

# 13<sup>th</sup> Annual Oncology Grand Rounds

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

## Prostate Cancer

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

### Medical Oncologists

**Charles J Ryan, MD  
A Oliver Sartor, MD  
Mary-Ellen Taplin, MD**

### Oncology Nurse Practitioners

**Kathy D Burns, RN, MSN, AGACNP-BC, OCN  
Brenda Martone, MSN, NP-BC, AOCNP  
Ronald Stein, JD, MSN, NP-C, AOCNP**

### Moderator

**Neil Love, MD**

## Medical Oncologists



**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



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

## Oncology Nurse Practitioners



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



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



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

## Commercial Support

This activity is supported by educational grants from Astellas and Pfizer Inc, AstraZeneca Pharmaceuticals LP, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, and Merck.

## 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.

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

# Dr Ryan — Disclosures

No relevant conflicts of interest to disclose

## Dr Sartor — Disclosures

<b>Consulting Agreements</b>	Advanced Accelerator Applications, Astellas, AstraZeneca Pharmaceuticals LP, Bavarian Nordic, Bayer HealthCare Pharmaceuticals, Blue Earth Diagnostics, Bristol-Myers Squibb Company, Clarity Pharmaceuticals, Clovis Oncology, Constellation Pharmaceuticals, Dendreon Pharmaceuticals Inc, EMD Serono Inc, Fusion Pharmaceuticals, ITM Isotopen Technologien Muenchen AG, Janssen Biotech Inc, Myovant Sciences, Myriad Genetic Laboratories Inc, Noria Therapeutics Inc, Novartis, Noxopharm, Pfizer Inc, Point Biopharma Inc, Progenics Pharmaceuticals Inc, Sanofi Genzyme, Telix Pharmaceuticals, TeneoBio, Theragnostics
<b>Contracted Research</b>	Advanced Accelerator Applications, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Constellation Pharmaceuticals, Dendreon Pharmaceuticals Inc, Endocyte Inc, Invitae, Janssen Biotech Inc, Merck, Progenics Pharmaceuticals Inc, Sanofi Genzyme, SOTIO LLC

# Dr Taplin — Disclosures

No relevant conflicts of interest to disclose

# Ms Burns — Disclosures

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<b>Speakers Bureau</b>	Astellas, Exelixis Inc, Merck, Pfizer Inc

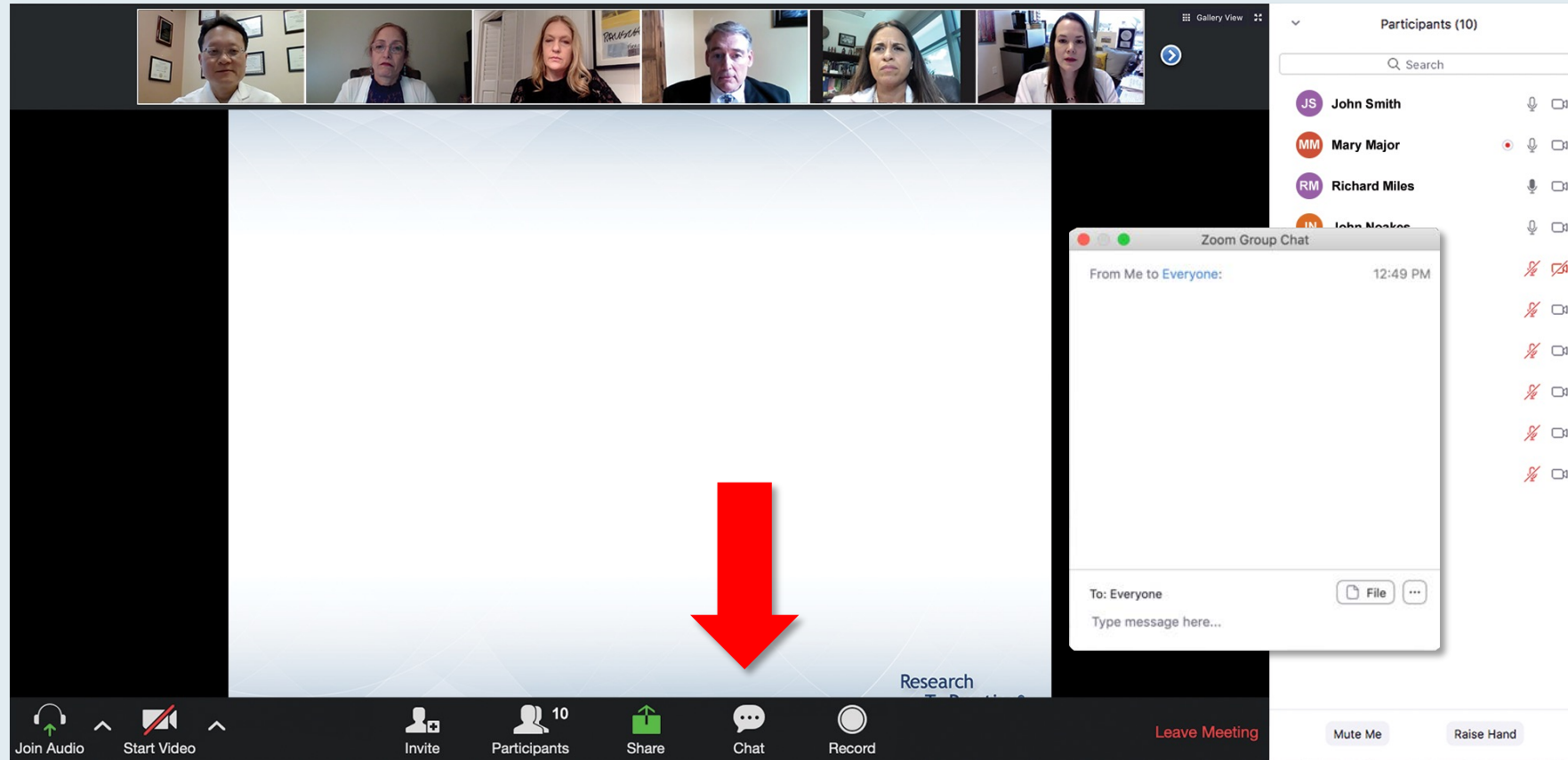
# Ms Martone — Disclosures

No relevant conflicts of interest to disclose

# Mr Stein — Disclosures

No relevant conflicts of interest to disclose

# We Encourage Clinicians in Practice to Submit Questions



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

# Familiarizing Yourself with the Zoom Interface

## How to answer poll questions

The screenshot displays a Zoom meeting interface. At the top, a gallery view shows six participants. The main screen displays a poll question: "What is your usual treatment recommendation for a patient with MM who has been followed by ASCT for 1-5 years who then experiences an asymptomatic relapse?". Below the question is a list of 10 treatment options, each preceded by a number. A "Quick Poll" dialog box is open, showing the same list of options with radio buttons for selection. The bottom of the screen features a toolbar with icons for "Join Audio", "Start Video", "Invite", "Participants" (showing 10), "Share", "Chat", "Record", and a "Leave Meeting" button. On the right side, a "Participants (10)" list is visible, showing names and status icons.

What is your usual treatment recommendation for a patient with MM who has been followed by ASCT for 1-5 years who then experiences an asymptomatic relapse?

Quick Poll

- ☐ Carfilzomib +/- dexamethasone
- ☐ Pomalidomide +/- dexamethasone
- ☐ Carfilzomib + pomalidomide +/- dexamethasone
- ☐ Elotuzumab + lenalidomide +/- dexamethasone
- ☐ Elotuzumab + pomalidomide +/- dexamethasone
- ☐ Daratumumab + lenalidomide +/- dexamethasone
- ☐ Daratumumab + pomalidomide +/- dexamethasone
- ☐ Daratumumab + bortezomib +/- dexamethasone
- ☐ Ixazomib + Rd
- ☐ Other

Submit

Co-provided by USF Health Research To Practice®

Join Audio Start Video Invite Participants 10 Share Chat Record Leave Meeting Mute Me Raise Hand

Participants (10)

Search

- JS John Smith
- MM Mary Major
- RM Richard Miles
- JN John Noakes
- AS Alice Suarez
- JP Jane Perez
- RS Robert Stiles
- JF Juan Fernandez
- AK Ashok Kumar
- JS Jeremy Smith

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

# Familiarizing Yourself with the Zoom Interface

## Expand chat submission box

The screenshot shows a Zoom meeting interface. At the top, there are video thumbnails for participants: RTP Coordinat..., Kirsten Miller, RTP Mike Rivera, and Lisa Suarez. Below the thumbnails is a 'Recording...' button. The main content area displays a slide titled 'Meet The Professor Program Steering Committee' with six members listed in two columns:

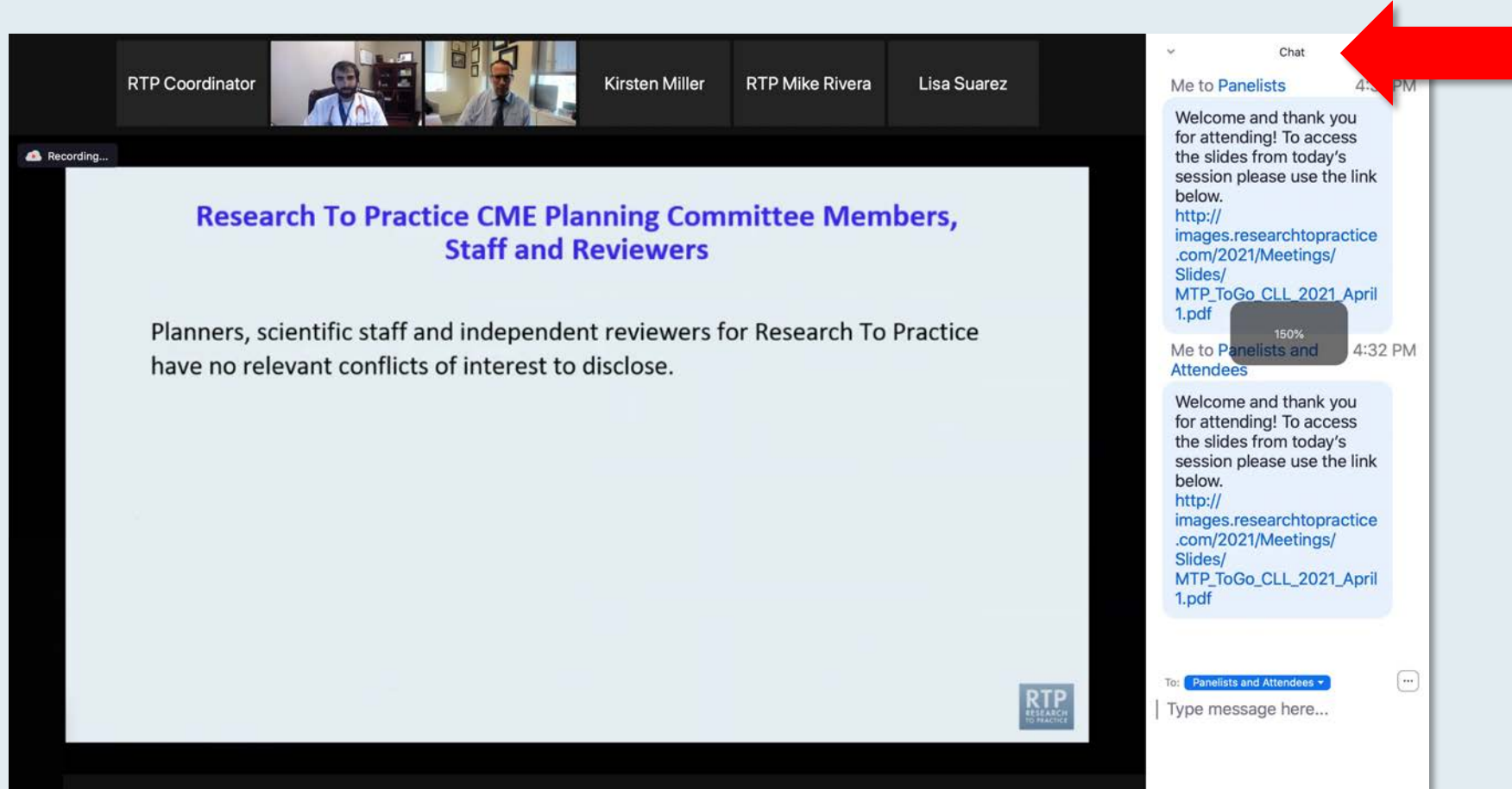
Portrait	Name and Title
	<b>John N Allan, MD</b> Assistant Professor of Medicine Weill Cornell Medicine New York, New York
	<b>Steven Coutre, MD</b> Professor of Medicine (Hematology) Stanford University School of Medicine Stanford, California
	<b>Matthew S Davids, MD, MMSc</b> Associate Professor of Medicine Harvard Medical School Director of Clinical Research Division of Lymphoma Dana-Farber Cancer Institute Boston, Massachusetts
	<b>Ian W Flinn, MD, PhD</b> Director of Lymphoma Research Program Sarah Cannon Research Institute Tennessee Oncology Nashville, Tennessee
	<b>Prof John G Gribben, MD, DSc, FMedSci</b> Chair of Medical Oncology Barts Cancer Institute Queen Mary University of London Charterhouse Square London, United Kingdom
	<b>Brian T Hill, MD, PhD</b> Director, Lymphoid Malignancy Program Cleveland Clinic Taussig Cancer Institute Cleveland, Ohio

The right side of the interface shows a chat window titled 'Chat'. It contains two messages from 'Me to Panelists' at 4:31 PM and 'Me to Panelists and Attendees' at 4:32 PM. Both messages welcome attendees and provide a link to access slides: [http://images.researchtopractice.com/2021/Meetings/Slides/MTP\\_ToGo\\_CLL\\_2021\\_April1.pdf](http://images.researchtopractice.com/2021/Meetings/Slides/MTP_ToGo_CLL_2021_April1.pdf). At the bottom of the chat window, there is a 'To:' dropdown menu set to 'Panelists and Attendees' and a text input field labeled 'Type message here...'. A large red arrow points to this input field.

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

# 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

## Side Effects of Hormonal Therapy in Prostate Cancer



DR ROBERTO IACOVELLI

FONDAZIONE POLICLINICO  
UNIVERSITARIO A GEMELLI



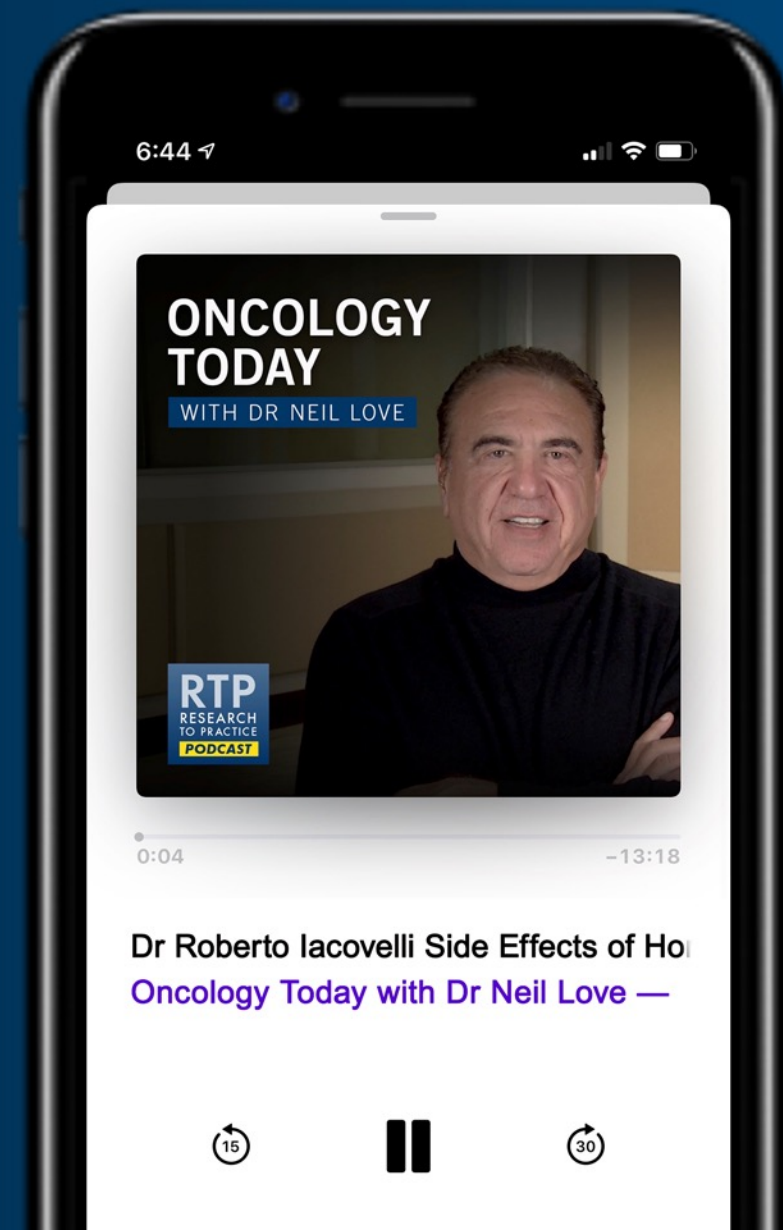
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**Google Podcasts**



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## **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

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**Thursday, April 29, 2021**

5:00 PM – 6:30 PM ET

# **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**

# 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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**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**

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**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**

***Thank you for joining us!***

***NCPD credit information will be emailed  
to each participant shortly.***

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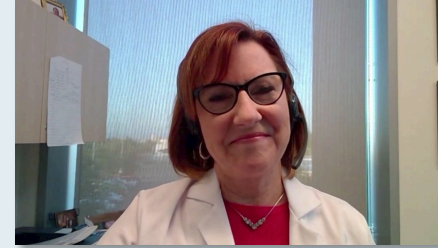


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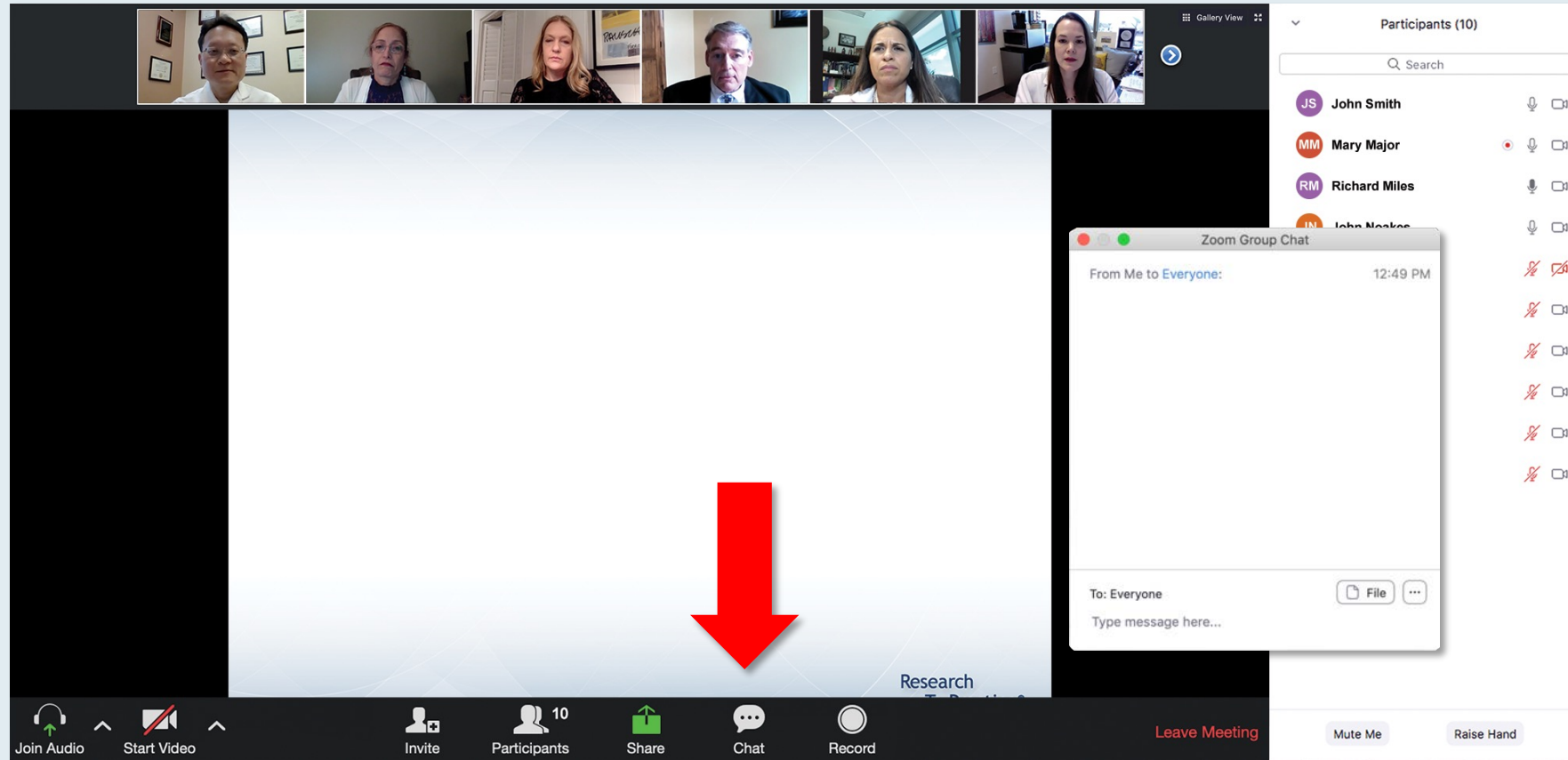


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Northwestern Memorial Hospital  
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**Quick Poll**

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6. Daratumumab + lenalidomide +/- dexamethasone
7. Daratumumab + pomalidomide +/- dexamethasone
8. Daratumumab + bortezomib +/- dexamethasone
9. Ixazomib + Rd
10. Other

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**Participants (10)**

Name	Status
JS John Smith	Microphone Off
MM Mary Major	Microphone On
RM Richard Miles	Microphone Off
JN John Noakes	Microphone Off
AS Alice Suarez	Microphone Off
JP Jane Perez	Microphone Off
RS Robert Stiles	Microphone Off
JF Juan Fernandez	Microphone Off
AK Ashok Kumar	Microphone Off
JS Jeremy Smith	Microphone Off

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# Medical Oncologists



**Jeremy Abramson, MD**

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# Medical Oncologists



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Director, Interdisciplinary Gastrointestinal  
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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**

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Division of Cancer Medicine  
The University of Texas MD Anderson Cancer Center  
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**Elisabeth I Heath, MD**

Associate Center Director, Translational Sciences  
Chair, Genitourinary Oncology Multidisciplinary Team  
Professor of Oncology and Medicine  
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Director, Prostate Cancer Research  
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Detroit, Michigan

# Medical Oncologists



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Vice-Chair, Quality and Safety  
Department of Obstetrics and Gynecology  
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# Medical Oncologists



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**Kathy D Miller, MD**

Ballvé-Lantero Professor  
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Associate Director for Clinical Research  
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**John M Pagel, MD, PhD**

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**Zofia Piotrowska, MD, MHS**

Assistant Professor of Medicine  
Harvard Medical School  
Massachusetts General Hospital  
Boston, Massachusetts

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**Noopur Raje, MD**

Director, Center for Multiple Myeloma  
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Assistant Dean for Oncology  
Tulane Medical School  
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**Paul G Richardson, MD**

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Dana-Farber Cancer Institute  
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New York, New York



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**Krishnansu S Tewari, MD**

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Division of Gynecologic Oncology  
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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

# Oncology Nurse Practitioners



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



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



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



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



**Lesley Camille Ballance, MSN, FNP-BC**  
Sarah Cannon Center for Blood Cancer  
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Nurse Practitioner  
Dana-Farber Cancer Institute  
Boston, Massachusetts

# 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



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



**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



**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



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



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

# Oncology Nurse Practitioners



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



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



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



**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



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



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

# 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

# Oncology Grand Rounds Nursing Webinar Series

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





# 13<sup>th</sup> 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

# 13<sup>th</sup> Annual Oncology Grand Rounds

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

## Prostate Cancer

Thursday, April 22, 2021

8:30 AM – 10:00 AM ET

### Medical Oncologists

Charles J Ryan, MD

A Oliver Sartor, MD

Mary-Ellen Taplin, MD

### Oncology Nurse Practitioners

Kathy D Burns, RN, MSN, AGACNP-BC, OCN

Brenda Martone, MSN, NP-BC, AOCNP

Ronald Stein, JD, MSN, NP-C, AOCNP

### Moderator

Neil Love, MD



Kathleen Burns, NP



Brenda Martone MSN NP-BC AOCNP



Ronald Stein, JD, MSN, NP-C, AOCNP

# Agenda

**Case 1 (Mr Stein): A 59-year-old man with metastatic hormone-sensitive prostate cancer (mHSPC) and high-volume disease burden**

**Case 2 (Ms Burns): A 70-year-old man with M0 disease and a rising PSA on ADT**

**Case 3 (Ms Martone): A 72-year-old man with metastatic castration-resistant prostate cancer (mCRPC) and a somatic BRCA2 mutation**

**Case 4 (Mr Stein): A 69-year-old man with metastatic castrate-resistant disease and a somatic BRCA1 mutation and loss of heterozygosity**

# Agenda

**Case 1 (Mr Stein): A 59-year-old man with metastatic hormone-sensitive prostate cancer (mHSPC) and high-volume disease burden**

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# Men who have metastatic prostate cancer on initial diagnosis have the greatest chance for sustained response with androgen deprivation and...

1. Endocrine-based therapy
2. Docetaxel
3. Either endocrine-based therapy or docetaxel — no difference
4. I don't know

# Case Presentation – A 59-year-old man with mHSPC and high-volume disease burden (Part 1)



Mr Stein

- Retired national park ranger living in a rural area presents to local clinic with significant back pain and unable to walk
- Workup reveals vertebral metastases all along spinal column
- PSA 6,400 ng/mL

# Case Presentation – A 59-year-old man with mHSPC and high-volume disease burden (Part 2)



Mr Stein

- Retired national park ranger living in a rural area presents to local clinic with significant back pain and unable to walk
- Workup reveals vertebral metastases all along spinal column
- PSA 6,400 ng/mL
- ***Patient receives leuprolide and enzalutamide and is responding well with pronounced improvement in back pain***

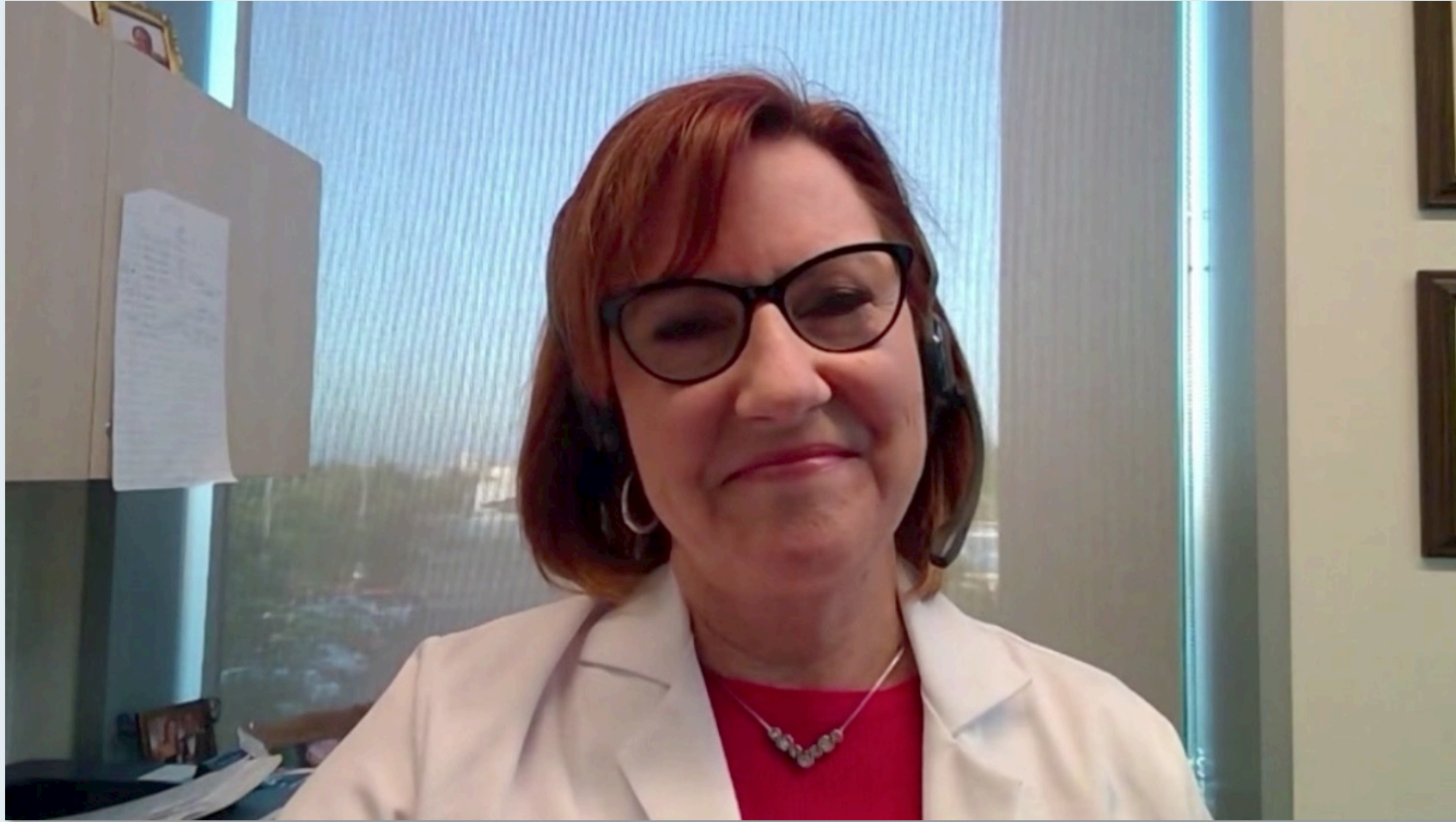
## Ms Martone: Side Effects Associated with Androgen Deprivation Therapy



## Ms Martone: Sexual Side Effects Associated with Androgen Deprivation Therapy



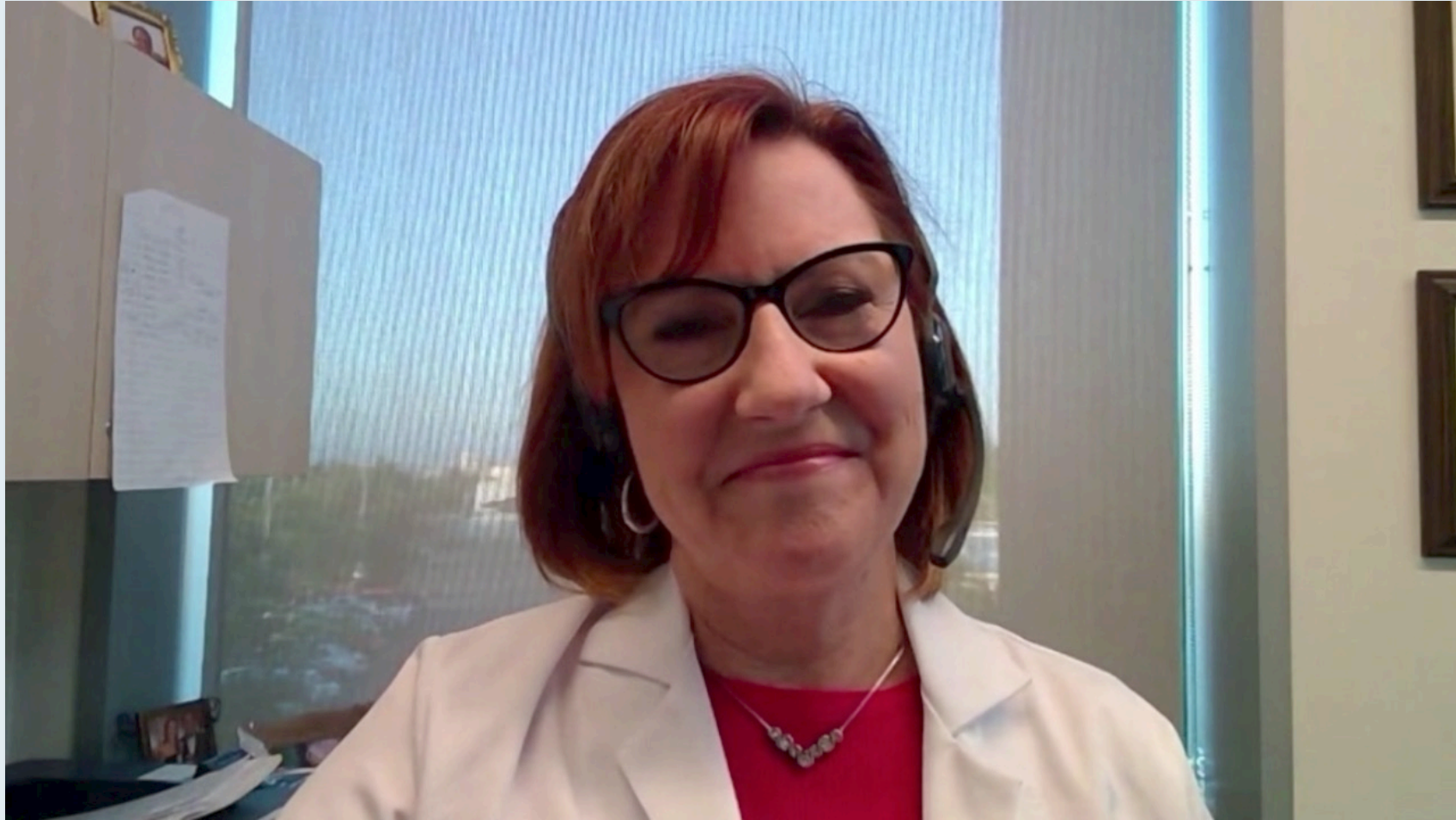
## Ms Burns: Relationship Between Patient and Family Caregivers



## Ms Martone: Selection of Androgen Deprivation Treatment



## Ms Burns: Abiraterone, Enzalutamide and Apalutamide



# FDA Approves Relugolix for Advanced Prostate Cancer

Press Release: December 18, 2020

“On December 18, 2020, the U.S. Food and Drug Administration approved the first oral gonadotropin-releasing hormone (GnRH) receptor antagonist, relugolix, for adult patients with advanced prostate cancer.

Efficacy was evaluated in HERO (NCT03085095), a randomized, open label trial in men requiring at least one year of androgen deprivation therapy with either prostate cancer recurrence following radiation or surgery or newly diagnosed castration-sensitive advanced prostate cancer.

Patients (N=934) were randomized (2:1) to receive relugolix 360 mg oral loading dose on the first day, followed by daily oral doses of 120 mg, or leuprolide acetate 22.5 mg injection subcutaneously every 3 months for 48 weeks.”

# HERO Phase III Trial: Results Comparing Relugolix, an Oral GnRH Receptor Antagonist, versus Leuprolide Acetate for Advanced Prostate Cancer<sup>1</sup>

## Oral Relugolix for Androgen-Deprivation Therapy in Advanced Prostate Cancer<sup>2</sup>

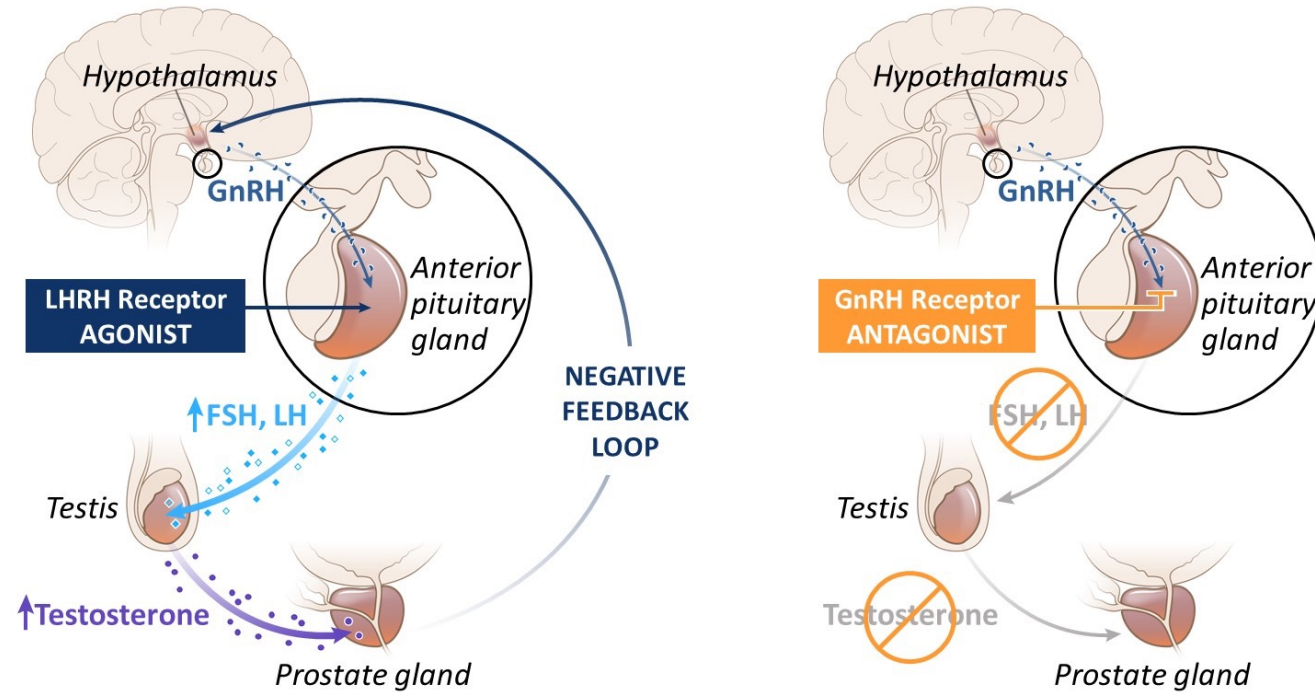
<sup>1</sup> Shore N et al.

ASCO 2020;Abstract 5602.

<sup>2</sup> Shore ND et al.

*N Engl J Med* 2020;382(23):2187-96.

# LHRH agonist vs antagonist MOA and side effect profile



PRESENTED AT: 2020 ASCO<sup>®</sup>  
ANNUAL MEETING

#ASCO20  
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permission required for reuse.

PRESENTED BY: Neal Shore, MD, FACS  
Carolina Urologic Research Center, SC, USA

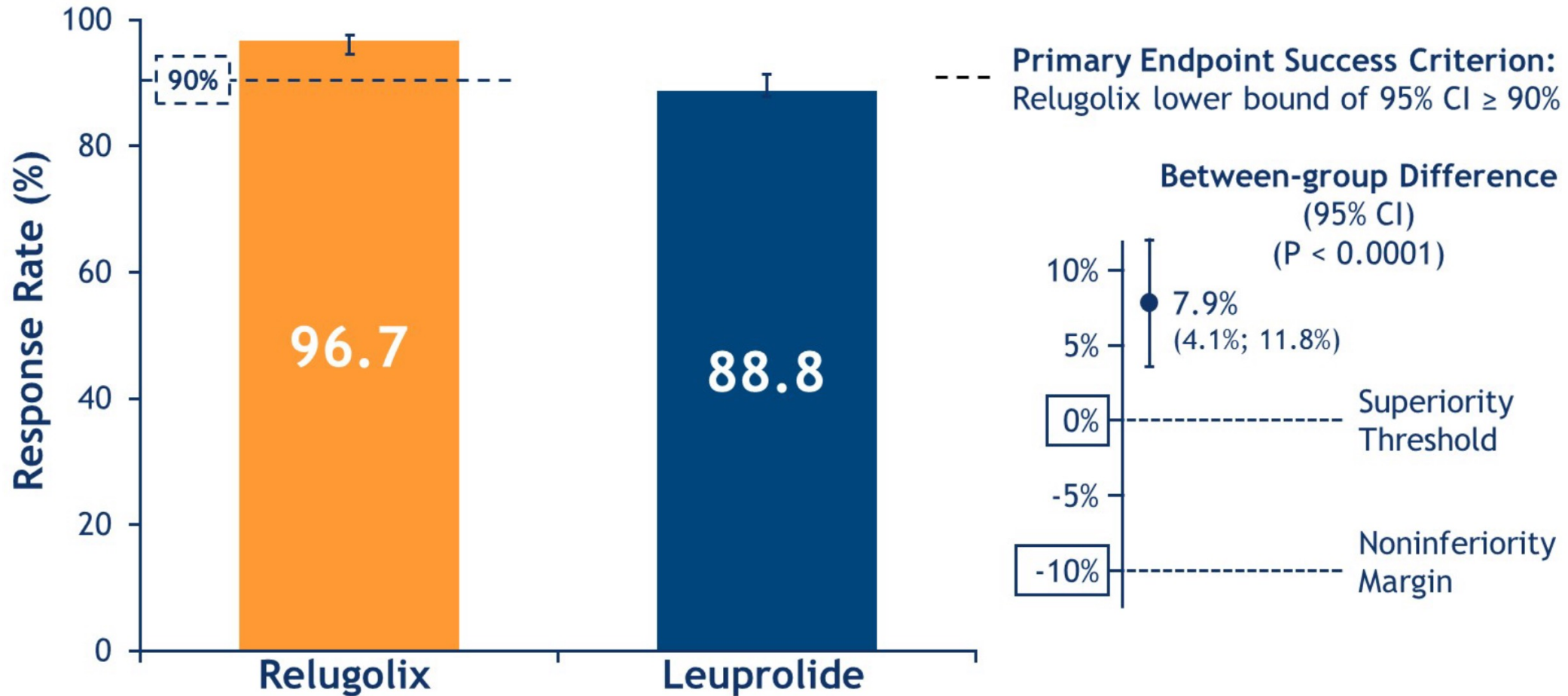
3

	Relugolix (N = 622)	Leuprolide (N = 308)
Hot flush	54.3%	51.6%
Fatigue	21.5%	18.5%
Constipation	12.2%	9.7%
Diarrhea*	12.2%	6.8%
Arthralgia	12.1%	9.1%
Hypertension	7.9%	11.7%

Courtesy of Tanya B Dorff, MD

# HERO: Primary Endpoint – Sustained Castration

## Key Secondary Endpoint – Noninferiority to Leuprolide



## Relugolix: Cardiovascular Safety

Event	Relugolix (n = 622)		Leuprolide (n = 308)	
	Any grade	Grade 3/4	Any grade	Grade 3/4
Major adverse cardiac event (MACE)*	2.9%	1.3%	6.2%	1.3%
In patients <i>without</i> prior history of MACE	2.8%	—	4.2%	—
In patients <i>with</i> prior history of MACE	3.6%	—	17.8%	—

\*Nonfatal myocardial infarction, nonfatal stroke and death from any cause

In the subgroup of patients with a reported medical history of MACE, the odds of having an event were 4.8 times as high with leuprolide as with relugolix.

# FDA-Approved Next-Generation Antiandrogens in Metastatic Hormone-Sensitive Prostate Cancer

Agent	Approval date	Pivotal study
Enzalutamide	December 16, 2019	ARCHES
Apalutamide	September 17, 2019	TITAN

original report

# ARCHES: A Randomized, Phase III Study of Androgen Deprivation Therapy With Enzalutamide or Placebo in Men With Metastatic Hormone-Sensitive Prostate Cancer

Andrew J. Armstrong, MD, ScM<sup>1</sup>; Russell Z. Szmulewitz, MD<sup>2</sup>; Daniel P. Petrylak, MD<sup>3</sup>; Jeffrey Holzbeierlein, MD<sup>4</sup>; Arnauld Villers, MD<sup>5</sup>; Arun Azad, MBBS, PhD<sup>6</sup>; Antonio Alcaraz, MD, PhD<sup>7</sup>; Boris Alekseev, MD<sup>8</sup>; Taro Iguchi, MD, PhD<sup>9</sup>; Neal D. Shore, MD<sup>10</sup>; Brad Rosbrook, MS<sup>11</sup>; Jennifer Sugg, MS<sup>12</sup>; Benoit Baron, MS<sup>13</sup>; Lucy Chen, MD<sup>12</sup>; and Arnulf Stenzl, MD<sup>14</sup>

*J Clin Oncol* 2019;37(32):2974-86.

## The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

JULY 4, 2019

VOL. 381 NO. 1

### Apalutamide for Metastatic, Castration-Sensitive Prostate Cancer

Kim N. Chi, M.D., Neeraj Agarwal, M.D., Anders Bjartell, M.D., Byung Ha Chung, M.D.,  
Andrea J. Pereira de Santana Gomes, M.D., Robert Given, M.D., Álvaro Juárez Soto, M.D.,  
Axel S. Merseburger, M.D., Mustafa Özgüroğlu, M.D., Hirotsugu Uemura, M.D., Dingwei Ye, M.D.,  
Kris Deprince, M.D., Vahid Naini, Pharm.D., Jinhui Li, Ph.D., Shinta Cheng, M.D., Margaret K. Yu, M.D.,  
Ke Zhang, Ph.D., Julie S. Larsen, Pharm.D., Sharon McCarthy, B.Pharm., and Simon Chowdhury, M.D.,  
for the TITAN Investigators\*

*N Engl J Med* 2019;381(1):13-24.

# Final Analysis Results From TITAN: A Phase 3 Study of Apalutamide vs Placebo in Patients With Metastatic Castration-Sensitive Prostate Cancer Receiving Androgen Deprivation Therapy

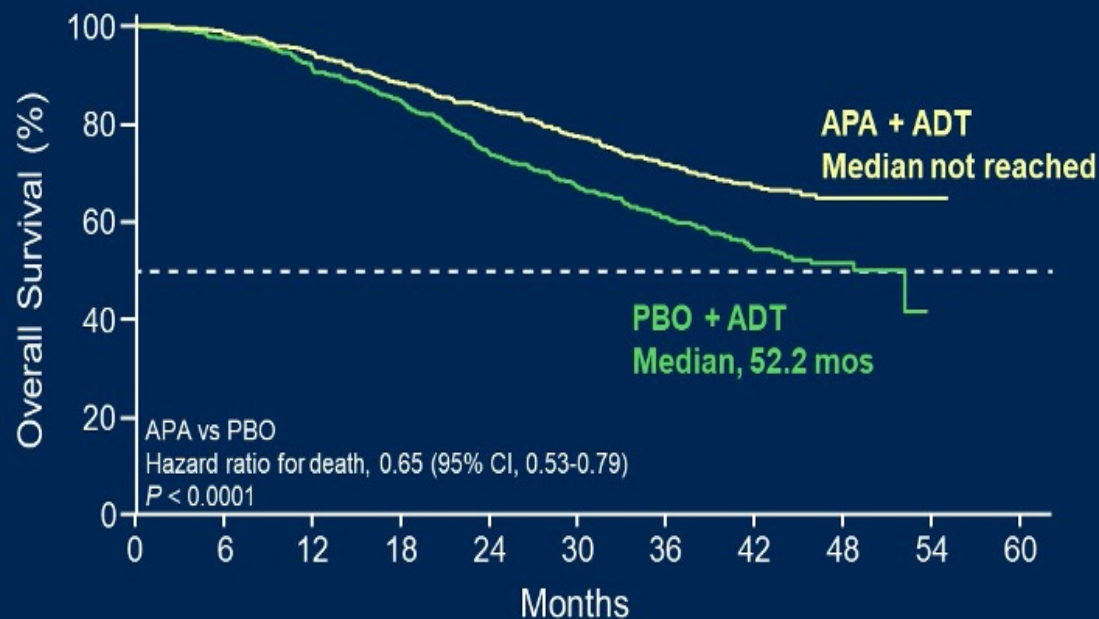
Kim N. Chi,<sup>1</sup> Simon Chowdhury,<sup>2</sup> Anders Bjartell,<sup>3</sup> Byung Ha Chung,<sup>4</sup> Andrea J. Pereira de Santana Gomes,<sup>5</sup> Robert Given,<sup>6</sup> Álvaro Juárez Soto,<sup>7</sup> Axel S. Merseburger,<sup>8</sup> Mustafa Özgüroğlu,<sup>9</sup> Hirotugu Uemura,<sup>10</sup> Dingwei Ye,<sup>11</sup> Spyros Triantos,<sup>12</sup> Sabine Brookman-May,<sup>12,13</sup> Suneel Mundle,<sup>14</sup> Sharon A. McCarthy,<sup>14</sup> Julie S. Larsen,<sup>15</sup> Weili Sun,<sup>15</sup> Katherine Bevans,<sup>16</sup> Ke Zhang,<sup>17</sup> Nibedita Bandyopadhyay,<sup>14</sup> Neeraj Agarwal,<sup>18</sup> for the TITAN Investigators

<sup>1</sup>BC Cancer and Vancouver Prostate Centre, Vancouver, BC, Canada; <sup>2</sup>Guy's, King's, and St. Thomas' Hospitals, and Sarah Cannon Research Institute, London, UK; <sup>3</sup>Skåne University Hospital, Lund University, Malmö, Sweden; <sup>4</sup>Yonsei University College of Medicine and Gangnam Severance Hospital, Seoul, South Korea; <sup>5</sup>Liga Norte Riograndense Contra O Cancer, Natal, Brazil; <sup>6</sup>Urology of Virginia, Eastern Virginia Medical School, Norfolk, VA; <sup>7</sup>Hospital Universitario de Jerez de la Frontera, Cadiz, Spain; <sup>8</sup>University Hospital Schleswig-Holstein, Campus Lübeck, Lübeck, Germany; <sup>9</sup>Istanbul University-Cerrahpaşa, Cerrahpaşa School of Medicine, Istanbul, Turkey; <sup>10</sup>Kindai University Faculty of Medicine, Osaka, Japan; <sup>11</sup>Fudan University Shanghai Cancer Center, Shanghai, China; <sup>12</sup>Janssen Research & Development, Spring House, PA; <sup>13</sup>Ludwig-Maximilians-University (LMU), Munich, Germany; <sup>14</sup>Janssen Research & Development, Raritan, NJ; <sup>15</sup>Janssen Research & Development, Los Angeles, CA; <sup>16</sup>Janssen Research & Development, Horsham, PA; <sup>17</sup>Janssen Research & Development, San Diego, CA; <sup>18</sup>Huntsman Cancer Institute, University of Utah, Salt Lake City, UT



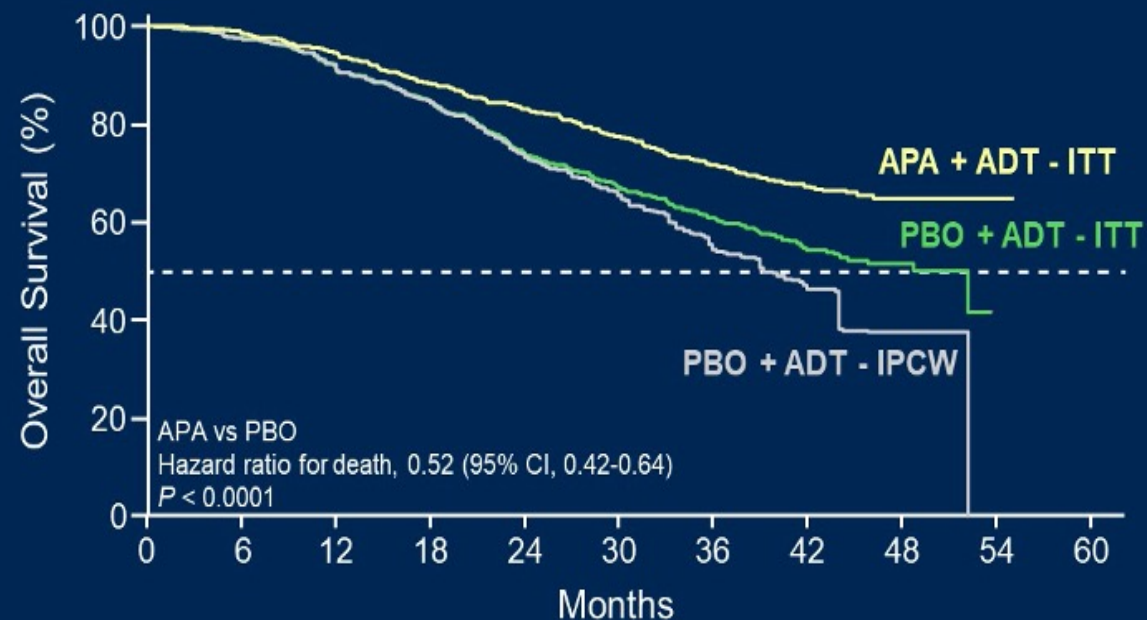
# TITAN – Final Analysis: Overall Survival

OS (Co-primary endpoint)  
Median follow-up: 44.0 months



No. at risk:											
APA + ADT	525	513	489	452	425	394	362	227	52	3	0
PBO + ADT	527	510	474	436	374	339	301	181	43	0	0

OS with adjustment for ~40%  
crossover from PBO



No. at risk:											
APA + ADT	525	513	489	452	425	394	362	227	52	3	0
PBO + ADT	527	510	474	436	374	339	301	181	43	0	0

# Agenda

**Case 1 (Mr Stein): A 59-year-old man with metastatic hormone-sensitive prostate cancer (mHSPC) and high-volume disease burden**

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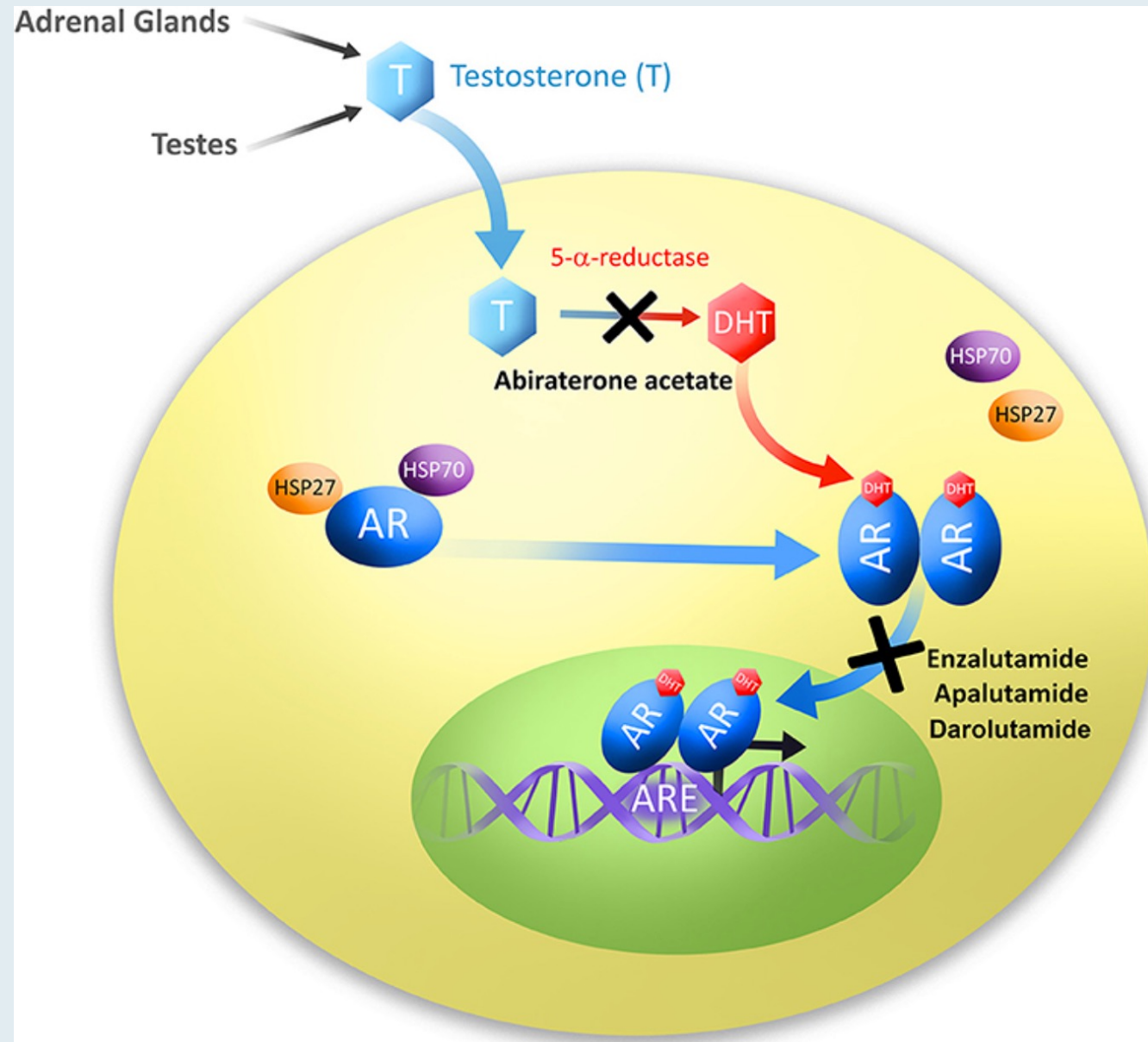
# Case Presentation – A 70-year-old man with M0 disease and a rising PSA on ADT



**Ms Burns**

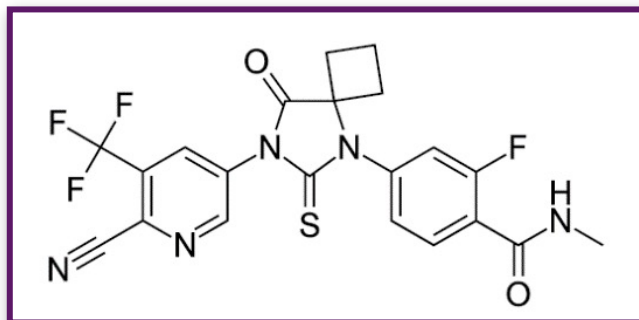
- S/p primary radiation therapy 2010
- 2016: PSA recurrence (M0); initially observed and then started on ADT
- 2020: PSA progression; doubling-time 8 months; apalutamide added to ADT
- More recently developed Grade 3 maculopapular skin rash all over body
  - Antihistamines

# Diagram of Androgen Production and Its Targeted Inhibition

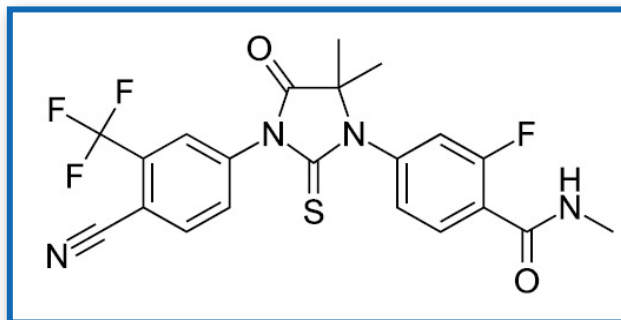


# Next-Generation Androgen Receptor Inhibitors<sup>1,2</sup>

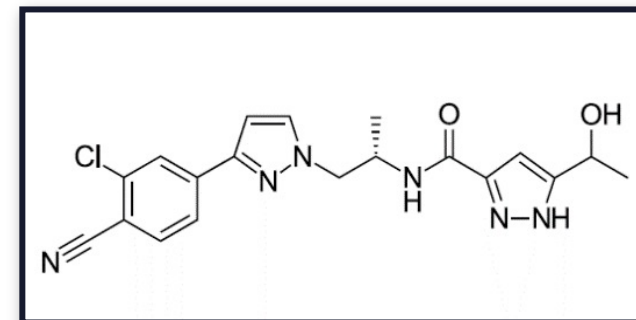
## Apalutamide



## Enzalutamide



## Darolutamide



- Apalutamide and enzalutamide have similar structures
- Darolutamide is structurally distinct from apalutamide and enzalutamide, characterized by low blood–brain barrier penetration<sup>1,2</sup>, and may have improved tolerability

1. Zurth C et al. *J Clin Oncol*. 2018;36(Suppl 6):Abstract 345.

2. Sandmann S et al. American Society of Clinical Oncology 2019 Genitourinary Cancers Symposium (ASCO GU 2019). Abstract 156.

The NEW ENGLAND JOURNAL of MEDICINE

**N Engl J Med 2020;383:1040-9.**

ORIGINAL ARTICLE

## Nonmetastatic, Castration-Resistant Prostate Cancer and Survival with Darolutamide

K. Fizazi, N. Shore, T.L. Tammela, A. Ulys, E. Vjaters, S. Polyakov, M. Jievaltas, M. Luz, B. Alekseev, I. Kuss, M.-A. Le Berre, O. Petrenciuc, A. Snapir, T. Sarapohja, and M.R. Smith, for the ARAMIS Investigators\*

The NEW ENGLAND JOURNAL of MEDICINE

**N Engl J Med 2020;382(23):2197-206.**

ORIGINAL ARTICLE

## Enzalutamide and Survival in Nonmetastatic, Castration-Resistant Prostate Cancer

Cora N. Sternberg, M.D., Karim Fizazi, M.D., Ph.D., Fred Saad, M.D., Neal D. Shore, M.D., Ugo De Giorgi, M.D., Ph.D., David F. Penson, M.D., M.P.H., Ubirajara Ferreira, M.D., Ph.D., Eleni Efstathiou, M.D., Ph.D., Katarzyna Madziarska, M.D., Ph.D., Michael P. Kolinsky, M.D., Daniel I. G. Cubero, M.D., Ph.D., Bettina Noerby, M.D., Fabian Zohren, M.D., Ph.D., Xun Lin, Ph.D., Katharina Modelska, M.D., Ph.D., Jennifer Sugg, M.S., Joyce Steinberg, M.D., and Maha Hussain, M.D., for the PROSPER Investigators\*



European Association of Urology

**Eur J Cancer 2020;[Online ahead of print].**

Prostate Cancer

## Apalutamide and Overall Survival in Prostate Cancer

Matthew R. Smith<sup>a,\*</sup>, Fred Saad<sup>b</sup>, Simon Chowdhury<sup>c</sup>, Stéphane Oudard<sup>d</sup>, Boris A. Hadaschik<sup>e</sup>, Julie N. Graff<sup>f</sup>, David Olmos<sup>g</sup>, Paul N. Mainwaring<sup>h</sup>, Ji Youl Lee<sup>i</sup>, Hiroji Uemura<sup>j</sup>, Peter De Porre<sup>k</sup>, Andressa A. Smith<sup>l</sup>, Sabine D. Brookman-May<sup>m,n</sup>, Susan Li<sup>l</sup>, Ke Zhang<sup>o</sup>, Brendan Rooney<sup>p</sup>, Angela Lopez-Gitlitz<sup>m</sup>, Eric J. Small<sup>q</sup>

# Overall Survival: Darolutamide, Enzalutamide, Apalutamide

	ARAMIS <sup>1</sup>	PROSPER <sup>2</sup>	SPARTAN <sup>3</sup>
Antiandrogen	Darolutamide	Enzalutamide	Apalutamide
Median follow-up	49 mo	47 mo	52 mo
Median OS	Not estimated	57 vs 56 mo	74 vs 60 mo
OS hazard ratio	0.69 ( $p = 0.003$ )	0.73 ( $p = 0.001$ )	0.78 ( $p = 0.0161$ )

<sup>1</sup> Fizazi K et al; ARAMIS Investigators. *N Engl J Med* 2020;383:1040-9.

<sup>2</sup> Sternberg CN et al; PROSPER Investigators. *N Engl J Med* 2020;382(23):2197-206.

<sup>3</sup> Smith MR et al; SPARTAN Investigators. *Eur Urol* 2021;79(1):150-158.

# Comparison of Toxicities: Darolutamide, Enzalutamide, Apalutamide

Toxicity	ARAMIS		PROSPER		SPARTAN	
	Darolutamide	Placebo	Enzalutamide	Placebo	Apalutamide	Placebo
Fatigue/asthenia	16%	11%	33%	14%	30%	21%
Falling	4%	5%	11%	4%	16%	9%
Dizziness	5%	4%	10%	4%	9%	6%
Mental impairment	1%	2%	5%	2%	5%	3%

Sternberg CN et al; PROSPER Investigators. *N Engl J Med* 2020;382(23):2197-206.

Fizazi K et al; ARAMIS Investigators. *N Engl J Med* 2020;383:1040-9.

Small EJ et al; SPARTAN Investigators. ASCO 2020;Abstract 5516.

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# Case Presentation – A 72-year-old man with mCRPC and a somatic BRCA2 mutation (Part 1)



**Ms Martone**

- Dentist diagnosed with mCRPC with a somatic BRCA2 mutation
- Olaparib therapy initiated

# Case Presentation – A 72-year-old man with mCRPC and a somatic BRCA2 mutation (Part 2)



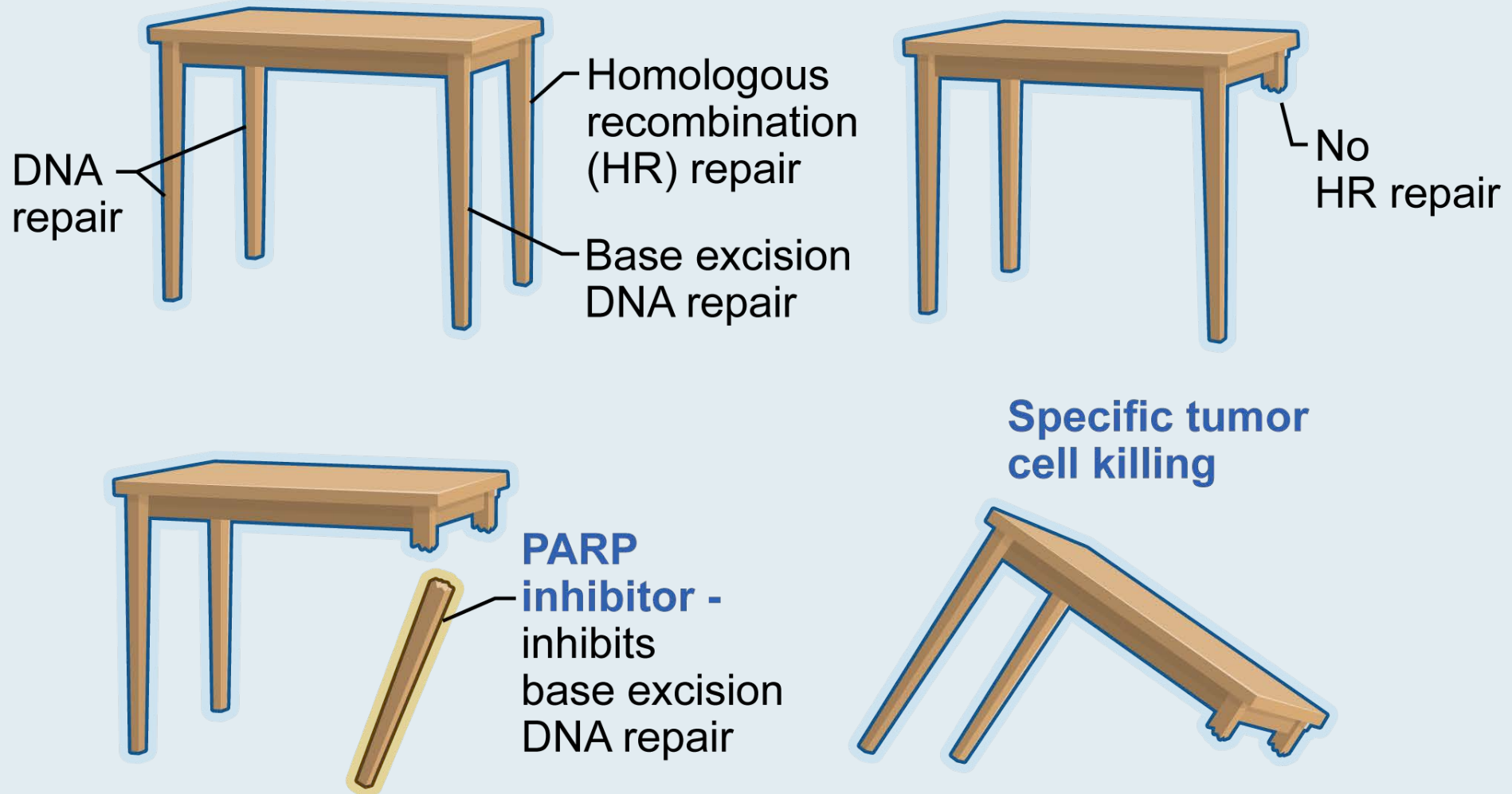
Ms Martone

- Dentist diagnosed with mCRPC with a somatic BRCA2 mutation
- Olaparib therapy initiated
- *Confusion regarding schedule to take oral pills led to underdosing*
- *Currently at full dose of olaparib and is responding well to treatment*

# Management of Metastatic Castration-Resistant Prostate Cancer

- Enzalutamide
- Abiraterone/prednisone
- Radium-223
- Sipuleucel-T
- Cabazitaxel
- Docetaxel
- PARP inhibitors

# Mechanism of Cell Death from Synthetic Lethality Induced by PARP Inhibition



## Recent FDA Approvals of PARP Inhibitors for mCRPC

PARP inhibitor	Approval date	Pivotal study
Olaparib	May 19, 2020	PROfound
Rucaparib	May 15, 2020	TRITON2

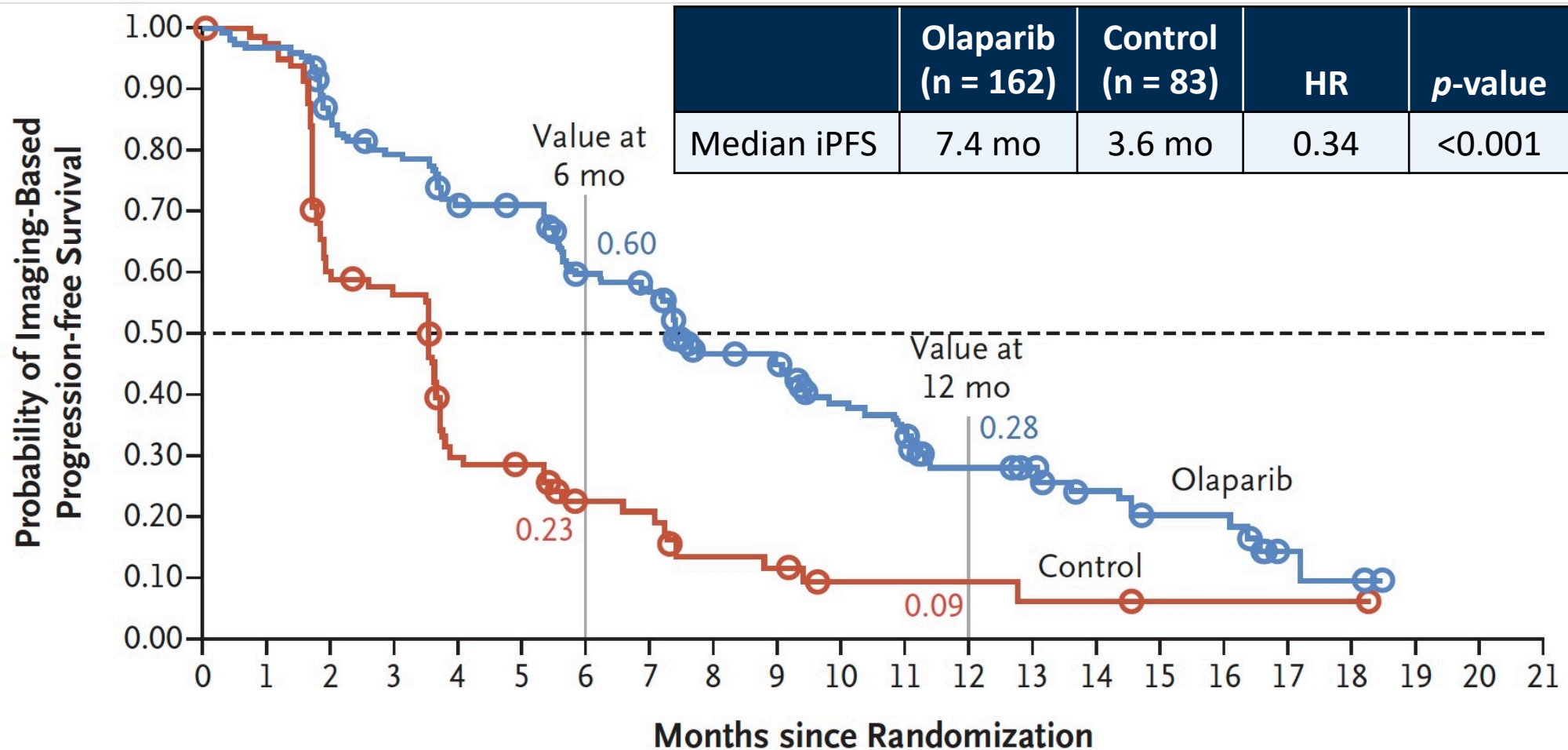
ORIGINAL ARTICLE

# Olaparib for Metastatic Castration-Resistant Prostate Cancer

J. de Bono, J. Mateo, K. Fizazi, F. Saad, N. Shore, S. Sandhu, K.N. Chi, O. Sartor, N. Agarwal, D. Olmos, A. Thiery-Vuillemin, P. Twardowski, N. Mehra, C. Goessl, J. Kang, J. Burgents, W. Wu, A. Kohlmann, C.A. Adelman, and M. Hussain

***N Engl J Med* 2020;382:2091-102.**

# PROfound Primary Endpoint: Imaging-Based PFS with Olaparib for Patients with mCRPC Who Had at Least 1 Alteration in BRCA1, BRCA2 or ATM (Cohort A)



ORIGINAL ARTICLE

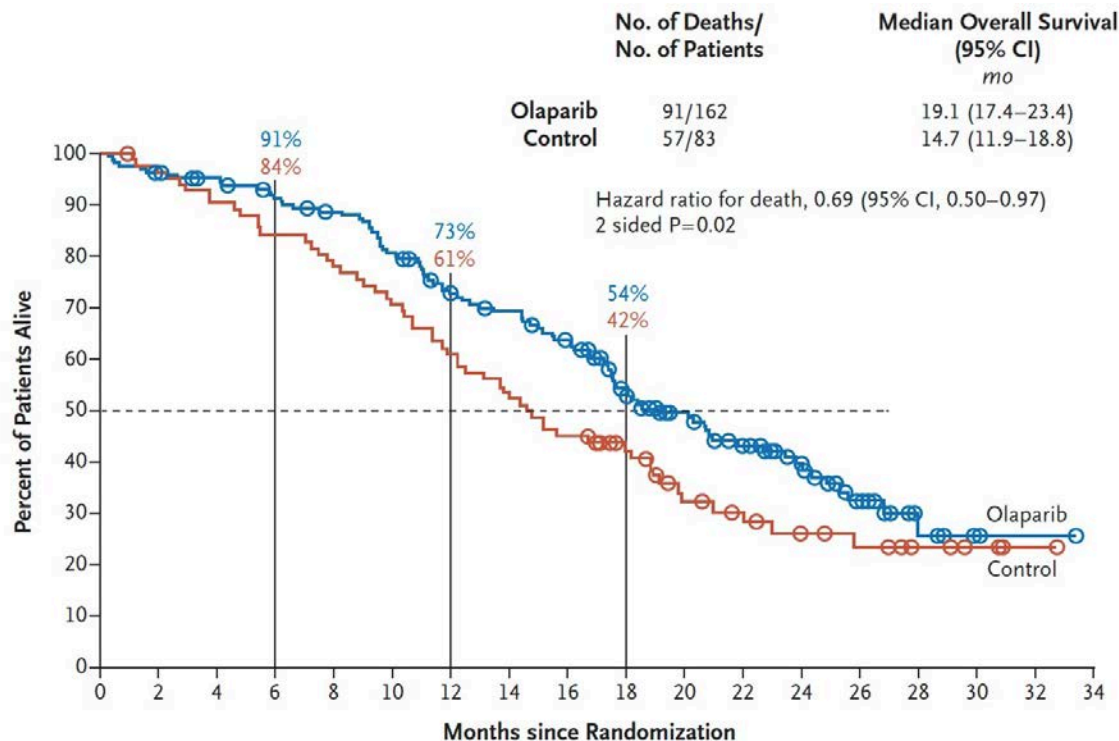
# Survival with Olaparib in Metastatic Castration-Resistant Prostate Cancer

M. Hussain, J. Mateo, K. Fizazi, F. Saad, N. Shore, S. Sandhu, K.N. Chi, O. Sartor, N. Agarwal, D. Olmos, A. Thiery-Vuillemin, P. Twardowski, G. Roubaud, M. Özgüroğlu, J. Kang, J. Burgents, C. Gresty, C. Corcoran, C.A. Adelman, and J. de Bono, for the PROfound Trial Investigators\*

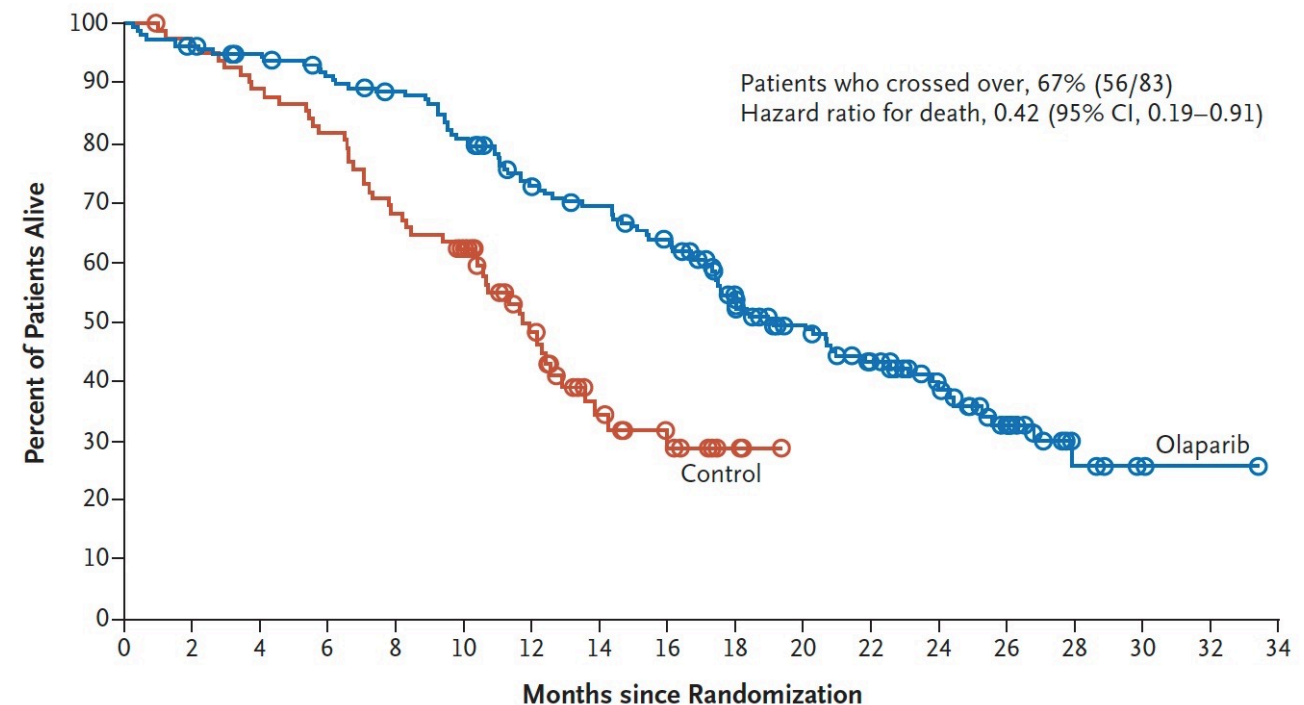
***N Engl J Med* 2020;[Online ahead of print].**

# PROfound: Overall Survival with Olaparib for Patients with mCRPC Who Had at Least 1 Alteration in BRCA1, BRCA2 or ATM (Cohort A)

## Overall survival



## Cross-over adjusted overall survival



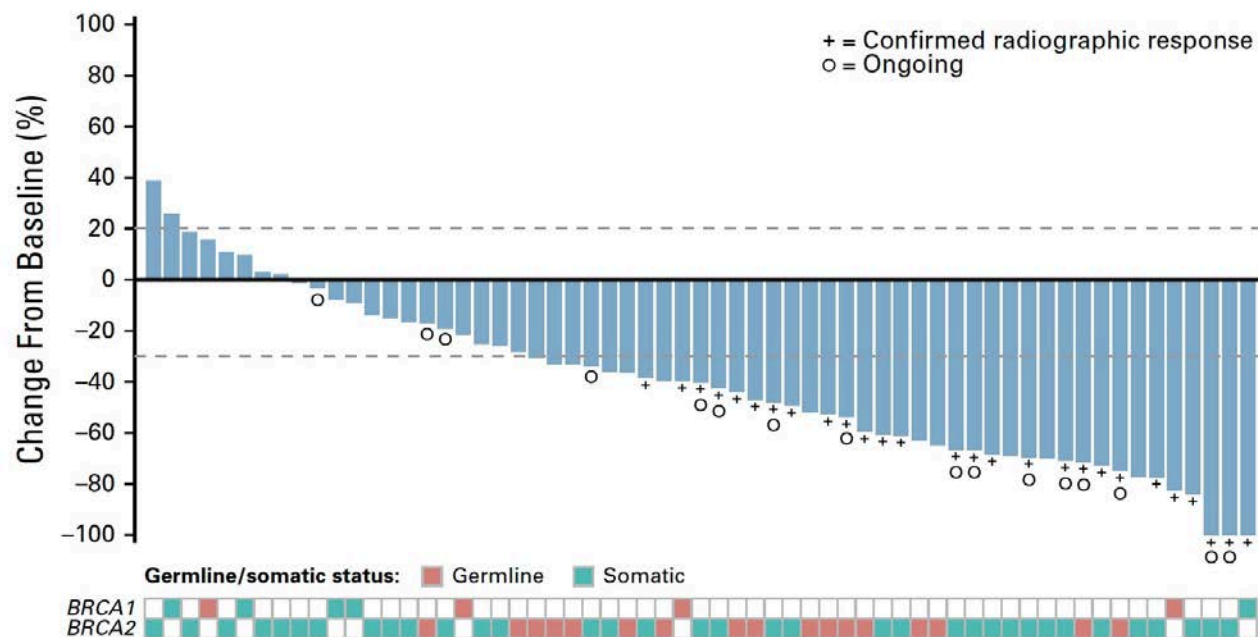
# Rucaparib in Men With Metastatic Castration-Resistant Prostate Cancer Harboring a *BRCA1* or *BRCA2* Gene Alteration

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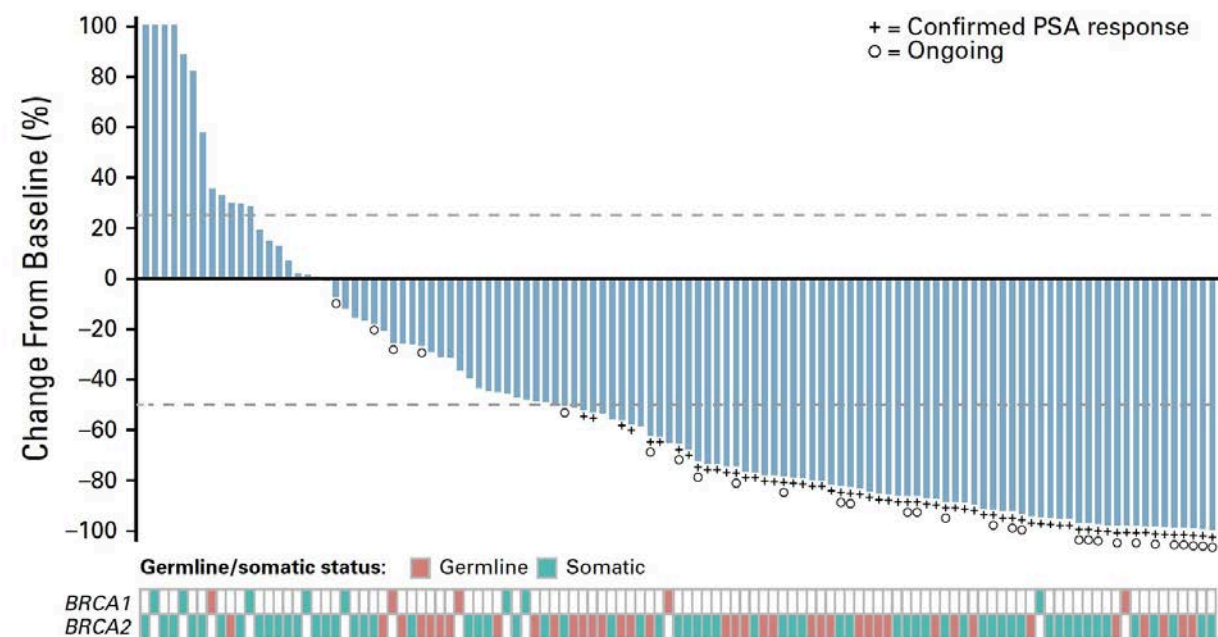
*J Clin Oncol* 2020;38(32):3763-72.

