

# **Year in Review: Prostate Cancer**

**Tuesday, April 12, 2022  
5:00 PM – 6:00 PM ET**

## **Faculty**

**Emmanuel S Antonarakis, MD  
Daniel P Petrylak, MD**

## **Moderator**

**Neil Love, MD**

# YiR Prostate Cancer Faculty



**Emmanuel S Antonarakis, MD**

Clark Endowed Professor of Medicine

Division of Hematology, Oncology and Transplantation

University of Minnesota

Minneapolis, Minnesota



**Daniel P Petrylak, MD**

Professor of Internal Medicine (Medical Oncology) and Urology

Yale School of Medicine

New Haven, Connecticut

## Commercial Support

This activity is supported by educational grants from Astellas and Pfizer Inc, and Exelixis Inc.

## 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, ADC Therapeutics, 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, BeyondSpring Pharmaceuticals Inc, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Coherus BioSciences, CTI BioPharma Corp, Daiichi Sankyo Inc, Eisai Inc, Elevation Oncology Inc, EMD Serono Inc, Epizyme Inc, Exact Sciences, Exelixis Inc, Five Prime Therapeutics Inc, Foundation Medicine, G1 Therapeutics Inc, Genentech, a member of the Roche Group, Genmab, 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, Mersana Therapeutics Inc, Natera Inc, Novartis, Novartis Pharmaceuticals Corporation on behalf of Advanced Accelerator Applications, Novocure Inc, Oncopeptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sanofi Genzyme, Seagen Inc, Servier Pharmaceuticals LLC, Sumitomo Dainippon Pharma Oncology Inc, Taiho Oncology Inc, Takeda Pharmaceuticals USA Inc, Tesaro, A GSK Company, TG Therapeutics Inc, Turning Point Therapeutics Inc, Verastem Inc and Zymeworks Inc.



# 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.

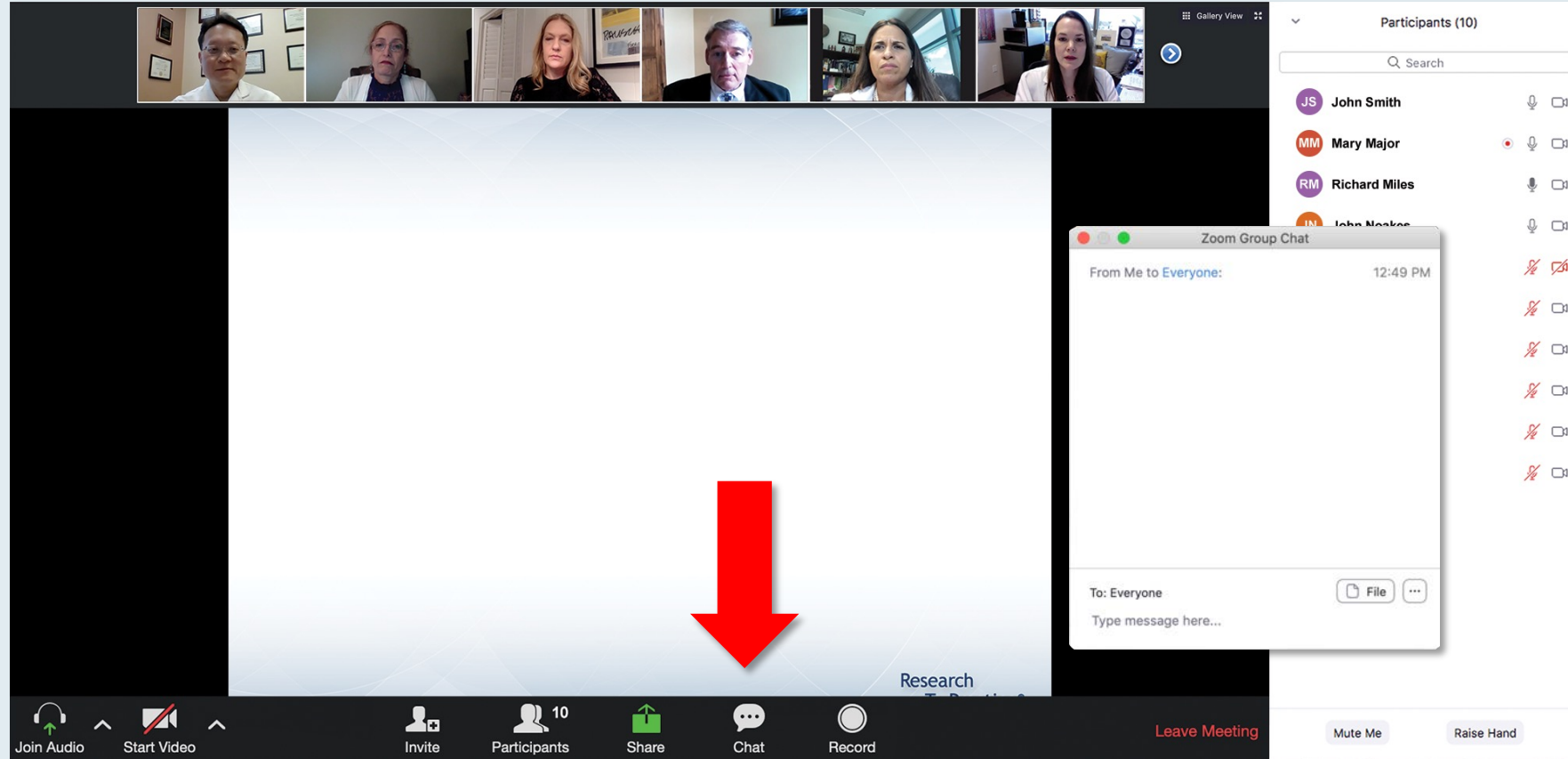
## Dr Antonarakis — Disclosures

<b>Advisory Committee</b>	Alkido Pharma Inc, Amgen Inc, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Blue Earth Diagnostics, Bristol-Myers Squibb Company, Constellation Pharmaceuticals, Curium Pharma, Exact Sciences, Foundation Medicine, Invitae, Ismar Healthcare NV, Merck, Orion Corporation, Tempus
<b>Consulting Agreements</b>	EcoR1 Capital LLC, KeyQuest Health
<b>Contracted Research</b>	AstraZeneca Pharmaceuticals LP, Celgene Corporation, Clovis Oncology
<b>Other</b>	QIAGEN: licensor of technology

## Dr Petrylak — Disclosures

<b>Consulting Agreements</b>	Gilead Sciences Inc, Ipsen Biopharmaceuticals Inc
<b>Contracted Research</b>	Gilead Sciences Inc

# 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

## Expand chat submission box

The screenshot displays a Zoom meeting interface. At the top, there's a header bar with participant names: RTP Coordinat..., Kirsten Miller, RTP Mike Rivera, and Lisa Suarez. Below this, a slide titled "Meet The Professor Program Participating Faculty" is shown. The slide lists six faculty members with their photos and titles:

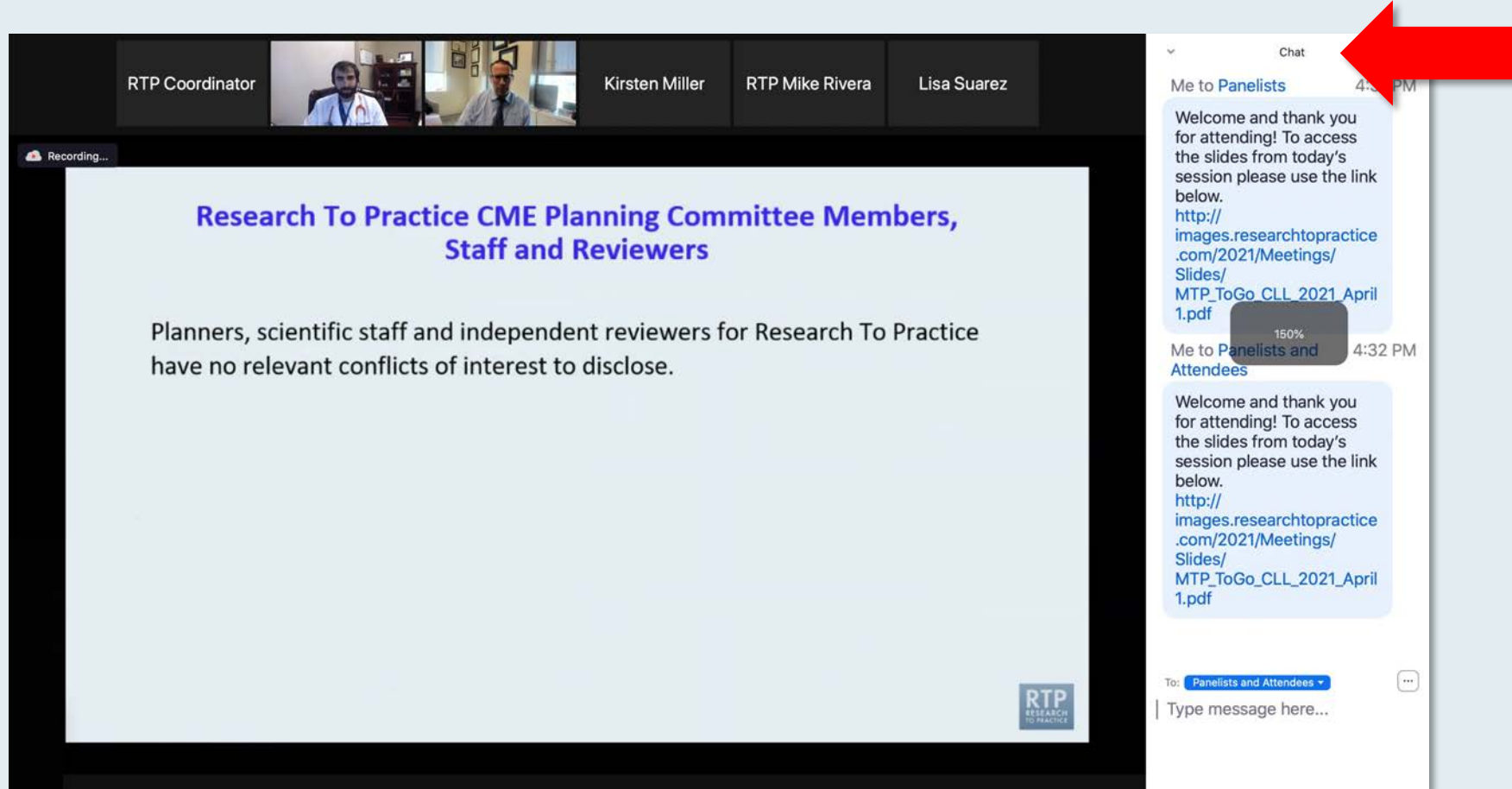
- Nancy L Bartlett, MD**  
Professor of Medicine  
Koman Chair in Medical Oncology  
Washington University School of Medicine  
St Louis, Missouri
- Jonathan W Friedberg, MD, MMSc**  
Samuel E Durand Professor of Medicine  
Director, James P Wilmot Cancer Institute  
University of Rochester  
Rochester, New York
- Carla Casulo, MD**  
Associate Professor of Medicine  
Division of Hematology/Oncology  
Director, Hematology/Oncology Fellowship Program  
University of Rochester  
Wilmot Cancer Institute  
Rochester, New York
- Brian T Hill, MD, PhD**  
Director, Lymphoid Malignancy Program  
Cleveland Clinic Taussig Cancer Institute  
Cleveland, Ohio
- Christopher R Flowers, MD, MS**  
Chair, Professor  
Department of Lymphoma/Myeloma  
The University of Texas MD Anderson Cancer Center  
Houston, Texas
- Brad S Kahl, MD**  
Professor of Medicine  
Washington University School of Medicine  
Director, Lymphoma Program  
Siteman Cancer Center  
St Louis, Missouri

On the right side, a chat window is open. It shows two messages from "Me to Panelists" and "Me to Panelists and Attendees". At the bottom of the chat window, there's a "To:" dropdown menu set to "Panelists and Attendees" and a text input field labeled "Type message here...". A red arrow points to the white line above this input field, indicating where to drag to expand the box.

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

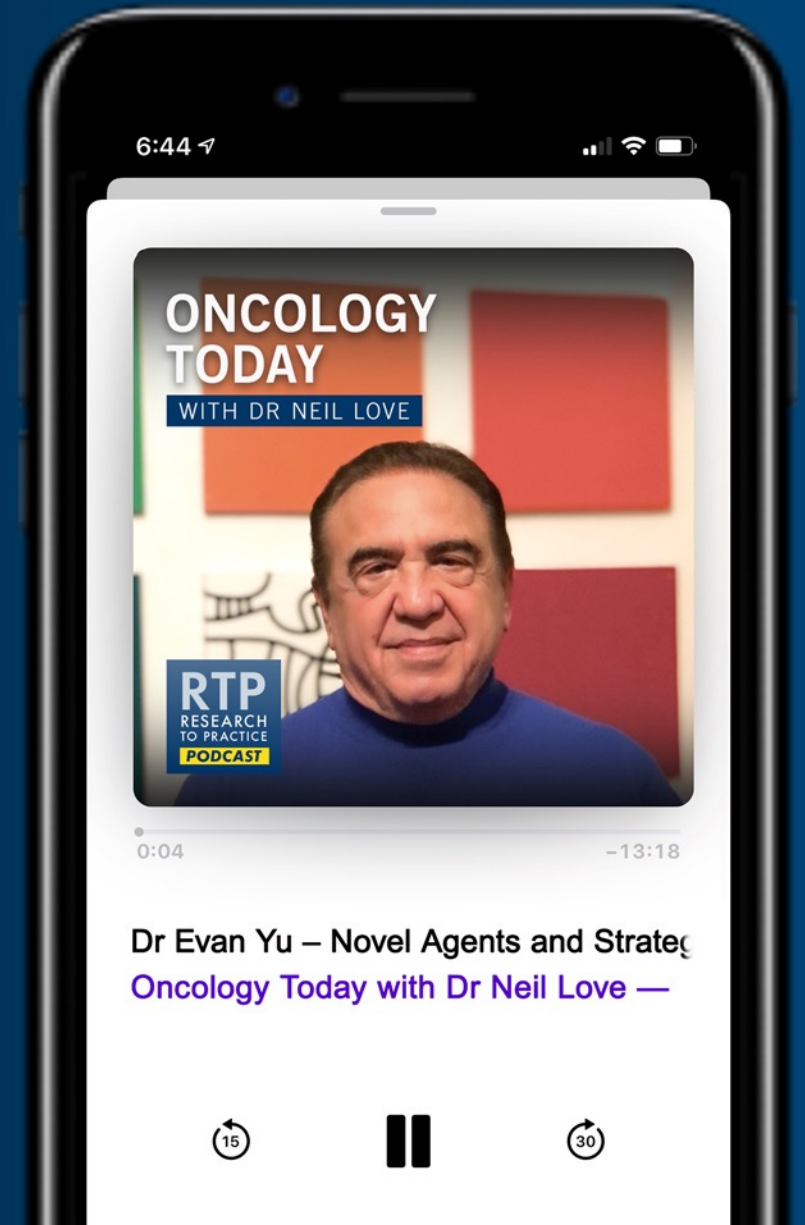
WITH DR NEIL LOVE

## Novel Agents and Strategies for the Treatment of Metastatic Castration-Resistant Prostate Cancer



DR EVAN YU

FRED HUTCHINSON CANCER RESEARCH CENTER



# **Year in Review: Hepatobiliary and Pancreatic Cancers**

**Wednesday, April 13, 2022  
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## **Faculty**

**Tanios Bekaii-Saab, MD  
Philip A Philip, MD, PhD, FRCP**

## **Special Topics**

- **HIMALAYA**



# ***Meet The Professor***

## **Chronic Lymphocytic Leukemia**

**Thursday, April 14, 2022**

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**Jennifer R Brown, MD, PhD**

**Special Topics**

- **Pirtobrutinib**
- **GLOW study**

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**D Ross Camidge, MD, PhD**

**Special Topics**

- **ALK+ NSCLC: First-line treatment, resistance mutations**

# What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

*A Complimentary NCPD Hybrid Symposium Series Held During the 47<sup>th</sup> Annual ONS Congress*

## Prostate Cancer

**Thursday, April 28, 2022**

6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)

### Faculty

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

Robert Dreicer, MD, MS

Sandy Srinivas, MD

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

## Non-Small Cell Lung Cancer

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Jennifer Filipi, MSN, NP

Kathleen N Moore, MD, MS

Krishnansu S Tewari, MD

Deborah Wright, MSN, APRN, AGCNS-BC

## Hepatobiliary Cancers

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Richard S Finn, MD

Amanda K Wagner, APRN-CNP, AOCNP

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Matthew Gubens, MD, MS

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Chaely J Medley, MSN, AGNP

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Monica Averia, MSN, AOCNP, NP-C

Shilpa Gupta, MD

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Sumanta Kumar Pal, MD

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Matthew R Smith, MD, PhD

*Additional faculty to be announced.*

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Emmanuel S Antonarakis, MD

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**Matthew D Galsky, MD**

**Ashish M Kamat, MD, MBBS**

**Stephen B Williams, MD, MBA, MS**

## **Moderator**

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*Thank you for joining us!*

*CME and MOC credit information will be emailed to each participant within 5 business days.*



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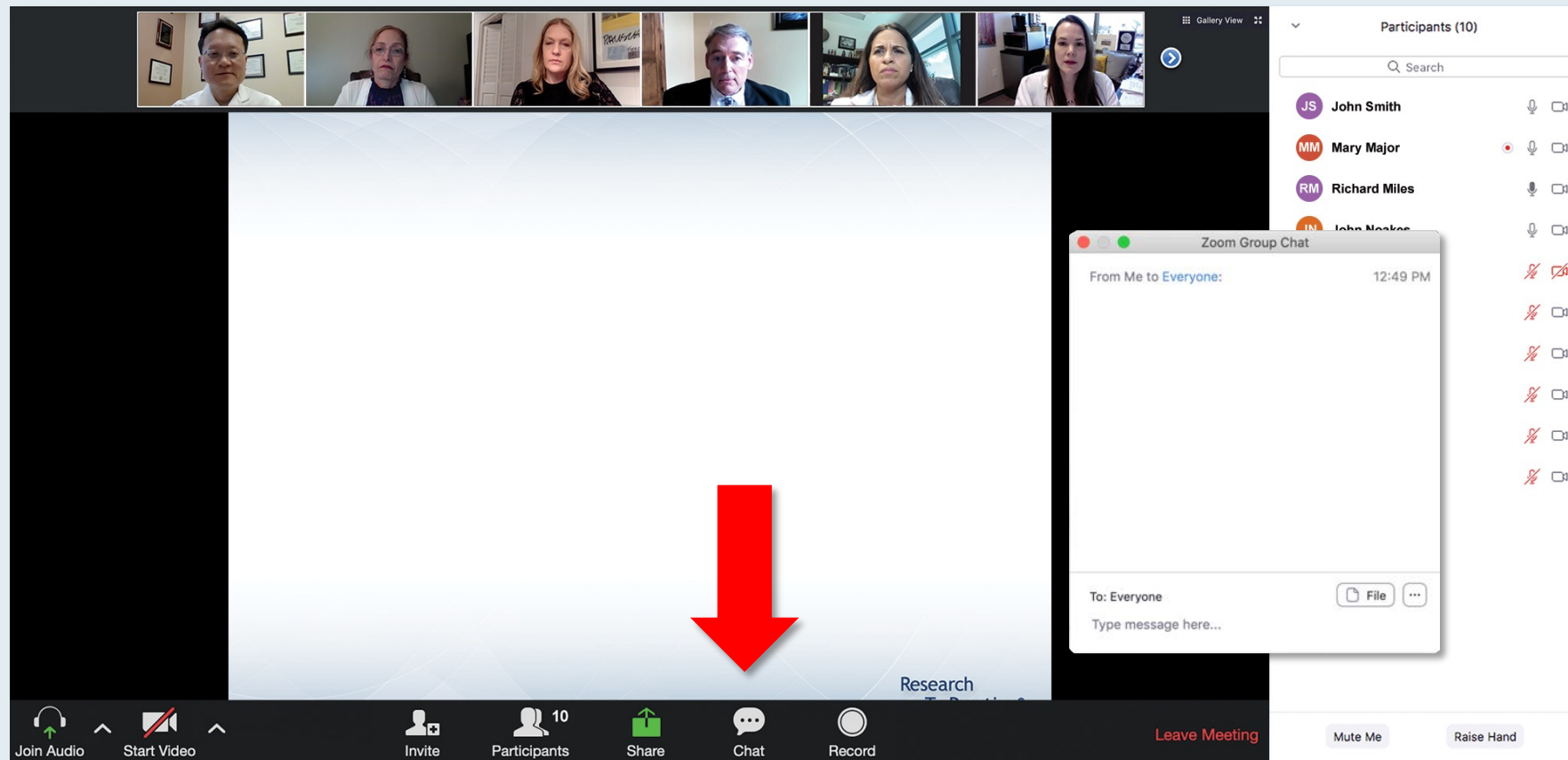
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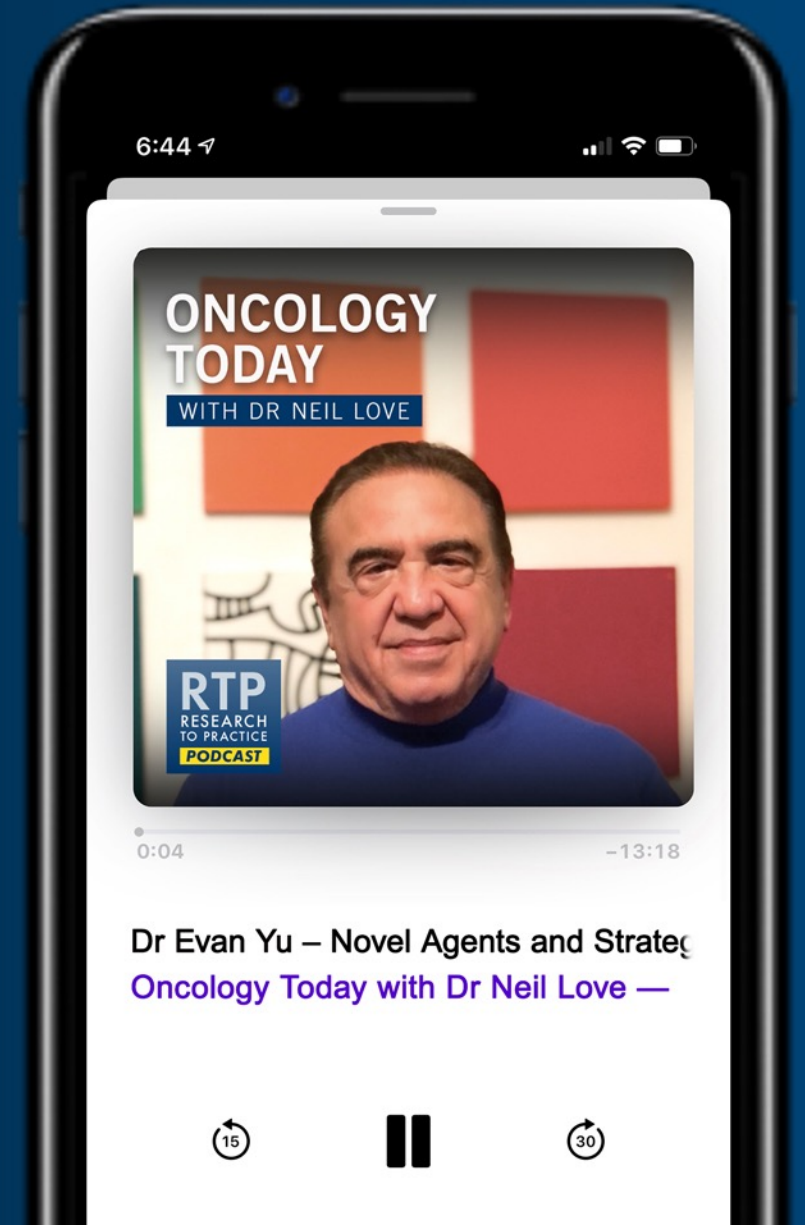
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## Dr Petrylak — Disclosures

<b>Consulting Agreements</b>	Gilead Sciences Inc, Ipsen Biopharmaceuticals Inc
<b>Contracted Research</b>	Gilead Sciences Inc



# Year in Review: Prostate Cancer

## Introduction

**MODULE 1: Endocrine Therapy**

**MODULE 2:  $^{177}$ Lutetium-PSMA-617**

**MODULE 3: PARP Inhibitors**

**MODULE 4: Immunotherapy**

March 31, 2022

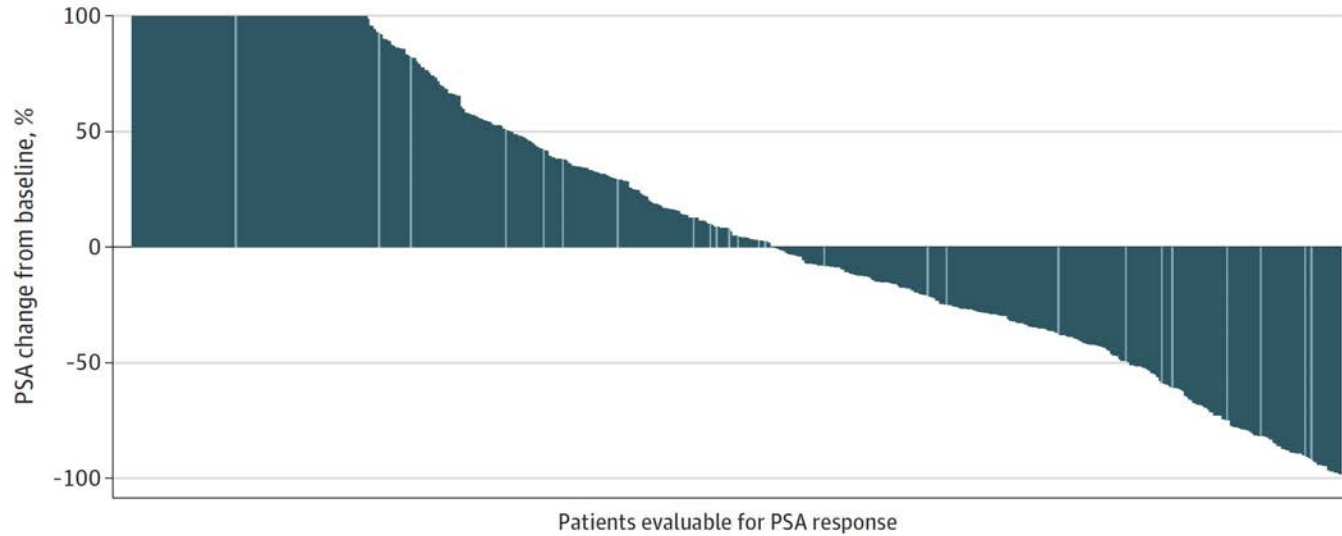
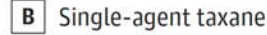
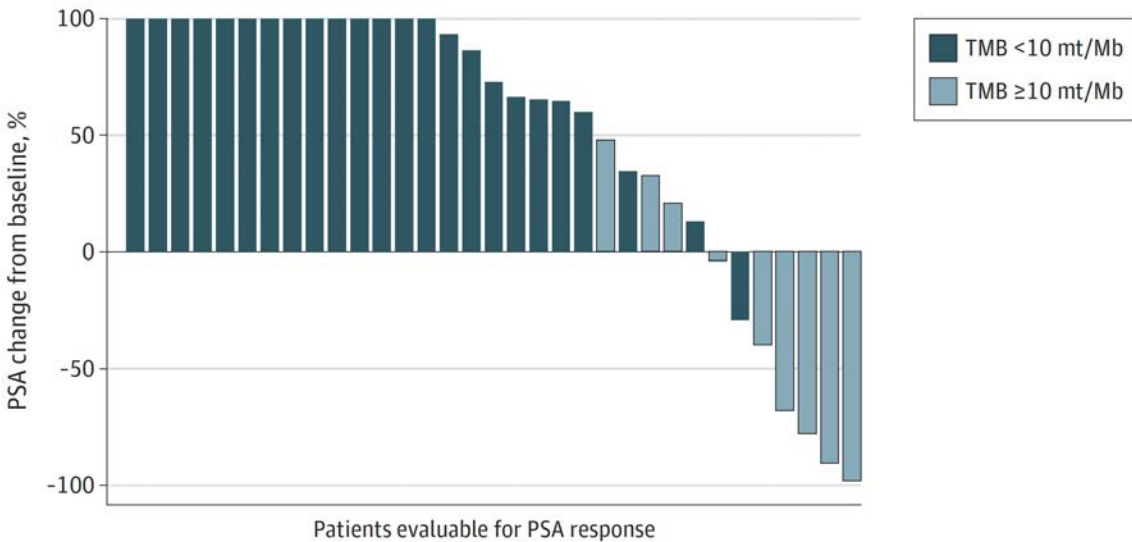


Original Investigation | Oncology

# Comparative Effectiveness of Immune Checkpoint Inhibitors vs Chemotherapy by Tumor Mutational Burden in Metastatic Castration-Resistant Prostate Cancer

Ryon P. Graf, PhD; Virginia Fisher, PhD; Janick Weberpals, RPh, PhD; Ole Gjoerup, PhD; Marni B. Tierno, PhD, RN; Richard S. P. Huang, MD; Nicolas Sayegh, MD; Douglas I. Lin, MD, PhD; Kira Raskina, MD, MS; Alexa B. Schrock, PhD; Eric Severson, MD, PhD; James F. Haberberger, BS; Jeffrey S. Ross, MD; James Creeden, MD, PhD; Mia A. Levy, MD, PhD; Brian M. Alexander, MD, MPH; Geoffrey R. Oxnard, MD; Neeraj Agarwal, MD

## Prostate-Specific Antigen (PSA) Response by Drug Class



# Year in Review: Prostate Cancer

## Introduction

### MODULE 1: Endocrine Therapy

### MODULE 2: $^{177}\text{Lu}$ -PSMA-617

### MODULE 3: PARP Inhibitors

### MODULE 4: Immunotherapy

# Overall survival with darolutamide versus placebo in combination with androgen-deprivation therapy and docetaxel for metastatic hormone-sensitive prostate cancer in the phase 3 ARASENS trial

Matthew R. Smith, MD, PhD,<sup>1</sup> Maha Hussain, MD,<sup>2</sup> Fred Saad, MD,<sup>3</sup> Karim Fizazi, MD, PhD,<sup>4</sup> Cora N. Sternberg, MD,<sup>5</sup> E. David Crawford, MD,<sup>6</sup> Evgeny Kopyltsov, MD,<sup>7</sup> Chandler H. Park, MD,<sup>8</sup> Boris Alekseev, MD,<sup>9</sup> Álvaro Montesa Pino, MD,<sup>10</sup> Dingwei Ye, MD,<sup>11</sup> Francis Parnis, MB, BS,<sup>12</sup> Felipe Melo Cruz, MD,<sup>13</sup> Teuvo L.J. Tammela, MD, PhD,<sup>14</sup> Hiroyoshi Suzuki, MD, PhD,<sup>15</sup> Heikki Joensuu, MD,<sup>16</sup> Silke Thiele, MD,<sup>17</sup> Rui Li, MS,<sup>18</sup> Iris Kuss, MD,<sup>17</sup> Bertrand Tombal, MD, PhD<sup>19</sup>

<sup>1</sup>Massachusetts General Hospital Cancer Center, Boston, MA; <sup>2</sup>Northwestern University, Feinberg School of Medicine, Chicago, IL; <sup>3</sup>University of Montreal Hospital Center, Montreal, Quebec, Canada; <sup>4</sup>Institut Gustave Roussy, University of Paris-Saclay, Villejuif, France; <sup>5</sup>Englander Institute for Precision Medicine, Weill Cornell Department of Medicine, Meyer Cancer Center, New York-Presbyterian Hospital, New York, NY; <sup>6</sup>UC San Diego School of Medicine, San Diego, CA; <sup>7</sup>Clinical Oncological Dispensary of Omsk Region, Omsk, Russian Federation; <sup>8</sup>Norton Cancer Institute, Louisville, KY; <sup>9</sup>P. Hertsen Moscow Oncology Research Institute, Moscow, Russian Federation; <sup>10</sup>UGC Intercentros de Oncología Médica, Hospitales Universitarios Regional y Virgen Victoria, IBIMA, Málaga, Spain; <sup>11</sup>Fudan University Shanghai Cancer Center, Xuhui District, Shanghai, China; <sup>12</sup>Ashford Cancer Centre Research, Kurralt Park, SA, Australia; <sup>13</sup>Núcleo de Pesquisa e Ensino da Rede São Camilo, São Paulo, Brazil; <sup>14</sup>Tampere University Hospital, Tampere, Finland; <sup>15</sup>Toho University Sakura Medical Center, Chiba, Japan; <sup>16</sup>Orion Corporation Orion Pharma, Espoo, Finland; <sup>17</sup>Bayer AG, Berlin, Germany; <sup>18</sup>Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ, USA; <sup>19</sup>Division of Urology, IREC, Cliniques Universitaires Saint Luc, UCLouvain, Brussels, Belgium



# ARASENS: Study Design

Global, randomized, double-blind, placebo-controlled phase III study (NCT02799602)

## Patients (N=1306)

- mHSPC
- ECOG PS 0 or 1
- Candidates for ADT and docetaxel

## Stratification

- Extent of disease: M1a vs M1b vs M1c
- ALP < vs ≥ ULN

1:1  
randomization  
(N=1305\*)

Docetaxel × 6

Darolutamide 600 mg twice daily + ADT

Placebo twice daily + ADT

Docetaxel × 6

FPFV: Nov 2016  
LPFV: June 2018

Primary analysis

Data cut-off  
Oct 25, 2021

## Endpoints

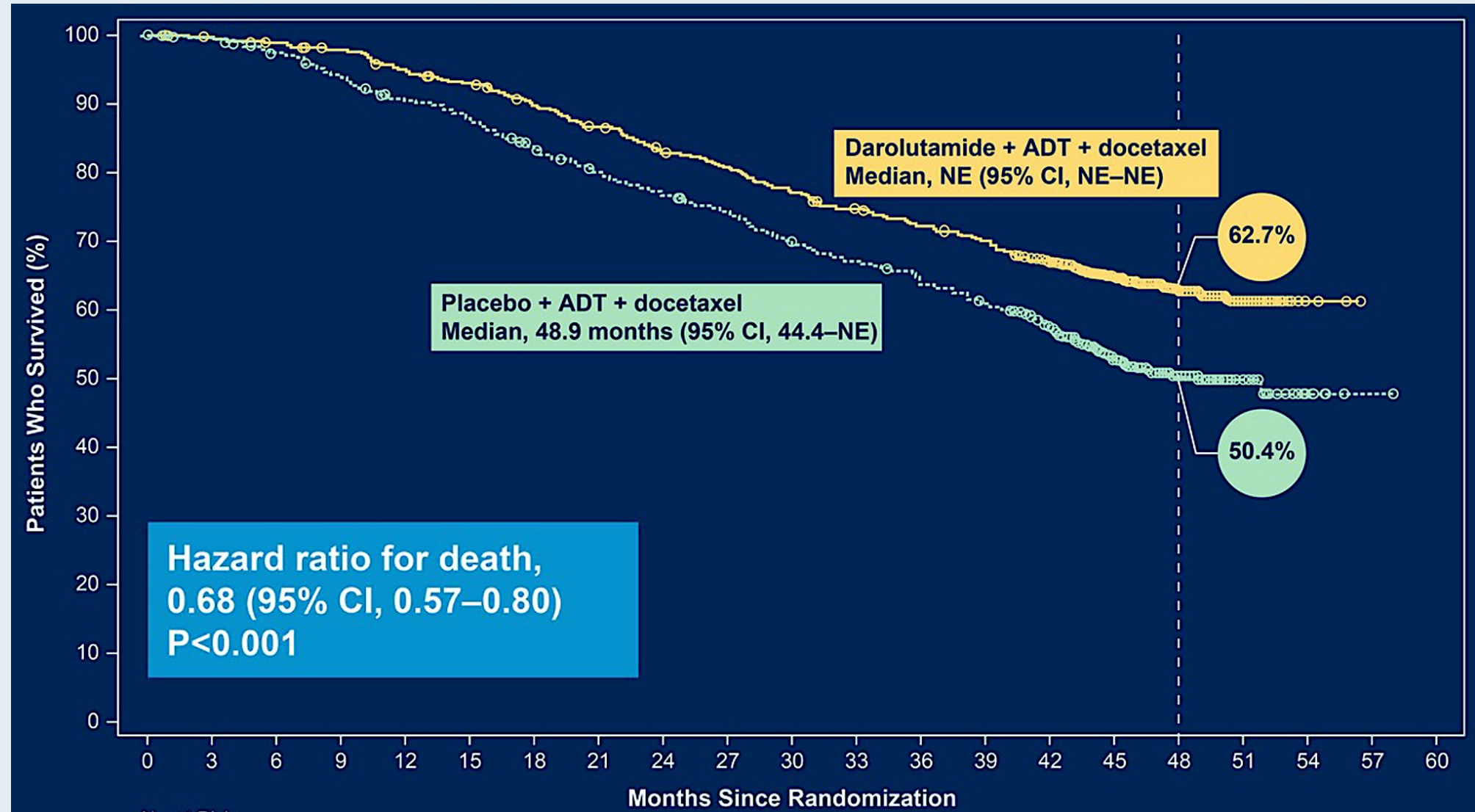
### Primary: OS

### Secondary

- Time to CRPC
- Time to pain progression
- SSE-free survival
- Time to first SSE
- Time to initiation of subsequent systemic antineoplastic therapy
- Time to worsening of disease-related physical symptoms
- Time to initiation of opioid use for ≥7 consecutive days
- Safety

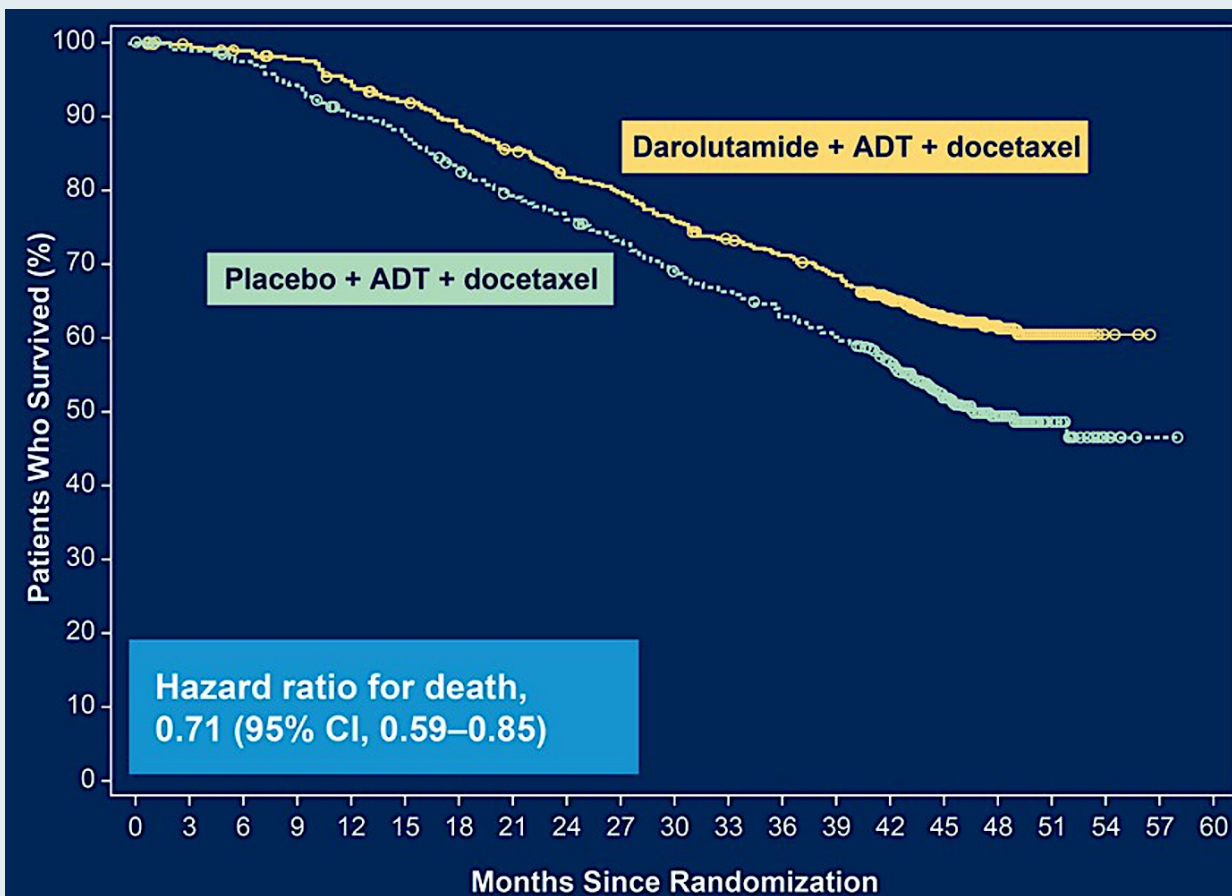
- The primary analysis was planned to occur after ~509 deaths
- Secondary efficacy endpoints were tested hierarchically

# ARASENS: Primary Endpoint — Overall Survival

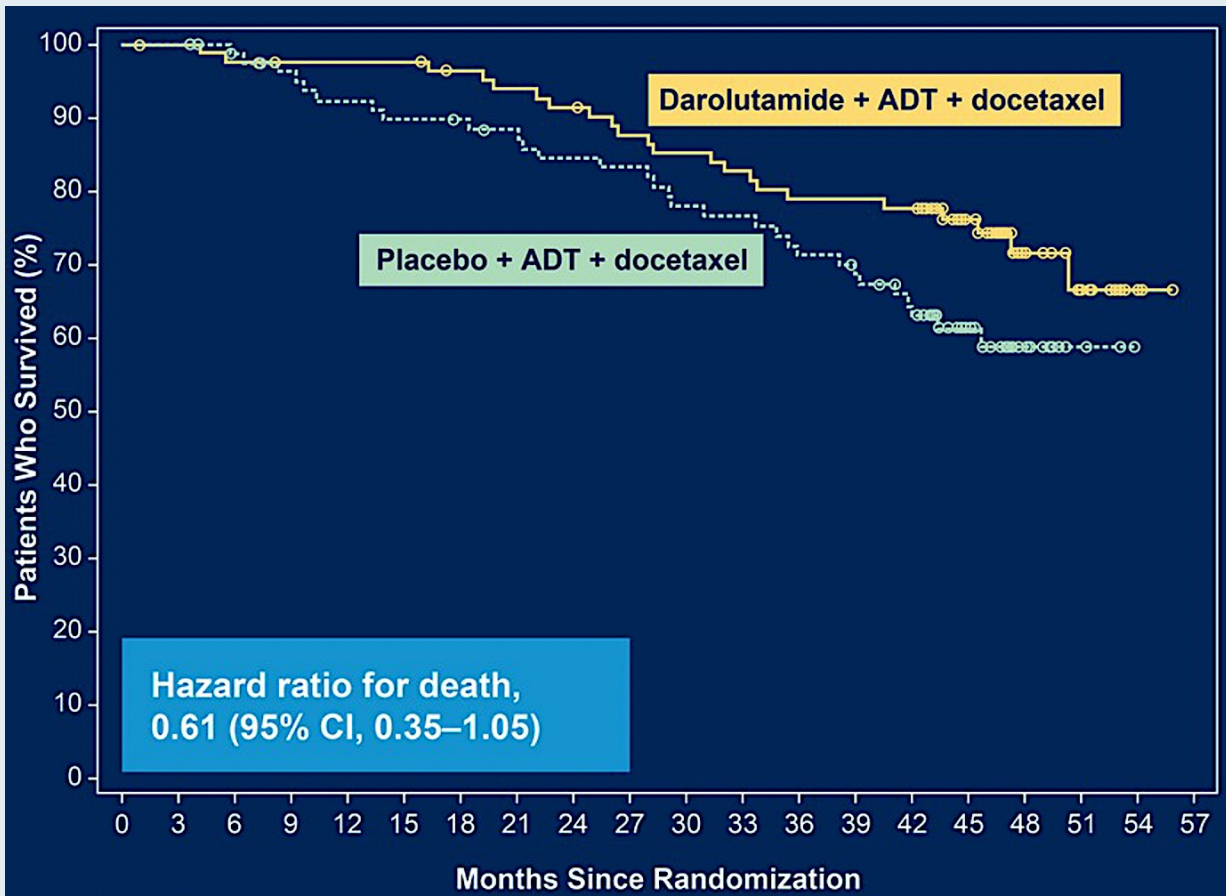


# ARASENS: Overall Survival by Metastatic Stage at Initial Diagnosis

## De novo metastatic disease



## Recurrent metastatic disease





## ARASENS: Grade 3-4 Adverse Events

Grade 3–4 AEs in $\geq 2\%$ of darolutamide-treated patients, n (%)	Darolutamide + ADT + docetaxel (n=652)	Placebo + ADT + docetaxel (n=650)
Any AE	431 (66.1)	413 (63.5)
Neutropenia*	220 (33.7)	222 (34.2)
Febrile neutropenia	51 (7.8)	48 (7.4)
Hypertension	42 (6.4)	21 (3.2)
Anemia	31 (4.8)	33 (5.1)
Pneumonia	21 (3.2)	20 (3.1)
Hyperglycemia	18 (2.8)	24 (3.7)
Increased alanine aminotransferase	18 (2.8)	11 (1.7)
Increased aspartate aminotransferase	17 (2.6)	7 (1.1)
Increased weight	14 (2.1)	8 (1.2)
Urinary tract infection	13 (2.0)	12 (1.8)

# ARASENS: Adverse Events of Special Interest with Androgen Receptor (AR) Pathway Inhibitors

AEs associated with AR pathway inhibitor therapy	Darolutamide + ADT + docetaxel (n=652)		Placebo + ADT + docetaxel (n=650)	
	Patients, n (%)	EAIR/100 PY*	Patients, n (%)	EAIR/100 PY*
Fatigue	216 (33.1)	12.5	214 (32.9)	17.8
Bone fracture	49 (7.5)	2.8	33 (5.1)	2.7
Falls	43 (6.6)	2.5	30 (4.6)	2.5
Rash†	108 (16.6)	6.2	88 (13.5)	7.3
Diabetes mellitus and hyperglycemia‡	99 (15.2)	5.7	93 (14.3)	7.7
Weight decreased	22 (3.4)	1.3	35 (5.4)	2.9
Vasodilatation and flushing	133 (20.4)	7.7	141 (21.7)	11.7
Breast disorders/gynecomastia‡	21 (3.2)	1.2	10 (1.5)	0.8
Hypertension‡	89 (13.7)	5.1	60 (9.2)	5.0
Cardiac disorder‡	71 (10.9)	4.1	76 (11.7)	6.3
Cerebral ischemia	8 (1.2)	0.5	8 (1.2)	0.7
Mental impairment disorder‡	23 (3.5)	1.3	15 (2.3)	1.2
Depressed mood disorder‡	21 (3.2)	1.2	24 (3.7)	2.0
Seizure	4 (0.6)	0.2	1 (0.2)	0.1



2021 ASCO  
ANNUAL MEETING



**A PHASE 3 TRIAL WITH A 2X2 FACTORIAL DESIGN OF ABIRATERONE ACETATE PLUS PREDNISONE AND/OR LOCAL RADIOTHERAPY IN MEN WITH *DE NOVO* METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (mCSPC): FIRST RESULTS OF PEACE-1**

Karim Fizazi, MD, PhD

Institut Gustave Roussy, France

June 8, 2021

Karim Fizazi, Xavier Maldonado, Stéphanie Foulon, Guilhem Roubaud, Ray McDermott, Aude Fléchon, Bertrand Tombal, Stéphane Supiot, Dominik Berthold, Philippe Ronchin, Gabriel Kacsó, Gwenaëlle Gravis, Fabio Calabro, Jean-François Berdah, Ali Hasbini, Marlon Silva, Antoine Thiery-Vuillemin, Isabelle Rieger, Marie-Laure Tanguy, Alberto Bossi

Articles

*Lancet* 2022;[Online ahead of print].

**Abiraterone plus prednisone added to androgen deprivation therapy and docetaxel in de novo metastatic castration-sensitive prostate cancer (PEACE-1): a multicentre, open-label, randomised, phase 3 study with a 2 × 2 factorial design**



Karim Fizazi, Stéphanie Foulon, Joan Carles, Guilhem Roubaud, Ray McDermott, Aude Fléchon, Bertrand Tombal, Stéphane Supiot, Dominik Berthold, Philippe Ronchin, Gabriel Kacsó, Gwenaëlle Gravis, Fabio Calabro, Jean-François Berdah, Ali Hasbini, Marlon Silva, Antoine Thiery-Vuillemin, Igor Latorzeff, Loïc Mourey, Brigitte Laguerre, Sophie Abadie-Lacourtoisie, Etienne Martin, Claude El Kouri, Anne Escande, Alvar Rosello, Nicolas Magne, Friederike Schlurmann, Frank Priou, Marie-Eve Chand-Fouche, Salvador Villà Freixa, Muhammad Jamaluddin, Isabelle Rieger, Alberto Bossi, on behalf of the PEACE-1 investigators\*

# PEACE-1: Study Design

## Key Eligibility Criteria

*De novo* mCSPC

Distant metastatic disease by  $\geq 1$  lesion on bone scan and/or CT scan

ECOG PS 0 -2

## On-Study Requirement

Continuous ADT

## Permitted

ADT  $\leq 3$  months

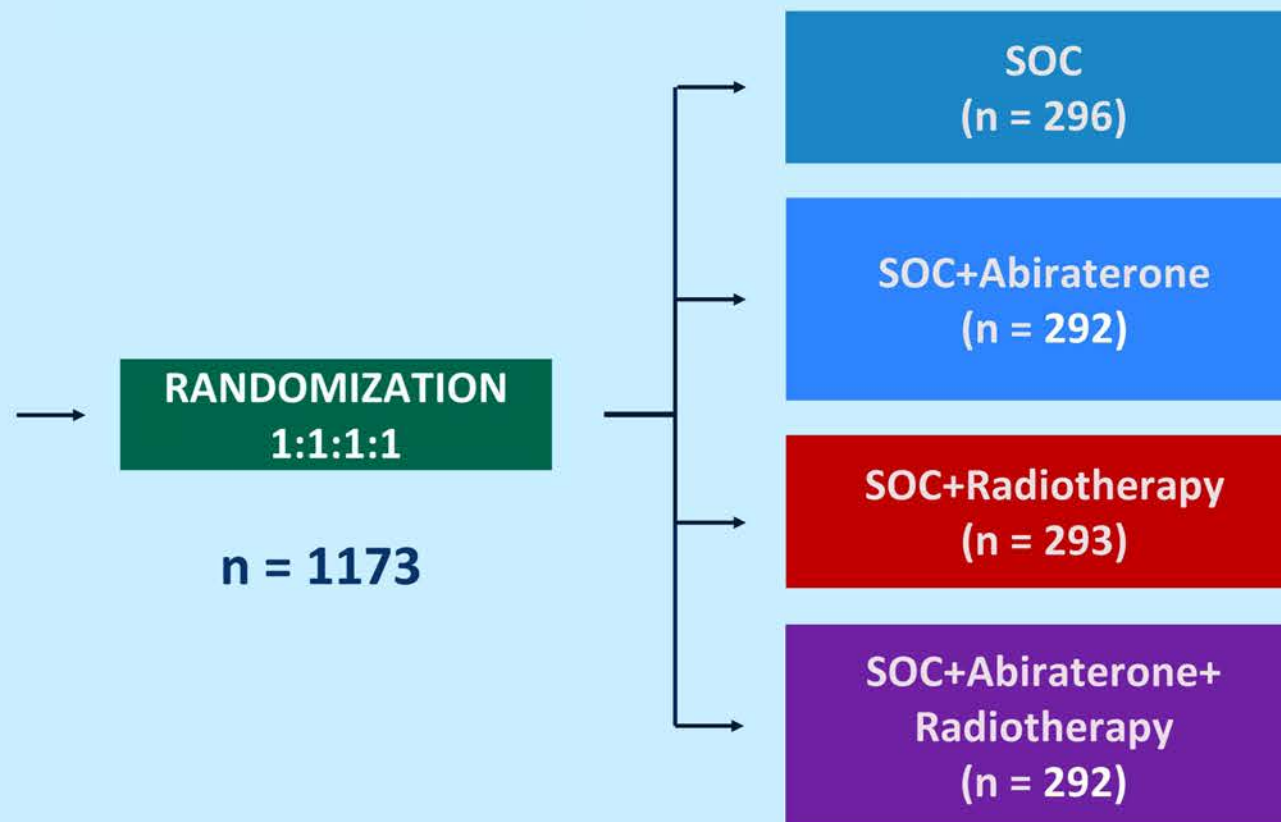
## Stratification

ECOG PS (0 vs 1-2)

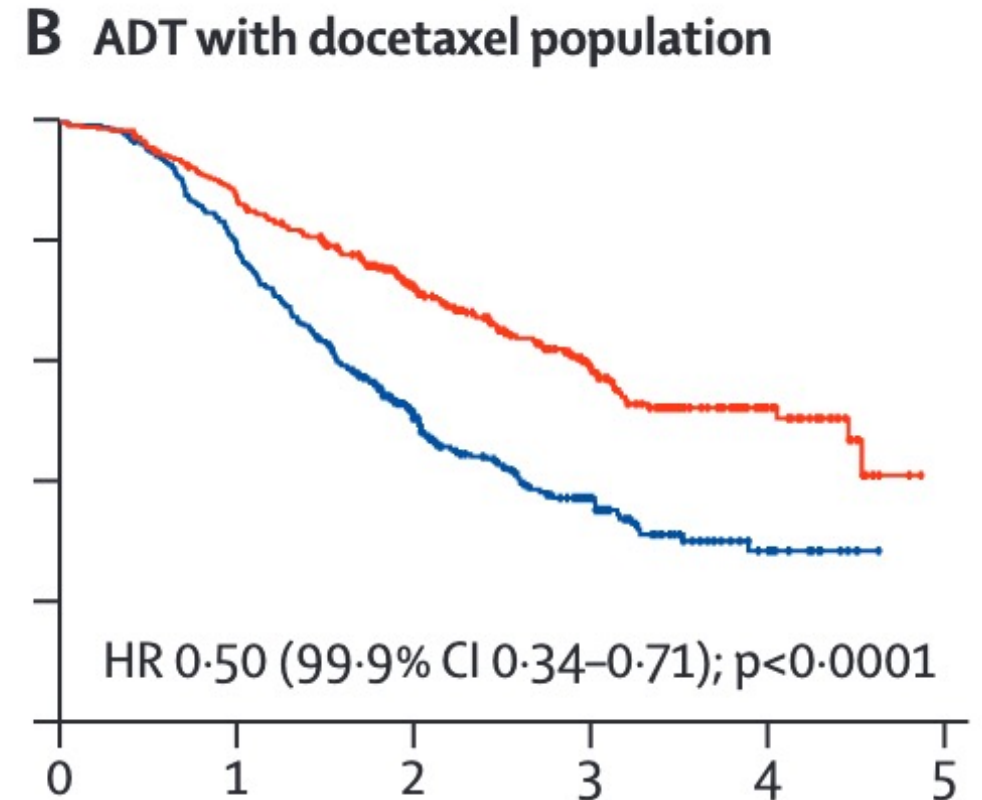
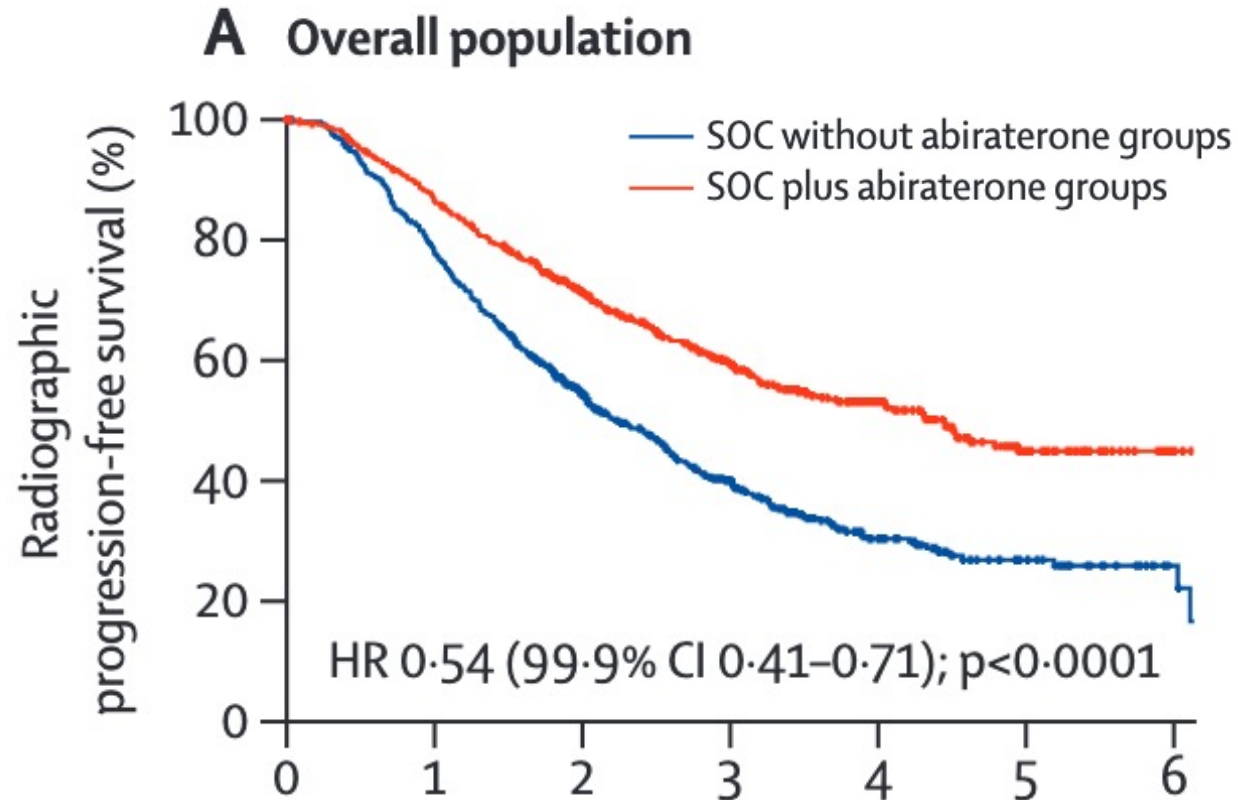
Metastatic sites (LN vs bone vs visceral)

Type of castration (orchidectomy vs LHRH agonist vs LHRH antagonist)

Docetaxel (yes vs no)

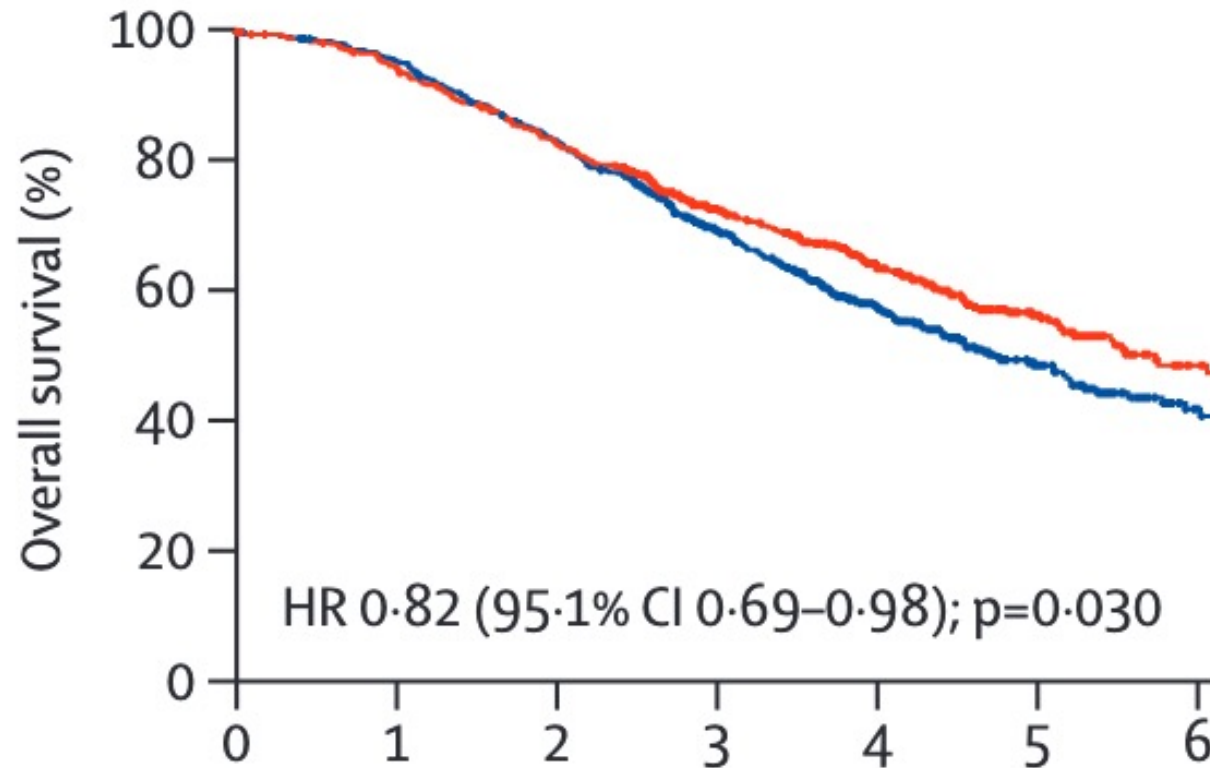


# PEACE-1: Radiographic Progression-Free Survival

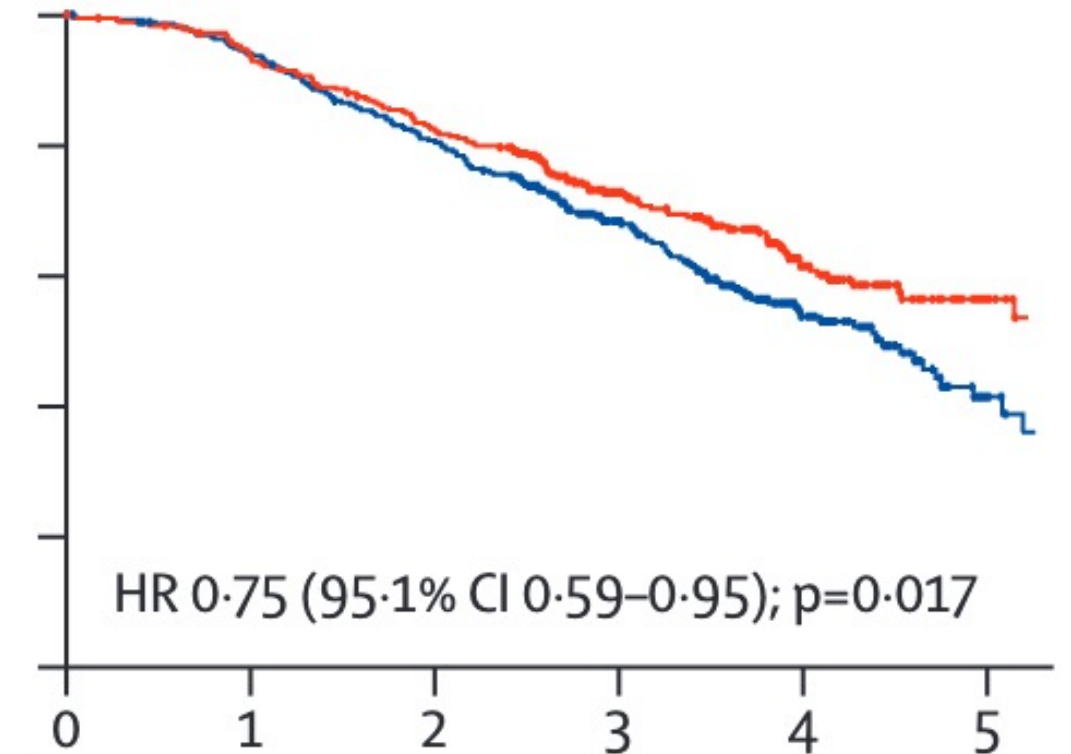


## PEACE-1: Overall Survival

**C** Overall population

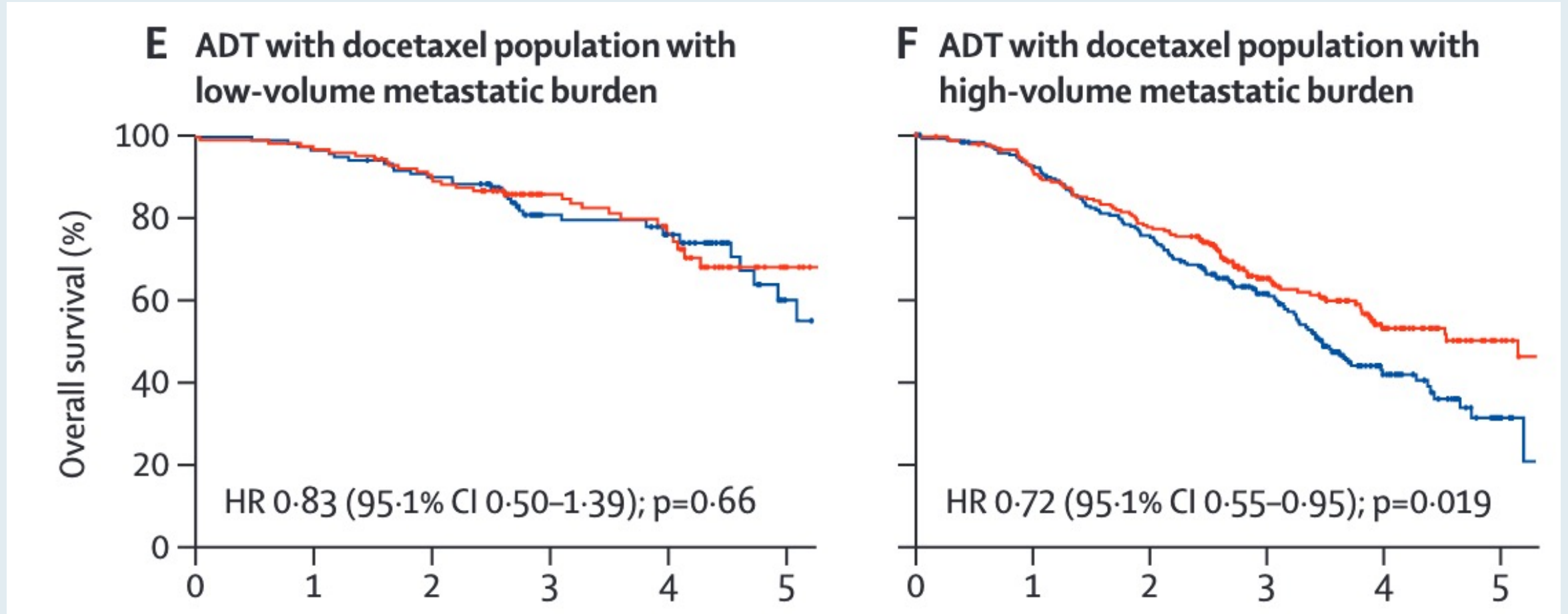


**D** ADT with docetaxel population





## PEACE-1: Overall Survival by Metastatic Burden



## Abstract 102

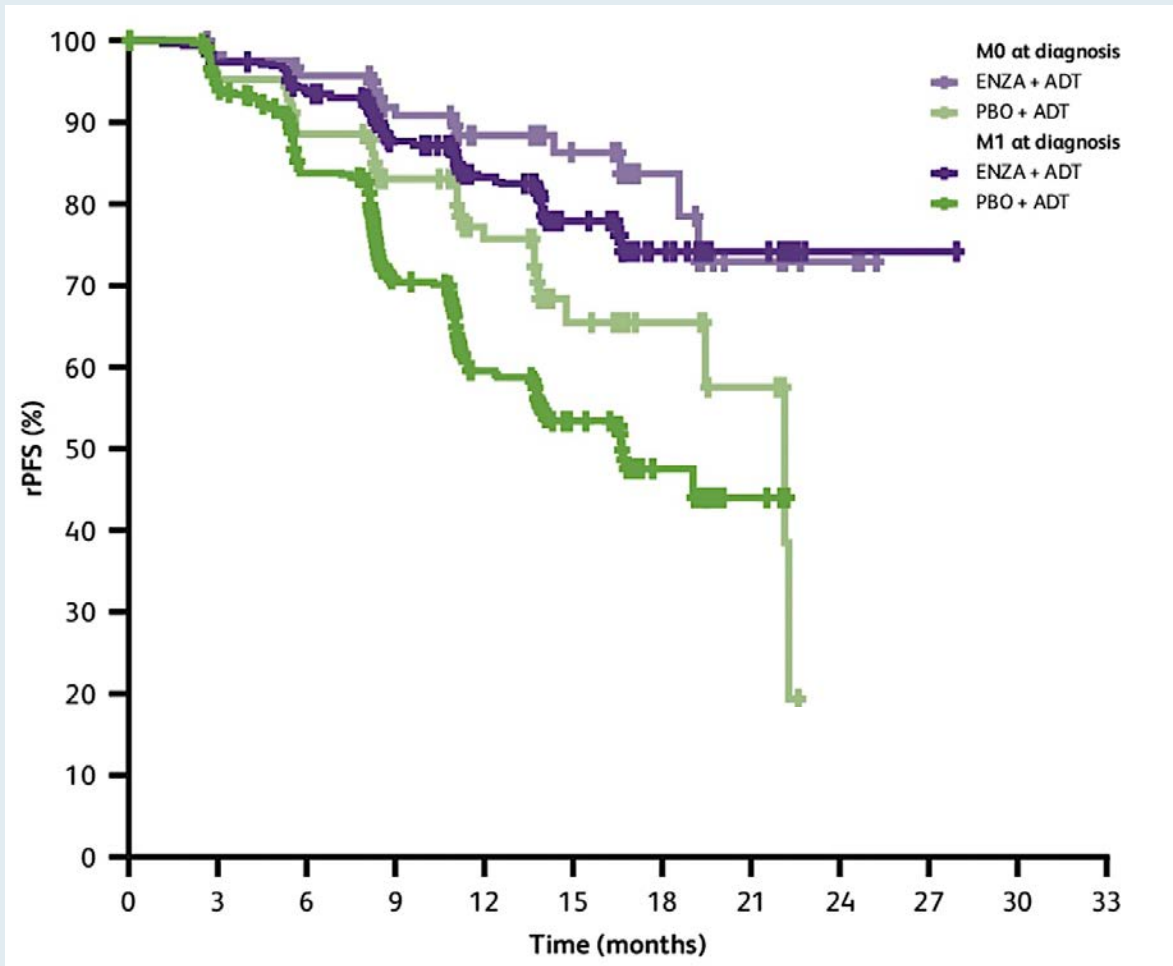
# Efficacy of enzalutamide plus androgen deprivation therapy in men with *de novo* (M1) metastatic hormone-sensitive prostate cancer versus progression to metastatic hormone-sensitive prostate cancer (M0): *post hoc* analysis of the Phase 3 ARCHES trial

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Arun Azad,<sup>1,\*</sup> Arnauld Villers,<sup>2</sup> Boris Alekseev,<sup>3</sup> Russell Z. Szmulewitz,<sup>4</sup> Antonio Alcaraz,<sup>5</sup> Neal D. Shore,<sup>6</sup> Daniel P. Petrylak,<sup>7</sup> Jeffrey Holzbeierlein,<sup>8</sup> Francisco Gomez-Veiga,<sup>9</sup> Brad Rosbrook,<sup>10</sup> Fabian Zohren,<sup>10</sup> Ho-Jin Lee,<sup>11</sup> Gabriel P. Haas,<sup>11</sup> Taro Iguchi,<sup>12</sup> Arnulf Stenzl,<sup>13</sup> Andrew J. Armstrong<sup>14</sup>



# ARCHES: Radiographic Progression-Free Survival (rPFS) by Metastatic Status



	M0 at diagnosis (n = 246)		M1 at diagnosis (n = 890)	
	ENZA + ADT (n = 117)	PBO + ADT (n = 129)	ENZA + ADT (n = 448)	PBO + ADT (n = 890)
Median, months	NR	22.11	NR	16.62
HR (95% CI)	0.42 (0.23-0.76)		0.38 (0.29-0.50)	

ENZA = enzalutamide; PBO = placebo;  
ADT = androgen deprivation therapy

# ARCHES: Treatment-Emergent Adverse Events (AEs) According to Adjudicated Metastatic Status at Initial Diagnosis

Event, n (%)	SAF (n=1146) <sup>a</sup>			
	M0 at diagnosis (progressed to M1)		M1 at diagnosis ( <i>de novo</i> )	
	ENZA + ADT (n=117)	PBO + ADT (n=128)	ENZA + ADT (n=447)	PBO + ADT (n=441)
Any AE leading to treatment withdrawal	6 (5.1)	6 (4.7)	21 (4.7)	15 (3.4)
Any AE	107 (91.5)	114 (89.1)	375 (83.9)	377 (85.5)
Most frequently reported AE (any grade occurring in ≥5% of patients in either subgroup)				
<b>Hot flash</b>	<b>45 (38.5)</b>	<b>38 (29.7)</b>	<b>109 (24.4)</b>	<b>89 (20.2)</b>
<b>Fatigue</b>	<b>43 (36.8)</b>	<b>35 (27.3)</b>	<b>68 (15.2)</b>	<b>52 (11.8)</b>
Arthralgia	18 (15.4)	14 (10.9)	51 (11.4)	47 (10.7)
Hypertension	12 (10.3)	11 (8.6)	<b>34 (7.6)</b>	<b>21 (4.8)</b>
Nausea	12 (10.3)	12 (9.4)	24 (5.4)	17 (3.9)
<b>Decreased appetite</b>	<b>9 (7.7)</b>	<b>2 (1.6)</b>	19 (4.3)	12 (2.7)
Diarrhea	9 (7.7)	8 (6.3)	25 (5.6)	25 (5.7)
<b>Headache</b>	<b>9 (7.7)</b>	<b>6 (4.7)</b>	16 (3.6)	12 (2.7)
<b>Musculoskeletal pain</b>	<b>7 (6.0)</b>	<b>4 (3.1)</b>	<b>28 (6.3)</b>	<b>19 (4.3)</b>
<b>Rib fracture</b>	<b>7 (6.0)</b>	<b>2 (1.6)</b>	7 (1.6)	4 (0.9)
<b>Weight decreased</b>	<b>7 (6.0)</b>	<b>1 (0.8)</b>	12 (2.7)	14 (3.2)
<b>Weight increased</b>	<b>7 (6.0)</b>	<b>5 (3.9)</b>	27 (6.0)	39 (8.8)
Back pain	6 (5.1)	11 (8.6)	37 (8.3)	51 (11.6)
<b>Insomnia</b>	<b>6 (5.1)</b>	<b>4 (3.1)</b>	15 (3.4)	16 (3.6)
Edema peripheral	6 (5.1)	10 (7.8)	23 (5.1)	28 (6.3)
Asthenia	5 (4.3)	7 (5.5)	26 (5.8)	21 (4.8)
Fall	5 (4.3)	7 (5.5)	16 (3.6)	8 (1.8)
Hematuria	5 (4.3)	7 (5.5)	10 (2.2)	7 (1.6)
Pain in extremity	5 (4.3)	7 (5.5)	13 (2.9)	16 (3.6)
Cough	4 (3.4)	7 (5.5)	10 (2.2)	10 (2.3)
<b>Dizziness</b>	<b>4 (3.4)</b>	<b>6 (4.7)</b>	<b>25 (5.6)</b>	<b>14 (3.2)</b>
Anemia	3 (2.6)	7 (5.5)	22 (4.9)	20 (4.5)
Bone pain	3 (2.6)	4 (3.1)	19 (4.3)	23 (5.2)
Constipation	3 (2.6)	8 (6.3)	25 (5.6)	23 (5.2)
Nasopharyngitis	1 (0.9)	4 (3.1)	22 (4.9)	22 (5.0)

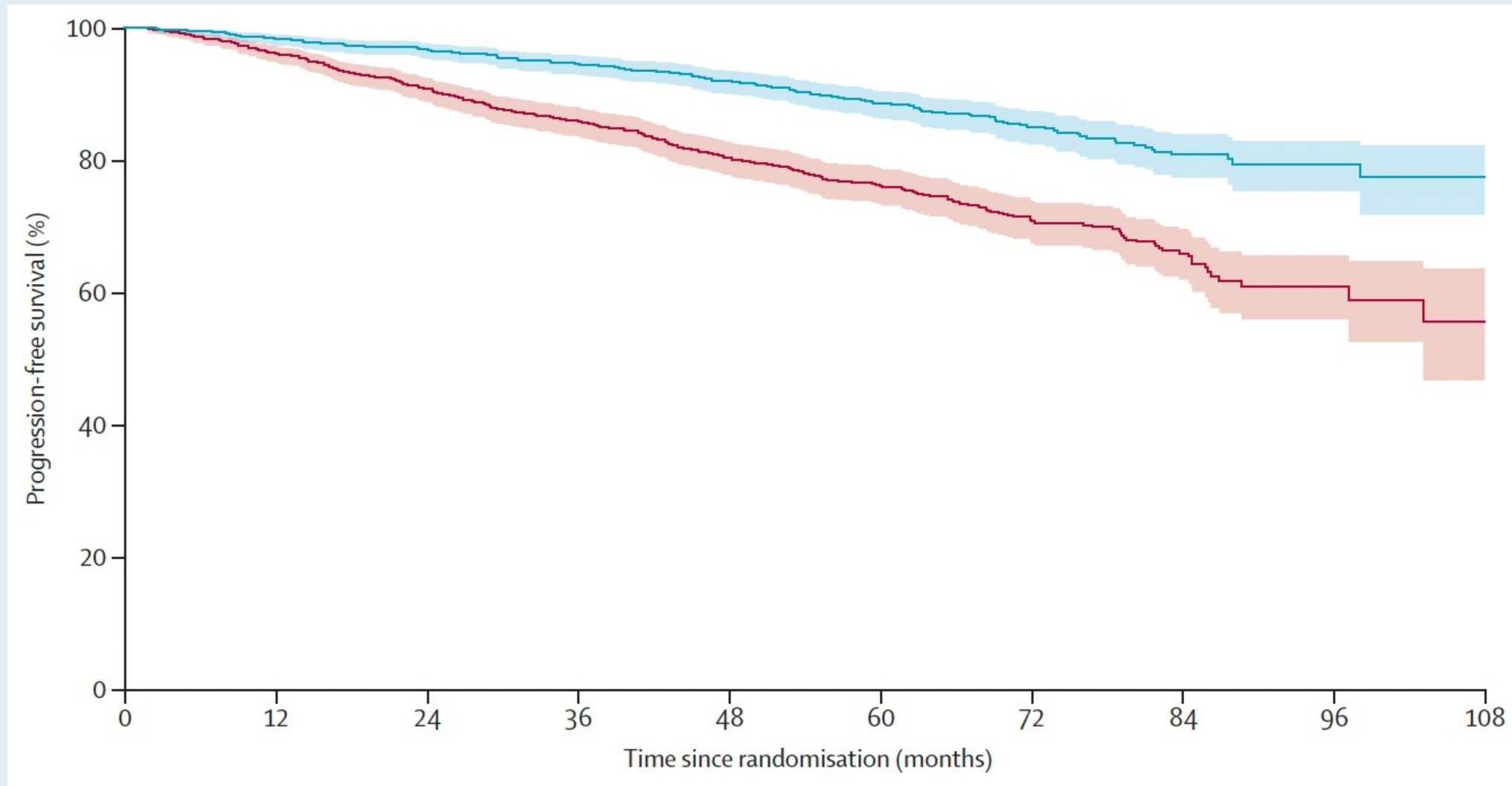
*Lancet* 2022;399(10323):447-60.

# Abiraterone acetate and prednisolone with or without enzalutamide for high-risk non-metastatic prostate cancer: a meta-analysis of primary results from two randomised controlled phase 3 trials of the STAMPEDE platform protocol

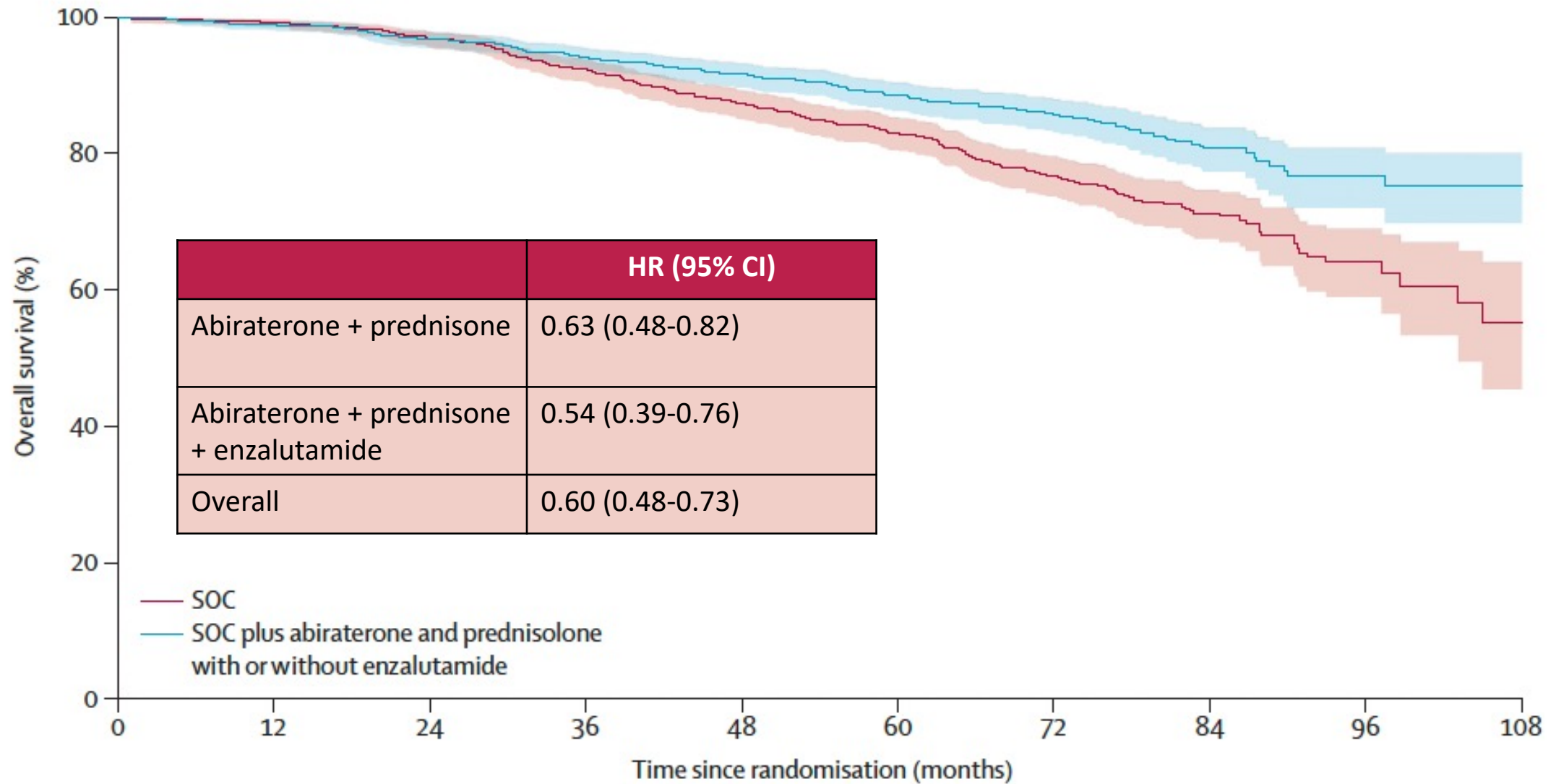


Gerhardt Attard, Laura Murphy, Noel W Clarke, William Cross, Robert J Jones, Christopher C Parker, Silke Gillessen, Adrian Cook, Chris Brawley, Claire L Amos, Nafisah Atako, Cheryl Pugh, Michelle Buckner, Simon Chowdhury, Zafar Malik, J Martin Russell, Clare Gilson, Hannah Rush, Jo Bowen, Anna Lydon, Ian Pedley, Joe M O'Sullivan, Alison Birtle, