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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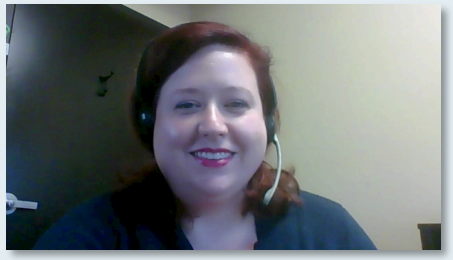
Medical Oncologists

Brian T Hill, MD, PhD
Director, Lymphoid Malignancy Program
Cleveland Clinic Taussig Cancer Institute
Cleveland, Ohio

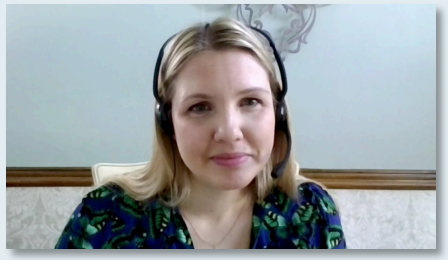
John M Pagel, MD, PhD
Chief of Hematologic Malignancies Program
Center for Blood Disorders and Stem Cell Transplantation
Swedish Cancer Institute
Seattle, Washington

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

Oncology Nurse Practitioners



Lesley Camille Ballance, MSN, FNP-BC
Sarah Cannon Center for Blood Cancer
Tennessee Oncology
Nashville, Tennessee



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Advanced Practice Providers
Memorial Sloan Kettering Cancer Center
New York, New York

Corinne Hoffman, MS, APRN-CNP, AOCNP
Nurse Practitioner, Hematology
The James Comprehensive Cancer Center
The Ohio State University Wexner Medical Center
Columbus, Ohio

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Commercial Support

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Dr Love — Disclosures

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Contracted Research	AbbVie Inc, Celgene Corporation, Genentech, a member of the Roche Group, Kite, A Gilead Company, Takeda Oncology

Dr Pagel — Disclosures

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Dr Woyach — Disclosures

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Ms Ballance — Disclosures

No relevant conflicts of interest to disclose.

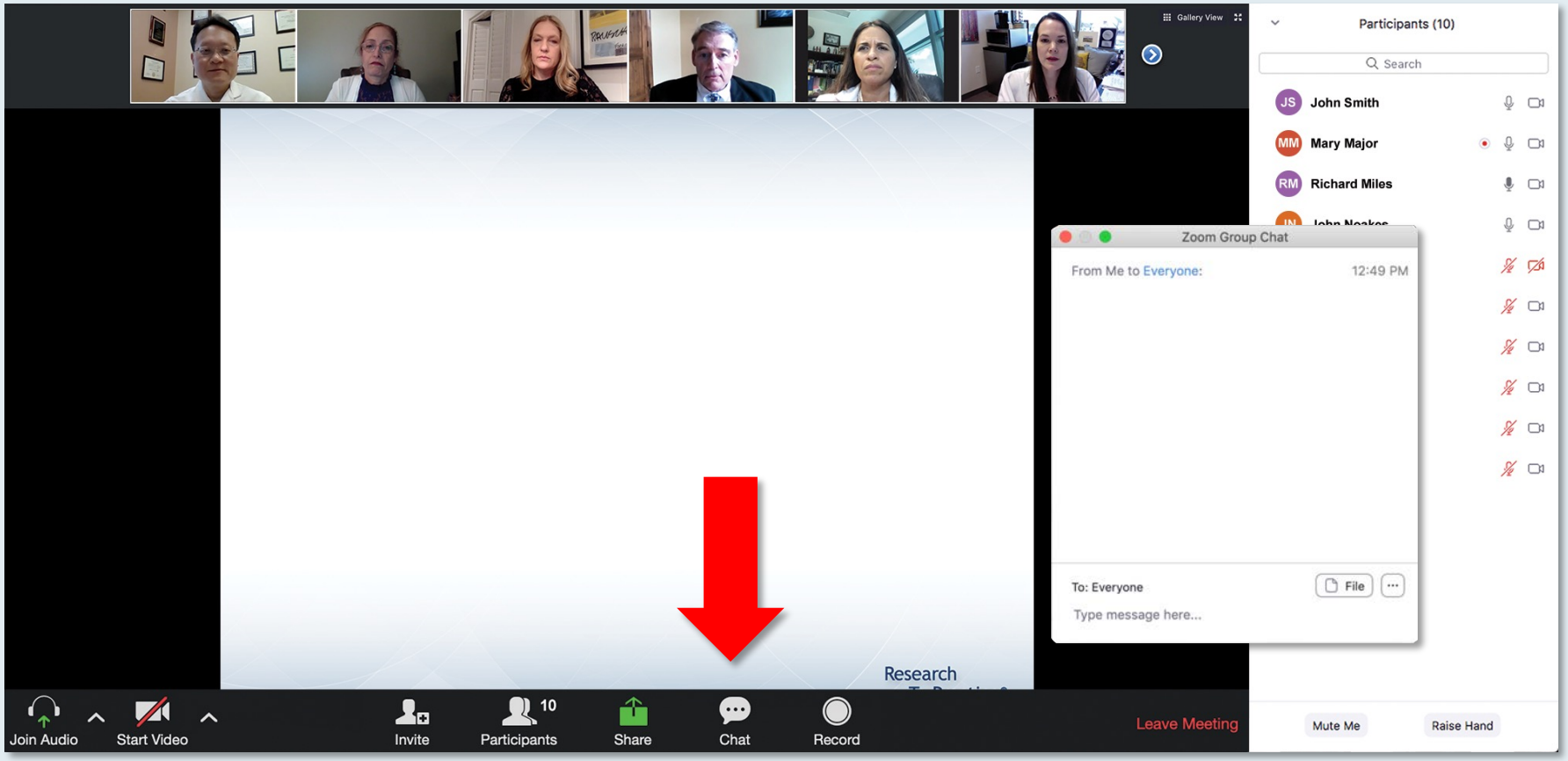
Ms Battiato — Disclosures

No relevant conflicts of interest to disclose.

Ms Hoffman — Disclosures

Advisory Committee	AstraZeneca Pharmaceuticals LP

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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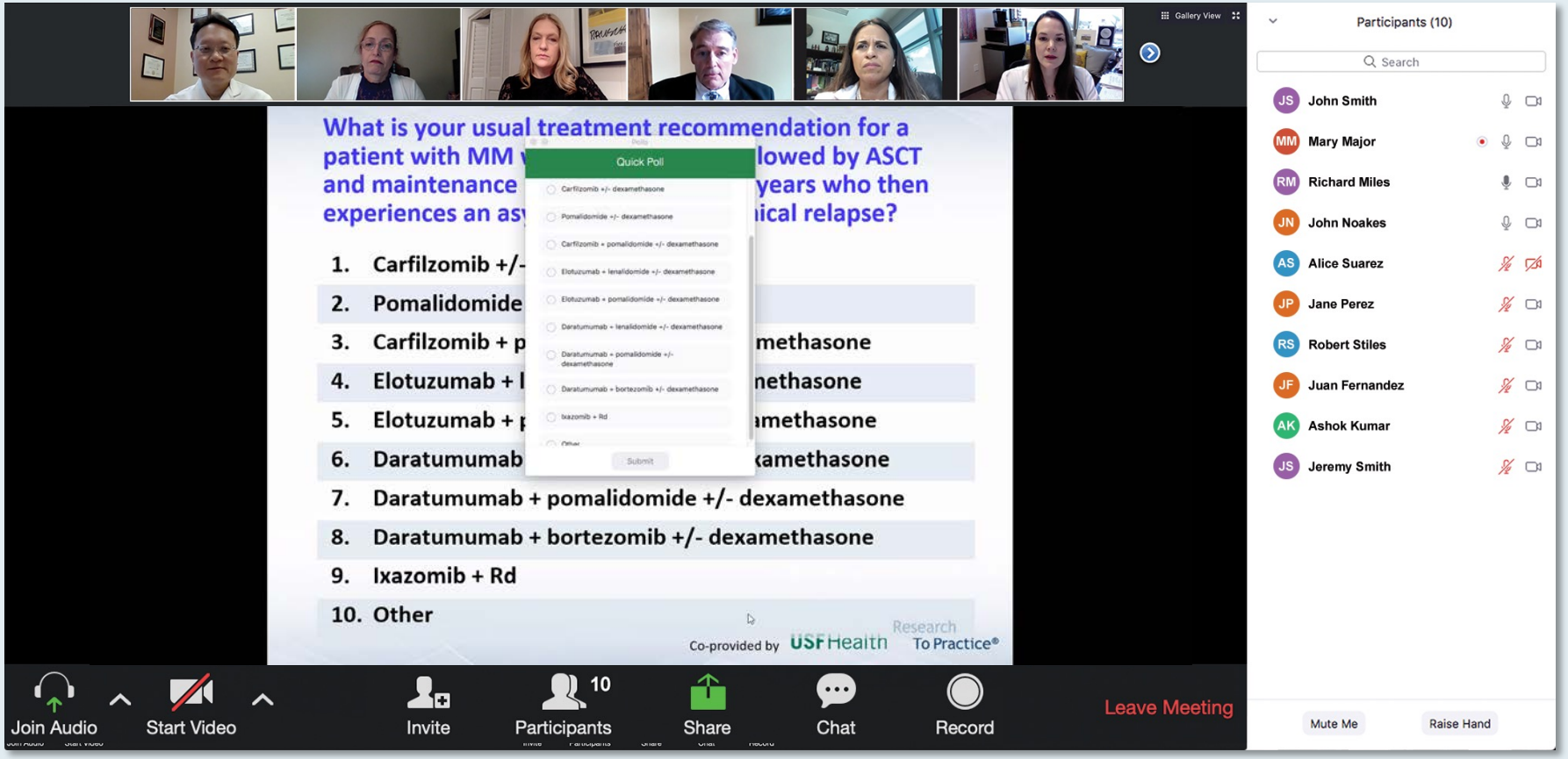
Familiarizing Yourself with the Zoom Interface

How to answer poll questions



When a poll question pops up, click your answer choice from the available options.

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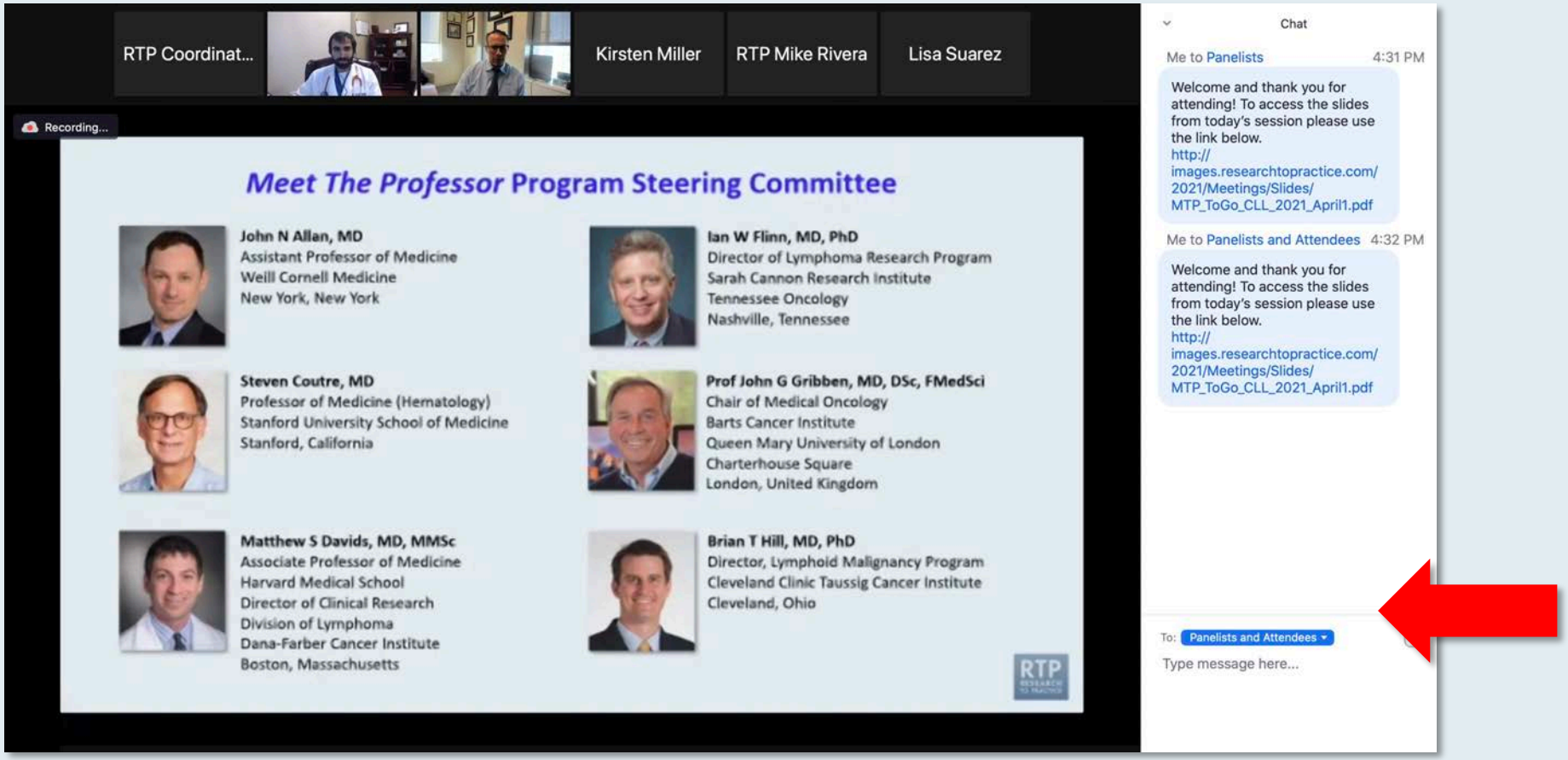
Familiarizing Yourself with the Zoom Interface

Expand chat submission box



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

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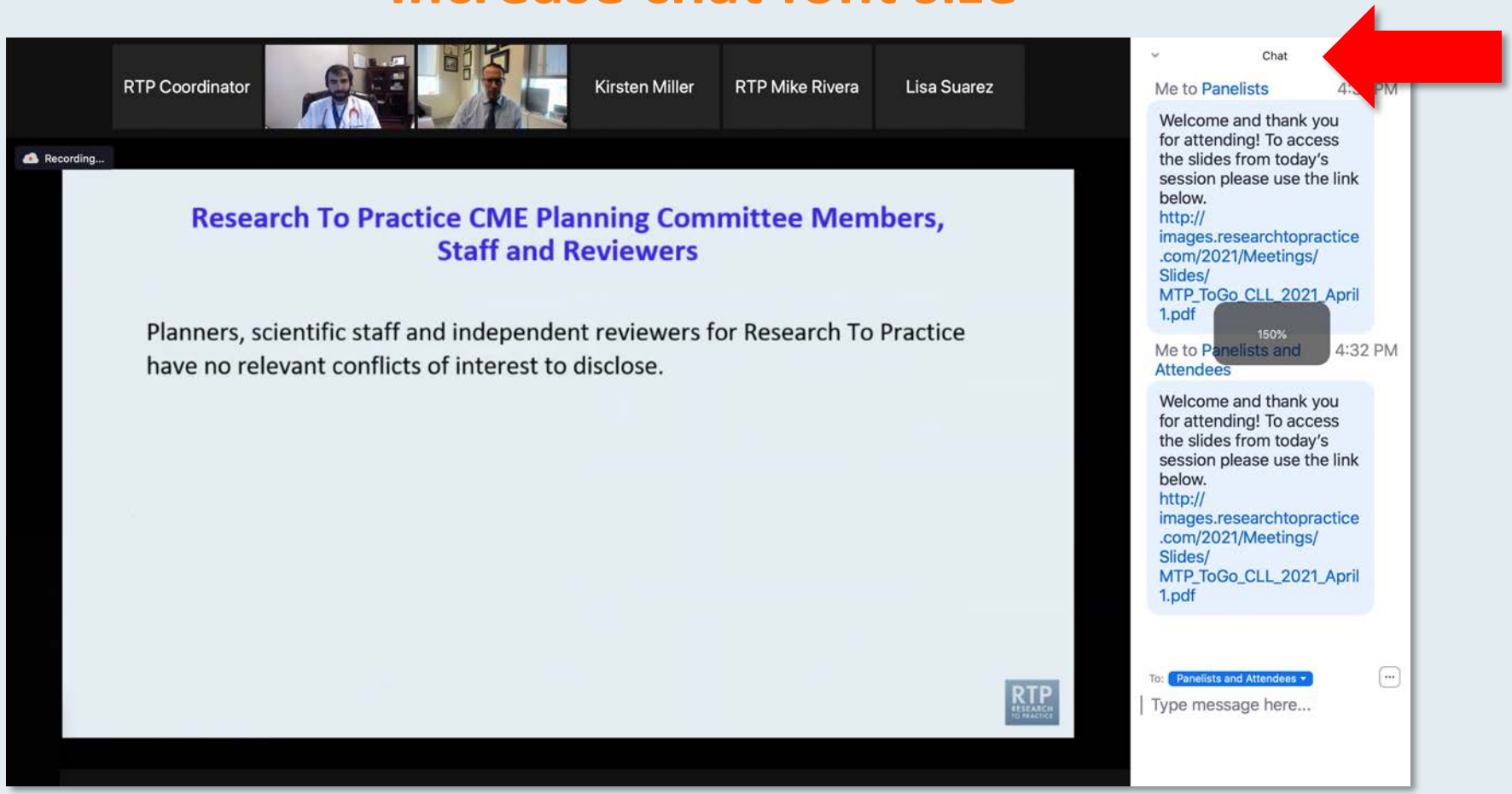
Familiarizing Yourself with the Zoom Interface

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

Current Role of Minimal Residual Disease Assessment in the Management of Multiple Myeloma and Chronic Lymphocytic Leukemia

DR PHILIP THOMPSON

THE UNIVERSITY OF TEXAS
MD ANDERSON CANCER CENTER

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Breast Cancer
Tuesday, April 20, 2021
8:30 AM – 10:00 AM ET

Non-Small Cell Lung Cancer
Tuesday, April 20, 2021
5:00 PM – 6:30 PM ET

Acute Myeloid Leukemia
Wednesday, April 21, 2021
12:00 PM – 1:00 PM ET

Colorectal and Gastroesophageal Cancers
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4:45 PM – 5:45 PM ET

Prostate Cancer
Thursday, April 22, 2021
8:30 AM – 10:00 AM ET

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Chimeric Antigen Receptor T-Cell Therapy
Thursday, April 29, 2021
5:00 PM – 6:30 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, May 4, 2021
5:00 PM – 6:00 PM ET

Faculty

Chung-Han Lee, MD, PhD

Moderator

Neil Love, MD

Current Concepts and Recent Advances in Oncology

A Daylong Clinical Summit Hosted in Partnership with Medical Oncology Association of Southern California (MOASC)

Saturday, May 15, 2021
10:30 AM – 6:30 PM ET

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Saturday, May 15, 2021

10:30 AM — Breast Cancer
Ruth O'Regan, Tiffany A Traina

11:30 AM — Multiple Myeloma
Kenneth Anderson, Noopur Raje

12:50 PM — Chronic Lymphocytic Leukemia and Lymphomas
Craig Moskowitz, Jeff Sharman

1:50 PM — Genitourinary Cancers
Joaquim Bellmunt, Sumanta Kumar Pal

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Saturday, May 15, 2021

3:15 PM — Gastrointestinal Cancers
Wells A Messersmith, Eileen M O'Reilly

4:15 PM — Acute Myeloid Leukemia and Myelodysplastic Syndromes
Harry Paul Erba, Rami Komrokji

5:35 PM — Lung Cancer
D Ross Camidge, Benjamin Levy

Up for Debate: Oncology Investigators Provide Their Take on Current Controversies in Patient Care

A Daylong Multitumor Educational Webinar
in Partnership with Florida Cancer Specialists

Saturday, May 22, 2021
10:15 AM – 4:15 PM ET

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Saturday, May 22, 2021

10:15 AM — Lung Cancer
John V Heymach, Stephen V Liu

11:30 AM — Genitourinary Cancers
Maha Hussain, Elizabeth R Plimack

12:45 PM — Chronic Lymphocytic Leukemia and Lymphomas
Jonathan W Friedberg, Laurie H Sehn

2:00 PM — Multiple Myeloma
Irene M Ghobrial, Sagar Lonial

3:15 PM — Breast Cancer
Virginia Kaklamani, Nancy U Lin

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Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.

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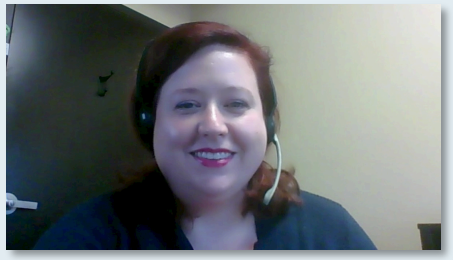

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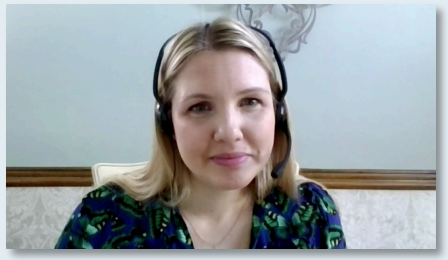

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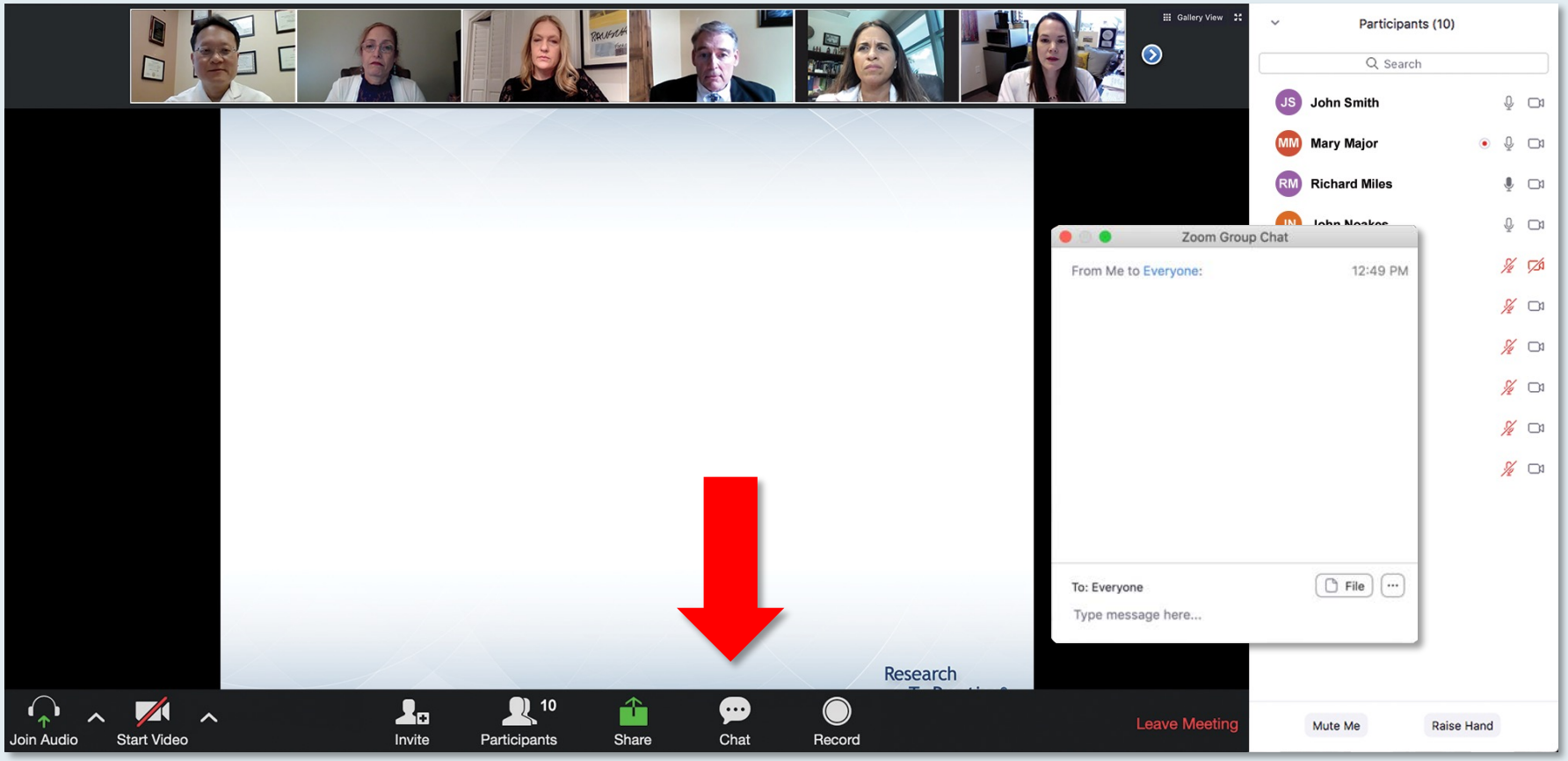

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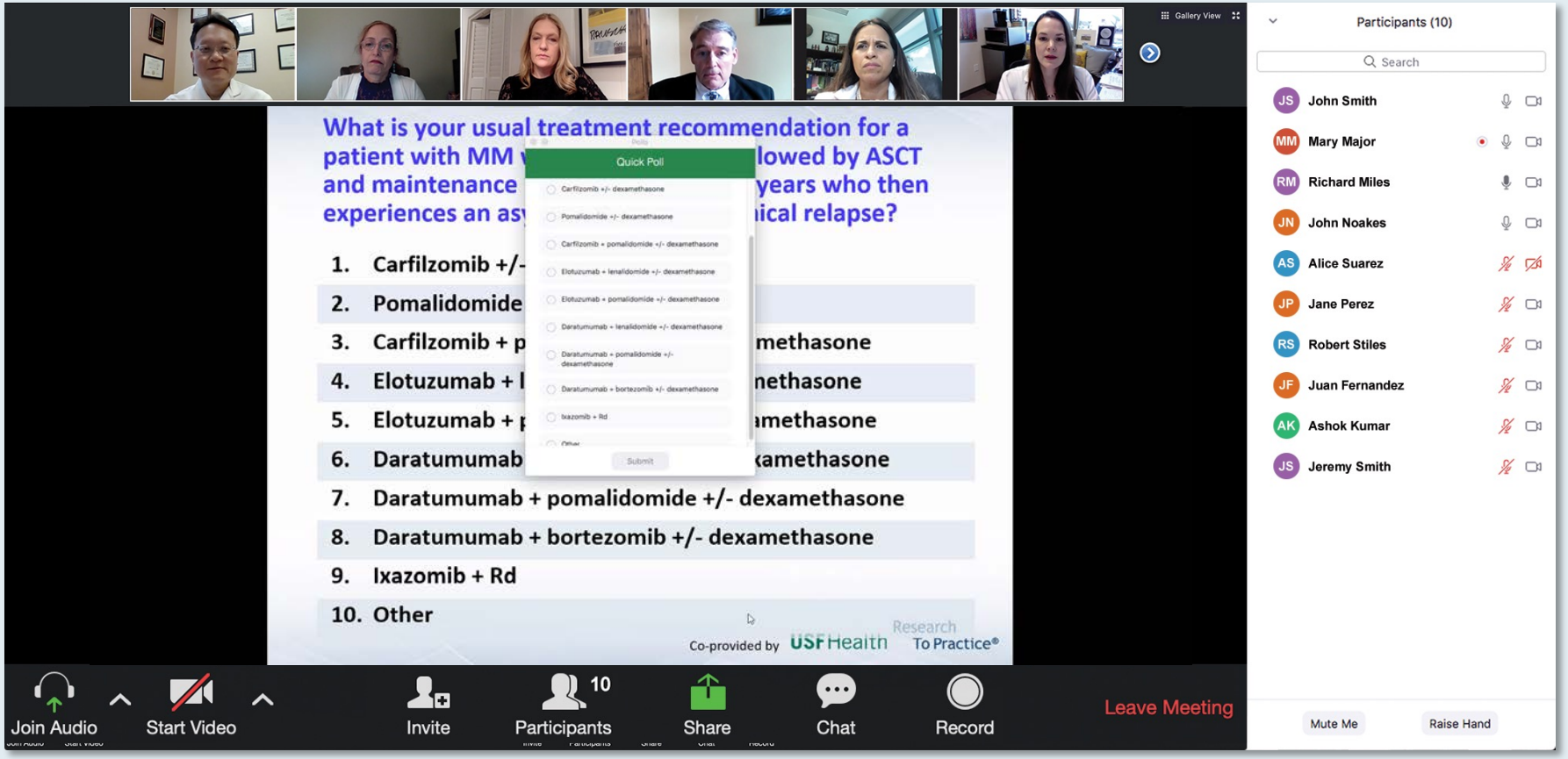

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Medical Oncologists

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Director of Breast Immunotherapy Clinical Research
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Associate Professor of Medicine
Harvard Medical School
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Los Angeles, California

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Oncology Nurse Practitioners

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Massachusetts General Hospital
Boston, Massachusetts

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Dana-Farber Cancer Institute
Boston, Massachusetts

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Philadelphia, Pennsylvania

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Northwestern Memorial Hospital
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Alli McClanahan, MSN, APRN, ANP-BC
Nurse Practitioner
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Mayo Clinic
Rochester, Minnesota

Jessica Mitchell, APRN, CNP, MPH
Assistant Professor of Oncology
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Rochester, Minnesota

Mollie Moran, APRN-CNP, AOCNP
The James Cancer Hospital and Solove
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Cleveland, Ohio

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Perelman Center for Advanced Medicine
University of Pennsylvania Medical Center
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APN Inpatient Hematopoietic Cellular Therapy Service
University of Chicago Medicine
Chicago, Illinois

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Oncology Grand Rounds Nursing Webinar Series

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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ONCOLOGY TODAY

WITH DR NEIL LOVE

A Personal Experience with COVID-19

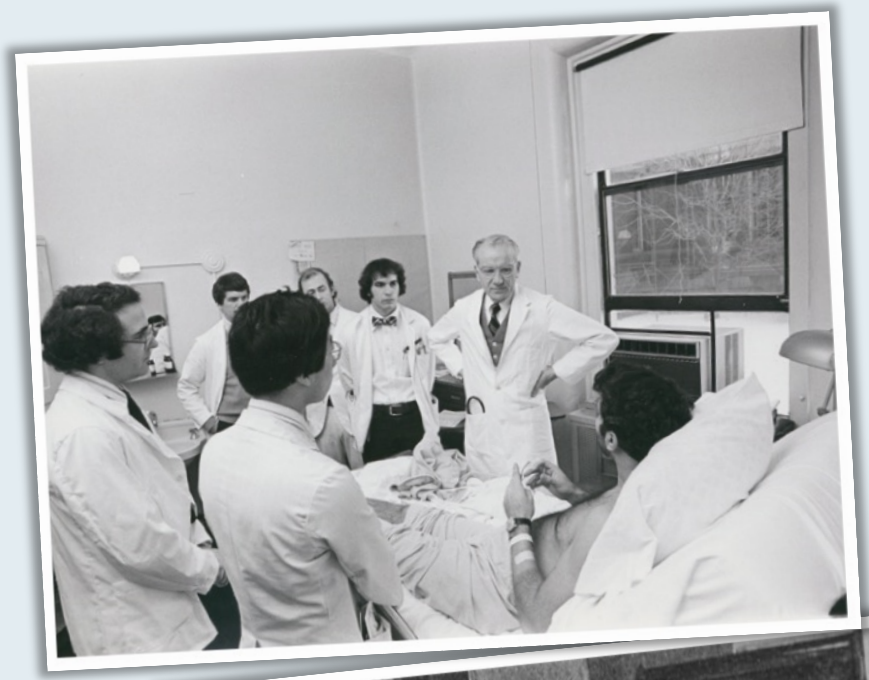
DR NOOPUR RAJE

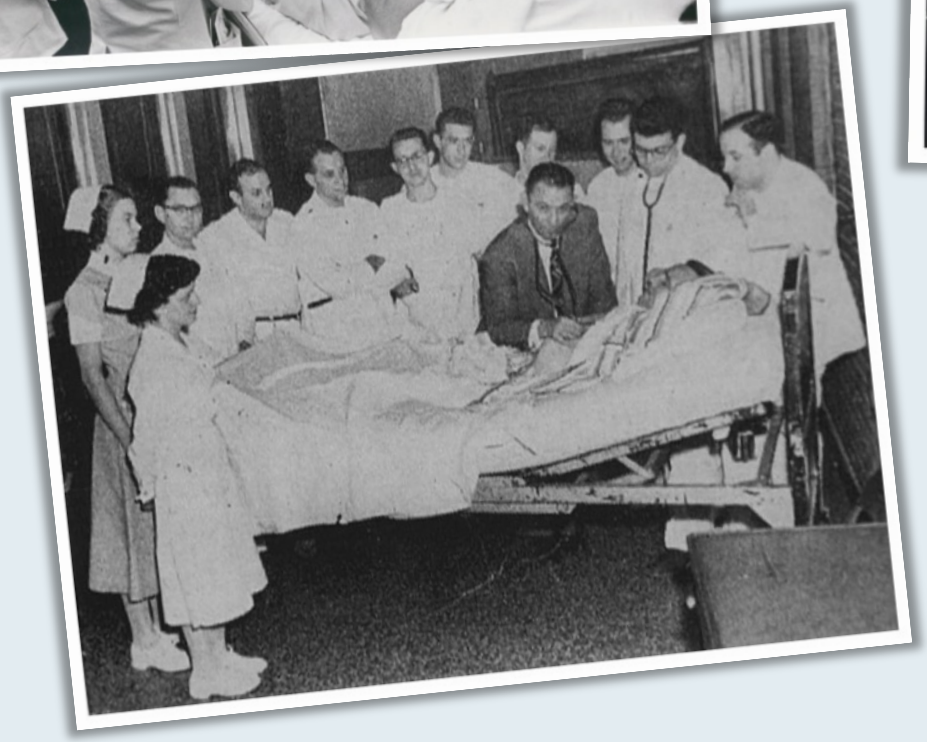
MASSACHUSETTS GENERAL HOSPITAL

Listen on Apple Podcasts

Spotify

Listen on Google Podcasts






The Birmingham News

13th Annual Oncology Grand Rounds

Oncology Nurse Practitioners

Case Presentations

- Key patient-education issues
- Biopsychosocial considerations:
  - Family/loved ones
  - The bond that heals

Clinical Investigators

Oncology Strategy

- New agents and regimens
- Predictive biomarkers
- Ongoing research and implications

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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

Contributing 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

Agenda

Module 1: Overview of the Current Era of CLL Treatment

Module 2: Up-Front Treatment with a BTK (Bruton Tyrosine Kinase) Inhibitor

- Case 1 (Ms Battiato): A 75-year-old woman with CLL who receives first-line ibrutinib
- Case 2 (Ms Ballance): A 51-year-old woman with previously untreated CLL who receives acalabrutinib

Module 3: Up-Front Treatment with Obinutuzumab/Venetoclax

- Case 3 (Ms Battiato): A 71-year-old man with CLL who desires time-limited therapy
- Case 4 (Ms Hoffman): A 67-year-old man with CLL and malignant pleural effusions
- Case 5 (Ms Ballance): A 44-year-old woman with CLL who was initially observed off treatment

Module 4: Future Directions in CLL (U2 Regimen, LOXO-305, CAR T-Cell Therapy)

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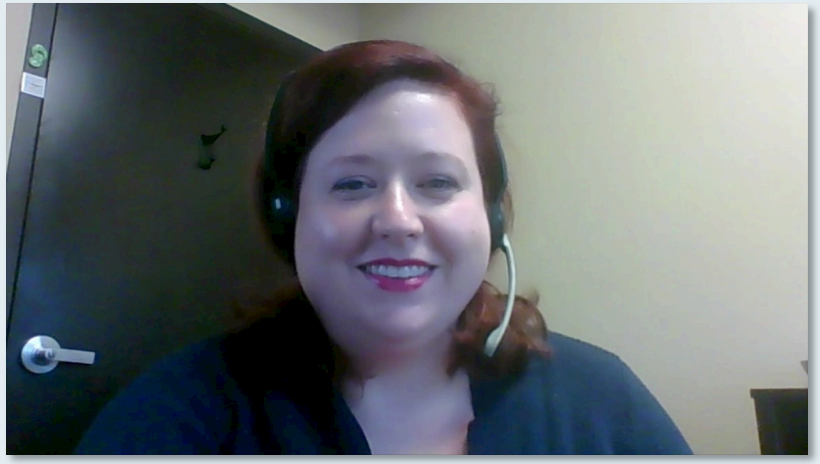
Module 4: Future Directions in CLL (U2 Regimen, LOXO-305, CAR T-Cell Therapy)

Reflections on managing patients with CLL

Ms Battiato

Ms Hoffman



Ms Ballance

Patients with newly diagnosed chronic lymphocytic leukemia (CLL) who feel well and are asymptomatic require treatment if…

1. Del(17p)/TP53 mutation is detected
2. White blood cell count exceeds 200,000
3. Both 1 and 2
4. Neither 1 nor 2
5. I don’t know

Available clinical trial data demonstrate that younger patients with CLL with IGHV mutation but without del(17p) or TP53 mutation can experience prolonged remissions after the completion of short-term therapy with which of the following regimens?

1. Ibrutinib
2. Acalabrutinib
3. FCR (fludarabine/cyclophosphamide/rituximab)
4. Obinutuzumab/chlorambucil
5. I don’t know

Patients with CLL and which of the following prognostic factors generally do not respond well to chemoimmunotherapy?

1. Del(17p)
2. TP53 mutation
3. IGHV mutation
4. All of the above
5. Only 1 and 2
6. I don’t know

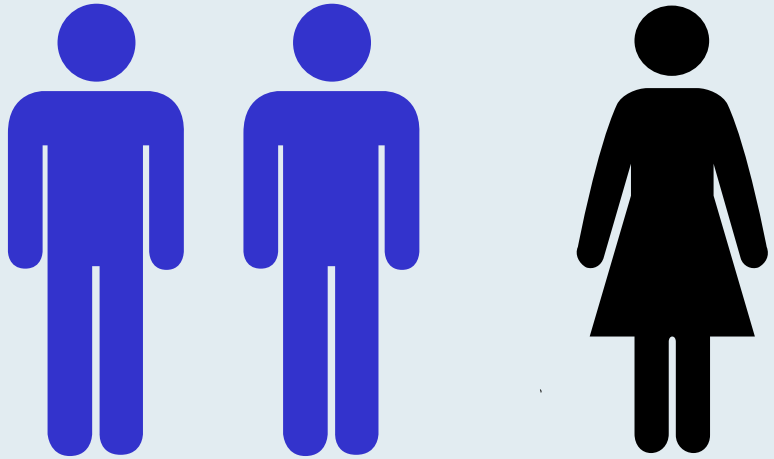
CLL Impacts a Significant Number of Patients Worldwide, Predominantly Affecting Older Patients

With an estimated 191,000 new cases globally, CLL represents 22% to 30% of all leukemia worldwide, being the most common leukemia in Western countries[1,2]

Median age at diagnosis[3]:

~90% of patients diagnosed with CLL are >55 years old[4]

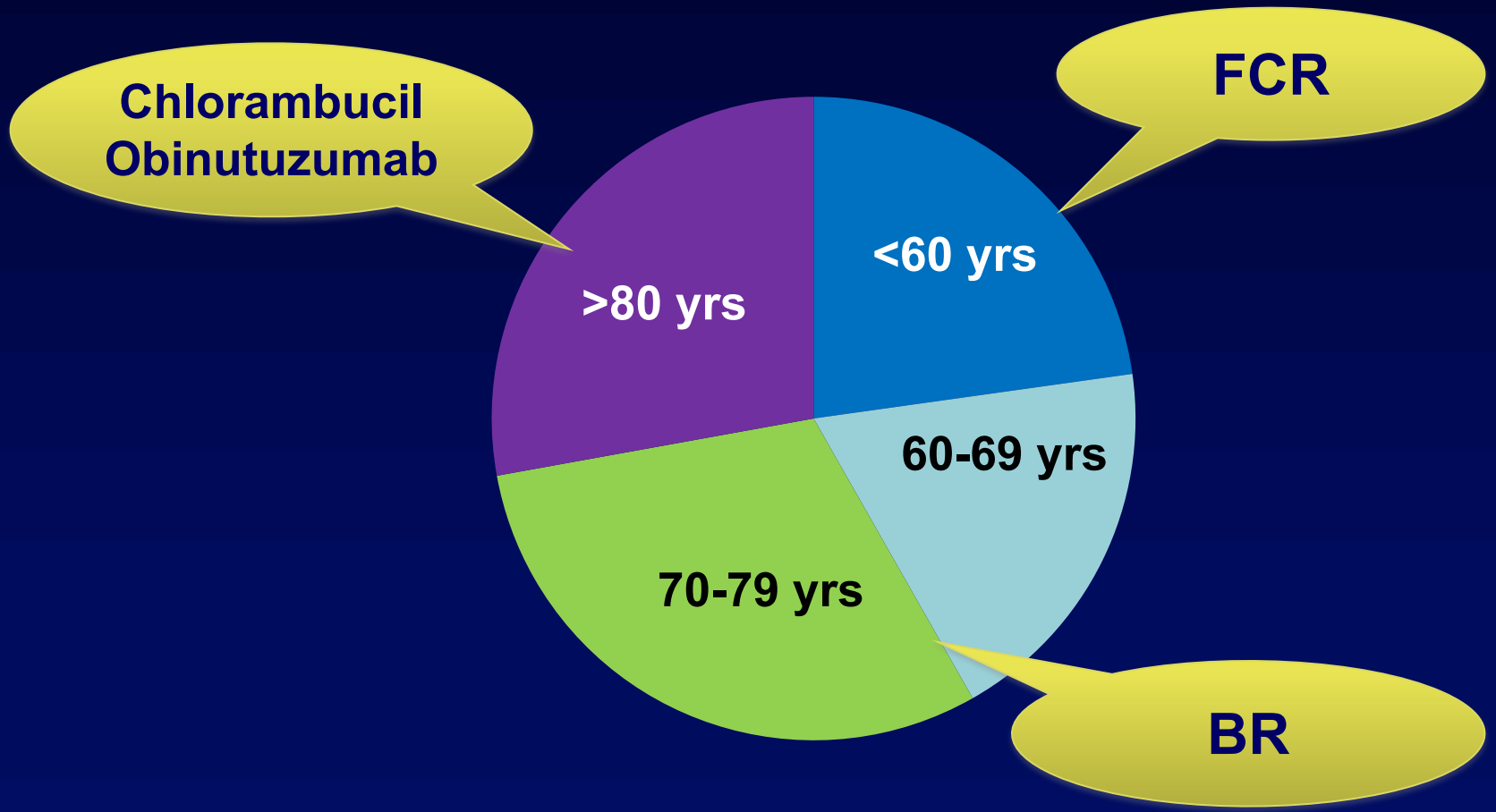
Men are ~2X more likely to develop CLL[5]



1. Union for International Cancer Control. https://www.who.int/selection_medicines/committees/expert/20/applications/CLL.pdf. Accessed November 6, 2019. 2. Combest AJ, et al. *J Hematol Oncol Pharm*. 2016;6(2):54-56. 3. Eichhorst B, et al. *Ann Oncol*. 2015;26(suppl 5):v78-v84. 4. Lymphoma Coalition. https://lymphomacoalition.org/images/subtype-reports/CLL_Europe _2017_Report.pdf. Accessed November 6, 2019. 5. Scarfò L, et al. *Crit Rev Oncol Hematol*. 2016;104:169-182.

