13th Annual Oncology Grand Rounds

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

Non-Small Cell Lung Cancer

Tuesday, April 20, 2021
5:00 PM – 6:30 PM ET

Medical Oncologists

John V Heymach, MD, PhD
Paul K Paik, MD
Zofia Piotrowska, MD, MHS

Oncology Nurse Practitioners

Kelly EH Goodwin, MSN, RN, ANP-BC
Tara Plues, APRN, MSN
Victoria Sherry, DNP, CRNP, AOCNP

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Medical Oncologists

John V Heymach, MD, PhD
The University of Texas
MD Anderson Cancer Center
Houston, Texas

Paul K Paik, MD
Memorial Sloan Kettering Cancer Center
New York, New York

Zofia Piotrowska, MD, MHS
Massachusetts General Hospital
Boston, Massachusetts

Oncology Nurse Practitioners

Kelly EH Goodwin, MSN, RN, ANP-BC
Massachusetts General Hospital
Boston, Massachusetts

Tara Plues, APRN, MSN
Cleveland Clinic
Cleveland, Ohio

Victoria Sherry, DNP, CRNP, AOCNP
Abramson Cancer Center
Philadelphia, Pennsylvania

RTP
RESEARCH
TO PRACTICE

Commercial Support

This activity is supported by educational grants from AstraZeneca Pharmaceuticals LP, Merck, Regeneron Pharmaceuticals Inc and Sanofi Genzyme, and Takeda Oncology.

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, Turning Point Therapeutics Inc and Verastem Inc.

RTP
RESEARCH
TO PRACTICE

Research To Practice CME Planning Committee Members, Staff and Reviewers

Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose.

Dr Heymach — Disclosures

Advisory Committee and Consulting Agreements	AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim Pharmaceuticals Inc, BrightPath Biotherapeutics Co Ltd, Bristol-Myers Squibb Company, Catalyst Pharmaceuticals, EMD Serono Inc, Foundation Medicine, Genentech, a member of the Roche Group, GlaxoSmithKline, Guardant Health, Hengrui Therapeutics Inc, Janssen Biotech Inc, Kairos Venture Investments LLC, Leads Biolabs, Lilly, Mirati Therapeutics, Nexus Health Systems, Novartis, Pneuma Respiratory, Roche Laboratories Inc, Sanofi Genzyme, Spectrum Pharmaceuticals Inc, Takeda Oncology
Contracted Research	AstraZeneca Pharmaceuticals LP, GlaxoSmithKline, Spectrum Pharmaceuticals Inc
Licensing and Fees	Spectrum Pharmaceuticals Inc

RTP
RESEARCH
TO PRACTICE

Dr Paik — Disclosures

Advisory Committee	Calithera Biosciences, EMD Serono Inc, Xencor
Consulting Agreements	Bicara Therapeutics, a wholly owned subsidiary of Biocon, Boehringer Ingelheim Pharmaceuticals Inc, GlaxoSmithKline
Contracted Research	EMD Serono Inc
Data and Safety Monitoring Board/Committee	Takeda Oncology

RTP RESEARCH TO PRACTICE

Dr Piotrowska — Disclosures

Advisory Committee	AstraZeneca Pharmaceuticals LP, Blueprint Medicines, C4 Therapeutics, Genentech, a member of the Roche Group, Incyte Corporation, Janssen Biotech Inc, Jazz Pharmaceuticals Inc, Lilly, Medtronic Inc, Takeda Oncology
Contracted Research	AbbVie Inc, AstraZeneca Pharmaceuticals LP, Cullinan Oncology, Daiichi Sankyo Inc, Janssen Biotech Inc, Novartis, Spectrum Pharmaceuticals Inc, Takeda Oncology, Tesaro, A GSK Company

RTP
RESEARCH
TO PRACTICE

Ms Goodwin — Disclosures

No relevant conflicts of interest to disclose.

Ms Plues — Disclosures

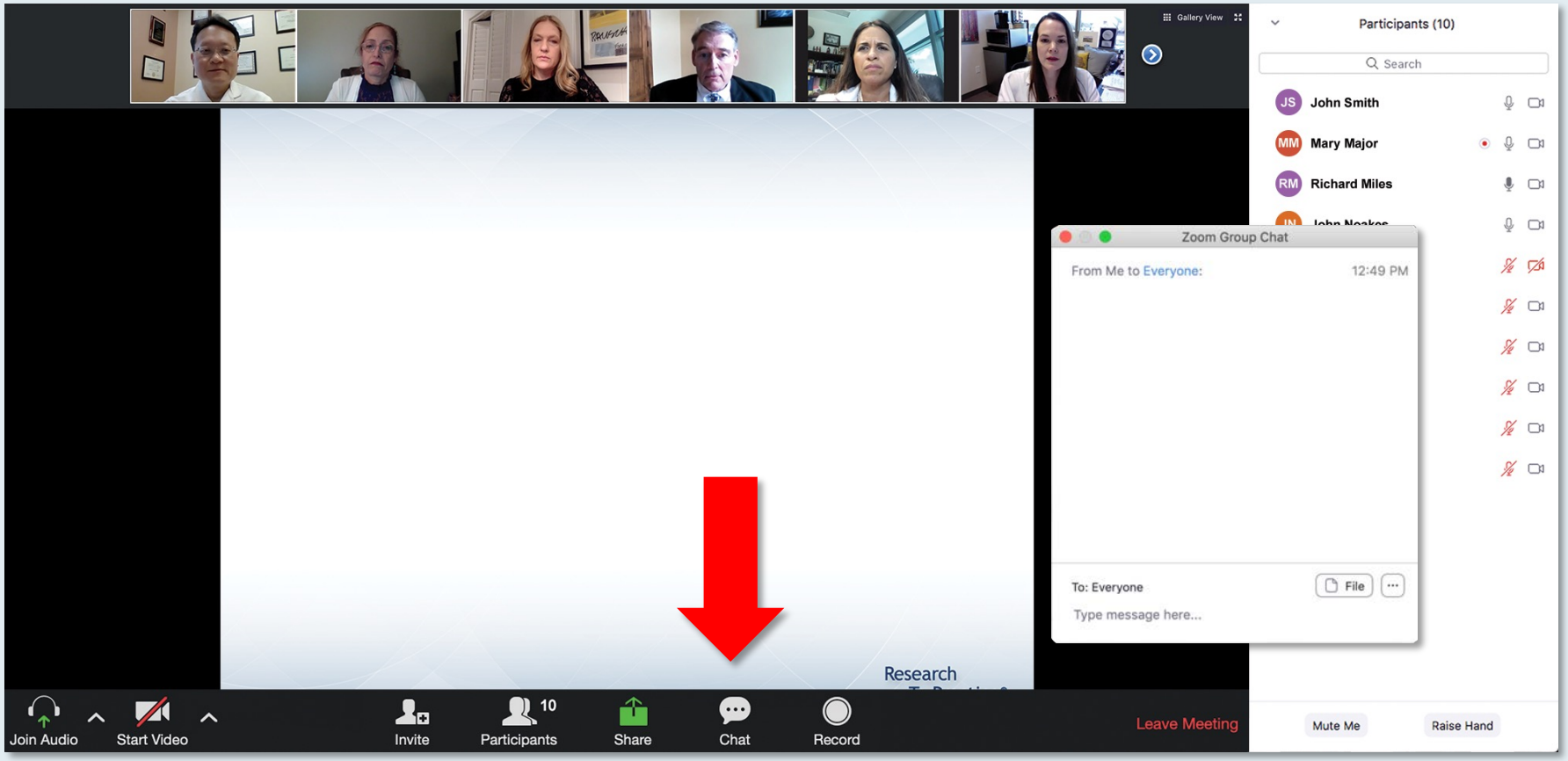
No relevant conflicts of interest to disclose.

Ms Sherry — Disclosures

Advisory Committee and Consulting Agreement	AstraZeneca Pharmaceuticals LP

RTP RESEARCH TO PRACTICE

We Encourage Clinicians in Practice to Submit Questions

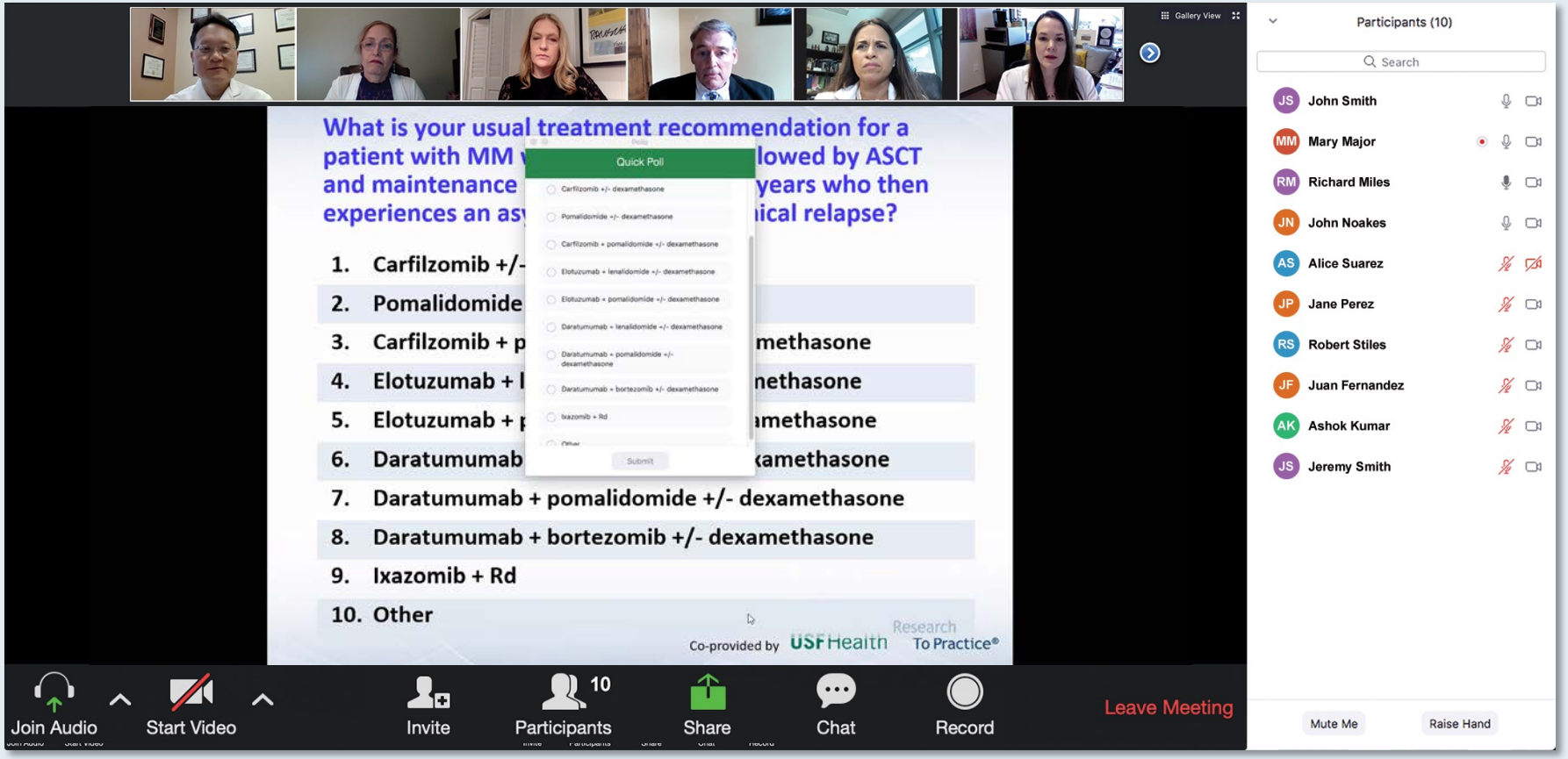


Feel free to submit questions now before the program begins and throughout the program.

RTP RESEARCH TO PRACTICE

Familiarizing Yourself with the Zoom Interface

How to answer poll questions

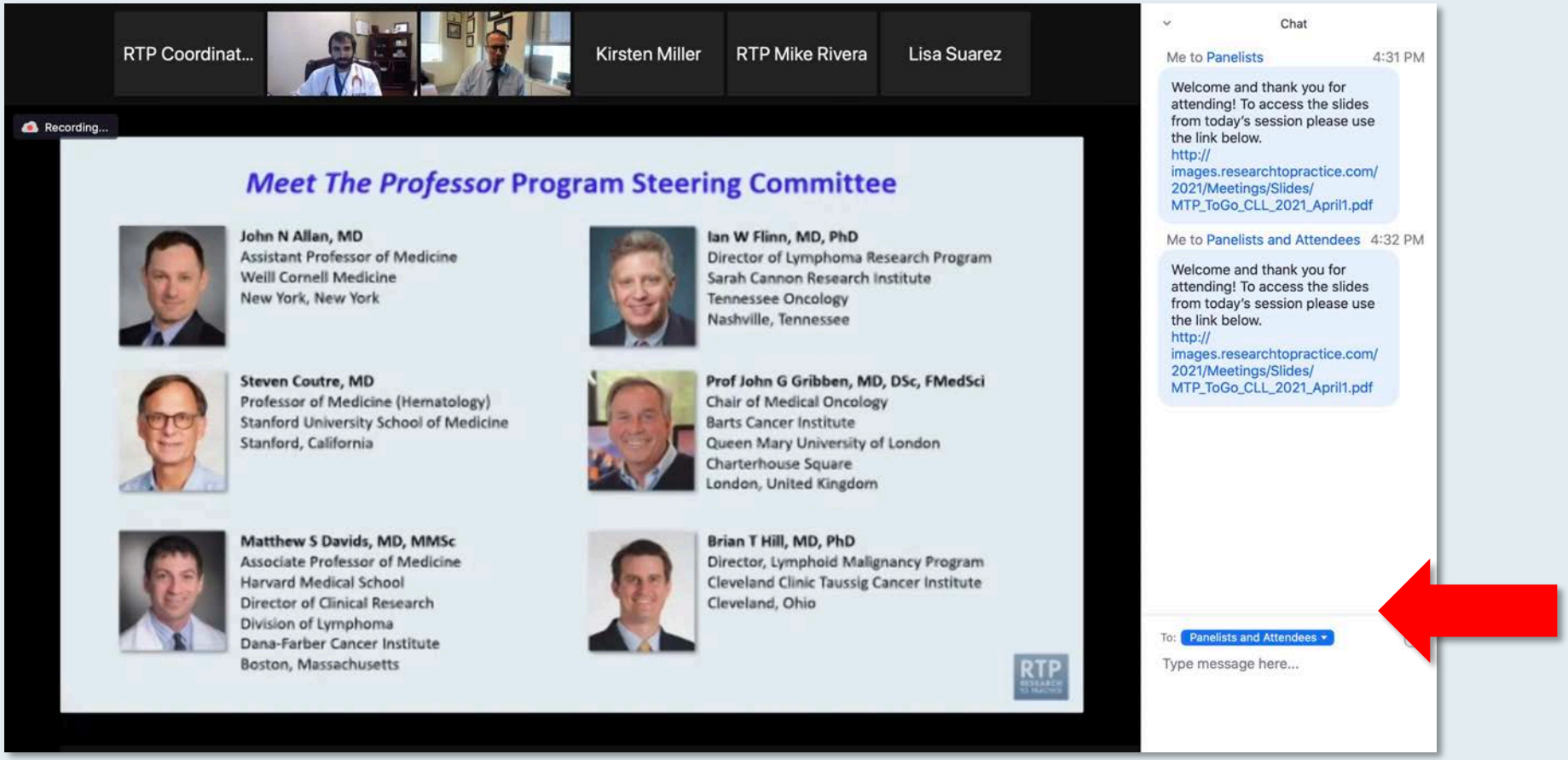


When a poll question pops up, click your answer choice from the available options.

RTP RESEARCH TO PRACTICE

Familiarizing Yourself with the Zoom Interface

Expand chat submission box

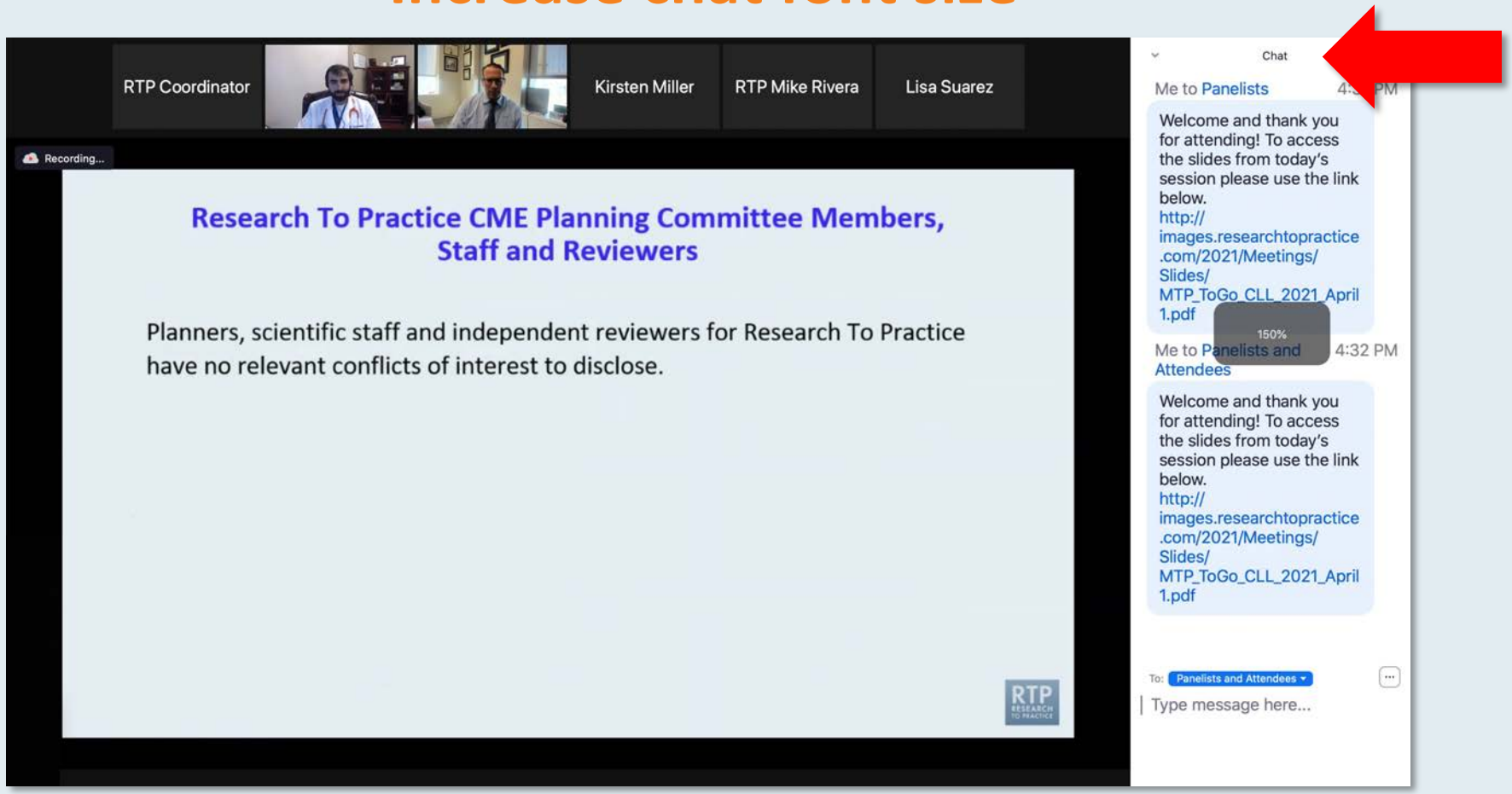


Drag the white line above the submission box up to create more space for your message.

RTP RESEARCH TO PRACTICE

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

Management of Localized Non-Small Cell Lung Cancer with EGFR Tumor Mutations

DR ROY HERBST

YALE CANCER CENTER

Listen on Apple Podcasts

Spotify

Listen on Google Podcasts

13th Annual Oncology Grand Rounds

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

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
Wednesday, April 21, 2021
4:45 PM – 5:45 PM ET

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

Hodgkin and Non-Hodgkin Lymphomas
Thursday, April 22, 2021
5:00 PM – 6:30 PM ET

Multiple Myeloma
Tuesday, April 27, 2021
8:30 AM – 10:00 AM ET

Gynecologic Cancers
Tuesday, April 27, 2021
5:00 PM – 6:30 PM ET

Urothelial Bladder Carcinoma
Wednesday, April 28, 2021
12:00 PM – 1:00 PM ET

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

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

RTP RESEARCH TO PRACTICE

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

RTP
RESEARCH TO PRACTICE

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

RTP
RESEARCH
TO PRACTICE

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

RTP
RESEARCH
TO PRACTICE

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

RTP
RESEARCH
TO PRACTICE

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

RTP
RESEARCH
TO PRACTICE

Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.

RTP
RESEARCH
TO PRACTICE

13th Annual Oncology Grand Rounds

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

Non-Small Cell Lung Cancer

Tuesday, April 20, 2021
5:00 PM – 6:30 PM ET

Medical Oncologists

John V Heymach, MD, PhD
Paul K Paik, MD
Zofia Piotrowska, MD, MHS

Oncology Nurse Practitioners

Kelly EH Goodwin, MSN, RN, ANP-BC
Tara Plues, APRN, MSN
Victoria Sherry, DNP, CRNP, AOCNP

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Medical Oncologists

John V Heymach, MD, PhD
The University of Texas
MD Anderson Cancer Center
Houston, Texas

Paul K Paik, MD
Memorial Sloan Kettering Cancer Center
New York, New York

Zofia Piotrowska, MD, MHS
Massachusetts General Hospital
Boston, Massachusetts

Oncology Nurse Practitioners

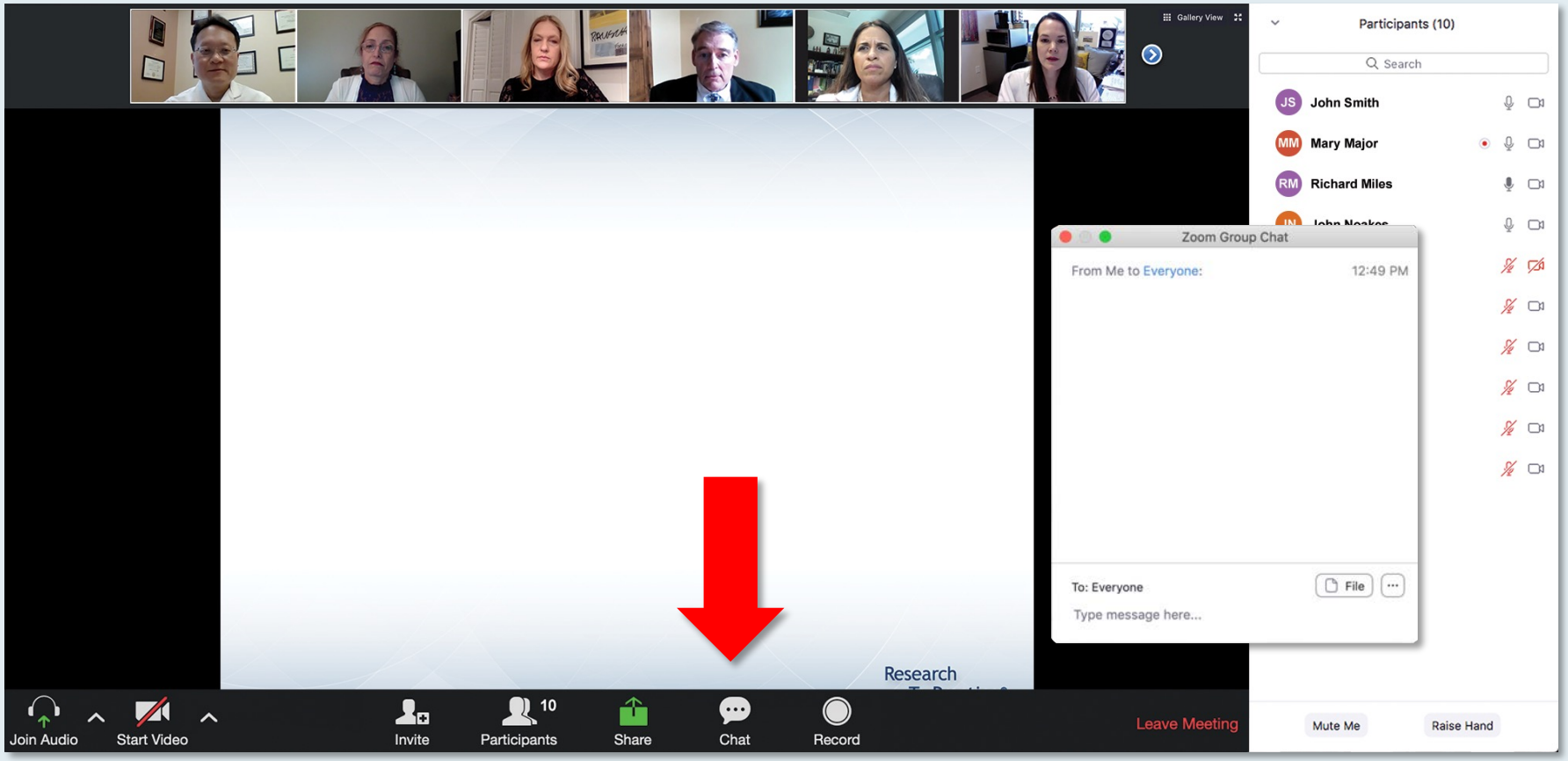
Kelly EH Goodwin, MSN, RN, ANP-BC
Massachusetts General Hospital
Boston, Massachusetts

Tara Plues, APRN, MSN
Cleveland Clinic
Cleveland, Ohio

Victoria Sherry, DNP, CRNP, AOCNP
Abramson Cancer Center
Philadelphia, Pennsylvania

RTP
RESEARCH
TO PRACTICE

We Encourage Clinicians in Practice to Submit Questions

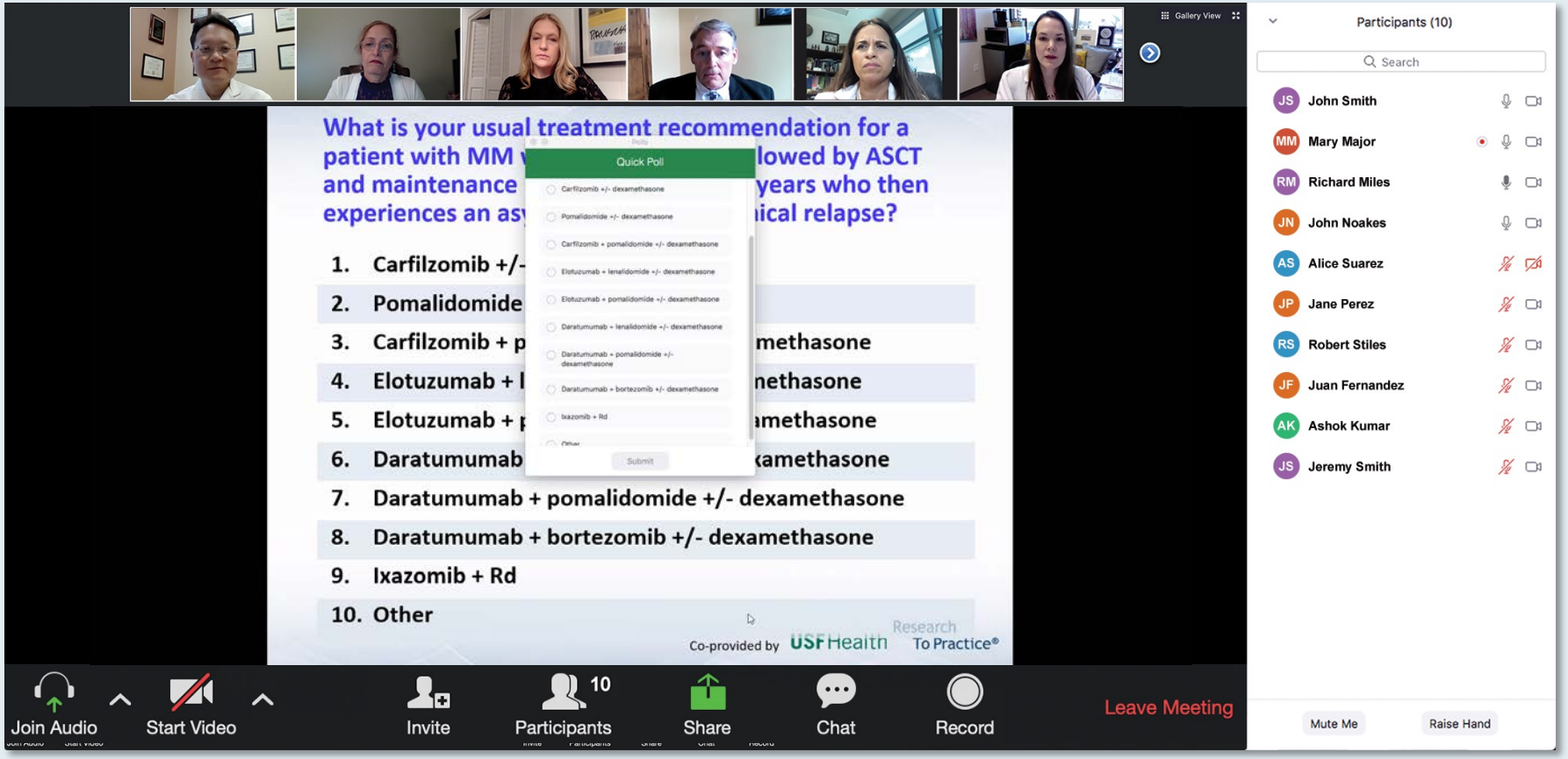


Feel free to submit questions now before the program begins and throughout the program.

RTP RESEARCH TO PRACTICE

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.

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

RTP
RESEARCH TO PRACTICE

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

RTP
RESEARCH
TO PRACTICE

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

RTP
RESEARCH
TO PRACTICE

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

RTP
RESEARCH
TO PRACTICE

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

RTP
RESEARCH
TO PRACTICE

13th Annual Oncology Grand Rounds

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

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
Wednesday, April 21, 2021
4:45 PM – 5:45 PM ET

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

Hodgkin and Non-Hodgkin Lymphomas
Thursday, April 22, 2021
5:00 PM – 6:30 PM ET

Multiple Myeloma
Tuesday, April 27, 2021
8:30 AM – 10:00 AM ET

Gynecologic Cancers
Tuesday, April 27, 2021
5:00 PM – 6:30 PM ET

Urothelial Bladder Carcinoma
Wednesday, April 28, 2021
12:00 PM – 1:00 PM ET

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

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

RTP RESEARCH TO PRACTICE

Medical Oncologists

Jeremy Abramson, MD
Director, Center for Lymphoma
Massachusetts General Hospital
Associate Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Carey K Anders, MD
Professor of Medicine
Medical Director of the Duke Center of Brain and Spine Metastases
Duke Cancer Institute
Durham, North Carolina

Stephen M Ansell, MD, PhD
Professor of Medicine
Chair, Lymphoma Group
Mayo Clinic
Rochester, Minnesota

Johanna Bendell, MD
Chief Development Officer
Director, Drug Development Unit Nashville
Sarah Cannon Research Institute
Tennessee Oncology
Nashville, Tennessee

Carla Casulo, MD
Associate Professor of Medicine
Division of Hematology/Oncology
Director, Hematology/Oncology Fellowship Program
University of Rochester
Wilmot Cancer Institute
New York, New York

RTP
RESEARCH TO PRACTICE

Medical Oncologists

Daniel Catenacci, MD
Associate Professor, Department of Medicine
Section of Hematology and Oncology
Director, Interdisciplinary Gastrointestinal Oncology Program
Assistant Director, Translational Research
Comprehensive Cancer Center
The University of Chicago Medical Center and Biological Sciences
Chicago, Illinois

Robert L Coleman, MD
Chief Scientific Officer
US Oncology Research
Gynecologic Oncology
The Woodlands, Texas

Courtney D DiNardo, MD, MSCE
Associate Professor, Department of Leukemia
Division of Cancer Medicine
The University of Texas MD Anderson Cancer Center
Houston, Texas

Elisabeth I Heath, MD
Associate Center Director, Translational Sciences
Chair, Genitourinary Oncology Multidisciplinary Team
Professor of Oncology and Medicine
Hartmann Endowed Chair for Prostate Cancer Research
Director, Prostate Cancer Research
Karmanos Cancer Institute
Wayne State University School of Medicine
Detroit, Michigan

RTP
RESEARCH TO PRACTICE

Medical Oncologists

Thomas J Herzog, MD
Paul and Carolyn Flory Professor
Deputy Director, University of Cincinnati Cancer Center
Vice-Chair, Quality and Safety
Department of Obstetrics and Gynecology
University of Cincinnati Medical Center
Associate Director, GOG Partners
Cincinnati, Ohio

John V Heymach, MD, PhD
Professor and Chair
Thoracic/Head and Neck Medical Oncology
The University of Texas MD Anderson Cancer Center
Houston, Texas

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

Caron Jacobson, MD
Assistant Professor of Medicine
Harvard Medical School
Dana-Farber Cancer Institute
Boston, Massachusetts

Shaji K Kumar, MD
Mark and Judy Mullins Professor of Hematological Malignancies
Consultant, Division of Hematology
Professor of Medicine
Mayo Clinic
Rochester, Minnesota

John P Leonard, MD
Richard T Silver Distinguished Professor of Hematology and Medical Oncology
Senior Associate Dean for Innovation and Initiatives
Executive Vice Chair, Joan and Sanford I Weill Department of Medicine
Weill Cornell Medicine
New York, New York

RTP RESEARCH TO PRACTICE

Medical Oncologists

Sagar Lonial, MD
Chair and Professor
Department of Hematology and Medical Oncology
Anne and Bernard Gray Family Chair in Cancer
Chief Medical Officer
Winship Cancer Institute
Emory University School of Medicine
Atlanta, Georgia

Kathy D Miller, MD
Ballvé-Lantero Professor
Division of Hematology/Oncology
Associate Director for Clinical Research
The Indiana University Melvin and Bren Simon Cancer Center
Indianapolis, Indiana

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

Paul K Paik, MD
Associate Attending Physician
Clinical Director, Thoracic Oncology Service
Memorial Sloan Kettering Cancer Center
New York, New York

Daniel P Petrylak, MD
Professor of Internal Medicine
(Medical Oncology) and Urology
Yale School of Medicine
New Haven, Connecticut

Zofia Piotrowska, MD, MHS
Assistant Professor of Medicine
Harvard Medical School
Massachusetts General Hospital
Boston, Massachusetts

RTP
RESEARCH TO PRACTICE

Medical Oncologists

Noopur Raje, MD
Director, Center for Multiple Myeloma
Massachusetts General Hospital Cancer Center
Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Paul G Richardson, MD
Clinical Program Leader and Director of Clinical Research
Jerome Lipper Multiple Myeloma Center
Dana-Farber Cancer Institute
RJ Corman Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Charles J Ryan, MD
Professor of Medicine
BJ Kennedy Chair in Clinical Medical Oncology
Director, Division of Hematology, Oncology and Transplantation
University of Minnesota
Minneapolis, Minnesota

A Oliver Sartor, MD
CE and Bernadine Laborde Professor for Cancer Research
Medical Director, Tulane Cancer Center
Assistant Dean for Oncology
Tulane Medical School
New Orleans, Louisiana

Eytan M Stein, MD
Assistant Attending Physician
Director, Program for Drug Development in Leukemia
Leukemia Service, Department of Medicine
Memorial Sloan Kettering Cancer Center
New York, New York

Mary-Ellen Taplin, MD
Professor of Medicine
Harvard School of Medicine
Dana-Farber Cancer Institute
Boston, Massachusetts

RTP
RESEARCH TO PRACTICE

Medical Oncologists

Krishnansu S Tewari, MD
Professor and Division Director
Division of Gynecologic Oncology
University of California, Irvine
Irvine, California

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

Sara M Tolaney, MD, MPH
Associate Director
Susan F Smith Center for Women's Cancers
Director of Clinical Trials, Breast Oncology
Director of Breast Immunotherapy Clinical Research
Senior Physician
Breast Oncology Program
Dana-Farber Cancer Institute
Associate Professor of Medicine
Harvard Medical School
Boston, Massachusetts

RTP
RESEARCH
TO PRACTICE

Oncology Nurse Practitioners

Paula J Anastasia, MN, RN, AOCN
GYN Oncology Advanced Practice Nurse
University of California, Los Angeles
Los Angeles, California

Courtney Arn, CNP
The James Cancer Hospital and
Solove Research Institute
The Ohio State University
Columbus, Ohio

Monica Averia, MSN, AOCNP, NP-C
Oncology Nurse Practitioner
USC Norris Cancer Center
Los Angeles, California

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

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

Kathy D Burns, RN, MSN, AGACNP-BC, OCN
GU Medical Oncology
City of Hope Comprehensive Cancer Center
Duarte, California

Gretchen Santos Fulgencio, MSN, FNP-BC
University of California, San Francisco
Berkeley, California

Ilene Galinsky, NP
Senior Adult Leukemia Program Research
Nurse Practitioner
Dana-Farber Cancer Institute
Boston, Massachusetts

RTP
RESEARCH
TO PRACTICE

Oncology Nurse Practitioners

Jacklyn Gideon, MSN, AGPCNP-BC
Advanced Practice Provider
Lead Apheresis APP
Hematopoietic Cellular Therapy Program
Section of Hematology/Oncology
The University of Chicago Medicine and
Biological Sciences
Chicago, Illinois

Charise Gleason, MSN, NP-C, AOCNP
Advanced Practice Provider Chief
Winship Cancer Institute of Emory University
Adjunct Faculty, Nell Hodgson Woodruff
School of Nursing
Atlanta, Georgia

Sonia Glennie, ARNP, MSN, OCN
Swedish Cancer Institute Center for
Blood Disorders
Seattle, Washington

Kelly EH Goodwin, MSN, RN, ANP-BC
Thoracic Cancer Center
Massachusetts General Hospital
Boston, Massachusetts

Allie Hershey, MSN, RN, ANP-BC, AOCNP
Oncology Nurse Practitioner, Breast Oncology
Susan F Smith Center for Women's Cancers
Dana-Farber Cancer Institute
Boston, Massachusetts

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

RTP
RESEARCH
TO PRACTICE

Oncology Nurse Practitioners

Robin Klebig, APRN, CNP, AOCNP
Nurse Practitioner
Assistant Professor of Medicine
Division of Hematology
Mayo Clinic
Rochester, Minnesota

Kelly Leonard, MSN, FNP-BC
Family Nurse Practitioner
Dana-Farber Cancer Institute
Boston, Massachusetts

Patricia Mangan, RN, MSN, CRNP, APN, BC
Nurse Lead, Hematologic Malignancies and
Stem Cell Transplant Programs
Abramson Cancer Center
University of Pennsylvania
Philadelphia, Pennsylvania

Brenda Martone, MSN, NP-BC, AOCNP
Northwestern Medicine
Northwestern Memorial Hospital
Chicago, Illinois

Alli McClanahan, MSN, APRN, ANP-BC
Nurse Practitioner
Division of Hematology
Mayo Clinic
Rochester, Minnesota

Jessica Mitchell, APRN, CNP, MPH
Assistant Professor of Oncology
Mayo Clinic College of Medicine and Science
Rochester, Minnesota

Mollie Moran, APRN-CNP, AOCNP
The James Cancer Hospital and Solove
Research Institute
The Ohio State University
Columbus, Ohio

RTP
RESEARCH
TO PRACTICE

Oncology Nurse Practitioners

Tara Plues, APRN, MSN
Hematology and Medical Oncology
Cleveland Clinic
Cleveland, Ohio

Kimberly A Spickes, MNSc, RN, APRN, OCN, ACNP-BC
Nurse Practitioner
UAMS Division of Gynecologic Oncology
University of Arkansas for Medical Sciences
Little Rock, Arkansas

Tiffany A Richards, PhD, ANP-BC, AOCNP
Nurse Practitioner
Department of Lymphoma/Myeloma
The University of Texas
MD Anderson Cancer Center
Houston, Texas

Ronald Stein, JD, MSN, NP-C, AOCNP
Clinical Instructor of Medicine
USC Norris Comprehensive Cancer Center
Los Angeles, California

Victoria Sherry, DNP, CRNP, AOCNP
Oncology Nurse Practitioner for Thoracic Malignancies
Abramson Cancer Center
Perelman Center for Advanced Medicine
University of Pennsylvania Medical Center
Faculty, University of Pennsylvania School of Nursing
Philadelphia, Pennsylvania

Elizabeth Zerante, MS, AGACNP-BC
APN Inpatient Hematopoietic Cellular Therapy Service
University of Chicago Medicine
Chicago, Illinois

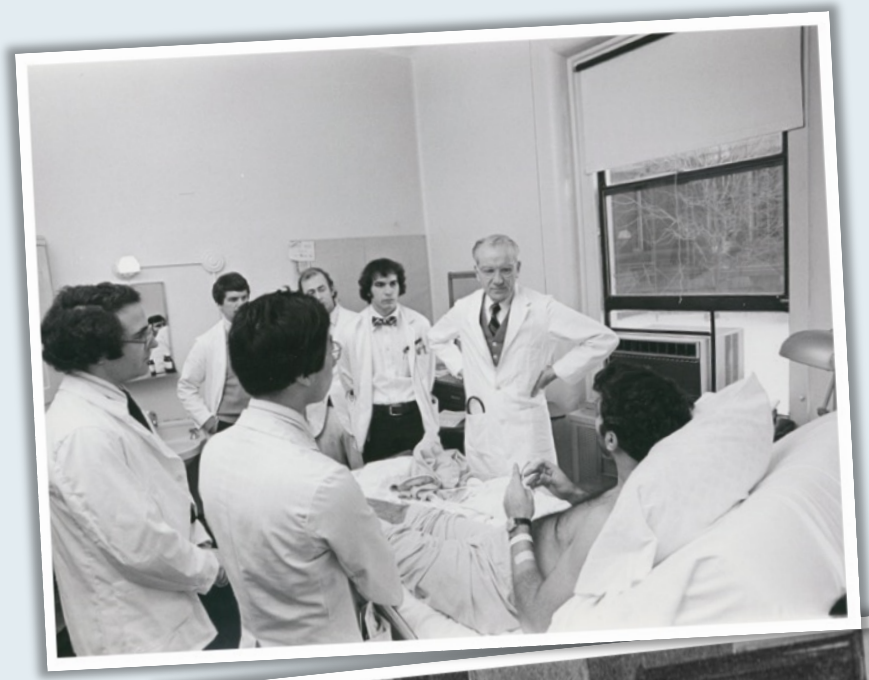
RTP
RESEARCH TO PRACTICE

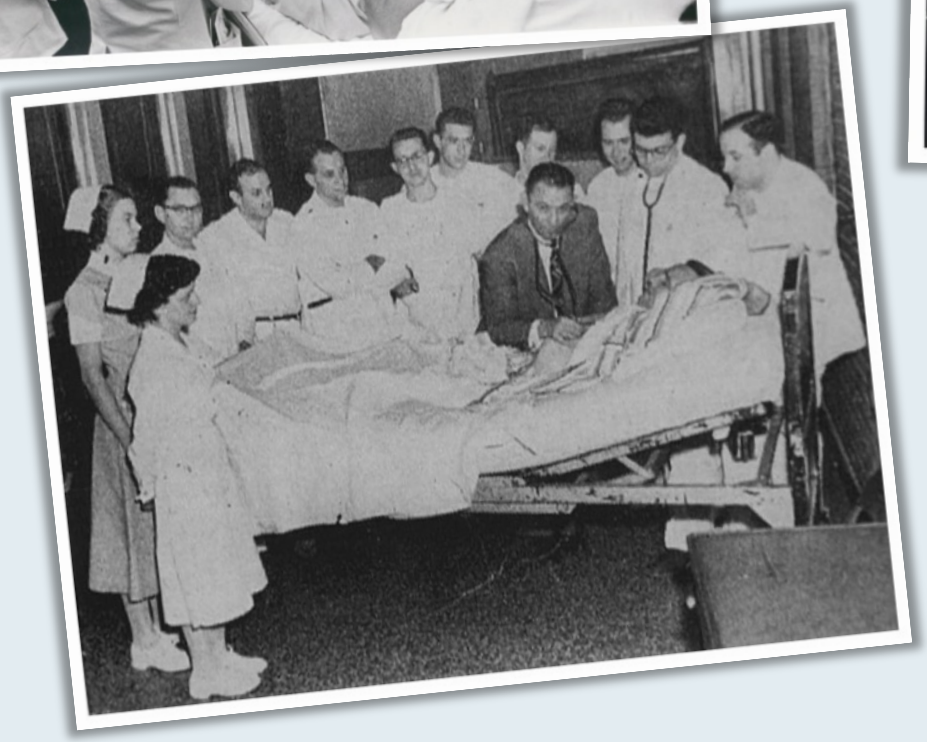

RYDER TRAUMA CENTER
Jackson Memorial Hospital

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 GI Ca 4:45 PM	22 Prostate Ca 8:30 AM Lymphomas 5:00 PM	23
26	27 Multiple Myeloma 8:30 AM GYN 5:00 PM	28 Bladder Ca 12:00 PM	29 CLL 8:30 AM CAR-T 5:00 PM	30

RTP
RESEARCH
TO PRACTICE






The Birmingham News


Tara Plues, APRN, MSN


Kelly EH Goodwin, MSN, RN, ANP-BC


Victoria Sherry, DNP, CRNP, AOCNP

The Core Oncology Triad
Developing an Individualized Oncology Strategy

RTP RESEARCH TO PRACTICE

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

RTP
RESEARCH
TO PRACTICE

13th Annual Oncology Grand Rounds

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

Non-Small Cell Lung Cancer

Tuesday, April 20, 2021
5:00 PM – 6:30 PM ET

Medical Oncologists

John V Heymach, MD, PhD
Paul K Paik, MD
Zofia Piotrowska, MD, MHS

Oncology Nurse Practitioners

Kelly EH Goodwin, MSN, RN, ANP-BC
Tara Plues, APRN, MSN
Victoria Sherry, DNP, CRNP, AOCNP

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Agenda

Targeted Therapy

- Case 1 (Ms Goodwin): A 54-year-old man with newly diagnosed NSCLC with brain metastases and an EGFR exon 19 deletion
- Case 2 (Ms Sherry): A 57-year-old woman and oncologist with localized NSCLC and an EGFR tumor mutation
- Case 3 (Ms Plues): A 64-year-old woman with metastatic NSCLC with a HER2 mutation – PD-L1: 40%
- Case 4 (Ms Goodwin): A 61-year-old woman with newly diagnosed metastatic NSCLC and an ALK mutation
- Case 5 (Ms Sherry): A 76-year-old woman with multiple regimen-relapsed metastatic NSCLC and an ALK mutation

Immunotherapy

- Case 6 (Ms Goodwin): A 58-year-old woman with Stage IIIB NSCLC without actionable mutations – PD-L1: 0%
- Case 7 (Ms Plues): A 64-year-old woman with locally advanced NSCLC – PD-L1: 40%
- Case 8 (Ms Plues): A 64-year-old man with newly diagnosed metastatic adenocarcinoma of the lung – PD-L1: 95%

RTP
RESEARCH
TO PRACTICE

Perspective on being an oncology nurse practitioner

Victoria Sherry, DNP, CRNP, AOCNP

RTP
RESEARCH
TO PRACTICE

Agenda

Targeted Therapy

- **Case 1 (Ms Goodwin): A 54-year-old man with newly diagnosed NSCLC with brain metastases and an EGFR exon 19 deletion**
- **Case 2 (Ms Sherry): A 57-year-old woman and oncologist with localized NSCLC and an EGFR tumor mutation**
- **Case 3 (Ms Plues): A 64-year-old woman with metastatic NSCLC with a HER2 mutation – PD-L1: 40%**
- **Case 4 (Ms Goodwin): A 61-year-old woman with newly diagnosed metastatic NSCLC and an ALK mutation**
- **Case 5 (Ms Sherry): A 76-year-old woman with multiple regimen-relapsed metastatic NSCLC and an ALK mutation**

Immunotherapy

- **Case 6 (Ms Goodwin): A 58-year-old woman with Stage IIIB NSCLC without actionable mutations – PD-L1: 0%**
- **Case 7 (Ms Plues): A 64-year-old woman with locally advanced NSCLC – PD-L1: 40%**
- **Case 8 (Ms Plues): A 64-year-old man with newly diagnosed metastatic adenocarcinoma of the lung – PD-L1: 95%**

RTP
RESEARCH
TO PRACTICE

Case Presentation – A 54-year-old man with newly diagnosed NSCLC with brain metastases and an EGFR exon 19 deletion (Part 1)

Ms Goodwin

- PMH: Obesity, depression, obstructive sleep apnea, GERD and recent head injury
- 12/2018: Head injury with subsequent headaches, memory impairment, word finding difficulties and slurred speech
- Work up: >15 brain metastases, with significant edema, midline shift
  - LLL mass, with extensive lymphadenopathy
  - Biopsy/testing: EGFR exon 19 deletion

RTP RESEARCH TO PRACTICE

Case Presentation – A 54-year-old man with newly diagnosed NSCLC with brain metastases and an EGFR exon 19 deletion (Part 2)

Ms Goodwin

- PMH: Obesity, depression, obstructive sleep apnea, GERD and recent head injury
- 12/2018: Head injury with subsequent headaches, memory impairment, word finding difficulties and slurred speech
- Work up: >15 brain metastases, with significant edema, midline shift
  - LLL mass, with extensive lymphadenopathy
  - Biopsy/testing: EGFR exon 19 deletion
- ***1/2019: Osimertinib, with significant response in brain x 1 year → PD***
  - ***Worsening cognitive impairment***

RTP RESEARCH TO PRACTICE

Targetable tumor driver mutations in non-small cell lung cancer (NSCLC) generally occur in patients with…

1. Nonsquamous cancer
2. Squamous cancer
3. Both a and b
4. Neither a nor b
5. I don’t know

RTP
RESEARCH
TO PRACTICE

Which of the following assays are considered standard in the evaluation of newly diagnosed metastatic NSCLC?

1. Multiplex genomic testing/NGS (next-generation sequencing)
2. PD-L1 assay
3. Both a and b
4. Neither a nor b
5. I don’t know

RTP
RESEARCH
TO PRACTICE

Compared to erlotinib, osimertinib…

1. Causes less skin toxicity
2. Has greater antitumor efficacy
3. Has a greater antitumor effect in the CNS
4. All of the above
5. Only a and b
6. Only b and c
7. Only a and c
8. I don’t know

RTP
RESEARCH
TO PRACTICE

In general, what is the most common initial treatment for patients with previously untreated NSCLC with an EGFR tumor mutation and multiple, bilateral asymptomatic brain metastases that would require whole-brain radiation therapy?

1. Whole-brain radiation therapy followed by osimertinib
2. Whole-brain radiation therapy
3. Chemotherapy
4. Osimertinib
5. Erlotinib
6. I don’t know

RTP
RESEARCH
TO PRACTICE

Targetable Oncogenic Drivers

EGFR sensitizing
- Gefitinib[4]
- Erlotinib[4]
- Afatinib[4]
- Osimertinib[4]
- Necitumumab[4]
- Rociletinib[3]

ALK
- Crizotinib[4]
- Alectinib[4]
- Ceritinib[4]
- Lorlatinib[2]
- Brigatinib[2]

MET
- Crizotinib[2]
- Cabozantinib[2]

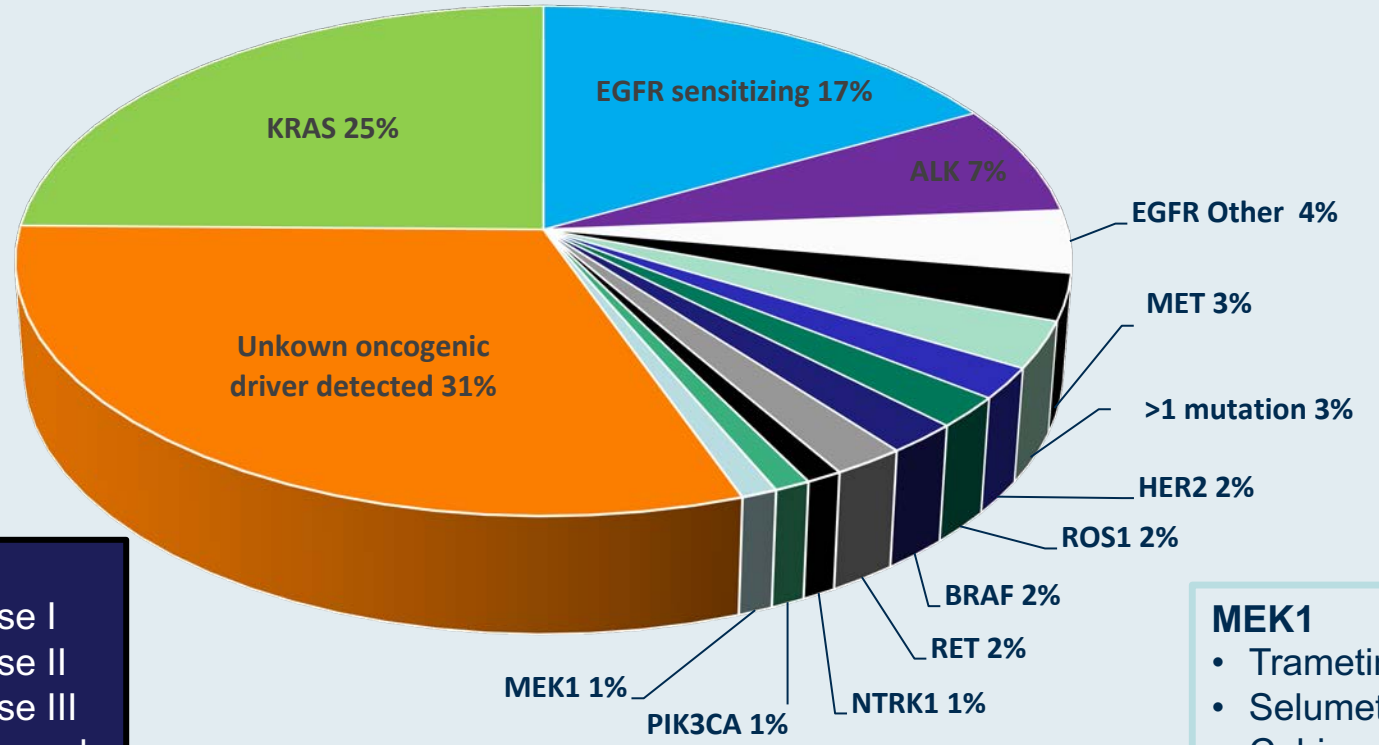
HER2
- Trastuzumab emtansine[2]
- Afatinib[2]
- Dacomitinib[2]

ROS1
- Crizotinib[4]
- Cabozantinib[2]
- Ceritinib[2]
- Lorlatinib[2]
- DS-6051b[1]

BRAF
- Vemurafenib[2]
- Dabrafenib[2]

RET
- Cabozantinib[2]
- Alectinib[2]
- Apatinib[2]
- Vandetanib[2]
- Ponatinib[2]
- Lenvatinib[2]

NTRK1
- Entrectinib[2]
- LOXO-101[2]
- Cabozantinib[2]
- DS-6051b[1]



KEY
1 - Phase I
2 - Phase II
3 - Phase III
4 - Approved

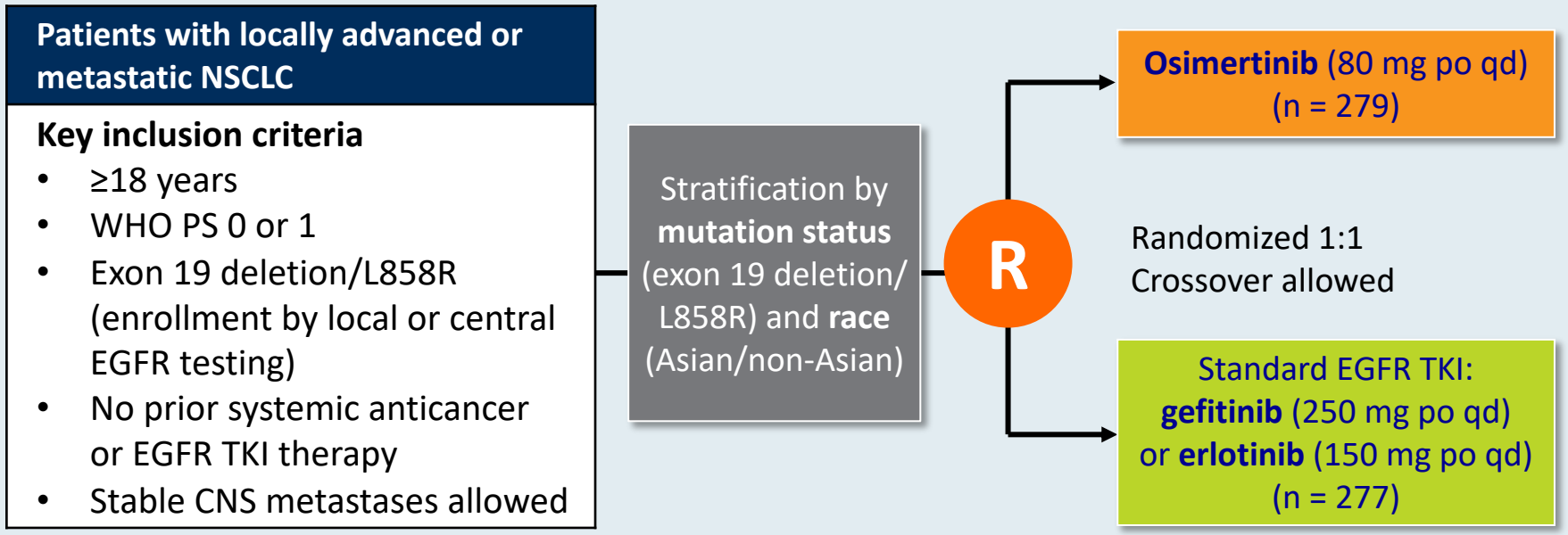
MEK1
- Trametinib[2]
- Selumetinib[3]
- Cobimetinib[1]

PIK3CA
- LY3023414[2]
- PQR 309[1]

Presented By Frances Shepherd at 2019 ASCO Annual Meeting.

RTP RESEARCH TO PRACTICE

FLAURA: A Phase III Study of Osimertinib versus Gefitinib or Erlotinib as First-Line Treatment for Advanced NSCLC with EGFR Tumor Mutation



Primary endpoint: Progression-free survival (PFS) based on investigator assessment (per RECIST 1.1)
Key secondary endpoints: Objective response rate, overall survival and quality of life

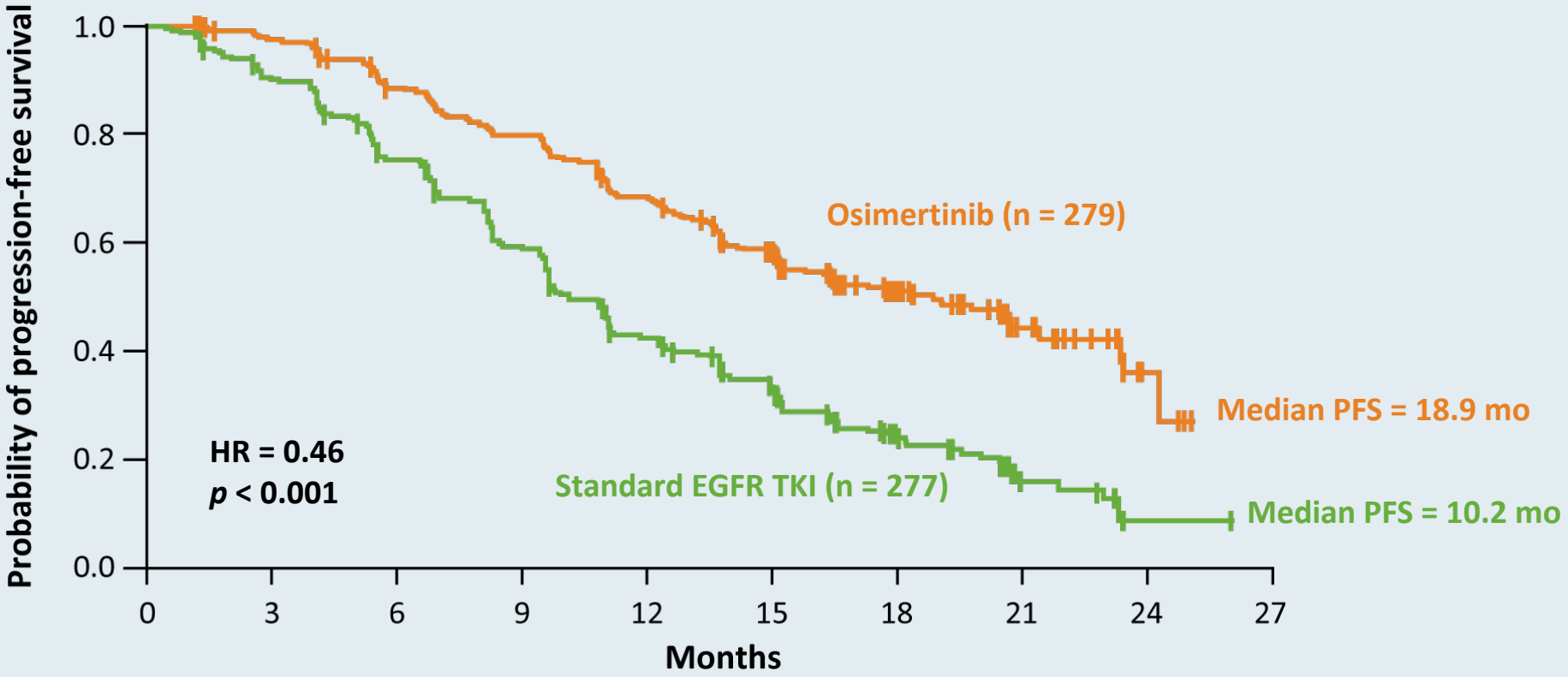
NSCLC= non-small cell lung cancer; TKI = tyrosine kinase inhibitor

www.clinicaltrials.gov. March 2020; Soria JC et al. *N Engl J Med* 2018;378(2):113-25.

RTP RESEARCH TO PRACTICE

FLAURA: PFS with Osimertinib for Patients with NSCLC and EGFR Tumor Mutations

FLAURA primary endpoint: PFS for patients with EGFR exon 19 del or L858R mutation (full analysis set)[1]

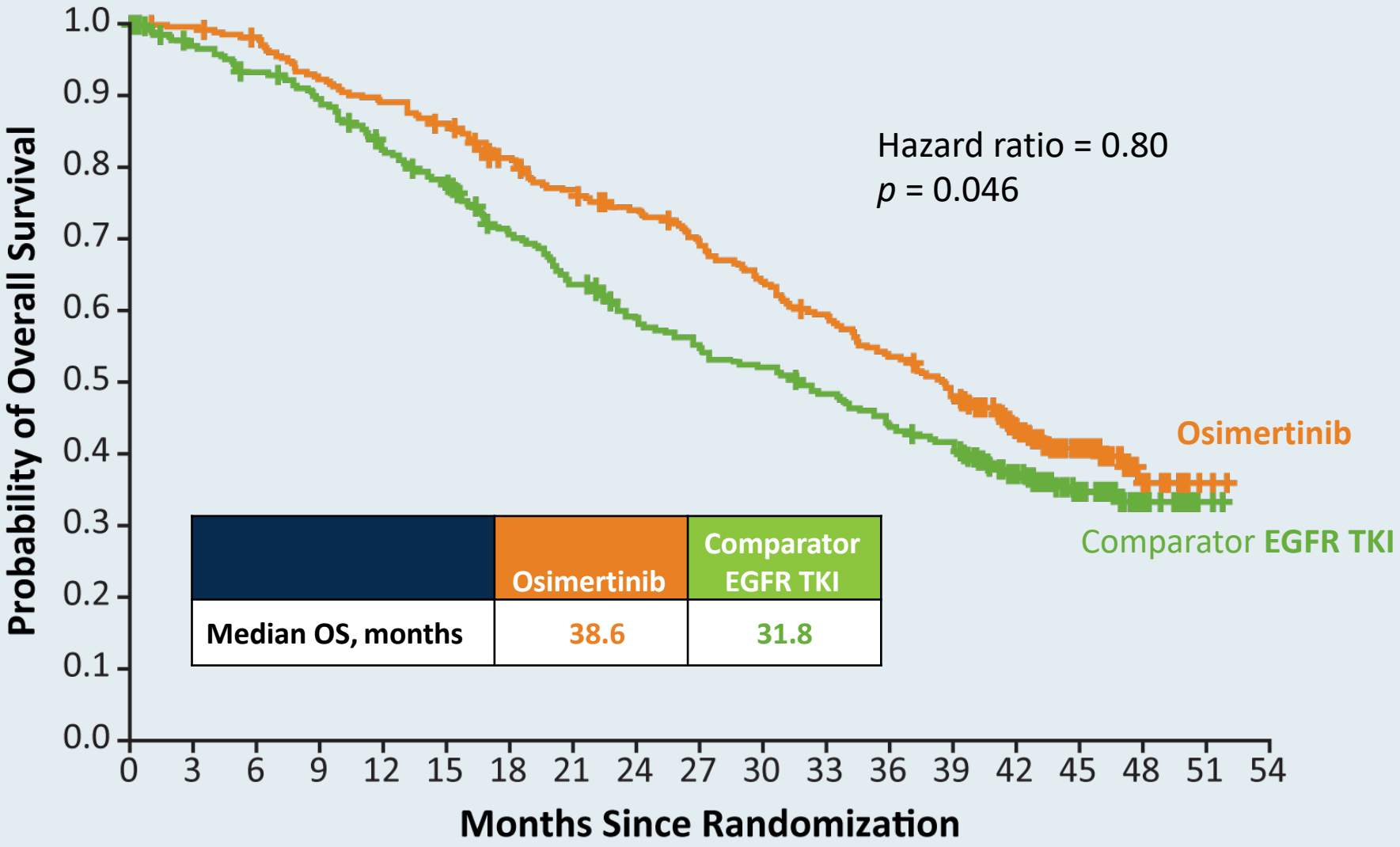


Interim overall survival (data immature), HR = 0.63, $p = 0.007$[1,2]

[1] Soria JC et al. *N Engl J Med* 2018;378(2):113-25.
[2] Planchard D et al. ELCC 2018;Abstract 128O.

RTP RESEARCH TO PRACTICE

FLAURA: Final Overall Survival Analysis



Ramalingam SS et al. *N Engl J Med* 2020;382(1):41-50.

CNS Efficacy of Osimertinib in Patients with Advanced NSCLC and EGFR Tumor Mutations on FLAURA Trial

FLAURA	Full-analysis set		Evaluable for response	
	Osimertinib (n = 61)	EGFR TKIs (n = 67)	Osimertinib (n = 22)	EGFR TKIs (n = 19)
CNS ORR	66%	43%	91%	68%
Median CNS DoR	Not reached	14.4 mo	15.2 mo	18.7 mo

CNS full-analysis set: measurable and nonmeasurable baseline CNS lesions; CNS evaluable for response: ≥1 measurable CNS lesion

Reungwetwattana T et al. *J Clin Oncol* 2018;[Online ahead of print].

RTP RESEARCH TO PRACTICE

rapid communications

Osimertinib in Patients With Epidermal Growth Factor Receptor Mutation–Positive Non–Small-Cell Lung Cancer and Leptomeningeal Metastases: The BLOOM Study

James C.H. Yang, MD, PhD[1]; Sang-We Kim, MD, PhD[2]; Dong-Wan Kim, MD, PhD[3]; Jong-Seok Lee, MD, PhD[4]; Byoung Chul Cho, MD, PhD[5]; Jin-Seok Ahn, MD, PhD[6]; Dae H. Lee, MD, PhD[2]; Tae Min Kim, MD[3]; Jonathan W. Goldman, MD[7]; Ronald B. Natale, MD[8]; Andrew P. Brown, MSc, MPhil[9]; Barbara Collins, PhD[9]; Juliann Chmielecki, PhD[10]; Karthick Vishwanathan, PhD[1,10]; Ariadna Mendoza-Naranjo, PhD[9]; and Myung-Ju Ahn, MD, PhD[6]

J Clin Oncol 2020;38(6):538-47.

RTP RESEARCH TO PRACTICE

BLOOM: Osimertinib in Patients with NSCLC with an EGFR Mutation and Leptomeningeal Metastases (LM)

Patients with cytologically confirmed LM received osimertinib 160 mg once daily.

	Leptomeningeal Metastases (N = 37)
ORR by BICR	62%
Complete response	32%
Partial response	30%
Stable disease ≥ 6 weeks	32%
Progression	3%
Not evaluable	3%
Median DoR	15.2 months

Yang JCH et al. *J Clin Oncol* 2020;38(6):538-47.

RTP RESEARCH TO PRACTICE

Agenda

Targeted Therapy

- Case 1 (Ms Goodwin): A 54-year-old man with newly diagnosed NSCLC with brain metastases and an EGFR exon 19 deletion
- Case 2 (Ms Sherry): A 57-year-old woman and oncologist with localized NSCLC and an EGFR tumor mutation
- Case 3 (Ms Plues): A 64-year-old woman with metastatic NSCLC with a HER2 mutation – PD-L1: 40%
- Case 4 (Ms Goodwin): A 61-year-old woman with newly diagnosed metastatic NSCLC and an ALK mutation
- Case 5 (Ms Sherry): A 76-year-old woman with multiple regimen-relapsed metastatic NSCLC and an ALK mutation

Immunotherapy

- Case 6 (Ms Goodwin): A 58-year-old woman with Stage IIIB NSCLC without actionable mutations – PD-L1: 0%
- Case 7 (Ms Plues): A 64-year-old woman with locally advanced NSCLC – PD-L1: 40%
- Case 8 (Ms Plues): A 64-year-old man with newly diagnosed metastatic adenocarcinoma of the lung – PD-L1: 95%

RTP
RESEARCH
TO PRACTICE

Case Presentation – A 57-year-old woman and oncologist with localized NSCLC and an EGFR tumor mutation (Part 1)

Ms Sherry

- Right upper lobectomy and right lower wedge resection
- Adjuvant pemetrexed/cisplatin
- Adjuvant osimertinib
  - Folliculitis on her face, fatigue but otherwise tolerating it well

RTP
RESEARCH
TO PRACTICE

Case Presentation – A 57-year-old woman and oncologist with localized NSCLC and an EGFR tumor mutation (Part 2)

Ms Sherry

- Right upper lobectomy and right lower wedge resection
- Adjuvant pemetrexed/cisplatin
- Adjuvant osimertinib
  - Folliculitis on her face, fatigue but otherwise tolerated it well
- ***Increased frequency of "toxicity checks" for patients with early-stage disease receiving osimertinib***

RTP
RESEARCH
TO PRACTICE

FDA Approves Osimertinib as Adjuvant Therapy for NSCLC with EGFR Mutations

Press Release – December 18, 2020

"The Food and Drug Administration approved osimertinib for adjuvant therapy after tumor resection in patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

Efficacy was demonstrated in a randomized, double-blind, placebo-controlled trial (ADAURA, NCT02511106) in patients with EGFR exon 19 deletions or exon 21 L858R mutation-positive NSCLC who had complete tumor resection, with or without prior adjuvant chemotherapy. Eligible patients with resectable tumors (stage IB – IIIA) were required to have predominantly non-squamous histology and EGFR exon 19 deletions or exon 21 L858R mutations identified prospectively from tumor tissue in a central laboratory by the cobas® EGFR Mutation Test. A total of 682 patients were randomized (1:1) to receive osimertinib 80 mg orally once daily or placebo following recovery from surgery and standard adjuvant chemotherapy, if given.

www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-osimertinib-adjuvant-therapy-non-small-cell-lung-cancer-egfr-mutations

RTP RESEARCH TO PRACTICE

N Engl J Med 2020;383(18):1711-23.

The NEW ENGLAND JOURNAL of MEDICINE

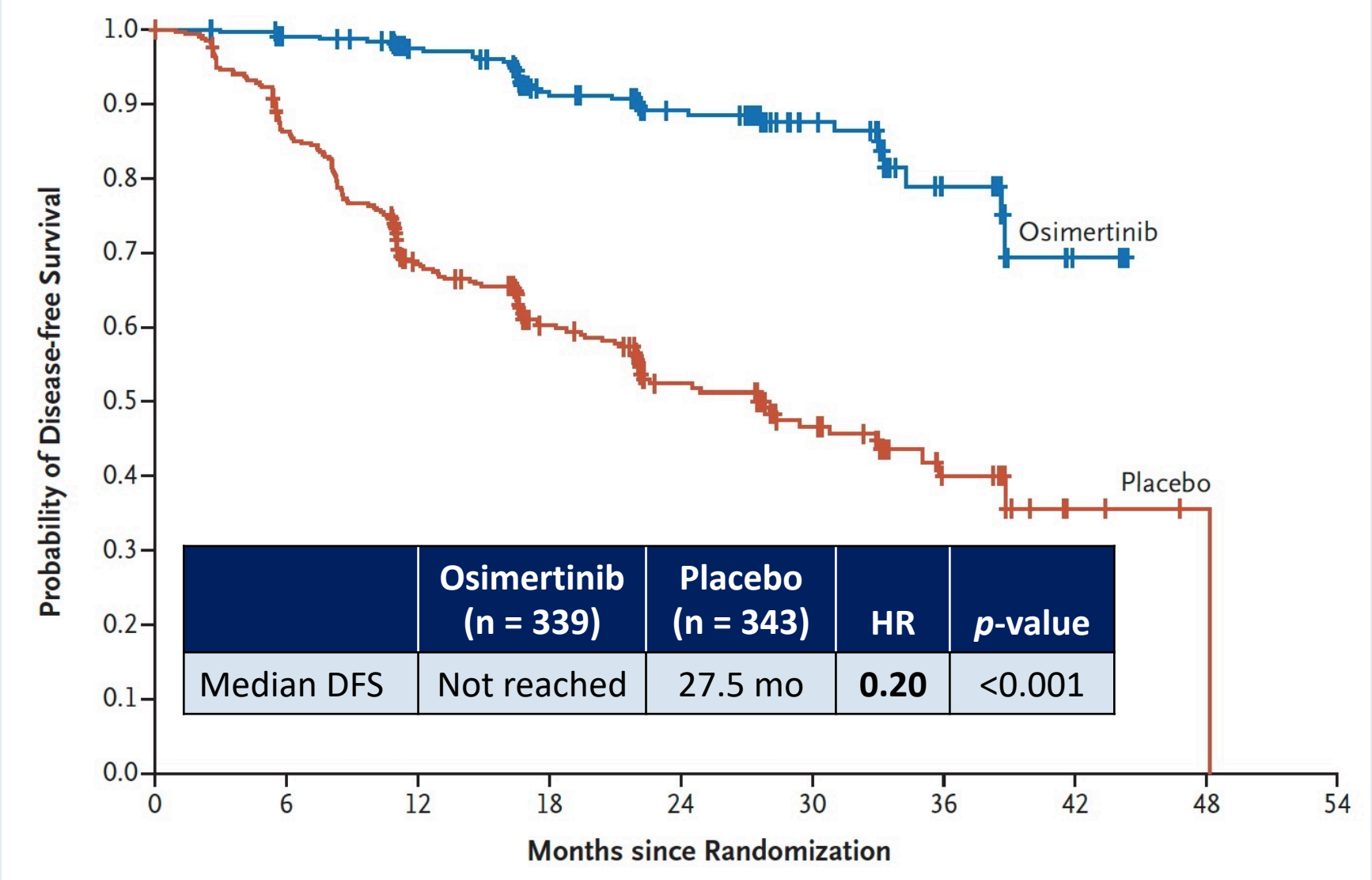
ORIGINAL ARTICLE

Osimertinib in Resected *EGFR*-Mutated Non–Small-Cell Lung Cancer

Yi-Long Wu, M.D., Masahiro Tsuboi, M.D., Jie He, M.D., Thomas John, Ph.D., Christian Grohe, M.D., Margarita Majem, M.D., Jonathan W. Goldman, M.D., Konstantin Laktionov, Ph.D., Sang-We Kim, M.D., Ph.D., Terufumi Kato, M.D., Huu-Vinh Vu, M.D., Ph.D., Shun Lu, M.D., Kye-Young Lee, M.D., Ph.D., Charuwan Akewanlop, M.D., Chong-Jen Yu, M.D., Ph.D., Filippo de Marinis, M.D., Laura Bonanno, M.D., Manuel Domine, M.D., Ph.D., Frances A. Shepherd, M.D., Lingmin Zeng, Ph.D., Rachel Hodge, M.Sc., Ajlan Atasoy, M.D., Yuri Rukazenkov, M.D., Ph.D., and Roy S. Herbst, M.D., Ph.D., for the ADAURA Investigators*

RTP RESEARCH TO PRACTICE

ADAURA: Disease-Free Survival in Stage IB to IIIA Disease

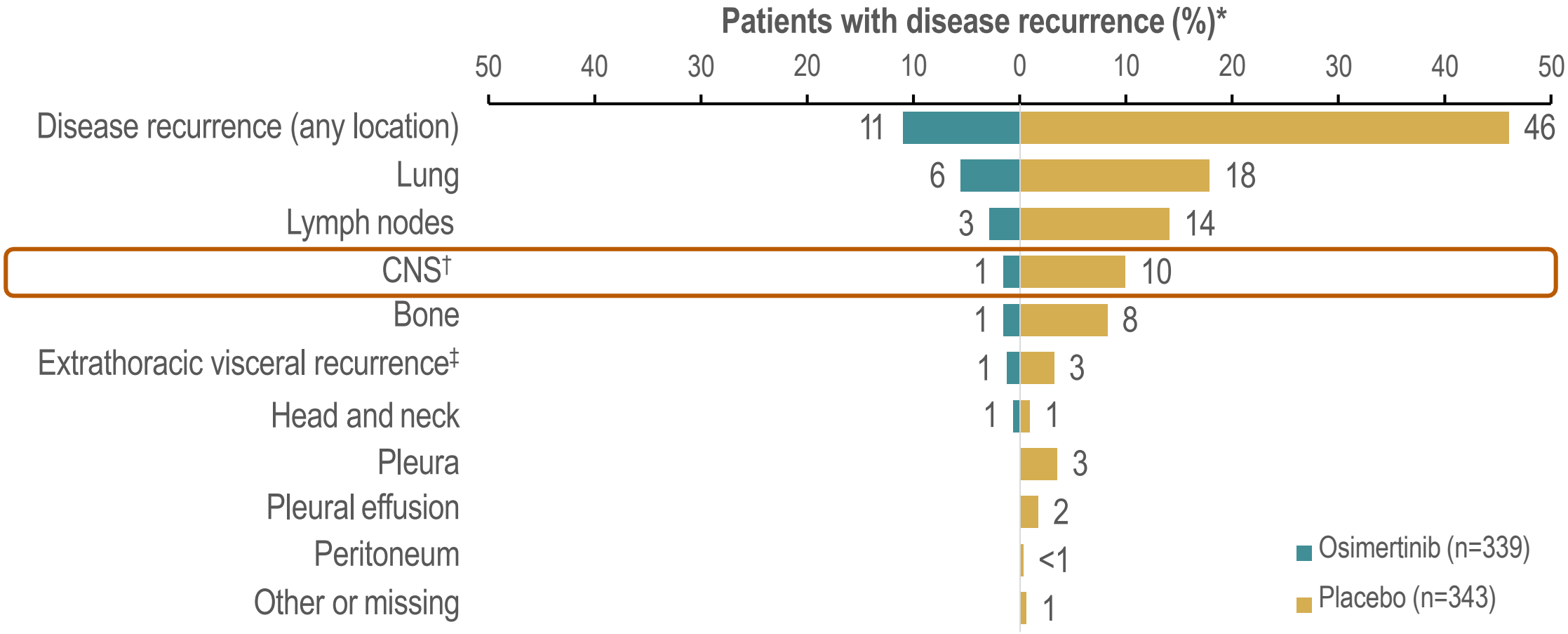


	Osimertinib (n = 339)	Placebo (n = 343)	HR	*p*-value
Median DFS	Not reached	27.5 mo	**0.20**	<0.001

Wu YL et al. *N Engl J Med* 2020;383(18):1711-23.

RTP RESEARCH TO PRACTICE

ADAURA: Sites of disease recurrence



*Number of patients with disease recurrence regardless of pathology results of the tumour recurrence location;
†Includes CNS only (osimertinib n=4 [1%]; placebo n=25 [7%]) and CNS plus other locations (osimertinib n=1 [<1%]; placebo n=9 [3%]).
One patient in the osimertinib arm and one patient in the placebo arm had CNS metastases at baseline; therefore, these two patients were censored on Day 1 and excluded from the CNS DFS efficacy analysis;
‡Includes disease recurrence in liver, renal and adrenal systems and pancreas.
ADAURA data cut-off: 17 January, 2020

Tsuboi M et al. ESMO 2020;Abstract LBA1.

ADAURA CNS DFS events

- Overall, 45 patients (osimertinib n=6, placebo n=39) had CNS DFS events*

	Overall population	
Patients, n (%)	**Osimertinib n=339**	**Placebo n=343**
CNS DFS events:	6 (2%)	39 (11%)
CNS recurrence	4 (1%)	33 (10%)
Death†	2 (1%)	6 (2%)

*Defined as CNS disease recurrence, or death without any CNS disease recurrence;
†Death in absence of CNS disease recurrence, or death within two visits of baseline where the patient has no evaluable assessments or no baseline data.
ADAURA data cut-off: 17 January, 2020

Tsuboi M et al. ESMO 2020;Abstract LBA1.

ADAURA: Most Common Treatment-Related Adverse Events

Adverse events	Osimertinib (n = 337)	Placebo (n = 343)
Dose interruptions due to AE	24%	11%
Dose reductions due to AE	9%	1%
Discontinuation of treatment due to AE	11%	3%
Diarrhea	39%	14%
Paronychia	23%	1%
Dry skin	20%	5%
Pruritus	17%	7%
Stomatitis	16%	2%

Wu YL et al. *N Engl J Med* 2020;383(18):1711-23.

RTP RESEARCH TO PRACTICE

Agenda

Targeted Therapy

- Case 1 (Ms Goodwin): A 54-year-old man with newly diagnosed NSCLC with brain metastases and an EGFR exon 19 deletion
- Case 2 (Ms Sherry): A 57-year-old woman and oncologist with localized NSCLC and an EGFR tumor mutation
- Case 3 (Ms Plues): A 64-year-old woman with metastatic NSCLC with a HER2 mutation – PD-L1: 40%
- Case 4 (Ms Goodwin): A 61-year-old woman with newly diagnosed metastatic NSCLC and an ALK mutation
- Case 5 (Ms Sherry): A 76-year-old woman with multiple regimen-relapsed metastatic NSCLC and an ALK mutation

Immunotherapy

- Case 6 (Ms Goodwin): A 58-year-old woman with Stage IIIB NSCLC without actionable mutations – PD-L1: 0%
- Case 7 (Ms Plues): A 64-year-old woman with locally advanced NSCLC – PD-L1: 40%
- Case 8 (Ms Plues): A 64-year-old man with newly diagnosed metastatic adenocarcinoma of the lung – PD-L1: 95%

RTP
RESEARCH
TO PRACTICE

Case Presentation – A 64-year-old woman with metastatic NSCLC with a HER2 mutation and PD-L1 40%

Ms Plues

- Diagnosed with Stage IIIA NSCLC
  - PD-L1: 40%
- Concurrent carboplatin/paclitaxel + RT → Left VATS pneumonectomy
- Consolidation durvalumab → disease progression
- Carboplatin/pemetrexed/pembrolizumab – discontinued due to tolerability issues
- T-DM1 → discontinued due to neuropathy
- Trastuzumab deruxtecan

RTP RESEARCH TO PRACTICE

Trastuzumab Deruxtecan in HER2-Mutated Metastatic Non-Small Cell Lung Cancer (NSCLC): Interim Results of DESTINY-Lung01[1]

Trastuzumab Deruxtecan in HER2-Overexpressing Metastatic Non-Small Cell Lung Cancer (NSCLC): Interim Results of DESTINY-Lung01[2]

[1] Smit EF et al.
IASLC/WCLC 2020;Abstract MA11.03.

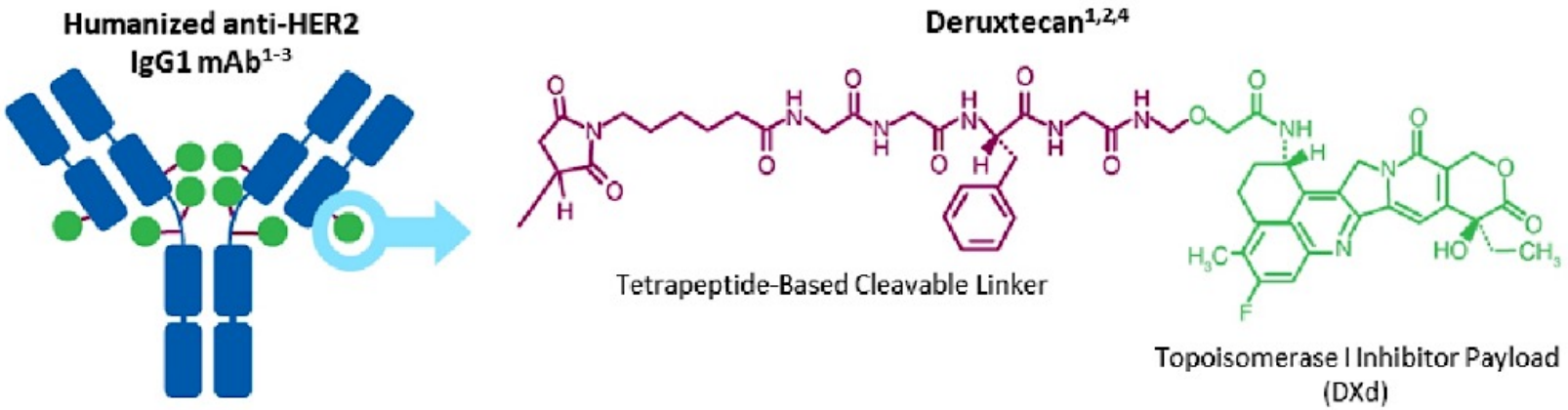
[2] Nakagawa K et al.
IASLC/WCLC 2020;Abstract OA04.05.

RTP
RESEARCH
TO PRACTICE

Antibody-Drug Conjugate
Trastuzumab Deruxtecan (T-DXd)

T-DXd is an ADC with 3 components:

- A humanized anti-HER2 IgG1 mAb with the same amino acid sequence as trastuzumab
- A topoisomerase I inhibitor payload, an exatecan derivative
- A tetrapeptide-based cleavable linker



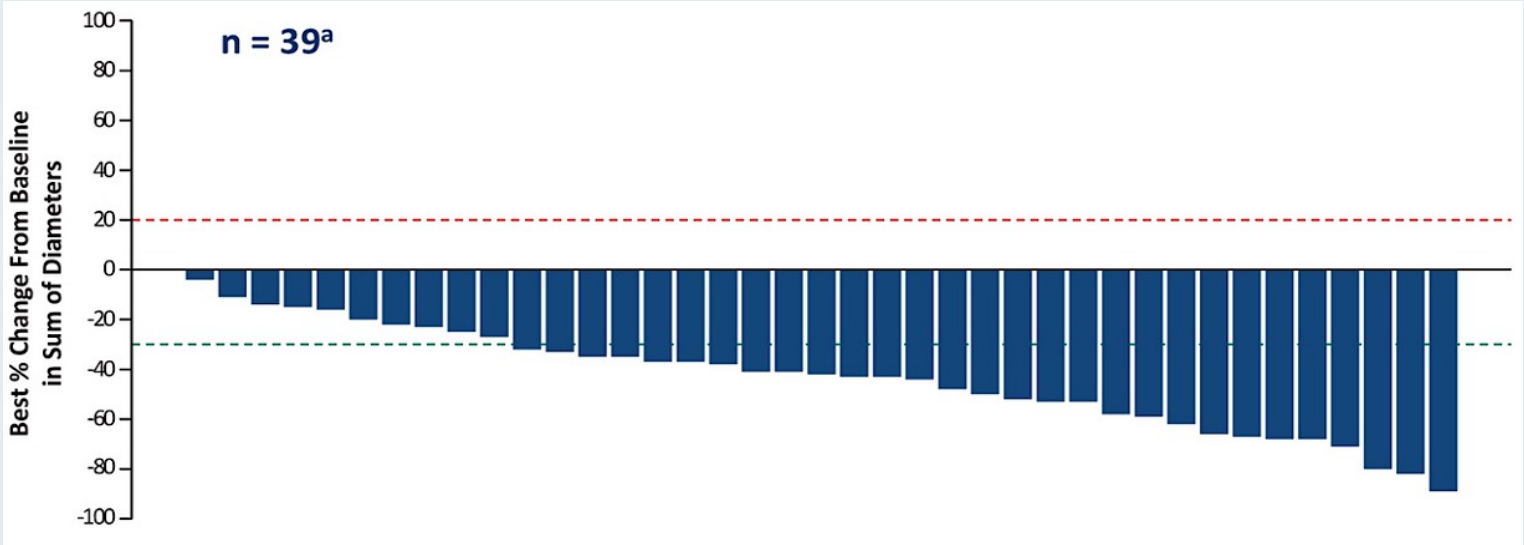
Payload mechanism of action: topoisomerase I inhibitor
High potency of payload
High drug to antibody ratio ≈ 8
Payload with short systemic half-life
Stable linker-payload
Tumor-selective cleavable linker
Membrane-permeable payload

Smit EF et al. ASCO 2020;Abstract 9504.

RTP RESEARCH TO PRACTICE

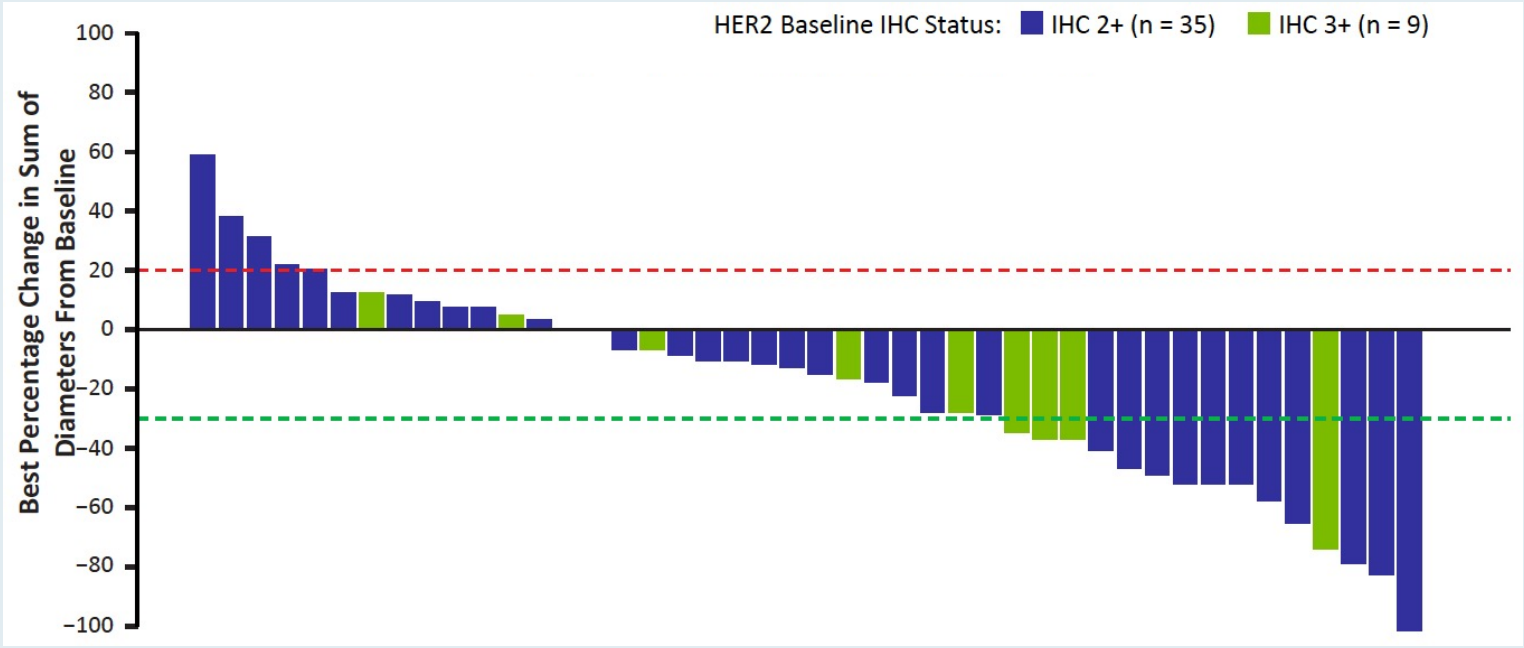
DESTINY-Lung01: Best Percentage Change in Tumor Size with T-DXd in NSCLC with HER2 Mutation versus Overexpression

Mutation



Confirmed ORR = 61.9%
DCR = 90.5%
Median DoR = not reached
Median PFS = 14.0 months

Overexpression



Confirmed ORR = 24.5%
DCR = 69.4%
Median DoR = 6.0 months
Median PFS = 5.4 months

Smit EF et al. IASLC/WCLC 2020;Abstract MA11.03; Nakagawa K et al. IASLC/WCLC 202o;Abstract OA04.05.

RTP RESEARCH TO PRACTICE

Agenda

Targeted Therapy

- Case 1 (Ms Goodwin): A 54-year-old man with newly diagnosed NSCLC with brain metastases and an EGFR exon 19 deletion
- Case 2 (Ms Sherry): A 57-year-old woman and oncologist with localized NSCLC and an EGFR tumor mutation
- Case 3 (Ms Plues): A 64-year-old woman with metastatic NSCLC with a HER2 mutation – PD-L1: 40%
- Case 4 (Ms Goodwin): A 61-year-old woman with newly diagnosed metastatic NSCLC and an ALK mutation
- Case 5 (Ms Sherry): A 76-year-old woman with multiple regimen-relapsed metastatic NSCLC and an ALK mutation

Immunotherapy

- Case 6 (Ms Goodwin): A 58-year-old woman with Stage IIIB NSCLC without actionable mutations – PD-L1: 0%
- Case 7 (Ms Plues): A 64-year-old woman with locally advanced NSCLC – PD-L1: 40%
- Case 8 (Ms Plues): A 64-year-old man with newly diagnosed metastatic adenocarcinoma of the lung – PD-L1: 95%

RTP
RESEARCH
TO PRACTICE

Case Presentation – A 61-year-old woman with newly diagnosed metastatic NSCLC and an ALK mutation

Ms Goodwin

- 5/2020: Diagnosed with metastatic adenocarcinoma of the lung
  - PD-L1: 80%
  - Liquid biopsy: Negative for actionable mutations
- Pembrolizumab x 1
- Molecular testing on tissue: ALK rearrangement
- Alectinib, with significant response
  - Skin toxicity (hives, redness, itching, pain) requiring steroids
- Alectinb held then re-introduced with desensitization after new metastases detected

RTP RESEARCH TO PRACTICE

Case Presentation – A 76-year-old woman with multiple regimen-relapsed metastatic NSCLC and an ALK mutation (Part 1)

Ms Sherry

- Diagnosed with metastatic disease 12 years ago
  - Informed with a prognosis of 3-6 months
- 2 lines of chemotherapy
- Biomarker testing “in its infancy” but sent for EGFR and ALK testing
- ALK mutation identified
- Patient treated with crizotinib, brigatinib, ceritinib and alectinib

RTP
RESEARCH
TO PRACTICE

Case Presentation – A 76-year-old woman with multiple regimen-relapsed metastatic NSCLC and an ALK mutation (Part 2)

Ms Sherry

- Diagnosed with metastatic disease 12 years ago
  - Informed with a prognosis of 3-6 months
- 2 lines of chemotherapy
- Biomarker testing “in its infancy” but sent for EGFR and ALK testing
- ALK mutation identified
- Patient treated with crizotinib, brigatinib, ceritinib and alectinib
- ***Pulmonary embolus and hospice discussion***

RTP
RESEARCH
TO PRACTICE

Case Presentation – A 76-year-old woman with multiple regimen-relapsed metastatic NSCLC and an ALK mutation (Part 3)

Ms Sherry

- Diagnosed with metastatic disease 12 years ago
  - Informed with a prognosis of 3-6 months
- 2 lines of chemotherapy
- Biomarker testing “in its infancy” but sent for EGFR and ALK testing
- ALK mutation identified
- Patient treated with crizotinib, brigatinib, ceritinib and alectinib
- Pulmonary embolus and hospice discussion
- ***Role of supportive caregiver***

RTP RESEARCH TO PRACTICE

Case Presentation – A 76-year-old woman with multiple regimen-relapsed metastatic NSCLC and an ALK mutation (Part 4)

Ms Sherry

- Diagnosed with metastatic disease 12 years ago
  - Informed with a prognosis of 3-6 months
- 2 lines of chemotherapy
- Biomarker testing “in its infancy” but sent for EGFR and ALK testing
- ALK mutation identified
- Patient treated with crizotinib, brigatinib, ceritinib and alectinib
- Pulmonary embolus and hospice discussion
- Role of supportive caregiver
- ***Importance of getting to know your patients; guiding them through end of life***

RTP RESEARCH TO PRACTICE

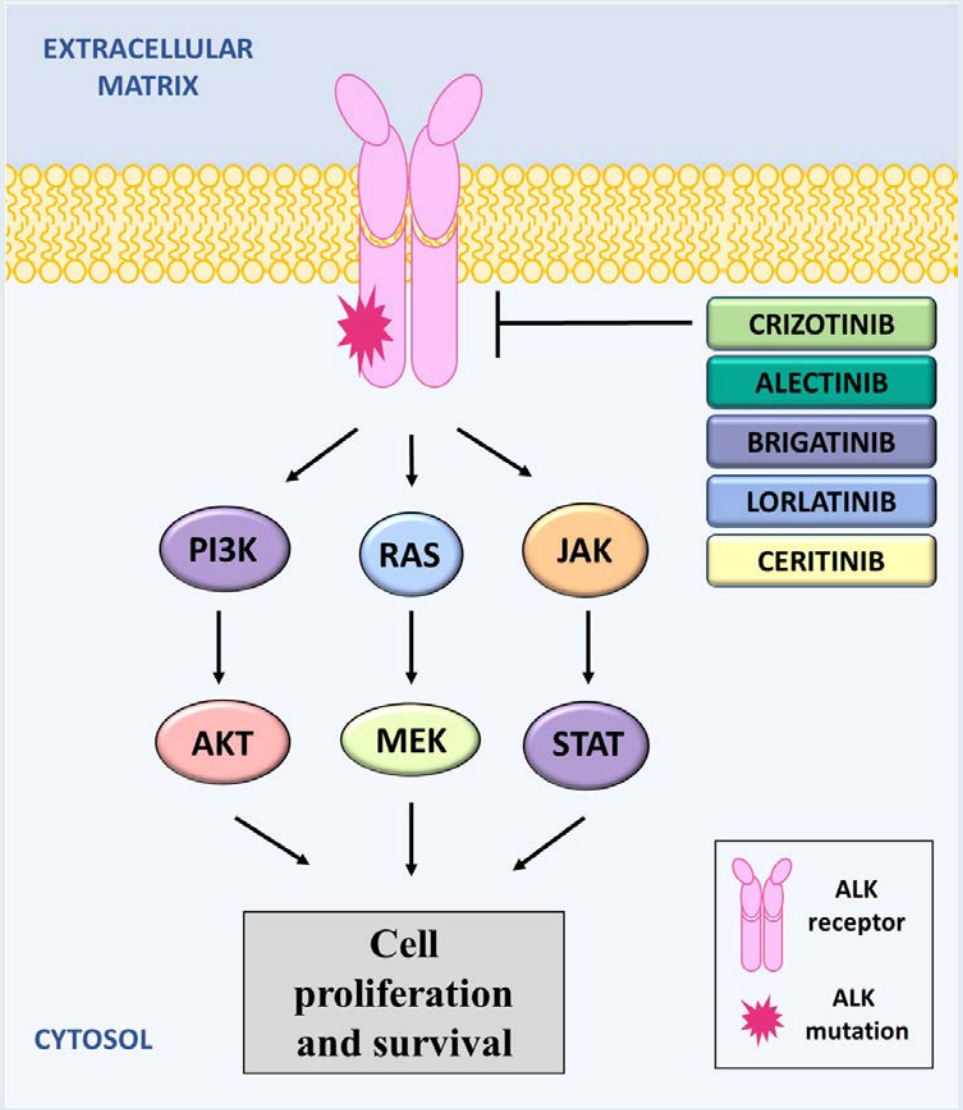
Case Presentation – A 76-year-old woman with multiple regimen-relapsed metastatic NSCLC and an ALK mutation (Part 5)

Ms Sherry

- Diagnosed with metastatic disease 12 years ago
  - Informed with a prognosis of 3-6 months
- 2 lines of chemotherapy
- Biomarker testing “in its infancy” but sent for EGFR and ALK testing
- ALK mutation identified
- Patient treated with crizotinib, brigatinib, ceritinib and alectinib
- Pulmonary embolus and hospice discussion
- Role of supportive caregiver
- Importance of getting to know your patients; guiding them through end of life
- ***Side effects and quality of life on ALK inhibitors***

RTP RESEARCH TO PRACTICE

Mechanism of Action of ALK Inhibitors



3-13% of NSCLCs

Seebacher NA et al. JECCR 2019;38(156).

RTP RESEARCH TO PRACTICE

Timeline of FDA Approvals for ALK TKIs

Xia B et al. *Transl Lung Cancer Res* 2020;9(6):2521-253.

RTP RESEARCH TO PRACTICE

FDA Expands Lorlatinib Approval to Front-Line Treatment of Metastatic NSCLC with ALK Fusion

Press Release – March 3, 2021

"The Food and Drug Administration granted regular approval to lorlatinib for patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive, detected by an FDA-approved test. The FDA also approved the Ventana ALK (D5F3) CDx Assay (Ventana Medical Systems, Inc) as a companion diagnostic for lorlatinib.

Lorlatinib received accelerated approval in November 2018 for the second- or third-line treatment of ALK-positive metastatic NSCLC.

This current approval is based on data from Study B7461006 (NCT03052608), a randomized, multicenter, open-label, active-controlled trial conducted in 296 patients with ALK-positive metastatic NSCLC who had not received prior systemic therapy for metastatic disease. Patients were required to have ALK-positive tumors detected by the VENTANA ALK (D5F3) CDx assay. Patients were randomized 1:1 to receive lorlatinib 100 mg orally once daily (n=149) or crizotinib 250 mg orally twice daily (n=147). Study B7461006 demonstrated an improvement in progression-free survival (PFS) as assessed by blinded independent central review (BICR), with a hazard ratio of 0.28 (95% CI: 0.19, 0.41; p<0.0001)."

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-lorlatinib-metastatic-alk-positive-nsclc?utm_medium=email&utm_source=govdelivery

RTP RESEARCH TO PRACTICE

Activity of ALK TKIs in the First-Line Setting for Advanced NSCLC with ALK Rearrangement

ALK TKI	Median PFS	ORR	Intracranial response
Crizotinib	10.9 mo	74%	NA
Ceritinib	16.6 mo	72.5%	72.7%
Alectinib	34.8 mo	82.9%	82.9%
Brigatinib	29.4 mo	71%	78%
Lorlatinib	Not reached	90%	66.7%
Ensartinib	26.2 mo	80%	64.3%

Xia B et al. *Transl Lung Cancer Res* 2020;9(6):2521-253.

RTP RESEARCH TO PRACTICE

Common and Unique Adverse Effects of ALK TKIs

ALK TKI	Most common adverse effects
Crizotinib	Vision disorders, nausea, diarrhea, vomiting, edema, constipation, elevated transaminases, fatigue, decreased appetite, upper respiratory infection, dizziness, and neuropathy
Ceritinib	Diarrhea, nausea, vomiting, fatigue, abdominal pain, decreased appetite, and weight loss
Alectinib	Constipation, fatigue, edema, myalgia and anemia
Brigatinib	Diarrhea, fatigue, nausea, rash , cough, myalgia, headache, hypertension, vomiting, and dyspnea
Lorlatinib	Hypercholesterolemia, hypertriglyceridemia, edema, peripheral neuropathy, weight gain, cognitive effects, fatigue, dyspnea, arthralgia, diarrhea
Ensartinib	Rash, nausea, pruritis, and vomiting

Crizotinib PI, rev 1/2021; Ceritinib PI, rev 3/2019; Alectinib PI, rev 1/2021; Brigatinib PI, rev 5/2020; Lorlatinib PI, rev 3/2021
Xia B et al. *Transl Lung Cancer Res* 2020;9(6):2521-253; Gristina V et al. *Pharmaceuticals* 2020;13:474.

RTP RESEARCH TO PRACTICE

Agenda

Targeted Therapy

- Case 1 (Ms Goodwin): A 54-year-old man with newly diagnosed NSCLC with brain metastases and an EGFR exon 19 deletion
- Case 2 (Ms Sherry): A 57-year-old woman and oncologist with localized NSCLC and an EGFR tumor mutation
- Case 3 (Ms Plues): A 64-year-old woman with metastatic NSCLC with a HER2 mutation – PD-L1: 40%
- Case 4 (Ms Goodwin): A 61-year-old woman with newly diagnosed metastatic NSCLC and an ALK mutation
- Case 5 (Ms Sherry): A 76-year-old woman with multiple regimen-relapsed metastatic NSCLC and an ALK mutation

Immunotherapy

- Case 6 (Ms Goodwin): A 58-year-old woman with Stage IIIB NSCLC without actionable mutations – PD-L1: 0%
- Case 7 (Ms Plues): A 64-year-old woman with locally advanced NSCLC – PD-L1: 40%
- Case 8 (Ms Plues): A 64-year-old man with newly diagnosed metastatic adenocarcinoma of the lung – PD-L1: 95%

RTP
RESEARCH
TO PRACTICE

Case Presentation – A 58-year-old woman with Stage IIIB NSCLC without actionable mutations – PD-L1: 0% (Part 1)

Ms Goodwin

- PMH: Hyperlipidemia, multiple basal and squamous cell skin cancers, current smoker
- 7/2020: Stage IIIB NSCLC with neuroendocrine differentiation
- Initiates concurrent cisplatin/etoposide + RT
- Plans to receive consolidation durvalumab

RTP RESEARCH TO PRACTICE

Case Presentation – A 58-year-old woman with Stage IIIB NSCLC without actionable mutations – PD-L1: 0% (Part 2)

Ms Goodwin

- PMH: Hyperlipidemia, multiple basal and squamous cell skin cancers, current smoker
- 7/2020: Stage IIIB NSCLC with neuroendocrine differentiation
- Initiates concurrent cisplatin/etoposide + RT
- Plans to receive consolidation durvalumab
- ***Side effects associated with chemoradiation therapy***

RTP RESEARCH TO PRACTICE

Case Presentation – A 58-year-old woman with Stage IIIB NSCLC without actionable mutations – PD-L1: 0% (Part 3)

Ms Goodwin

- PMH: Hyperlipidemia, multiple basal and squamous cell skin cancers, current smoker
- 7/2020: Stage IIIB NSCLC with neuroendocrine differentiation
- Initiates concurrent cisplatin/etoposide + RT
- Plans to receive consolidation durvalumab
- Side effects associated with chemoradiation therapy
- ***Preparing patients for durvalumab consolidation***

RTP RESEARCH TO PRACTICE

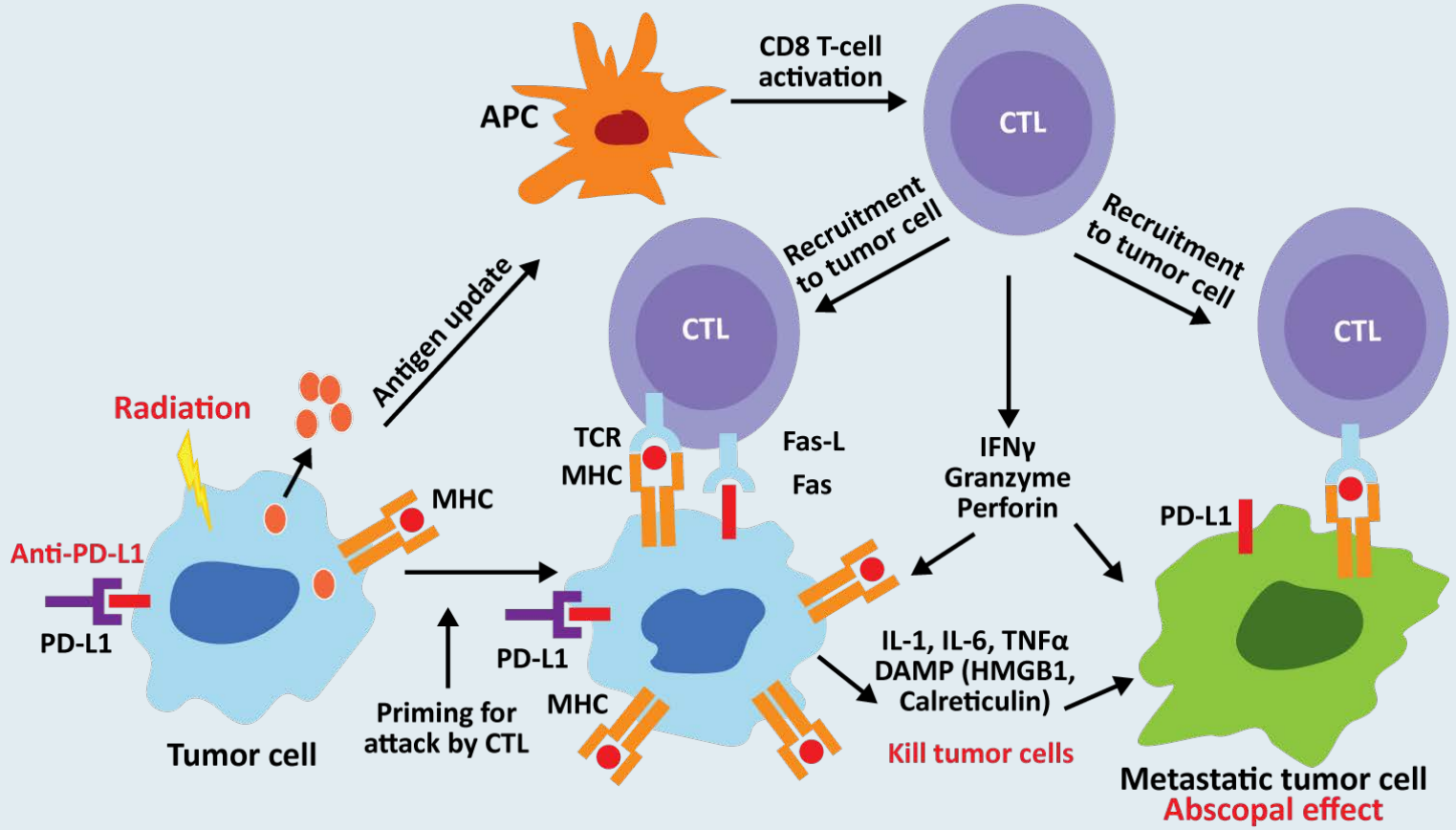
Case Presentation – A 64-year-old woman with locally advanced NSCLC and PD-L1 40%

Ms Plues

- Diagnosed with Stage IIIA NSCLC
  - PD-L1: 40%
- Concurrent carboplatin/paclitaxel + RT → Left VATS pneumonectomy
- Consolidation durvalumab

RTP
RESEARCH
TO PRACTICE

Rationale for Immune Checkpoint Inhibitors After Chemoradiation Therapy for Locally Advanced NSCLC

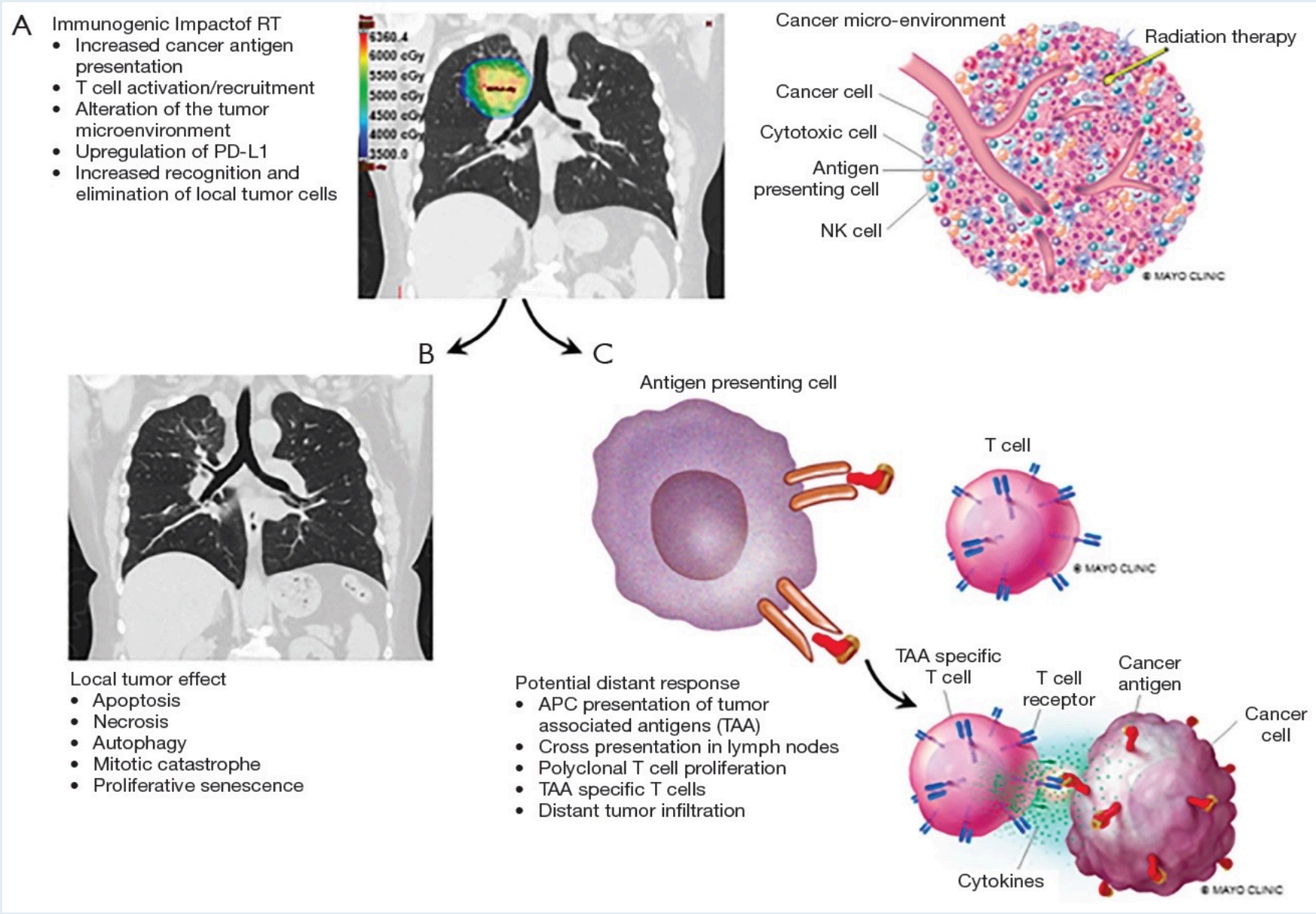


- Chemoradiation therapy may increase neoantigen production, which promotes T-cell infiltration
- Immune checkpoint inhibitors prevent PD-1/PD-L1 proteins from interfering with cytotoxic T-cell response

Chen HHW et al. *Oncotarget* 2017;8(37):62742-58.

RTP RESEARCH TO PRACTICE

Immunogenic Impact of Radiation Therapy



Breen WG et al. J Thorac Dis 2020;12(11):7011-23.

RTP RESEARCH TO PRACTICE

J Thorac Oncol 2021;[Online ahead of print].

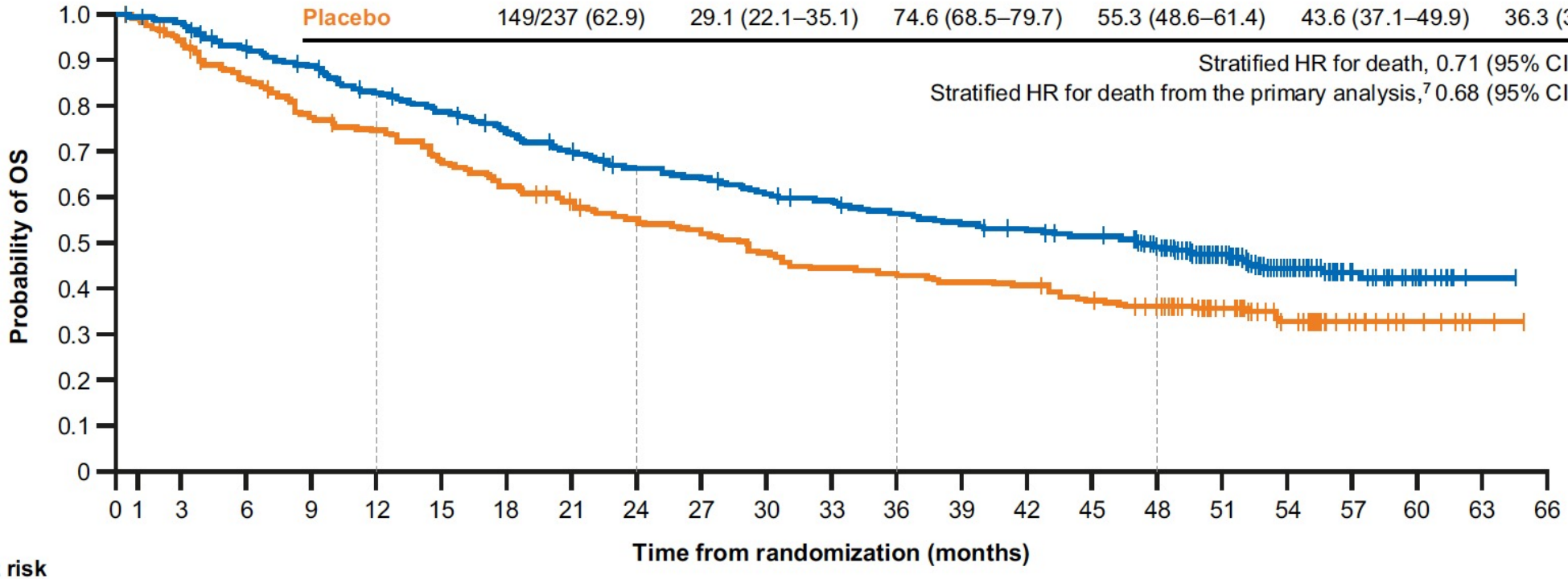
BRIEF REPORT

Four-Year Survival With Durvalumab After Chemoradiotherapy in Stage III NSCLC—an Update From the PACIFIC Trial

Corinne Faivre-Finn, MD, PhD,[a,b,*] David Vicente, MD,[c] Takayasu Kurata, MD,[d] David Planchard, MD, PhD,[e] Luis Paz-Ares, MD, PhD,[f,g] Johan F. Vansteenkiste, MD, PhD,[h] David R. Spigel, MD,[i] Marina C. Garassino, MD,[j] Martin Reck, MD, PhD,[k] Suresh Senan, PhD,[l] Jarushka Naidoo, MBBCH, MHS,[m,n] Andreas Rimner, MD,[o] Yi-Long Wu, MD,[p] Jhanelle E. Gray, MD,[q] Mustafa Özgüroğlu, MD,[r] Ki H. Lee, MD,[s] Byoung C. Cho, MD, PhD,[t] Terufumi Kato, MD,[u] Maike de Wit, MD, PhD,[v] Michael Newton, PharmD,[w] Lu Wang, PhD,[w] Piruntha Thiyagarajah, MD,[x] Scott J. Antonia, MD, PhD[q]

PACIFIC: 4-Year Overall Survival – Intent-To-Treat Population

	No. of events/ total no. of patients (%)	Median OS (95% CI), months	12-month OS rate (95% CI) %	24-month OS rate (95% CI) %	36-month OS rate (95% CI) %	48-month OS rate (95% CI) %
Durvalumab	247/476 (51.9)	47.5 (38.4–52.6)	83.1 (79.4–86.2)	66.3 (61.8–70.4)	56.7 (52.1–61.1)	49.6 (44.9–54.1)
Placebo	149/237 (62.9)	29.1 (22.1–35.1)	74.6 (68.5–79.7)	55.3 (48.6–61.4)	43.6 (37.1–49.9)	36.3 (30.1–42.6)

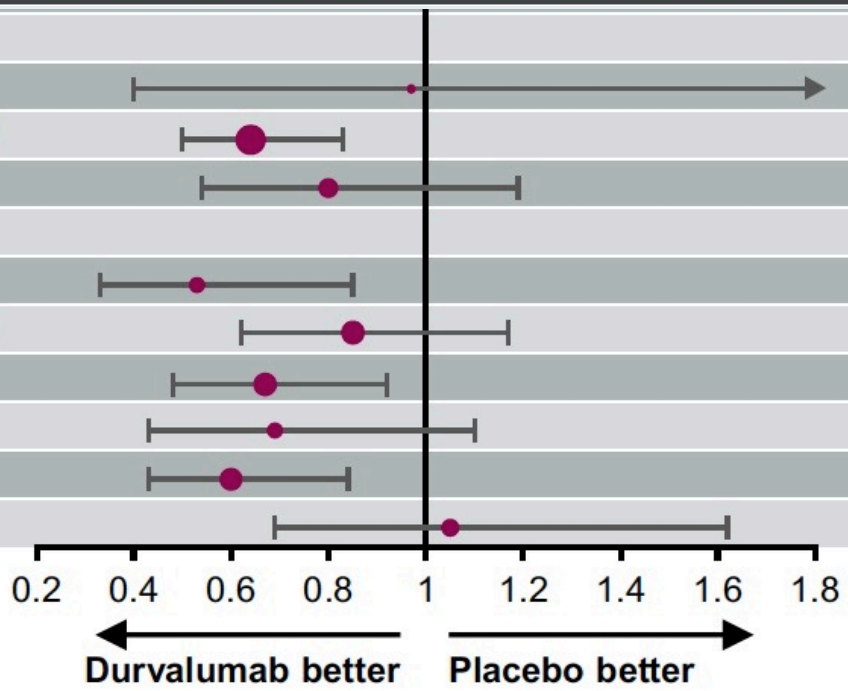


Faivre-Finn C et al. *J Thorac Oncol* 2021;[Online ahead of print].

RTP RESEARCH TO PRACTICE

PACIFIC: 4-Year Overall Survival by EGFR and PD-L1 Status

	No. of events / No. of patients (%)		Unstratified HR (95% CI)
	Durvalumab	Placebo	
***EGFR* mutation**			
Positive	17/29 (58.6%)	7/14 (50.0%)	0.97 (0.40–2.33)
Negative	156/317 (49.2%)	105/165 (63.6%)	0.64 (0.50–0.83)
Unknown	74/130 (56.9%)	37/58 (63.8%)	0.80 (0.54–1.19)
PD-L1 status			
≥25%	50/115 (43.5%)	26/44 (59.1%)	0.53 (0.33–0.85)
<25%	102/187 (54.5%)	62/105 (59.0%)	0.85 (0.62–1.17)
Unknown	95/174 (54.6%)	61/88 (69.3%)	0.67 (0.48–0.92)
1–24% (post hoc analysis)	47/97 (48.5%)	28/47 (59.6%)	0.69 (0.43–1.10)
≥1% (post hoc analysis)	97/212 (45.8%)	54/91 (59.3%)	0.60 (0.43–0.84)
<1% (post hoc analysis)	55/90 (61.1%)	34/58 (58.6%)	1.05 (0.69–1.62)



Faivre-Finn C et al. *J Thorac Oncol* 2021;[Online ahead of print].

PACIFIC: Select Grade 3 or 4 Toxicity with Durvalumab After Chemoradiation for Stage III NSCLC

Adverse events (Grade 3 or 4)	Durvalumab (N = 475)	Placebo (N = 234)
Any Grade 3 or 4	29.9%	26.1%
Cough	0.4%	0.4%
Dyspnea	1.5%	2.6%
Diarrhea	0.6%	1.3%
Pneumonia	4.4%	3.8%
Anemia	2.9%	3.4%

Adverse events leading to discontinuation of treatment occurred in approximately 15.4% in the durvalumab group and 9.8% in the placebo group

Antonia SJ et al. *N Engl J Med* 2017;377(20):1919-29; *N Eng J Med* 2018;379(24):2342-50.

RTP RESEARCH TO PRACTICE

IASLC/WCLC 2020;Abstract 0A02.03.

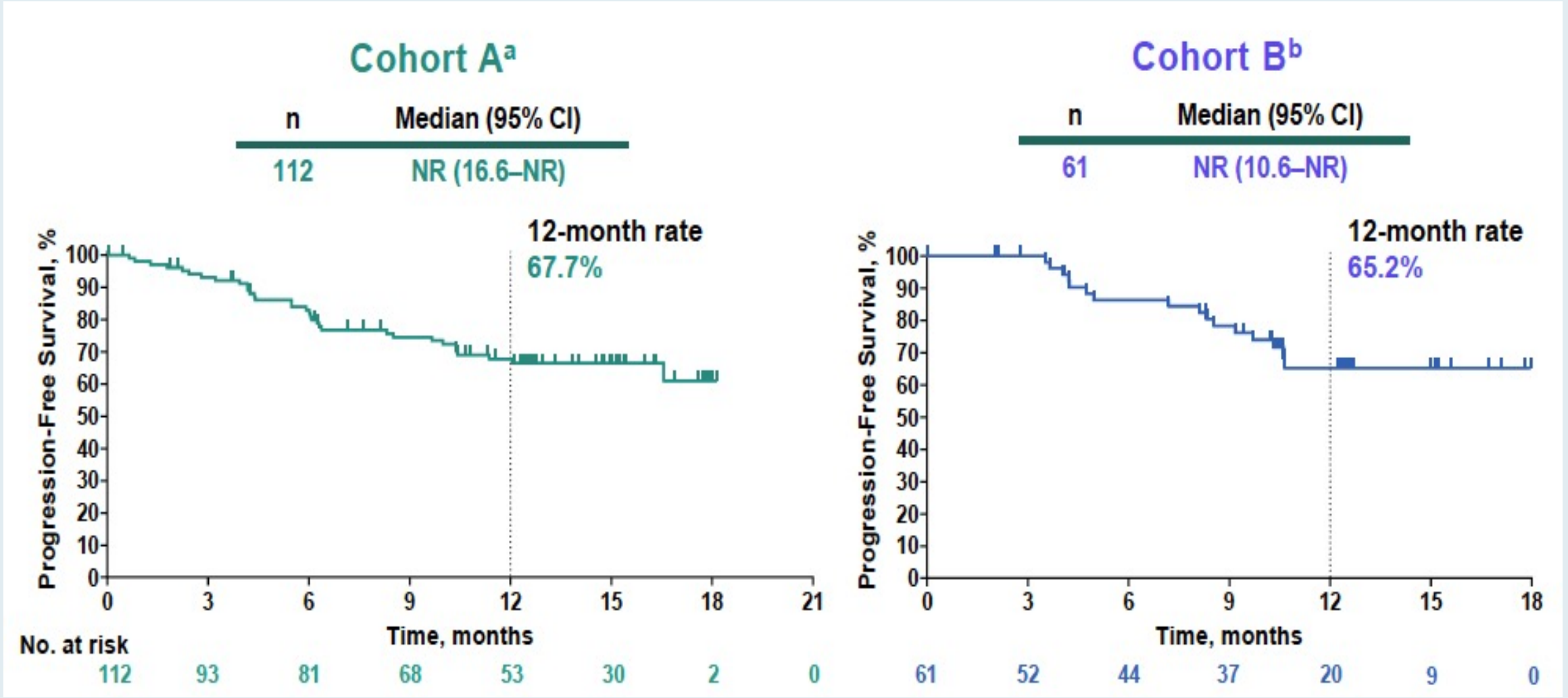
Pembrolizumab Plus Platinum Chemotherapy and Radiotherapy in Unresectable, Locally Advanced, Stage III NSCLC: KEYNOTE-799

M. Reck,[1] K.H. Lee,[2] N. Frost,[3] D.M. Kowalski,[4] V. Breder,[5] T. Pollock,[6] N. Reguart,[7] B. Houghton,[8] X. Quantin,[9] S.M. Keller,[10] H. Liu,[10] B. Piperdi,[10] S.K. Jabbour[11]

[1]LungenClinic, Airway Research Center North, German Center for Lung Research, Grosshansdorf, Germany; [2]Chungbuk National University Hospital, Chungbuk National University College of Medicine, Cheongju, South Korea; [3]Department of Infectious Diseases and Respiratory Medicine, Charité–Universitätsmedizin Berlin, corporate member of Freie Universität Berlin, Humboldt-Universität zu Berlin, and Berlin Institute of Health, Berlin, Germany; [4]The Maria Sklodowska-Curie National Research Institute of Oncology, Warsaw, Poland; [5]N.N. Blokhin Russian Cancer Research Center, Moscow, Russia; [6]Southwestern Regional Medical Center, Inc., Cancer Treatment Centers of America, Tulsa, OK, USA; [7]Hospital Clínic de Barcelona, Barcelona, Spain; [8]Mid North Coast Cancer Institute, Port Macquarie Base Hospital, Port Macquarie, NSW, Australia; [9]Department of Medical Oncology, Montpellier Cancer Institute, Montpellier, France; [10]Merck & Co., Inc., Kenilworth, NJ, USA; [11]Department of Radiation Oncology, Rutgers Cancer Institute of New Jersey, Robert Wood Johnson Medical School, Rutgers University, New Brunswick, NJ, USA

RTP RESEARCH TO PRACTICE

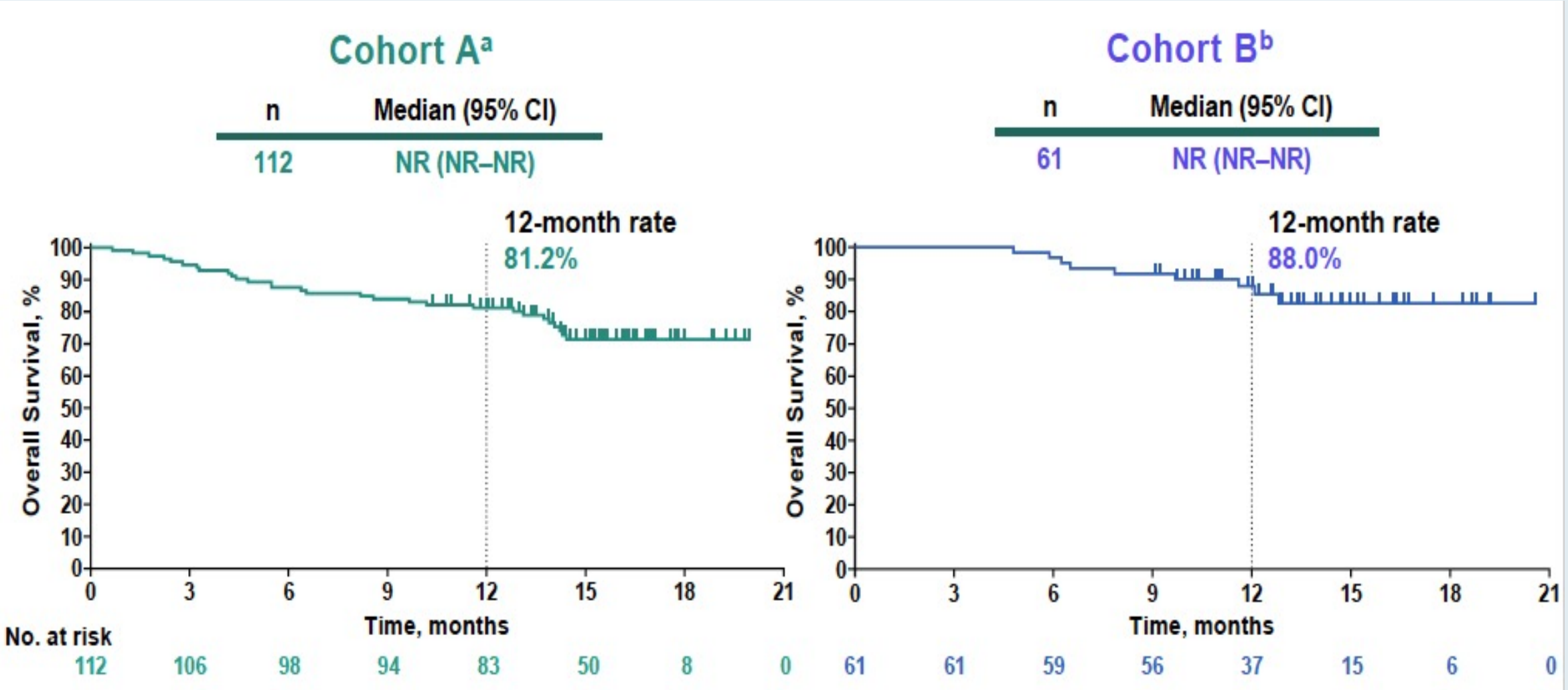
KEYNOTE-799: Progression-Free Survival



Reck M et al. IASLC/WCLC 2020;Abstract 0A02.03.

RTP RESEARCH TO PRACTICE

KEYNOTE-799: Overall Survival



Reck M et al. IASLC/WCLC 2020;Abstract 0A02.03.

KEYNOTE-799: Study Conclusions

- Pembrolizumab plus cCRT continues to show promising antitumor activity in patients with unresectable, locally advanced, stage III NSCLC, regardless of PD-L1 TPS and tumor histology
  - ORR was ~70% in both cohorts
  - Estimated response duration was ≥12 months in most patients with a response
  - 1-year OS rate was >80% in both cohorts

- Incidence of AEs among patients who received pembrolizumab plus cCRT was consistent with established toxicity profiles of cCRT for stage III NSCLC[1] and pembrolizumab monotherapy[2]
  - Incidence of grade ≥3 pneumonitis was 8.0% in cohort A and 7.9% in cohort B
  - Observed rates of grade ≥3 pneumonitis were within the expected range for immunotherapy combined with cCRT[3]

Reck M et al. IASLC/WCLC 2020;Abstract 0A02.03.

RTP RESEARCH TO PRACTICE

Agenda

Targeted Therapy

- Case 1 (Ms Goodwin): A 54-year-old man with newly diagnosed NSCLC with brain metastases and an EGFR exon 19 deletion
- Case 2 (Ms Sherry): A 57-year-old woman and oncologist with localized NSCLC and an EGFR tumor mutation
- Case 3 (Ms Plues): A 64-year-old woman with metastatic NSCLC with a HER2 mutation – PD-L1: 40%
- Case 4 (Ms Goodwin): A 61-year-old woman with newly diagnosed metastatic NSCLC and an ALK mutation
- Case 5 (Ms Sherry): A 76-year-old woman with multiple regimen-relapsed metastatic NSCLC and an ALK mutation

Immunotherapy

- Case 6 (Ms Goodwin): A 58-year-old woman with Stage IIIB NSCLC without actionable mutations – PD-L1: 0%
- Case 7 (Ms Plues): A 64-year-old woman with locally advanced NSCLC – PD-L1: 40%
- Case 8 (Ms Plues): A 64-year-old man with newly diagnosed metastatic adenocarcinoma of the lung – PD-L1: 95%

RTP RESEARCH TO PRACTICE

Case Presentation – A 64-year-old man with newly diagnosed metastatic adenocarcinoma of the lung – PD-L1: 95% (Part 1)

Ms Plues

- Diagnosed with metastatic adenocarcinoma of the lung
  - PD-L1: 95%
- Diagnosed around the same time with seropositive rheumatoid arthritis (RA)
- Pembrolizumab x 1, with significant response but exacerbation of RA requiring hospitalization
  - Held treatment x 5 months, managed by rheumatology
- Pembrolizumab re-introduced, with continued response (near NED)

RTP RESEARCH TO PRACTICE

Case Presentation – A 64-year-old man with newly diagnosed metastatic adenocarcinoma of the lung – PD-L1: 95% (Part 2)

Ms Plues

- Diagnosed with metastatic adenocarcinoma of the lung
  - PD-L1: 95%
- Diagnosed around the same time with seropositive RA
- Pembrolizumab x 1, with significant response but exacerbation of RA requiring hospitalization
  - Held treatment x 5 months, managed by rheumatology
- Pembrolizumab re-introduced, with continued response (near NED)
- ***Impact of the durable effects of immunotherapy***

RTP
RESEARCH
TO PRACTICE

Immunotherapy side effects: Pneumonitis

Tara Plues, APRN, MSN

RTP
RESEARCH
TO PRACTICE

Immunotherapy side effects: Colitis

Tara Plues, APRN, MSN

RTP
RESEARCH
TO PRACTICE

Approximately what proportion of patients with metastatic NSCLC and a PD-L1 level >50% who receive pembrolizumab will be alive in 5 years?

1. Less than 5%
2. 10%-15%
3. 20%-25%
4. 30%-40%
5. More than 50%

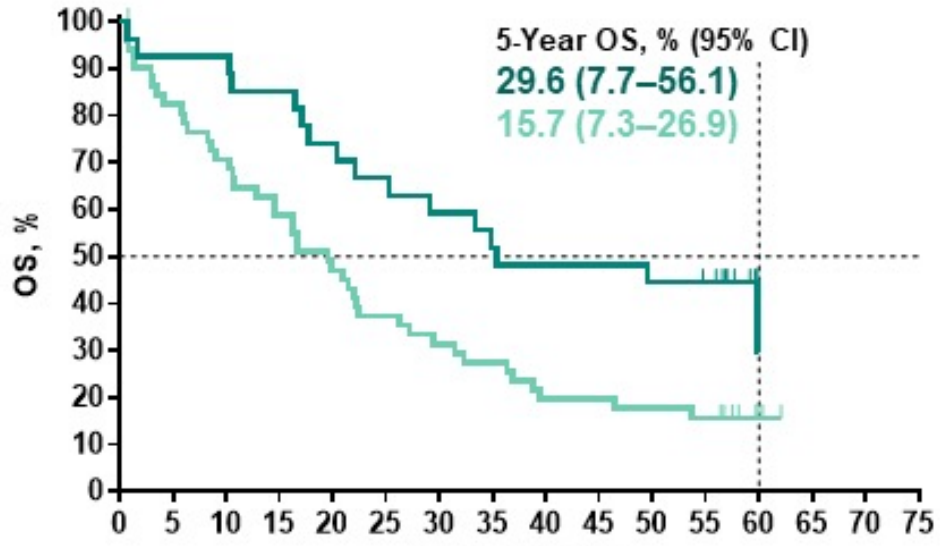
RTP
RESEARCH
TO PRACTICE

KEYNOTE-001: Overall Survival

By PD-L1 Tumor Proportion Score (TPS)

Treatment-Naive Patients

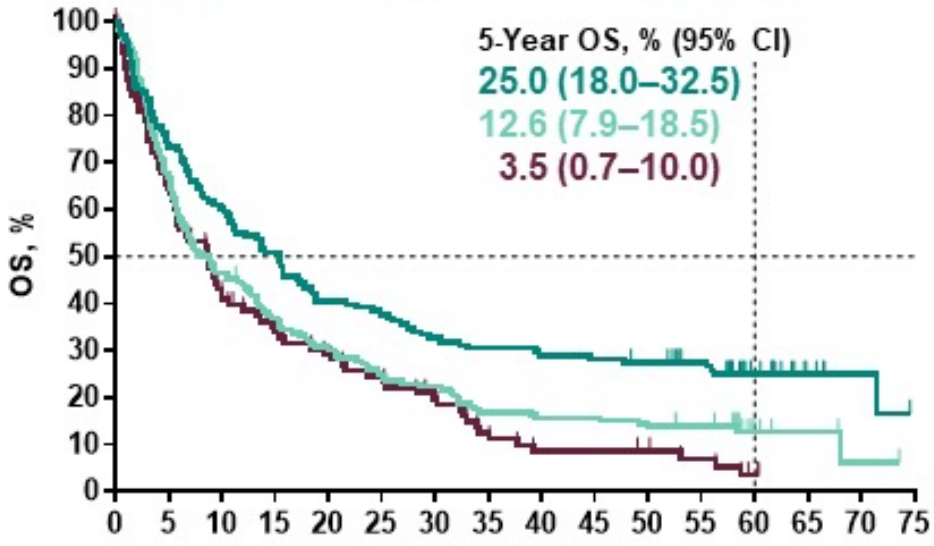
PD-L1 TPS	Events, n/N	Median (95% CI) OS, mo
TPS ≥50%	17/27	35.4 (20.3–63.5)
TPS 1%–49%	43/52	19.5 (10.7–26.3)



No. at risk																
TPS ≥50%	27	25	25	23	20	18	16	14	13	13	12	11	1	0	0	0
TPS 1%–49%	52	42	36	30	24	19	16	14	10	10	9	8	2	0	0	0

Previously Treated Patients

PD-L1 TPS	Events, n/N	Median (95% CI) OS, mo
TPS ≥50%	104/138	15.4 (10.6–18.8)
TPS 1%–49%	146/168	8.5 (6.0–12.6)
TPS <1%	83/90	8.6 (5.5–10.6)



No. at risk																
TPS ≥50%	138	101	83	70	56	52	45	42	40	39	37	32	16	6	3	1
TPS 1%–49%	168	112	78	61	51	41	37	28	26	26	23	21	6	3	1	0
TPS <1%	90	58	36	29	25	21	16	10	7	7	5	4	1	0	0	0

n, number of patients who died; N, number of patients in the subgroup; OS, overall survival; PD-L1, programmed death-ligand 1; TPS, tumor proportion score.
[a]PD-L1 TPS <1% group not presented because of small patient numbers (n = 12).

Garon EB et al. ASCO 2019;Abstract LBA9015.

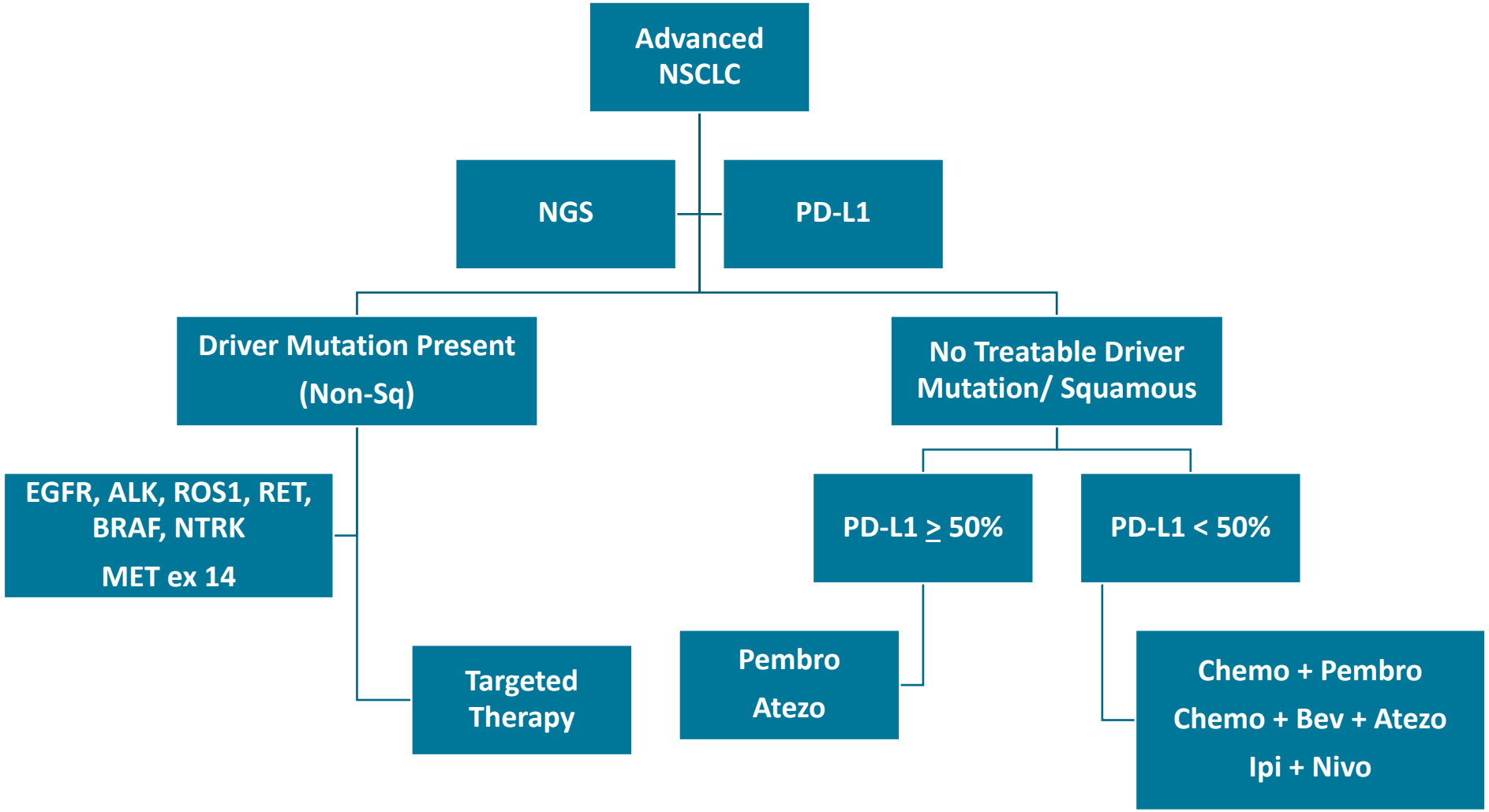
Courtesy of Edward B Garon, MD, MS

Checkpoint inhibitors are generally included as part of first-line treatment for patients with metastatic NSCLC and a PD-L1 level <1%.

1. Agree
2. Disagree
3. I don’t know

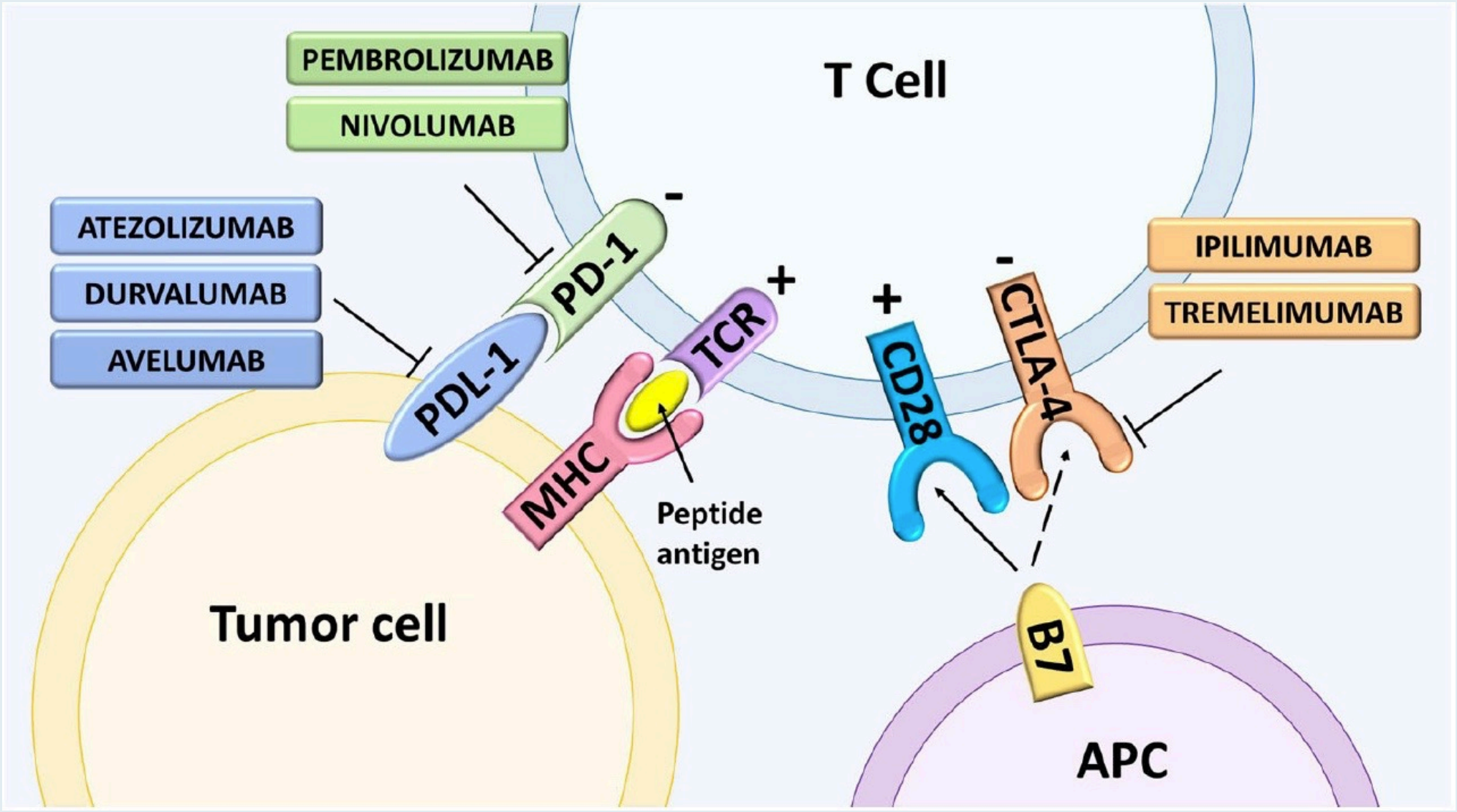
RTP
RESEARCH
TO PRACTICE

Treatment Algorithm for Advanced NSCLC



Courtesy, Suresh Ramalingam, MD

Mechanism of Action of Immune Checkpoint Inhibitors



Seebacher NA et al. JECCR 2019;38(156).

RTP RESEARCH TO PRACTICE

First-Line Treatment in Select Clinical Situations for Patients with Metastatic NSCLC without a Targetable Mutation

Clinical situation	Treatment questions
High PD-L1 level (>50%)	Adding chemotherapy to a checkpoint inhibitor? Nivolumab/ipilimumab?
Negative PD-L1 level (<1%)	Chemotherapy + checkpoint inhibitor? Chemotherapy + nivolumab/ipilimumab? Nivolumab/ipilimumab?