# TRITON2: Response to Rucaparib in Patients with mCRPC Harboring a BRCA1 or BRCA2 Gene Alteration

ORR per independent radiology review: 43.5%



Confirmed PSA response rate: 54.8%

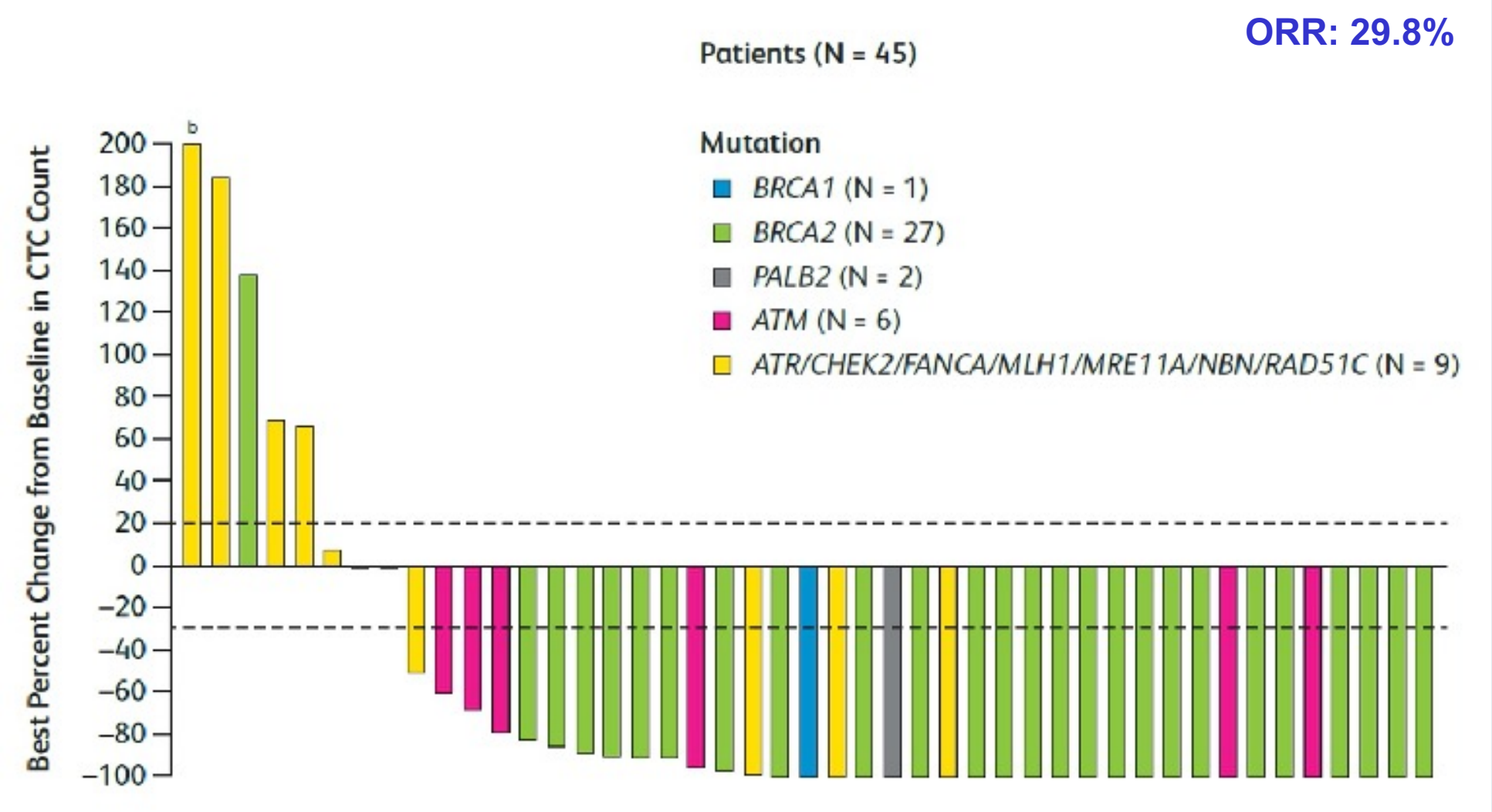


# **TALAPRO-1: Phase II Study of Talazoparib (TALA) in Patients (pts) with DNA Damage Repair Alterations (DDRm) and Metastatic Castration-Resistant Prostate Cancer (mCRPC)**

de Bono JS et al.

Genitourinary Cancers Symposium 2021;Abstract 93.

# TALAPRO-1: Best Change from Baseline in Circulating Tumor Cell Count with Talazoparib



# Agenda

**Case 1 (Mr Stein): A 59-year-old man with metastatic hormone-sensitive prostate cancer (mHSPC) and high-volume disease burden**

**Case 2 (Ms Burns): A 70-year-old man with M0 disease and a rising PSA on ADT**

**Case 3 (Ms Martone): A 72-year-old man with metastatic castration-resistant prostate cancer (mCRPC) and a somatic BRCA2 mutation**

**Case 4 (Mr Stein): A 69-year-old man with metastatic castrate-resistant disease and a somatic BRCA1 mutation and loss of heterozygosity**

# Case Presentation – A 69-year-old man with metastatic castrate-resistant disease and a somatic BRCA1 mutation and loss of heterozygosity



Mr Stein

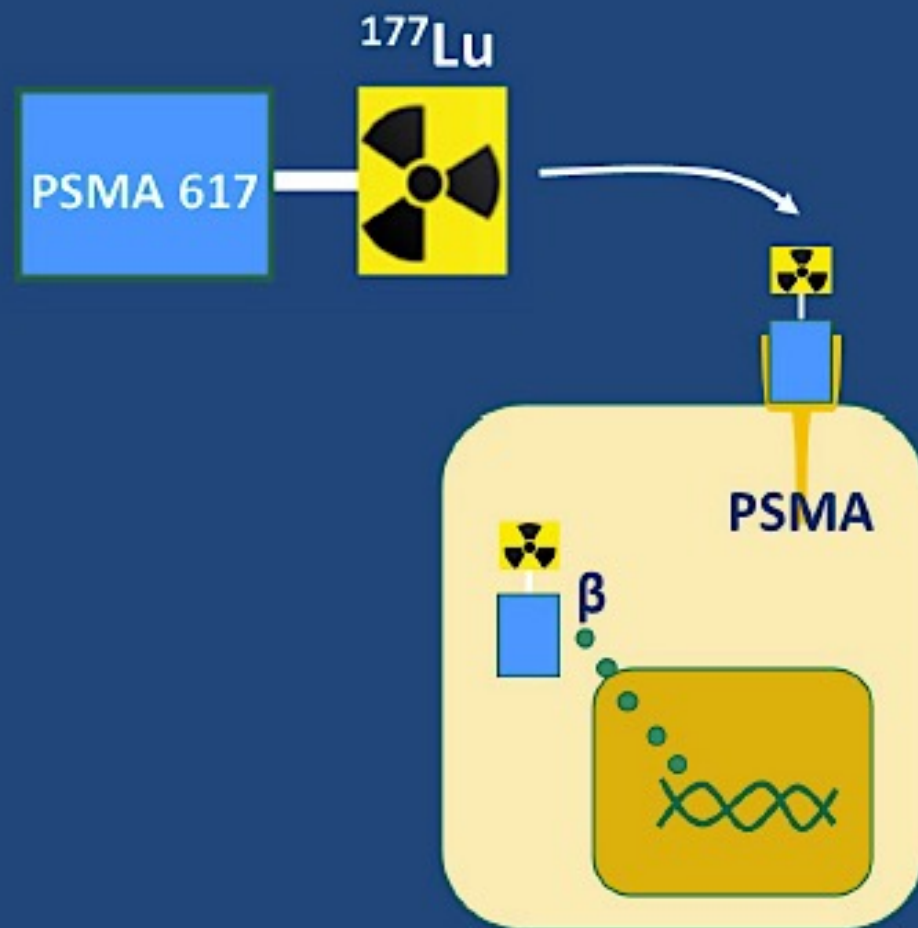
- Initially diagnosed in 2014 with metastatic disease, and now has rapidly progressing disease
- Developed spinal cord compression treated with radiation and IV steroids
  - “Code Spine”

# **CARD: Overall Survival Analysis of Patients with Metastatic Castration-Resistant Prostate Cancer Receiving Cabazitaxel vs Abiraterone or Enzalutamide**

Tombal B et al.

ASCO 2020;Abstract 5569.

## $^{177}\text{Lu}$ -PSMA-617 is a small molecule RLT targeting PSMA



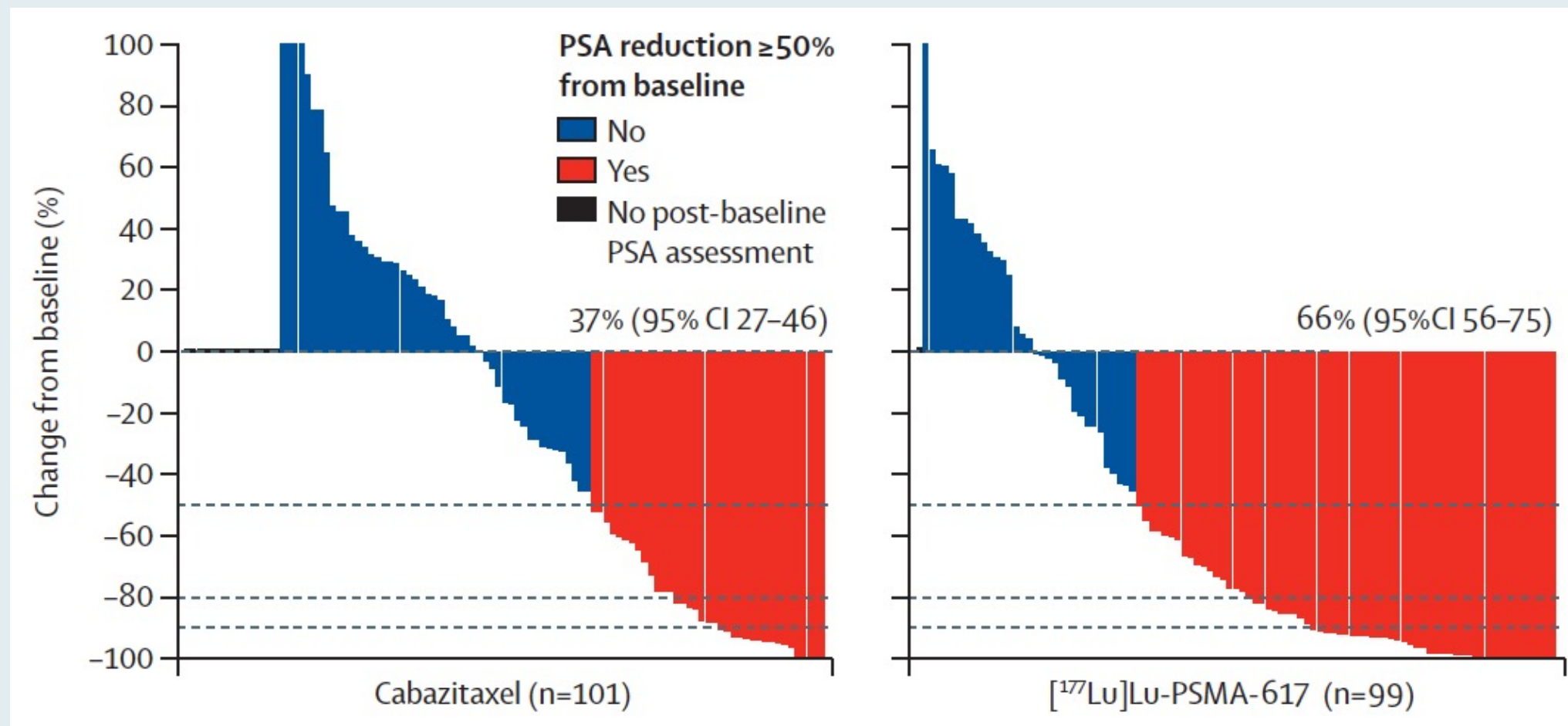
***Lancet* 2021;397:797-804.**

# **[<sup>177</sup>Lu]Lu-PSMA-617 versus cabazitaxel in patients with metastatic castration-resistant prostate cancer (TheraP): a randomised, open-label, phase 2 trial**



*Michael S Hofman, Louise Emmett, Shahneen Sandhu, Amir Iravani, Anthony M Joshua, Jeffrey C Goh, David A Pattison, Thean Hsiang Tan, Ian D Kirkwood, Siobhan Ng, Roslyn J Francis, Craig Gedy, Natalie K Rutherford, Andrew Weickhardt, Andrew M Scott, Sze-Ting Lee, Edmond M Kwan, Arun A Azad, Shakher Ramdave, Andrew D Redfern, William Macdonald, Alex Guminski, Edward Hsiao, Wei Chua, Peter Lin, Alison Y Zhang, Margaret M McJannett, Martin R Stockler, John A Violet\*, Scott G Williams, Andrew J Martin, Ian D Davis, for the TheraP Trial Investigators and the Australian and New Zealand Urogenital and Prostate Cancer Trials Group†*

## TheraP: Primary Endpoint — PSA Response $\geq 50\%$



## TheraP: Select Adverse Events

Event	<sup>177</sup> Lu-PSMA-617 (n = 98)		Cabazitaxel (n = 85)	
	Grade 1/2	Grade 3/4	Grade 1/2	Grade 3/4
Pain	61%	11%	61%	5%
Thrombocytopenia	18%	11%	5%	0
Anemia	19%	8%	13%	8%
Neutropenia	7%	4%	5%	13%

# Positive Results Announced from the Phase III VISION Trial of Radioligand Therapy $^{177}\text{Lu}$ -PSMA-617 for Advanced Prostate Cancer

Press Release: Mar 23, 2021

“The Phase III VISION study [is] evaluating the efficacy and safety of  $^{177}\text{Lu}$ -PSMA-617, a targeted radioligand therapy in patients with progressive PSMA-positive metastatic castration-resistant prostate cancer (mCRPC) compared to best standard of care alone.

The trial met both primary endpoints of overall survival and radiographic progression-free survival... The safety profile was consistent with data reported in previous clinical studies.

Results from the VISION trial will be presented at an upcoming medical meeting and included in US and EU regulatory submissions.”

# 13<sup>th</sup> Annual Oncology Grand Rounds

*A Complimentary NCPD Live Webinar Series  
Held During the 46<sup>th</sup> Annual ONS Congress*

## Hodgkin and Non-Hodgkin Lymphomas

Thursday, April 22, 2021

5:00 PM – 6:30 PM ET

### Medical Oncologists

Stephen M Ansell, MD, PhD

Carla Casulo, MD

John P Leonard, MD

### Oncology Nurse Practitioners

Jacklyn Gideon, MSN, AGPCNP-BC

Robin Klebig, APRN, CNP, AOCNP

Mollie Moran, APRN-CNP, AOCNP

### Moderator

Neil Love, MD

***Thank you for joining us!***

***NCPD credit information will be emailed  
to each participant shortly.***