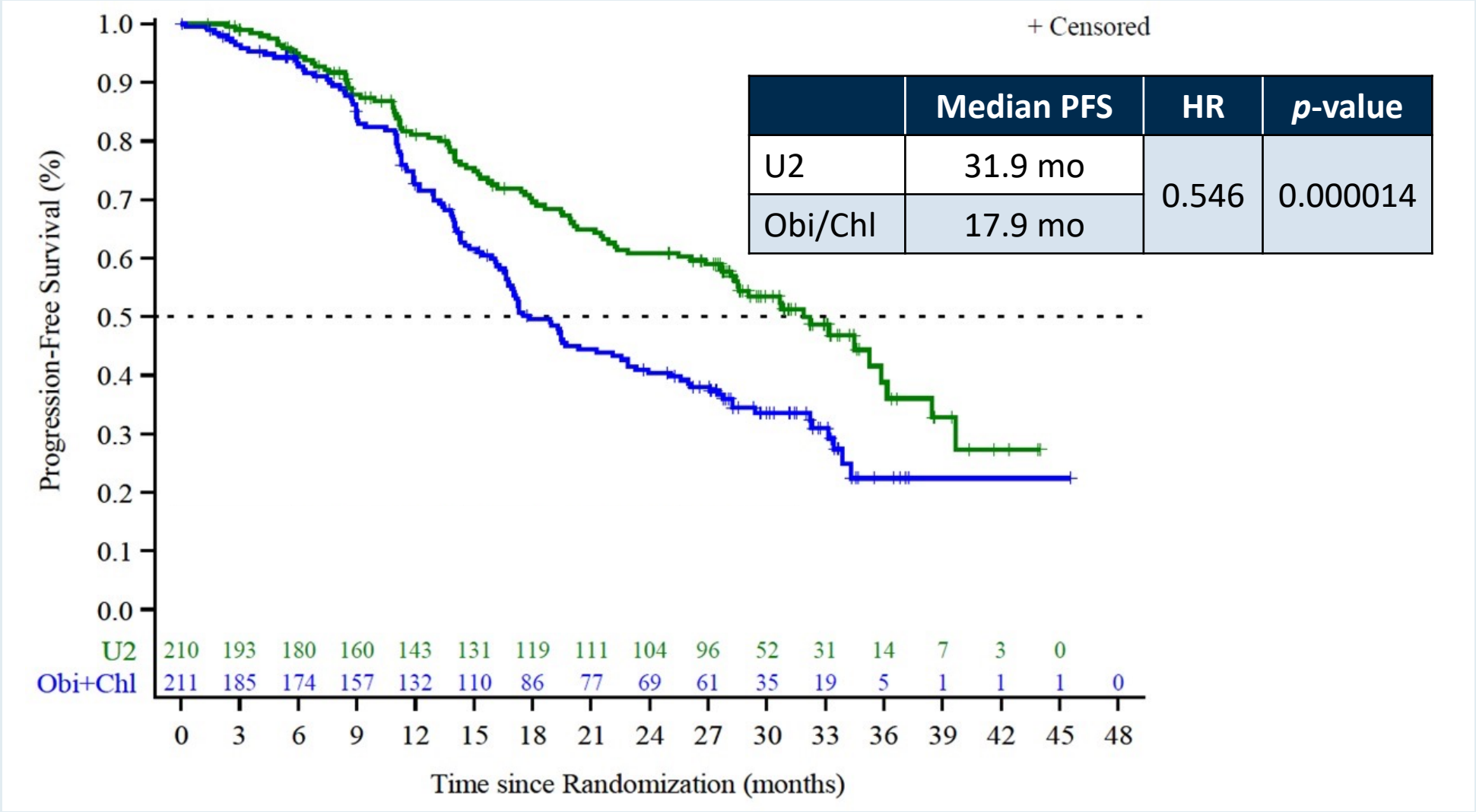
Umbralisib plus Ublituximab (U2) Is Superior to Obinutuzumab plus Chlorambucil (O + Chl) in Patients with Treatment Naïve (TN) and Relapsed/Refractory (R/R) Chronic Lymphocytic Leukemia (CLL): Results from the Phase 3 Unity-CLL Study

Gribben JG et al.

ASH 2020;Abstract 543.

UNITY-CLL: PFS with Umbralisib/Ublituximab (U2) versus Obinutuzumab/Chlorambucil



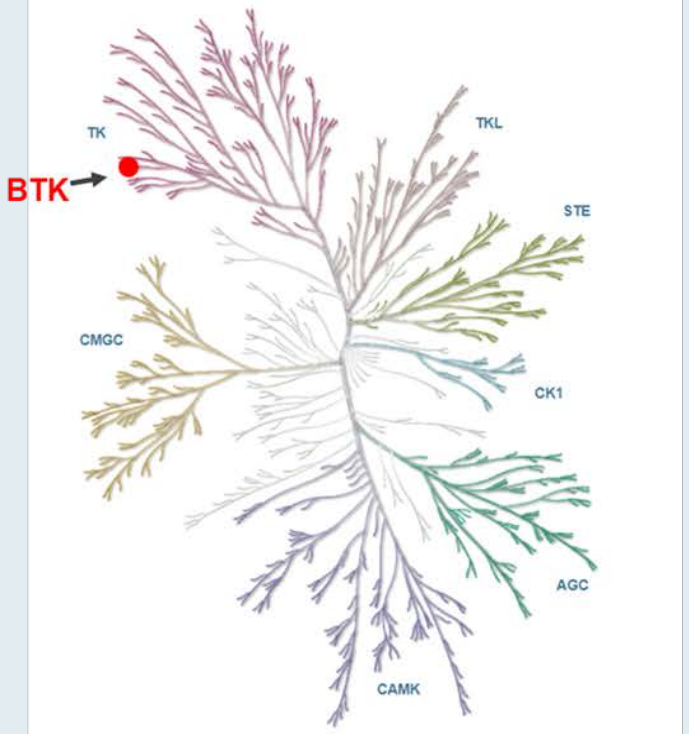
	Median PFS	HR	*p*-value
U2	31.9 mo	0.546	0.000014
Obi/Chl	17.9 mo		

Gribben JG et al. ASH 2020;Abstract 543.

LOXO-305 is a Highly Potent and Selective Non-Covalent BTK Inhibitor

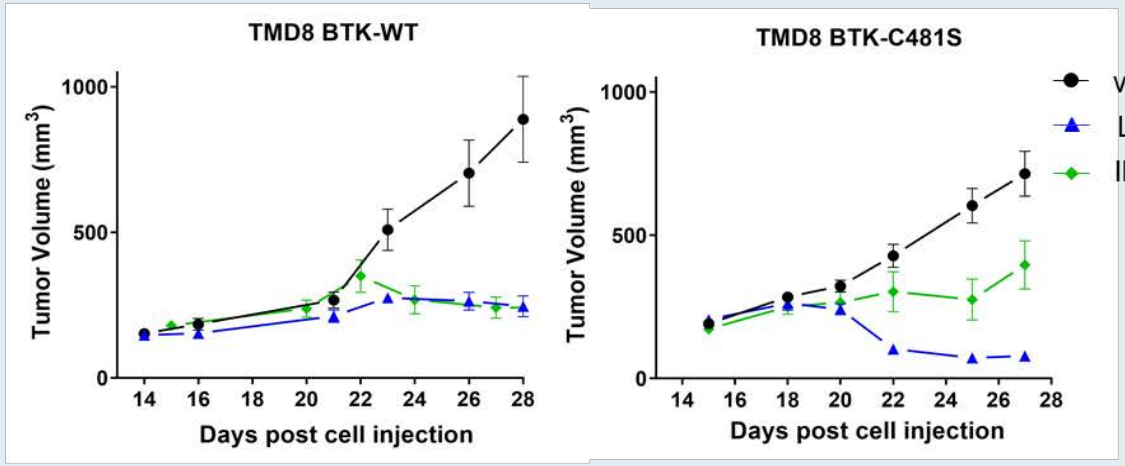
Kinome selectivity

Highly selective for BTK



Xenograft models

In vivo activity similarly efficacious as ibrutinib in WT; superior in C481S



- Nanomolar potency against WT & C481-mutant BTK in cell and enzyme assays[1,2]
- >300-fold selectivity for BTK vs 370 other kinases[1]
- Due to reversible binding mode, BTK inhibition not impacted by intrinsic rate of BTK turnover[1]
- Favorable pharmacologic properties allow sustained BTK inhibition throughout dosing interval[1]

BID, twice-daily; BTK, Bruton tyrosine kinase. Illustration reproduced courtesy of Cell Signaling Technology, Inc. (www.cellsignal.com). [1]Brandhuber et al. *Clin. Lymphoma Myeloma Leuk*. 2018;18:S216. [2]Mato et al. *Blood*. 2019:134 (Suppl 1):501.