Courtesy of John M Pagel, MD, PhD

A simplistic (and outdated) approach to CLL



Courtesy of Brad S Kahl, MD

Novel agents in CLL have recently revolutionized therapy

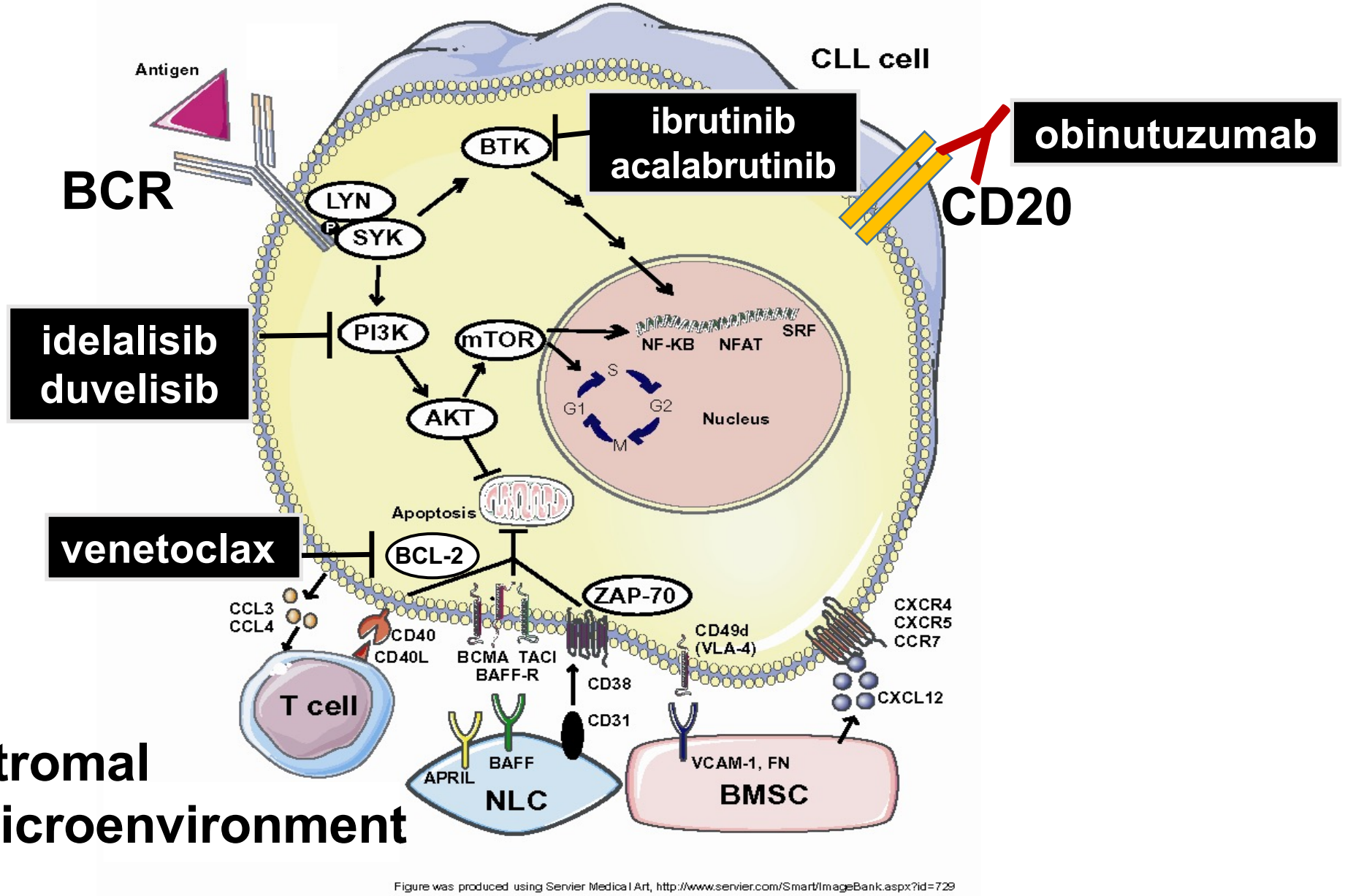


Figure was produced using Servier Medical Art, http://www.servier.com/Smart/ImageBank.aspx?id=729

Courtesy of Matthew S Davids, MD

Adapted from Davids and Brown, *Leuk Lymphoma*, 2012

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Module 4: Future Directions in CLL (U2 Regimen, LOXO-305, CAR T-Cell Therapy)

The use of anticoagulant therapy is an absolute contraindication to the use of ibrutinib for patients with CLL.

1. Agree
2. Disagree
3. I don’t know

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BTK inhibitors should be temporarily discontinued in patients scheduled to undergo surgical procedures.

1. Agree
2. Disagree
3. I don’t know

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Case Presentation – A 75-year-old woman with CLL who receives first-line ibrutinib (Part 1)

Ms Battiato

- History of untreated depression and anxiety; general distrust of the healthcare system
- Observation for CLL “for some time”
- 2018: Presents for second opinion; Hgb 7.1 and starting to require blood transfusions
  - IGHV unmutated, trisomy 12
- Ibrutinib 420 mg prescribed but patient does not take for 1 month
- Counseled her about need for treatment; patient only willing to take ibrutinib 280 mg
- Epistaxis requiring cauterization by ENT; patient reluctant to restart therapy but agrees to ibrutinib 140 mg

Case Presentation – A 75-year-old woman with CLL who receives first-line ibrutinib (Part 2)

Ms Battiato

- History of untreated depression and anxiety; general distrust of the healthcare system
- Observation for CLL "for some time"
- 2018: Presents for second opinion; Hgb 7.1 and starting to require blood transfusions
  - IGHV unmutated, trisomy 12
- Ibrutinib 420 mg prescribed but patient does not take for 1 month
- Counseled her about need for treatment; patient only willing to take ibrutinib 280 mg
- Epistaxis requiring cauterization by ENT; patient reluctant to restart therapy but agrees to ibrutinib 140 mg
- ***Challenges of building rapport and trust with the patient and her partner***
- ***Considerations when recommending BTK inhibitor therapy***

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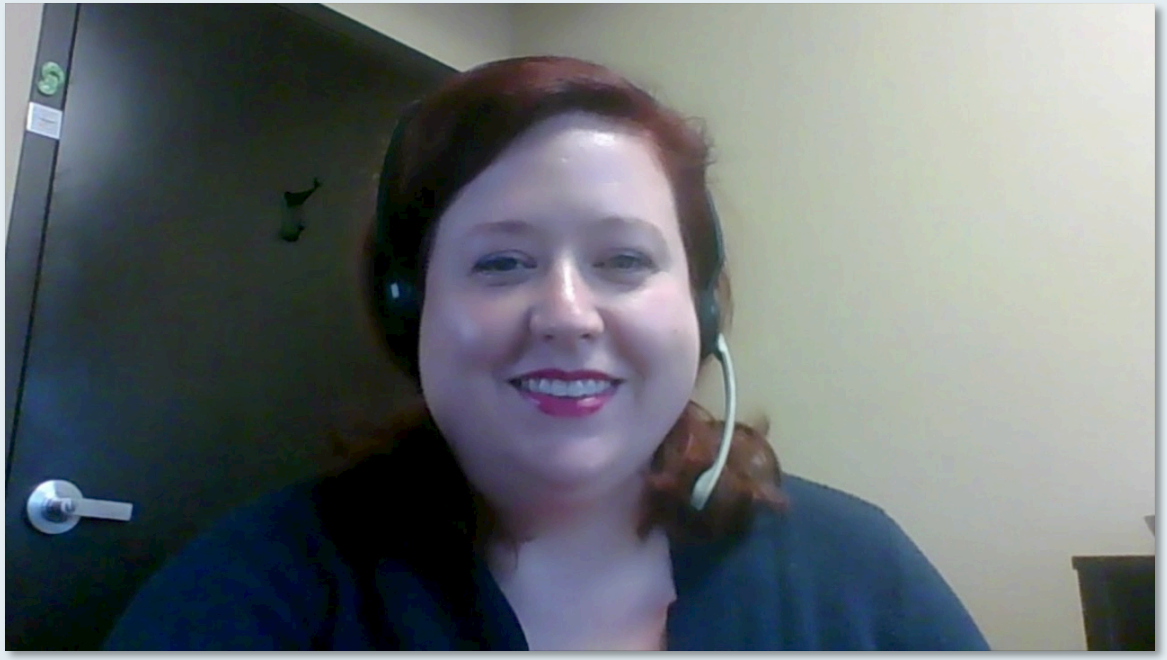
Educating patients about watchful waiting and risk of infections

Ms Hoffman



Ms Ballance

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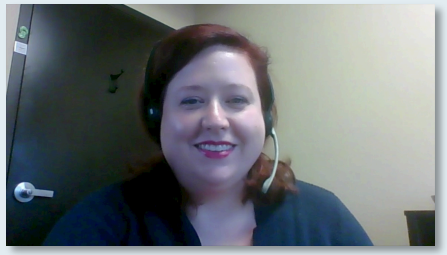
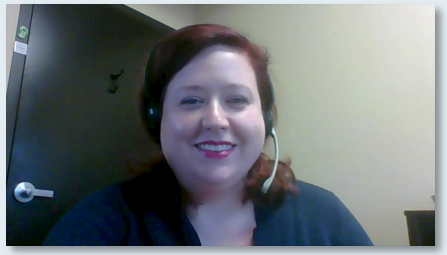
Case Presentation – A 51-year-old woman with previously untreated CLL who receives acalabrutinib (Part 1)



Ms Ballance

- 2014: Diagnosed with CLL, on watch and wait past 6 years
- In the past few months, WBC increasing, Hgb <11, platelets decreasing, asymptomatic
- IGHV mutated, del(13q)
- Prefers oral medication
- Reluctant to begin treatment
- Acalabrutinib
- Very active mother, who homeschools her children; informed them she has a chronic disease

Case Presentation – A 51-year-old woman with previously untreated CLL who receives acalabrutinib (Part 2)



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- Prefers oral medication
- Reluctant to begin treatment
- Acalabrutinib
- Very active mother, who homeschools her children; informed them she has a chronic disease
- ***Educated the patient about acalabrutinib-related headache, lymphocytosis, importance of adherence***

Ms Hoffman: Holding BTK inhibitor therapy for medical procedures; educating patients about therapy-associated arthralgias

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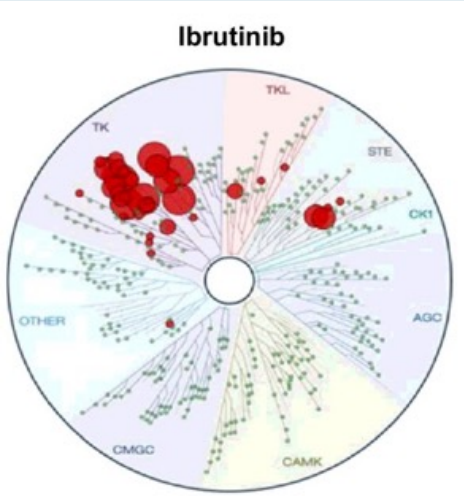
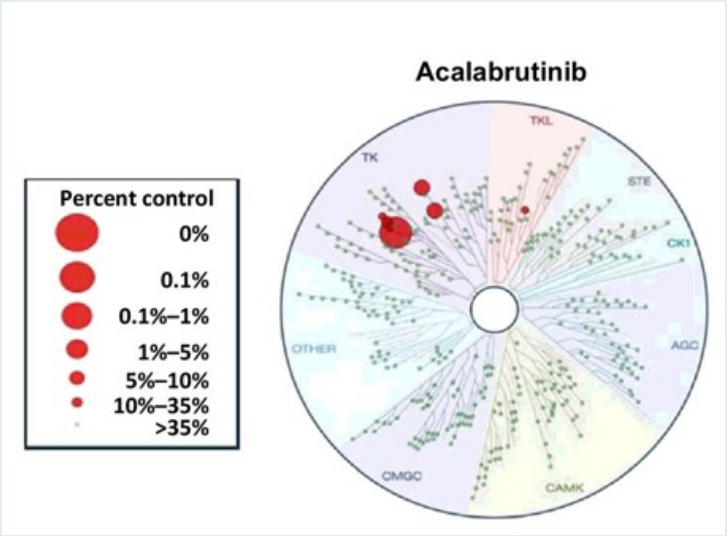
Overview of BTK Inhibitors in CLL

Irreversible

Ibrutinib



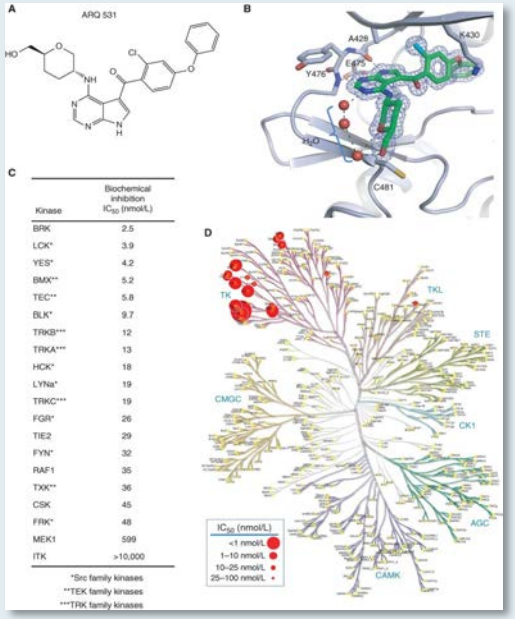
Acalabrutinib



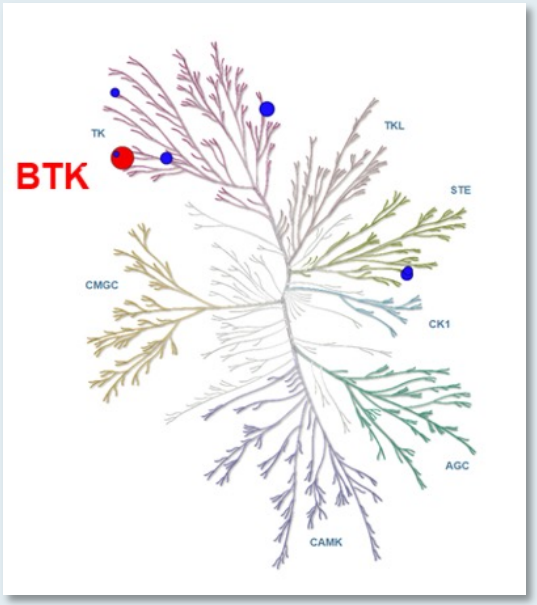
Zanubrutinib

Reversible

ARQ-531 (MK-1026)



LOXO-305



Courtesy of Matthew S Davids, MD, MMSc

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The NEW ENGLAND JOURNAL of MEDICINE

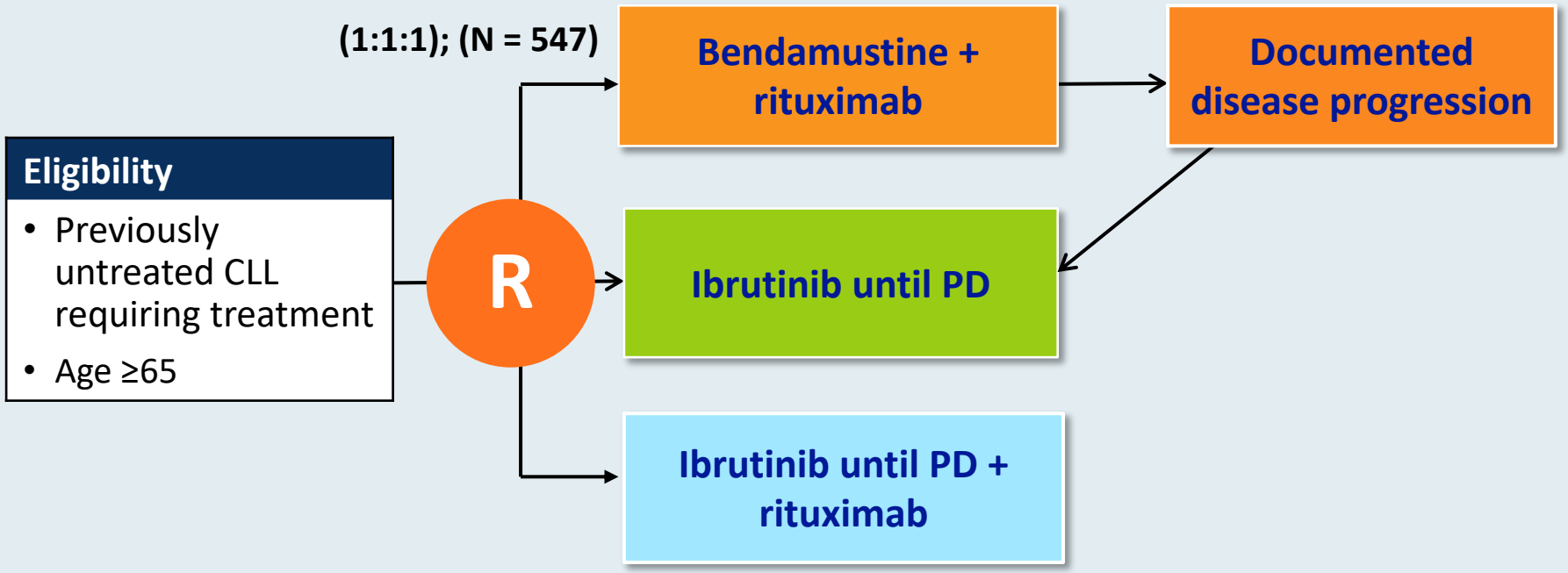
ORIGINAL ARTICLE

Ibrutinib Regimens versus Chemoimmunotherapy in Older Patients with Untreated CLL

J.A. Woyach, A.S. Ruppert, N.A. Heerema, W. Zhao, A.M. Booth, W. Ding, N.L. Bartlett, D.M. Brander, P.M. Barr, K.A. Rogers, S.A. Parikh, S. Coutre, A. Hurria,* J.R. Brown, G. Lozanski, J.S. Blachly, H.G. Ozer, B. Major-Elechi, B. Fruth, S. Nattam, R.A. Larson, H. Erba, M. Litzow, C. Owen, C. Kuzma, J.S. Abramson, R.F. Little, S.E. Smith, R.M. Stone, S.J. Mandrekar, and J.C. Byrd

N Engl J Med 2018;379(26):2517-28.

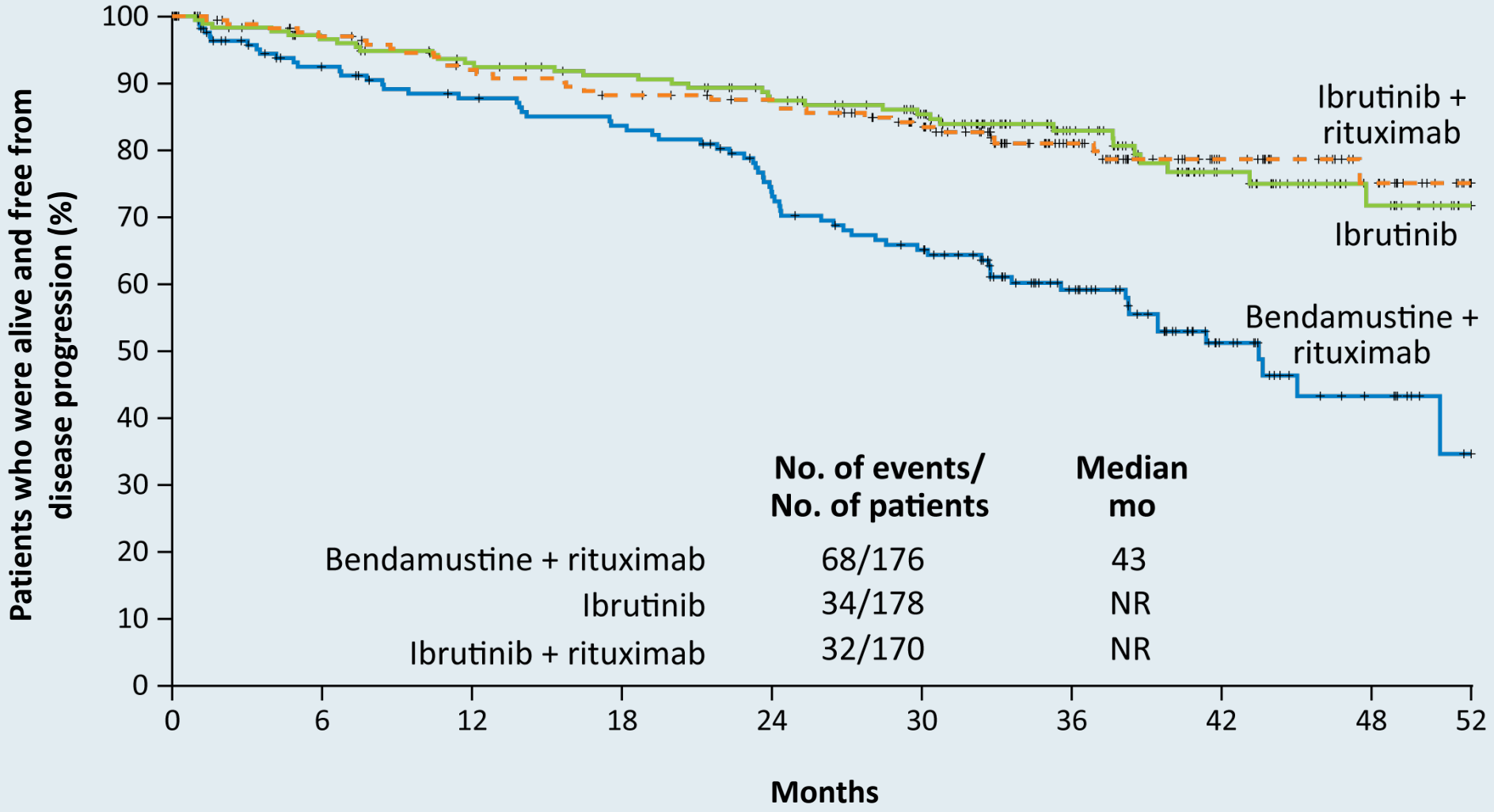
Phase III Alliance A041202 Study Design



Primary endpoint: Progression-free survival (PFS)
Secondary endpoints: OS, ORR, Impact of MRD on PFS and OS, Duration of response, Toxicity and Tolerability

Woyach JA et al. *N Engl J Med* 2018;379(26):2517-28.
Woyach J et al. Alliance Fall Group Meeting, November 5, 2015.

Alliance A041202: Efficacy with Ibrutinib Alone or in Combination with Rituximab Compared to Bendamustine/Rituximab



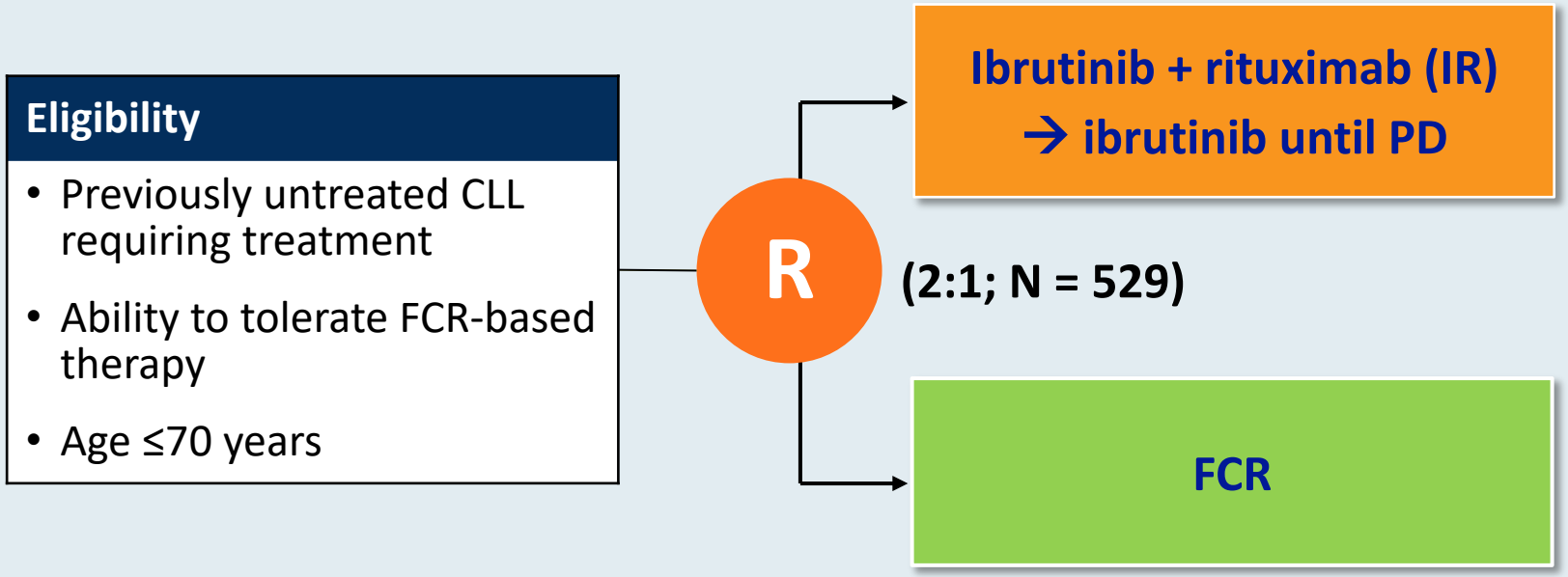
Woyach JA et al. *N Engl J Med* 2018;379(26):2517-28.

Ibrutinib and Rituximab Provides Superior Clinical Outcome Compared to FCR in Younger Patients with Chronic Lymphocytic Leukemia (CLL): Extended Follow-Up from the E1912 Trial

Shanafelt TD et al.

ASH 2019;Abstract 33.

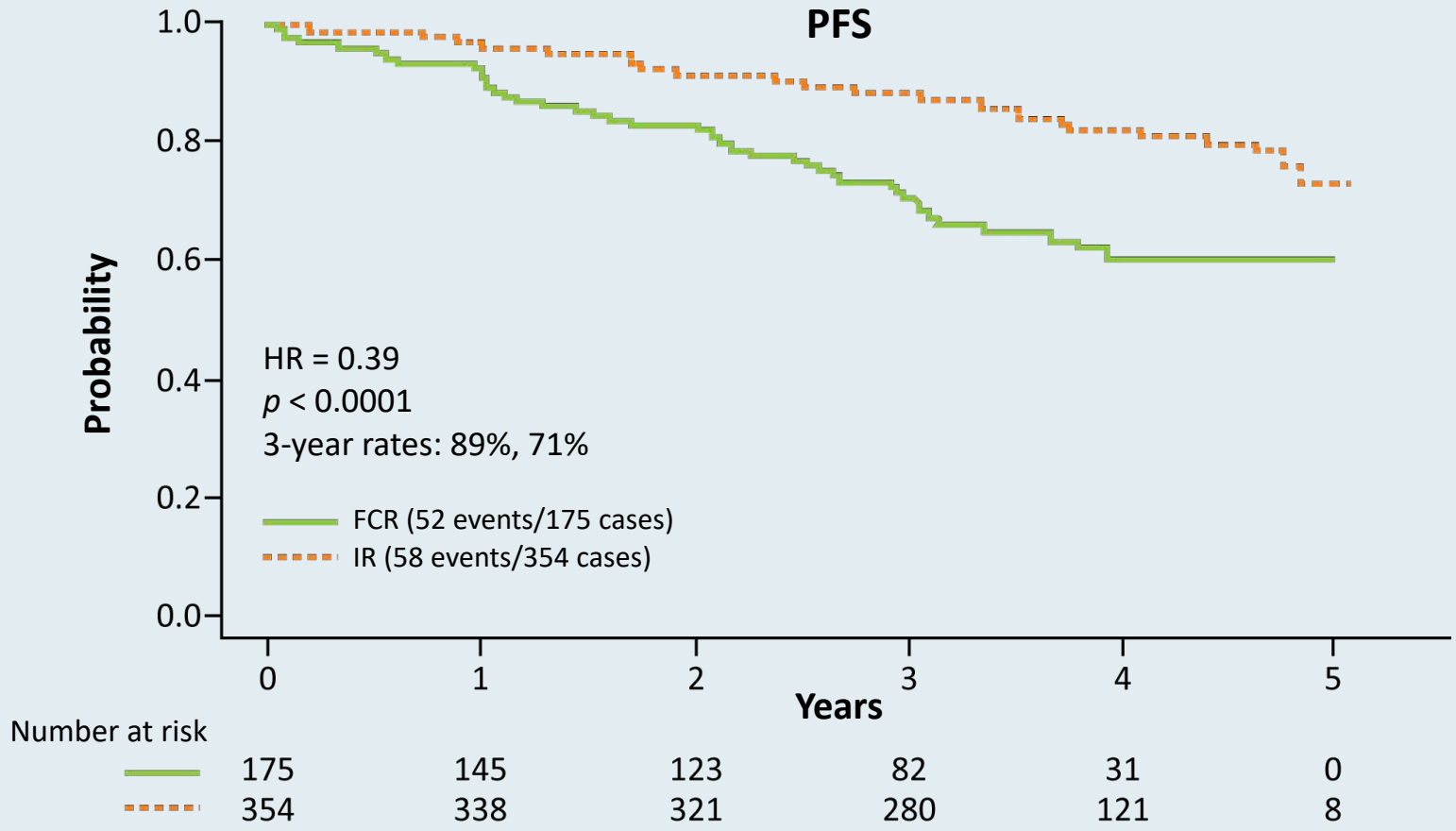
Phase III ECOG-ACRIN E1912 Study Design



Primary endpoint: PFS
Secondary endpoints: OS, ORR, Toxicity and Tolerability

ECOG-ACRIN E1912 Physician Fact Sheet, version 01/15/16;
www.clinicaltrials.gov (NCT02048813); Shanafelt TD et al. ASH 2018;Abstract LBA-4.

ECOG-ACRIN E1912 Extended Follow-Up: Up-Front IR Compared to FCR for Younger Patients with CLL



- Grade ≥3 treatment-related AEs were reported in 70% of patients receiving IR and 80% of patients receiving FCR (odds ratio = 0.56; $p = 0.013$).
- Among the 95 patients who discontinued ibrutinib, the most common cause was AE or complication.

Shanafelt TD et al. ASH 2019;Abstract 33.

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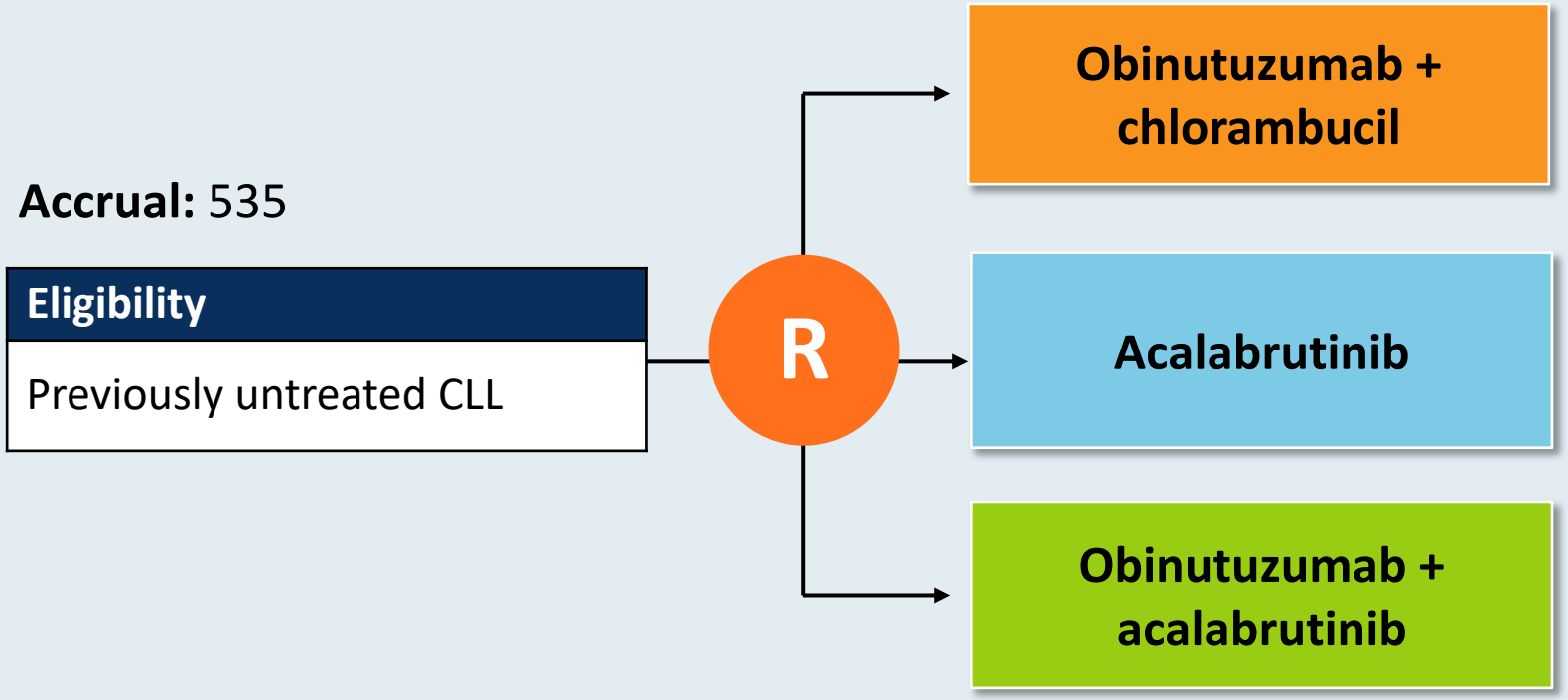
Articles

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.

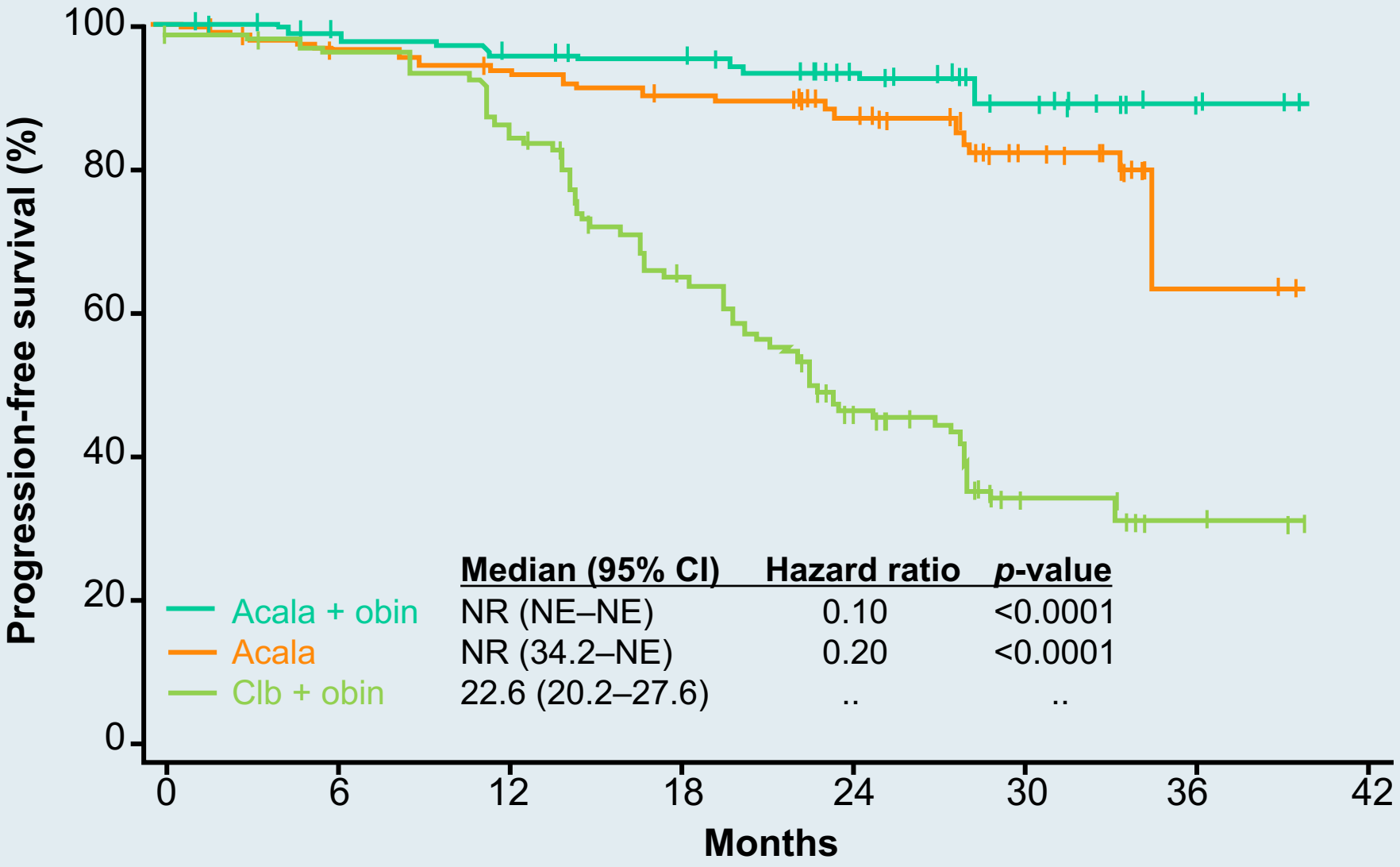
ELEVATE-TN Phase III Trial Schema



Primary endpoint: Progression-free survival

www.clinicaltrials.gov (NCT02475681). Accessed August 2020.

ELEVATE-TN: PFS (IRC)



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

Acalabrutinib Met Primary Efficacy Endpoint in Head-to-Head Trial Against Ibrutinib for Chronic Lymphocytic Leukemia

Press Release — January 25, 2021

"Positive high-level results from the ELEVATE-RR Phase III trial showed acalabrutinib met the primary endpoint demonstrating non-inferior progression-free survival (PFS) for adults with previously treated, high-risk chronic lymphocytic leukemia (CLL) compared to ibrutinib.

The trial also met a key secondary endpoint for safety, showing patients treated with acalabrutinib had statistically significantly lower incidence of atrial fibrillation compared to patients treated with ibrutinib. Atrial fibrillation is an irregular heart rate that can increase the risk of stroke, heart failure and other heart-related complications. Further hierarchical testing revealed no difference for Grade 3 or higher infections or Richter's transformation. There was a descriptive trend for numerically favorable overall survival. Overall, the safety and tolerability of acalabrutinib were consistent with the profile seen in the broader acalabrutinib clinical development program.

ELEVATE-RR is the first Phase III trial to compare two Bruton's tyrosine kinase (BTK) inhibitors in patients with CLL, the most common type of leukemia in adults."

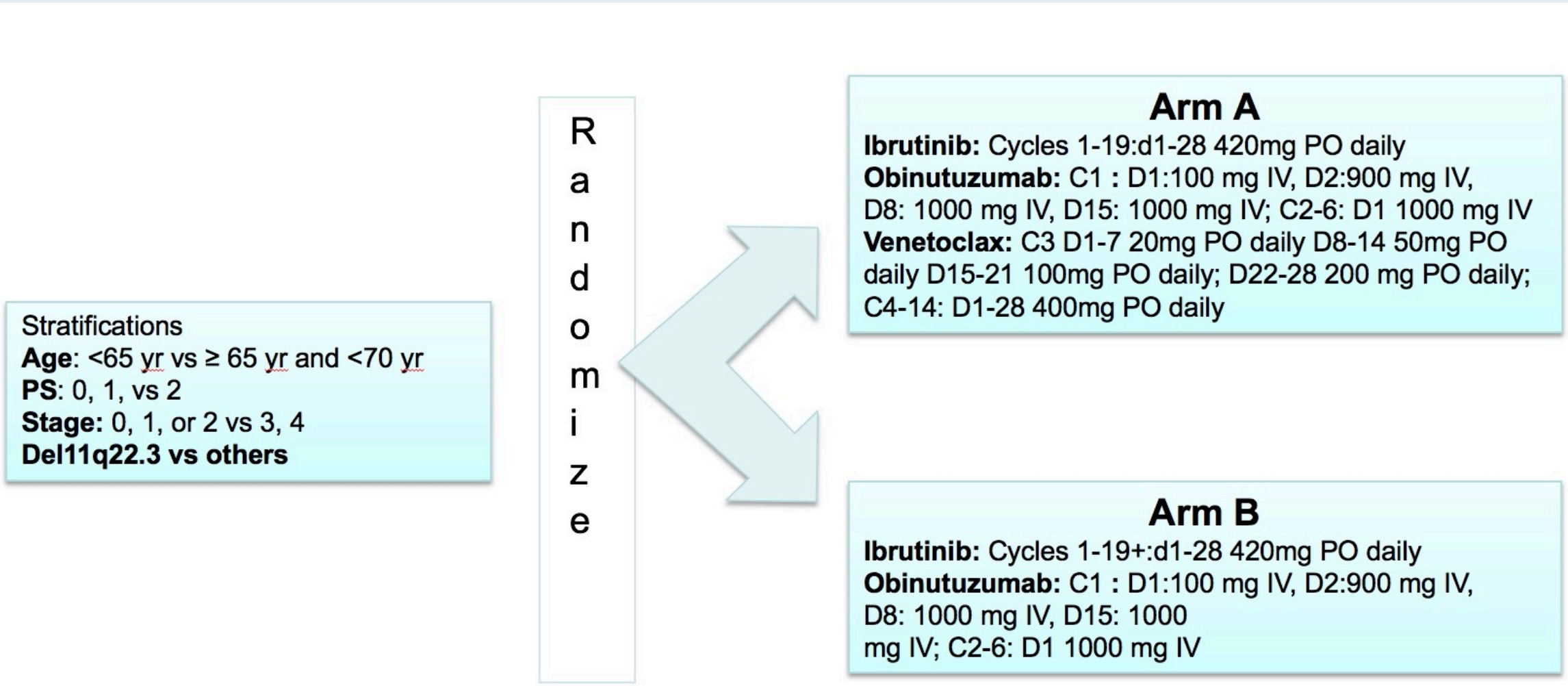
https://www.astrazeneca.com/media-centre/press-releases/2021/calquence-met-primary-endpoint-against-ibrutinib.html

Bruton Tyrosine Kinase (BTK) Inhibitor-Associated Side Effects

BTK inhibitor	Common side effects	Warnings and precautions
Ibrutinib	• Thrombocytopenia • Diarrhea • Fatigue • Anemia • Musculoskeletal pain • Neutropenia • Rash • Bruising	• Infections • Hemorrhage • Cytopenias • Second primary cancer • Cardiac arrhythmias and cardiac failure • Hypertension • Tumor lysis syndrome
Acalabrutinib	• Thrombocytopenia • Diarrhea • Anemia • Musculoskeletal pain • Neutropenia • Upper respiratory tract infection • Headache	• Serious and opportunistic infections • Hemorrhage • Cytopenias • Second primary cancer • Atrial fibrillation

Ibrutinib PI, rev 12/2020; Acalabrutinib PI, rev 11/2019

Phase III EA9161 Schema



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

Efficacy and Safety of Zanubrutinib in Patients with Treatment-Naïve (TN) Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL) with del(17p): Follow-up Results from Arm C of the SEQUOIA (BGB-3111-304) Trial

Brown JR et al.

ASH 2020;Abstract 1306.

***Author Conclusions**:* Extended follow-up of zanubrutinib monotherapy in TN CLL/SLL pts with del(17p) showed the durability of responses in this high-risk cohort, with an estimated 18-mo PFS of 88.6% and estimated 18-mo OS of 95.1%. Zanubrutinib was generally well tolerated, with low rates of discontinuation due to AEs. These data support the potential utility of zanubrutinib in the frontline management of pts with high-risk disease.

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

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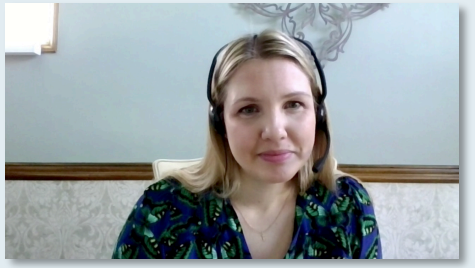
Module 4: Future Directions in CLL (U2 Regimen, LOXO-305, CAR T-Cell Therapy)

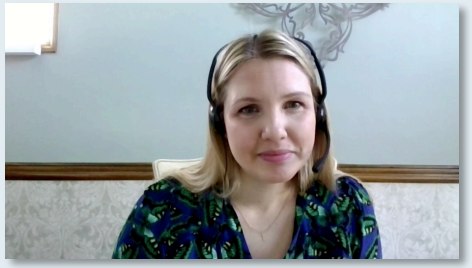
Case Presentation – A 71-year-old man with CLL who desires time-limited therapy (Part 1)



Ms Battiato

- Presented with profound anemia; transfusion dependent
  - IGHV mutated
- Patient is a psychiatrist, desires time-limited therapy
- Obinutuzumab/venetoclax
  - Protocol for minimizing infusion reaction

Case Presentation – A 71-year-old man with CLL who desires time-limited therapy (Part 2)



Ms Battiato

- Presented with profound anemia; transfusion dependent
  - IGHV mutated
- Patient is a psychiatrist, desires time-limited therapy
- Obinutuzumab/venetoclax
  - Protocol for minimizing infusion reaction
  - ***Venetoclax ramp up and laboratory results***
- ***Currently, MRD undetectable and enrolled on the Veneto-STOP study***
- ***Very active, plays tennis several times per week, Hgb: 15.4***

Case Presentation – A 67-year-old man with CLL and malignant pleural effusions (Part 1)

Ms Hoffman

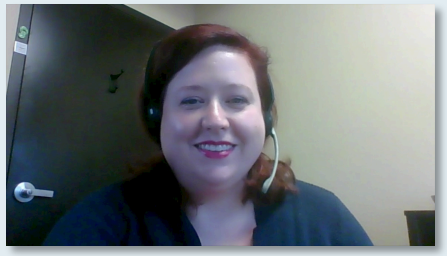
- Presents to the ER with hypoxia
- Imaging: pleural effusions and large para-aortic mass
- Admitted to the hospital → thoracentesis: CLL; bulky lymphadenopathy
  - IGHV unmutated, del(11q)
  - Cardiac arrest → cardiac catheterization and stent placement
- Obinutuzumab/venetoclax
  - Significant improvement in pleural effusions and fatigue; resolution of lymphadenopathy

Case Presentation – A 67-year-old man with CLL and malignant pleural effusions (Part 2)

Ms Hoffman

- Presents to the ER with hypoxia
- Imaging: pleural effusions and large para-aortic mass
- Admitted to the hospital → thoracentesis: CLL; bulky lymphadenopathy
  - IGHV unmutated, del(11q)
  - Cardiac arrest → cardiac catheterization and stent placement
- Obinutuzumab/venetoclax
  - Significant improvement in pleural effusions and fatigue; resolution of lymphadenopathy
- ***Prevention and treatment of tumor lysis syndrome***

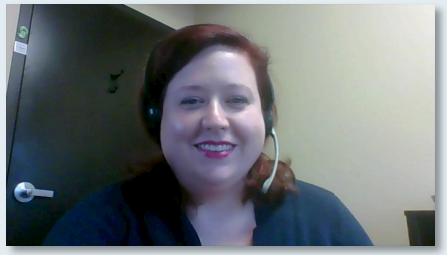
Case Presentation – A 44-year-old woman with CLL who was initially observed off treatment (Part 1)



Ms Ballance

- 2017: Research nurse diagnosed with CLL → Observation
- Doubling of WBC in the past 6 months
  - IGHV mutated, trisomy 12
- Obinutuzumab/venetoclax completed beginning 2021
  - WBC decreased, but significant fatigue

Case Presentation – A 44-year-old woman with CLL who was initially observed off treatment (Part 2)



Ms Ballance

- 2017: Research nurse diagnosed with CLL → Observation
- Doubling of WBC in the past 6 months
  - IGHV mutated, trisomy 12
- Obinutuzumab/venetoclax completed beginning 2021
  - WBC decreased, but significant fatigue
- ***Counseling patient about what to expect from obinutuzumab/venetoclax***
- ***Explaining tumor lysis syndrome***

RTP RESEARCH TO PRACTICE

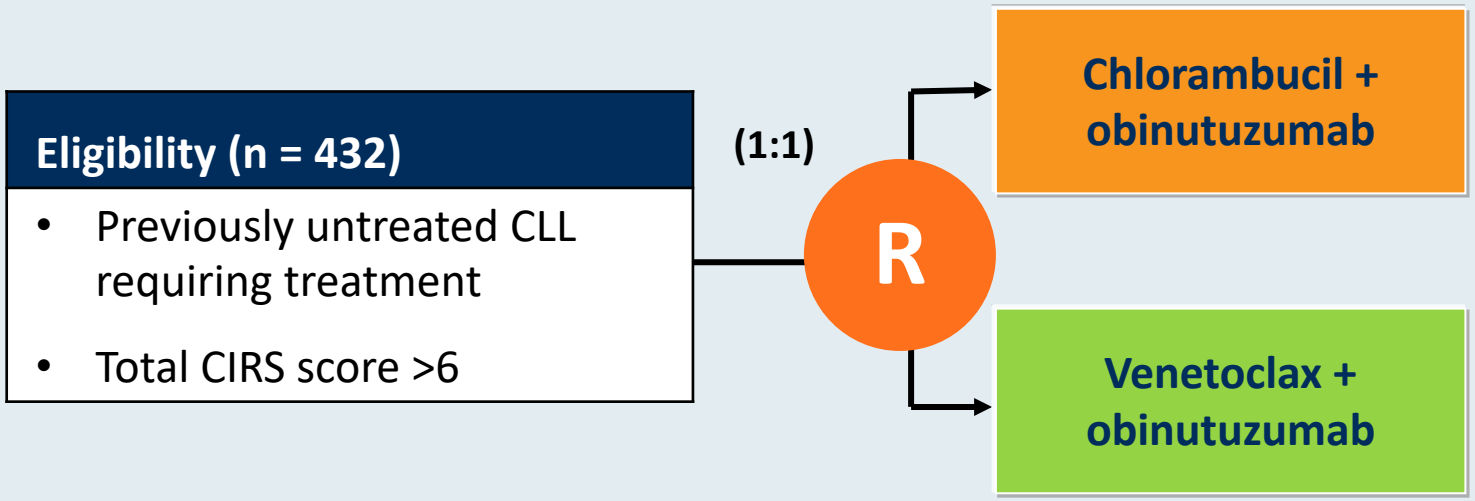
Articles

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 Phase III Study Schema

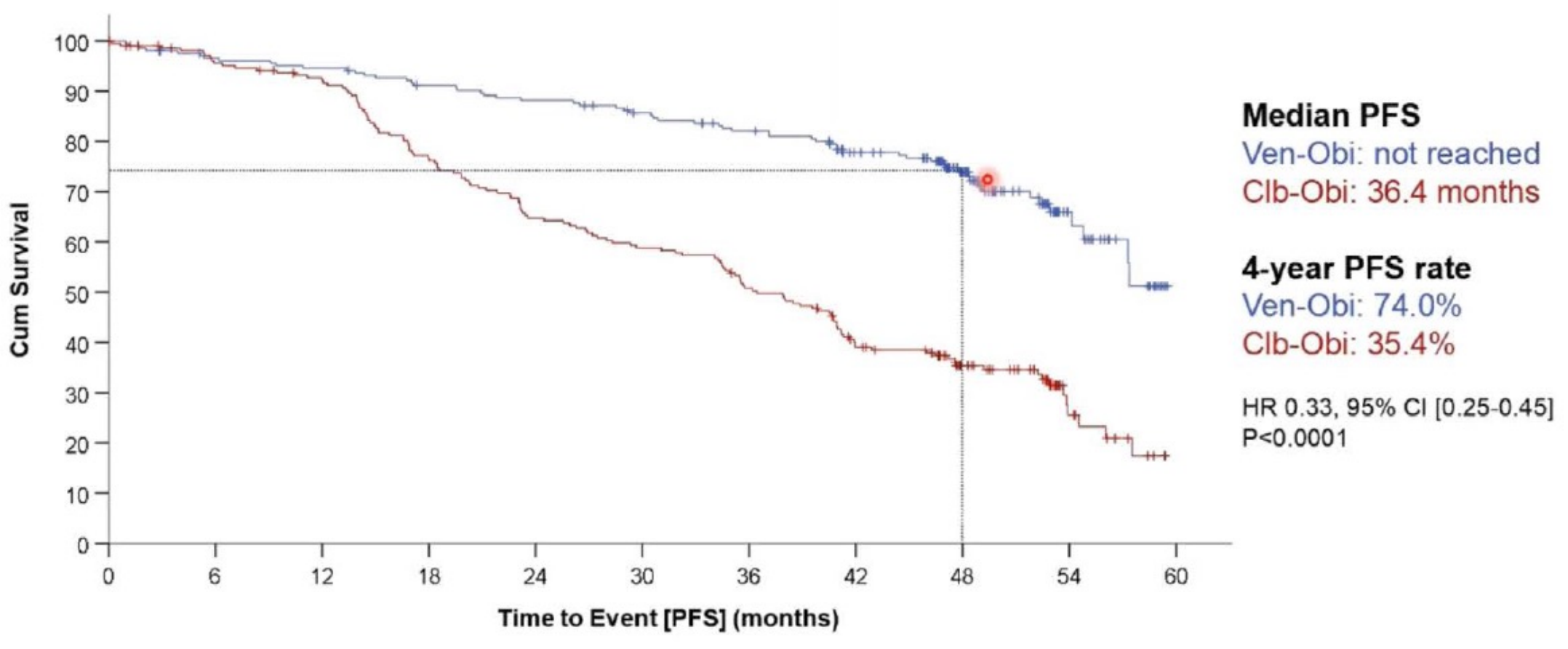


Primary endpoint: Progression-free survival

- Treatment duration in both groups: 12 cycles, 28 days each
- No crossover was allowed
- Daily oral venetoclax regimen:
  - Initiated on day 22 of cycle 1, starting with a 5-week dose ramp-up (1 week each of 20, 50, 100 and 200 mg, then 400 mg daily for 1 week)
  - Thereafter continuing at 400 mg daily until completion of cycle 12

www.clinicaltrials.gov (NCT02242942). Accessed August 2020.
Fischer K et al. *N Engl J Med* 2019;380(23):2225-36.

CLL14: Updated 4-Year PFS



Median observation time: 52.4 months

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

RTP RESEARCH TO PRACTICE

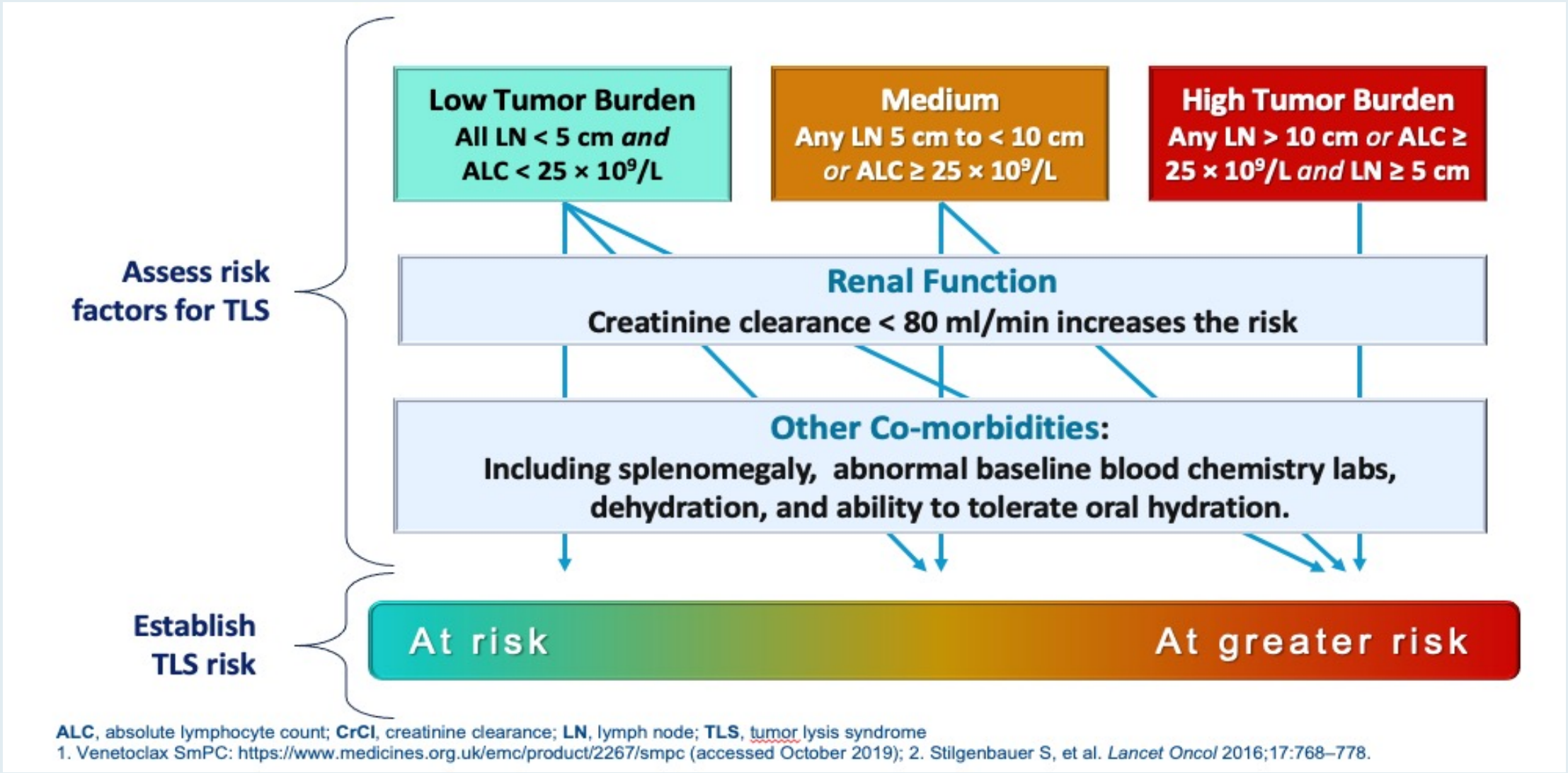
Which of the following disease-related factors is critical in attempting to determine an individual's risk of developing tumor lysis syndrome from treatment with venetoclax for CLL?