RTP
RESEARCH
TO PRACTICE

FDA-Approved Immunotherapy Combination Options for First-Line Therapy

Combination regimen	FDA approval	Pivotal study	Histologic type	HR (OS)
Pembrolizumab + Platinum and pemetrexed[1]	8/20/18	KEYNOTE-189	Nonsquamous	0.49
Pembrolizumab + Carboplatin, paclitaxel or *nab* paclitaxel[2]	10/30/18	KEYNOTE-407	Squamous	0.64
Atezolizumab + Carboplatin and paclitaxel and bevacizumab[3]	12/6/18	IMpower150	Nonsquamous	0.78
Atezolizumab + Carboplatin and *nab* paclitaxel[4]	12/3/19	IMpower130	Nonsquamous	0.79
Nivolumab + Ipilimumab[5]	5/15/20	CheckMate-227	PD-L1 TPS ≥1, EGFR and/or ALK wt	0.62
Nivolumab + Ipilimumab and chemotherapy[6]	5/26/20	CheckMate-9LA	EGFR and/or ALK wt	0.69

[1] Gandhi. *NEJM* 2018. [2] Paz-Ares.*NEJM* 2018. [3] Socinski *NEJM* 2018. [4] West. *Lancet Oncol* 2019. [5] Hellmann. *N Engl J Med* 2019. [6] Reck. ASCO 2020;Ab 9501.

RTP RESEARCH TO PRACTICE

FDA-Approved Immunotherapy Monotherapy Options for First-Line Therapy (continued)

Monotherapy	FDA approval	Pivotal study	Histologic type	HR (OS)
Pembrolizumab[1,2]	4/11/19 10/24/16	KEYNOTE-042 KEYNOTE-024	PD-L1 TPS ≥1%	0.63
Atezolizumab[3]	5/18/20	IMpower110	PD-L1 TPS ≥50, EGFR and/or ALK wt	0.59
Cemiplimab[4]	2/22/2021	EMPOWER-Lung 1 (Study 1624)	PD-L1 TPS ≥50, EGFR and/or ALK and/or ROS1 wt	0.57

[1] Mok. *Lancet* 2019. [2] Reck. *J Clin Oncol* 2019. [3] Spigel. ESMO 2019;Ab LBA78. [4] Sezer. *Lancet* 2021.

RTP
RESEARCH
TO PRACTICE

FDA Approves Cemiplimab-rwlc Monotherapy for NSCLC with High PD-L1 Expression

Press Release – February 22, 2021

"The Food and Drug Administration approved cemiplimab-rwlc (Libtayo, Regeneron Pharmaceuticals, Inc.) for the first-line treatment of patients with advanced non-small cell lung cancer (NSCLC) (locally advanced who are not candidates for surgical resection or definitive chemoradiation or metastatic) whose tumors have high PD-L1 expression (Tumor Proportion Score [TPS] > 50%) as determined by an FDA-approved test, with no EGFR, ALK or ROS1 aberrations.

Efficacy was evaluated in Study 1624 (NCT03088540), a multi-center, randomized, open-label trial in 710 patients with locally advanced NSCLC who were not candidates for surgical resection or definitive chemoradiation or with metastatic NSCLC. Patients were randomized (1:1) to receive cemiplimab-rwlc 350 mg intravenously every 3 weeks for up to 108 weeks or a platinum-based chemotherapy. The main efficacy outcome measures were overall survival (OS) and progression-free survival (PFS) per blinded independent central review (BICR)."

www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-cemiplimab-rwlc-non-small-cell-lung-cancer-high-pd-l1-expression

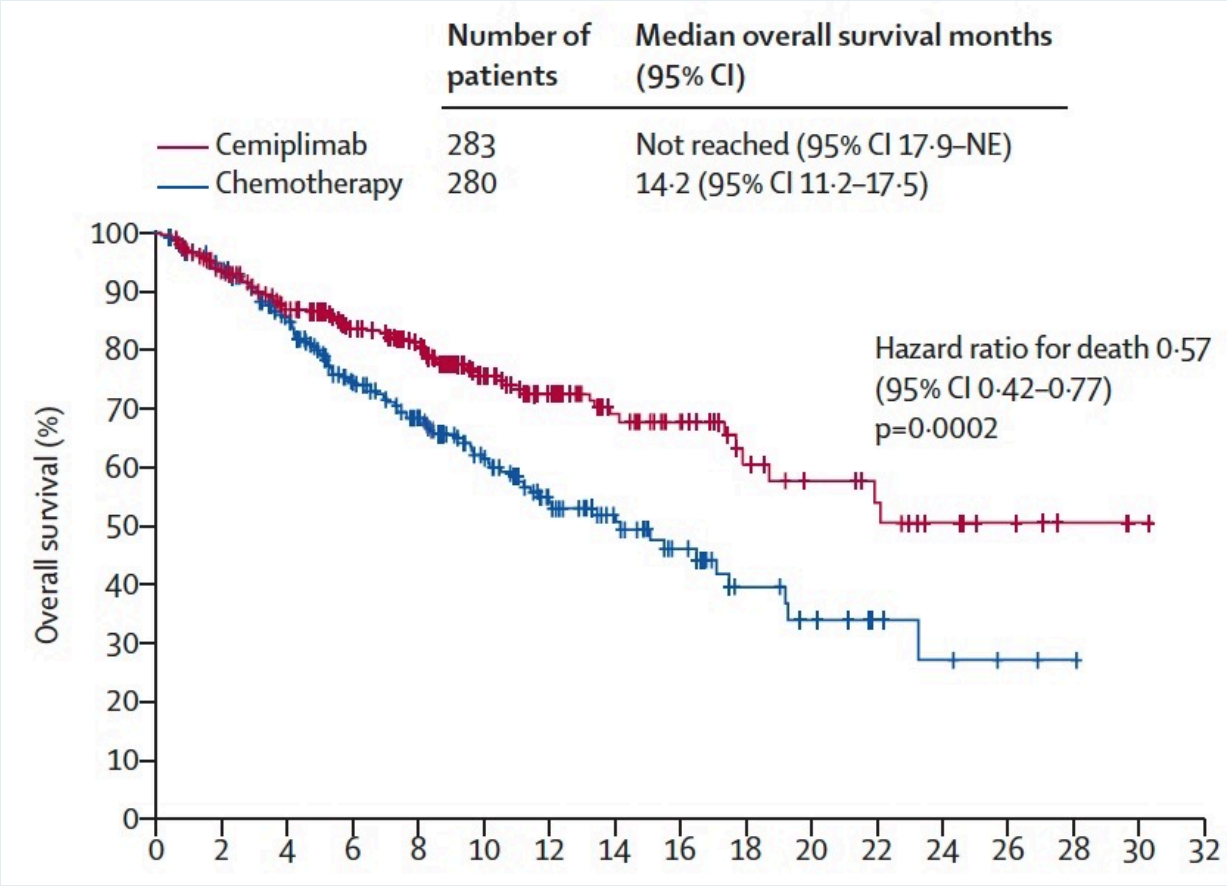
RTP RESEARCH TO PRACTICE

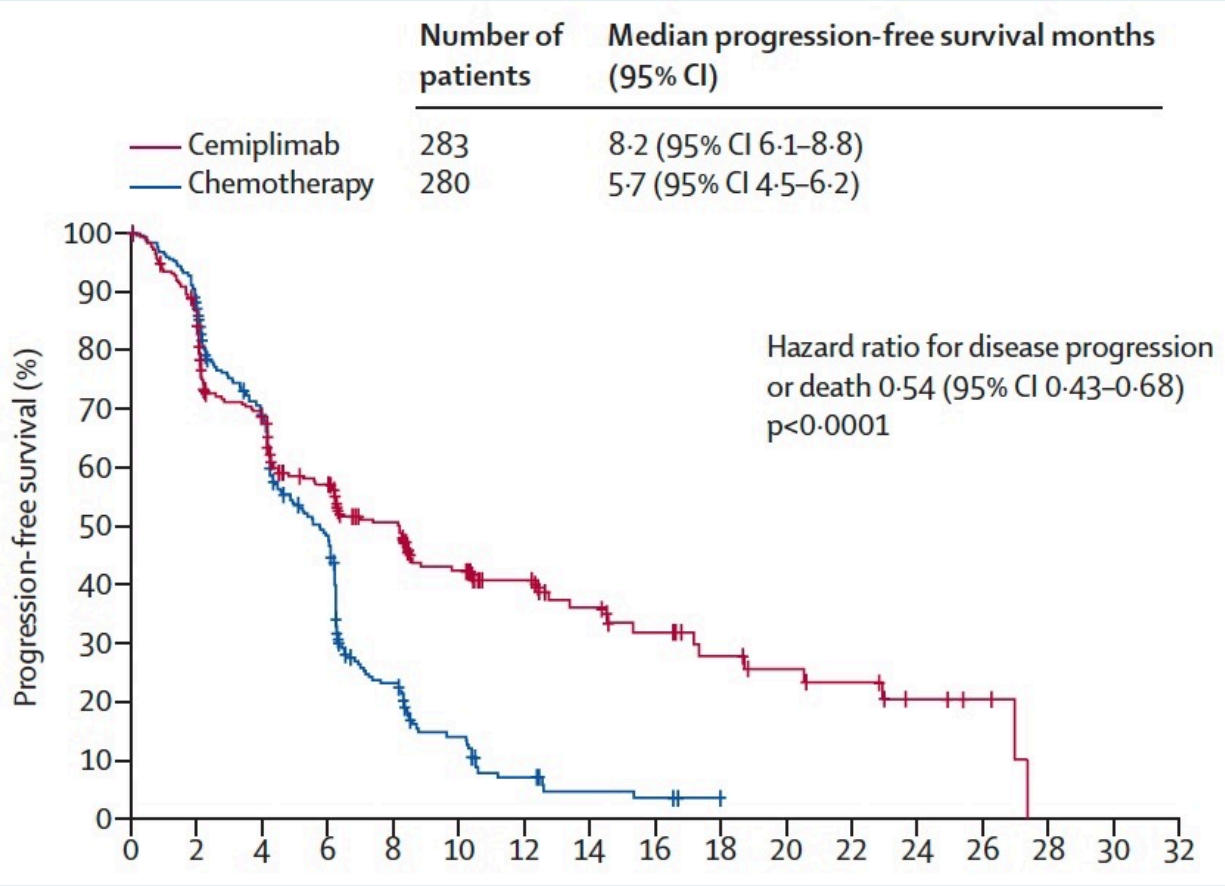
Lancet 2021;397(10274):592-604.

Cemiplimab monotherapy for first-line treatment of advanced non-small-cell lung cancer with PD-L1 of at least 50%: a multicentre, open-label, global, phase 3, randomised, controlled trial

Ahmet Sezer, Saadettin Kilickap, Mahmut Gümüş, Igor Bondarenko, Mustafa Özgüroğlu, Miranda Gogishvili, Haci M Turk, Irfan Cicin, Dmitry Bentsion, Oleg Gladkov, Philip Clingan, Virote Sriuranpong, Naiyer Rizvi, Bo Gao, Siyu Li, Sue Lee, Kristina McGuire, Chieh-I Chen, Tamta Makharadze, Semra Paydas, Marina Nechaeva, Frank Seebach, David M Weinreich, George D Yancopoulos, Giuseppe Gullo, Israel Lowy, Petra Rietschel

Overall and Progression-Free Survival with First-Line Cemiplimab versus Chemotherapy





Sezer A et al. *Lancet* 2021;397(10274):592-604.

RTP RESEARCH TO PRACTICE

Appendix

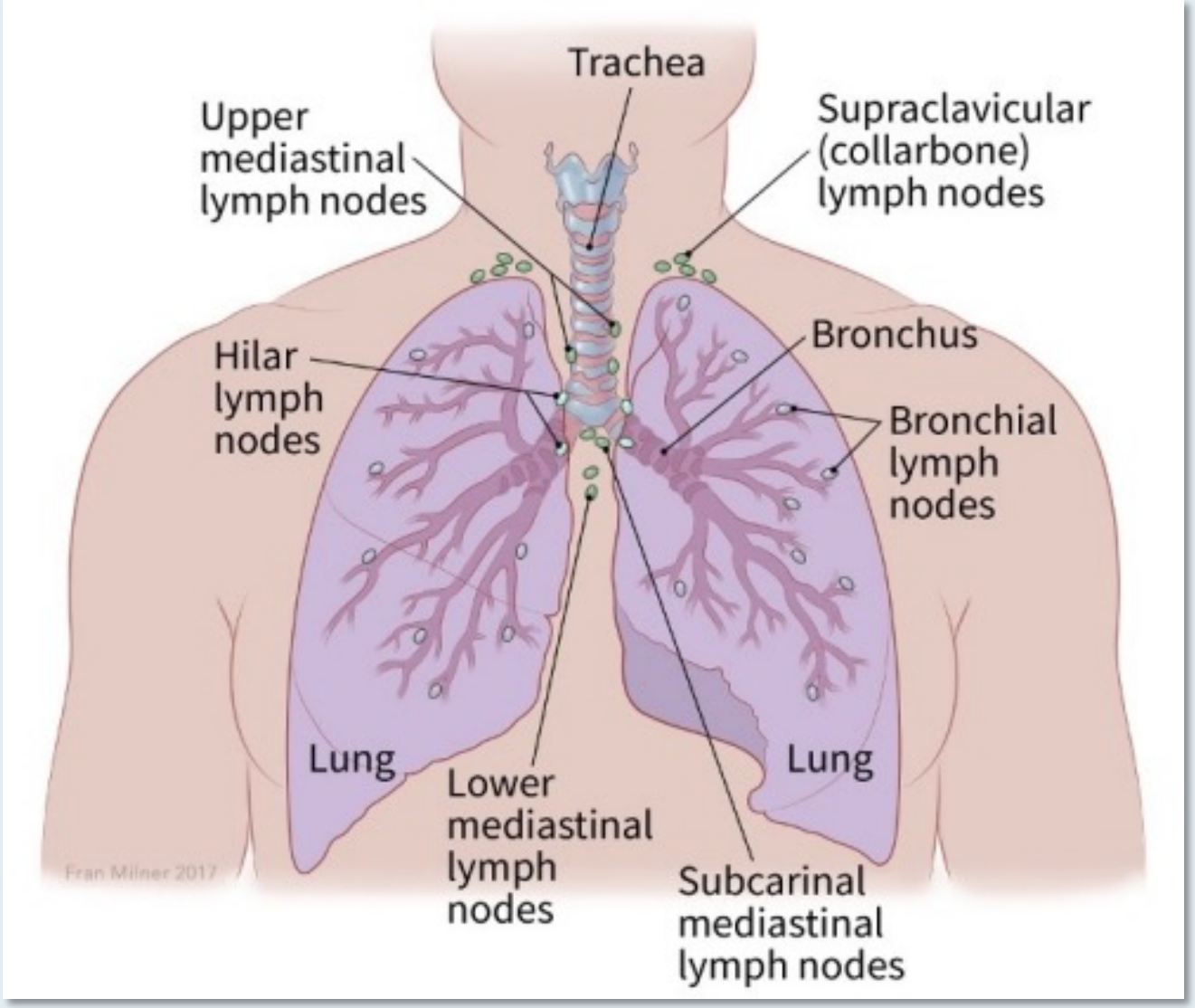
RTP
RESEARCH
TO PRACTICE

Staging Regional Lymph Nodes in Lung Cancer

NX	Regional lymph nodes cannot be assessed
N0	No regional node metastasis
N1	Metastasis in ipsilateral peribronchial and/or ipsilateral hilar lymph nodes and intrapulmonary nodes, including involvement by direct extension
N2	Metastasis in ipsilateral mediastinal and/or subcarinal lymph node(s)
N3	Metastasis in the contralateral mediastinal, contralateral hilar, ipsilateral or contralateral scalene or supraclavicular lymph node(s)

RTP
RESEARCH
TO PRACTICE

Lung Anatomy: Distribution of Lymph Nodes



RTP RESEARCH TO PRACTICE

Lung Cancer Stage Grouping (AJCC 8th Edition)

T/M	Label	N0	N1	N2	N3
T1	T1a ≤1	IA1	IIB	IIIA	IIIB
	T1b >1-2	IA2	IIB	IIIA	IIIB
	T1c >2-3	IA3	IIB	IIIA	IIIB
T2	T2a *Cent, Visc Pl*	IB	IIB	IIIA	IIIB
	T2a >3-4	IB	IIB	IIIA	IIIB
	T2b >4-5	IIA	IIB	IIIA	IIIB
T3	T3 >5-7	IIB	IIIA	IIIB	IIIC
	T3 *Inv*	IIB	IIIA	IIIB	IIIC
	T3 *Satell*	IIB	IIIA	IIIB	IIIC
T4	T4 >7	IIIA	IIIA	IIIB	IIIC
	T4 *Inv*	IIIA	IIIA	IIIB	IIIC
	T4 *Ipsi Nod*	IIIA	IIIA	IIIB	IIIC
M1	M1a *Contr Nod*	IVA	IVA	IVA	IVA
	M1a *Pl Dissem*	IVA	IVA	IVA	IVA
	M1b *Single*	IVA	IVA	IVA	IVA
	M1c *Multi*	IVB	IVB	IVB	IVB

Detterbeck FC et al. *Chest* 2017;151(1):193-203.

RTP RESEARCH TO PRACTICE

Stage Distribution at Diagnosis of Patients with Lung Cancer

SEER Analysis: (2004-2010, N = 344,797)

Stage at Diagnosis (AJCC, 7th Edition)	I	II	III	IV	Unknown
% of Patients	18%	7%	19%	49%	5%
Est No. of Patients in USA, 2019	41,067	15,971	43,349	111,794	11,408

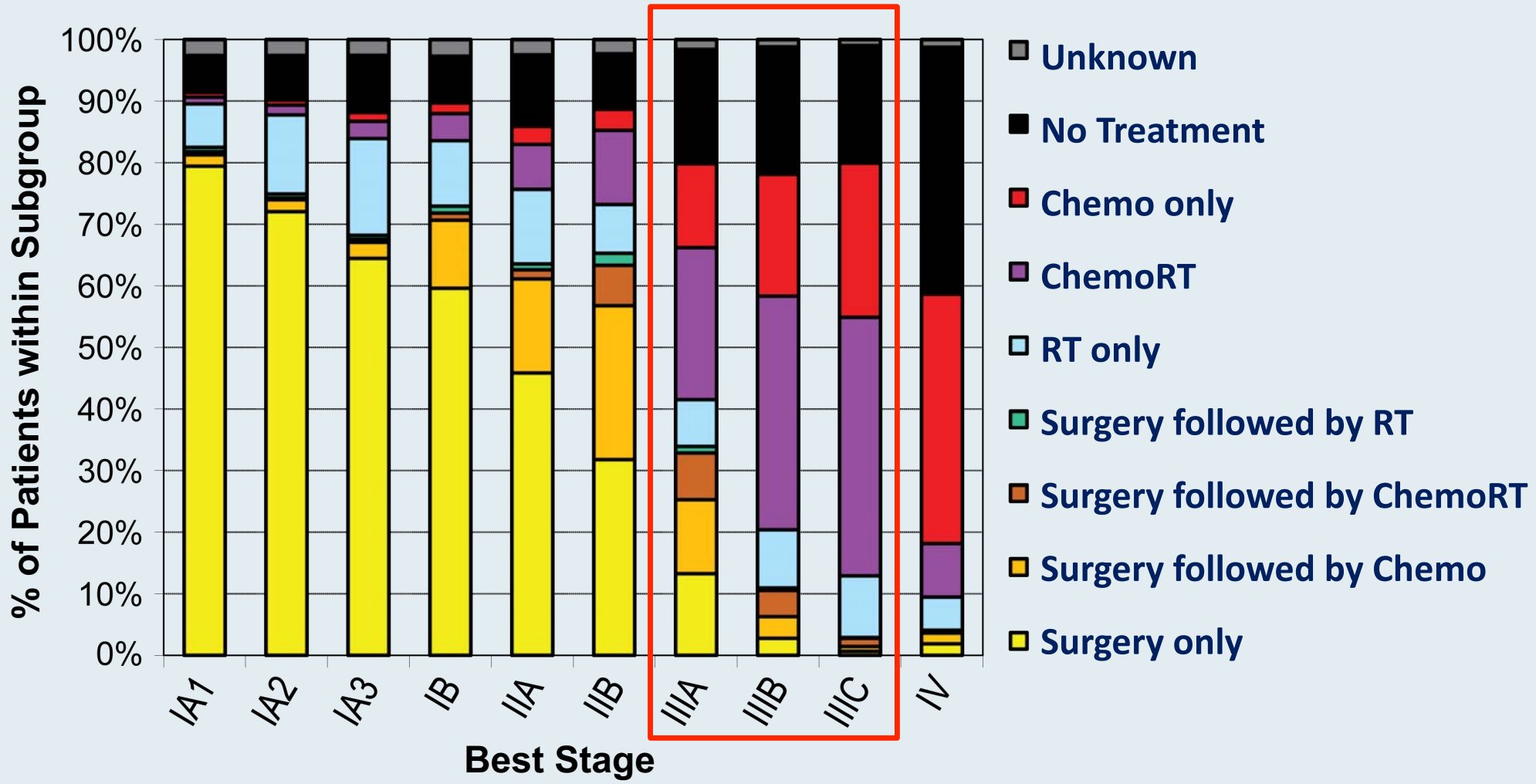
Occult disease accounts for approximately 1.5%

Chen VW et al. *Cancer* 2014;120:3781-92. Siegel RL et al. *CA Cancer J Clin*. 2019;69(1):7-34.

RTP RESEARCH TO PRACTICE

Treatment Received for NSCLC (2000-2012, N = 780,294)

Based on the National Cancer Data Base (NCDB) according to TNM 8th Edition



Chansky K et al. *J Thorac Oncol* 2017;12(7):1109-21.

RTP RESEARCH TO PRACTICE

13th Annual Oncology Grand Rounds

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

Acute Myeloid Leukemia

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

Medical Oncologists

Courtney D DiNardo, MD, MSCE
Eytan M Stein, MD

Oncology Nurse Practitioners

Ilene Galinsky, NP
Sonia Glennie, ARNP, MSN, OCN

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.

RTP
RESEARCH
TO PRACTICE