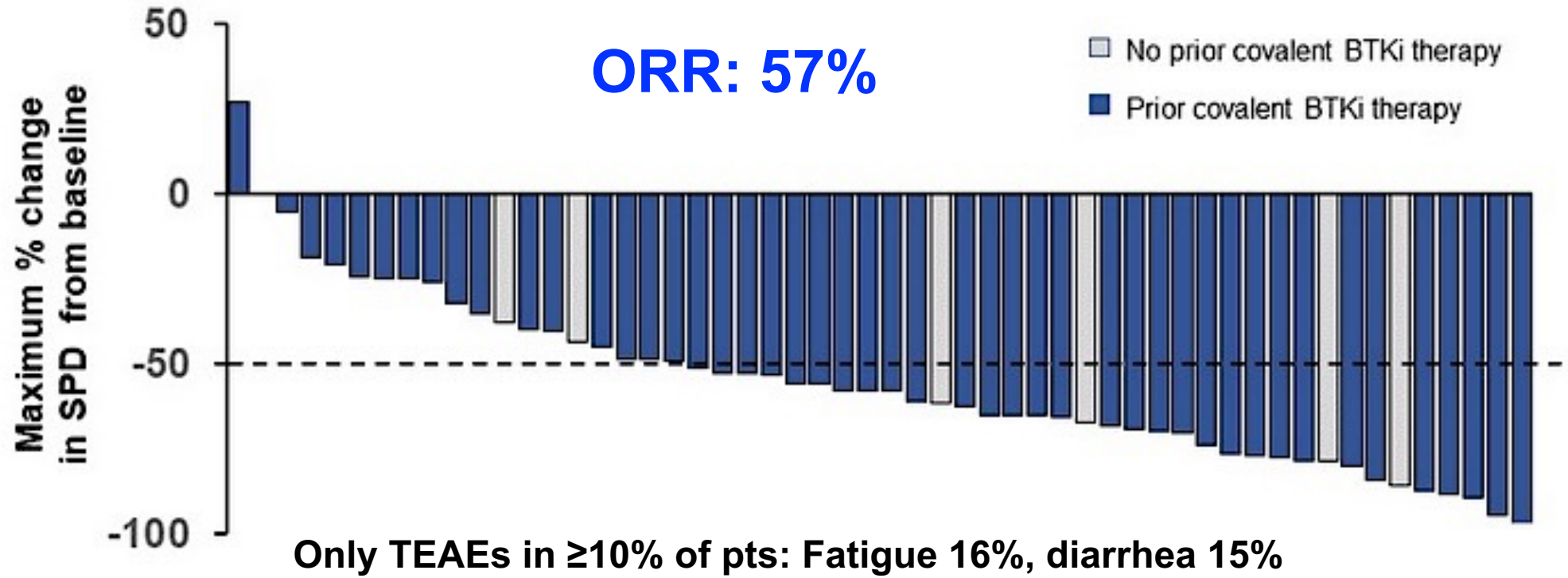
Mato AR et al. ASH 2020;Abstract 542.

LOXO-305, a Next Generation, Highly Selective, Non-Covalent BTK Inhibitor in Previously Treated CLL/SLL: Results from the Phase 1/2 BRUIN Study

Mato AR et al.

ASH 2020;Abstract 542.

BRUIN: LOXO-305 for Previously Treated CLL/SLL
(Median prior therapies: 4)



Only TEAEs in ≥10% of pts: Fatigue 16%, diarrhea 15%

* 11 efficacy-evaluable pts are not included in the waterfall plot, including 1 pt who discontinued prior to first response assessment, and 10 pts (4 pts with PR/PR-L and 6 pts with SD) with incomplete tumor lesion measurement data at the time of data cut

Mato AR et al. ASH 2020;Abstract 542.

Updated Follow-Up of Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Treated with Lisocabtagene Maraleucel in the Phase 1 Monotherapy Cohort of Transcend CLL 004, Including High-Risk and Ibrutinib-Treated Patients

Siddiqi T et al.

ASH 2020;Abstract 546.

Meet The Professor
Management of Ovarian Cancer

Tuesday, June 15, 2021
4:00 PM – 5:00 PM ET

Faculty
Susana Banerjee, MBBS, MA, PhD

Moderator
Neil Love, MD

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Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.

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