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

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

1. Hepatic function
2. Renal function
3. Body mass index
4. I don't know

TLS Risk with Venetoclax Is a Continuum Based on Multiple Factors

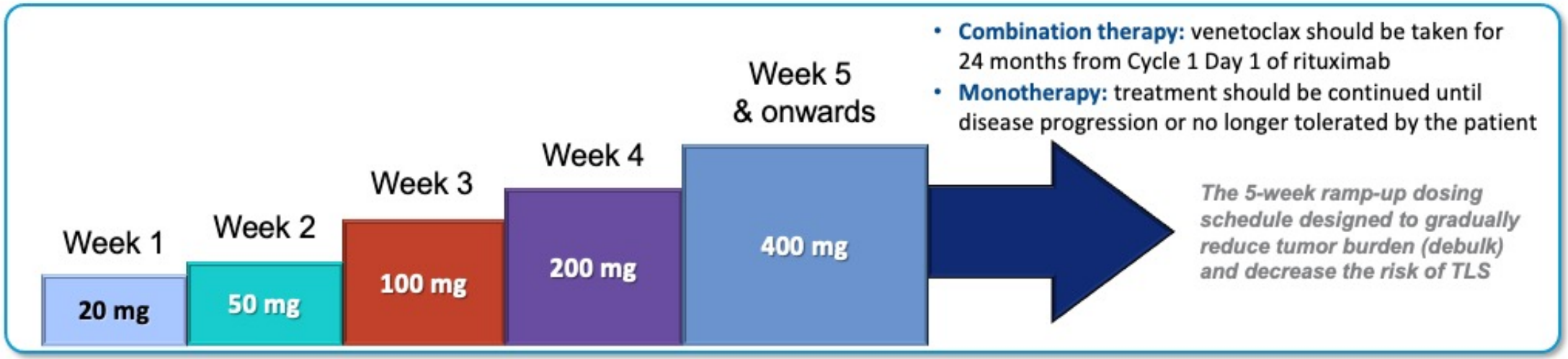


ALC, absolute lymphocyte count; **CrCl**, creatinine clearance; **LN**, lymph node; **TLS**, tumor lysis syndrome

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: Overview of the Current Era of CLL Treatment

Module 2: Up-Front Treatment with a BTK (Bruton Tyrosine Kinase) Inhibitor

- **Case 1 (Ms Battiato): A 75-year-old woman with CLL who receives first-line ibrutinib**
- **Case 2 (Ms Ballance): A 51-year-old woman with previously untreated CLL who receives acalabrutinib**

Module 3: Up-Front Treatment with Obinutuzumab/Venetoclax

- **Case 3 (Ms Battiato): A 71-year-old man with CLL who desires time-limited therapy**
- **Case 4 (Ms Hoffman): A 67-year-old man with CLL and malignant pleural effusions**
- **Case 5 (Ms Ballance): A 44-year-old woman with CLL who was initially observed off treatment**

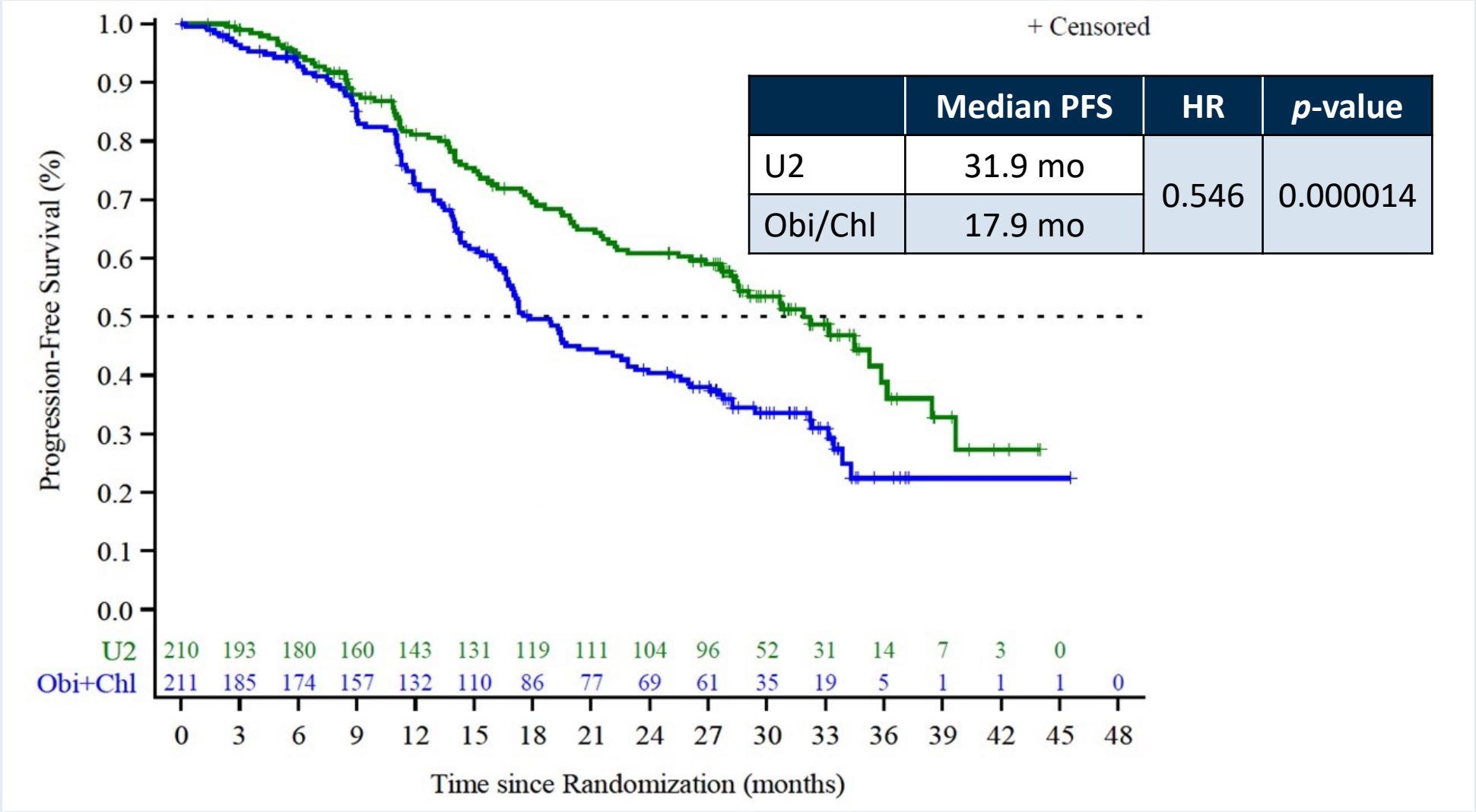
Module 4: Future Directions in CLL (U2 Regimen, LOXO-305, CAR T-Cell Therapy)

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



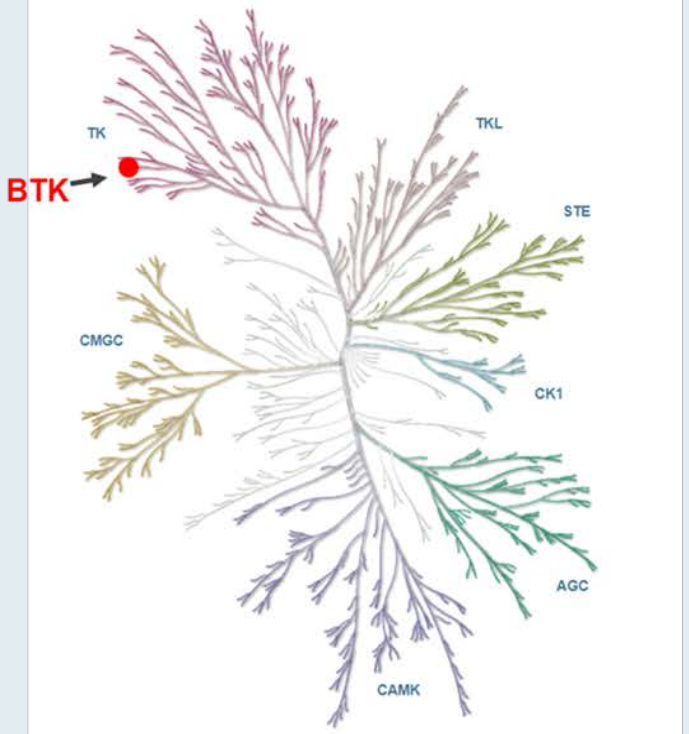
	Median PFS	HR	*p*-value
U2	31.9 mo	0.546	0.000014
Obi/Chl	17.9 mo		

Gribben JG et al. ASH 2020;Abstract 543.

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

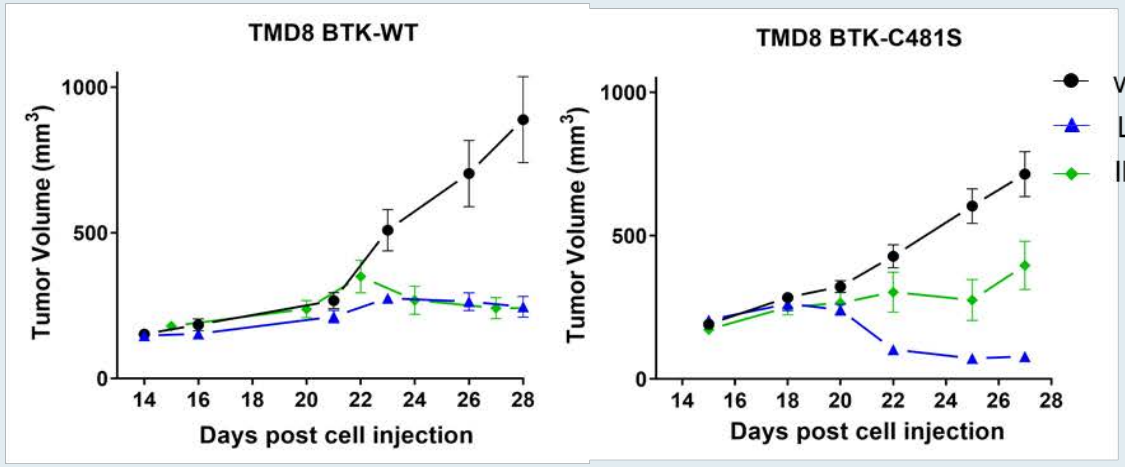
Kinome selectivity

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.

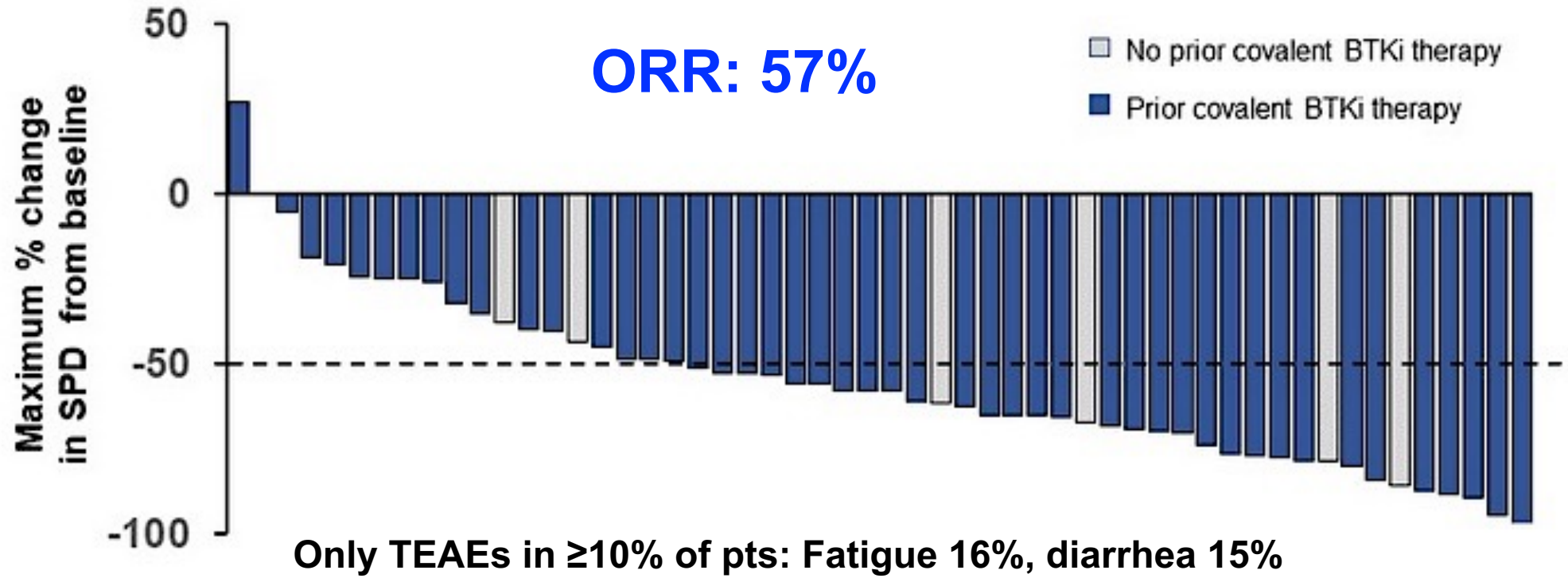
Mato AR et al. ASH 2020;Abstract 542.

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.

Ms Battiato: Reflections on being an oncology nurse practitioner


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

13th Annual Oncology Grand Rounds

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

Chimeric Antigen Receptor T-Cell Therapy

Thursday, April 29, 2021
5:00 PM – 6:30 PM ET

Medical Oncologists

Jeremy Abramson, MD
Caron Jacobson, MD
Noopur Raje, MD

Oncology Nurse Practitioners

Sonia Glennie, ARNP, MSN, OCN
Alli McClanahan, MSN, APRN, ANP-BC
Elizabeth Zerante, MS, AGACNP-BC

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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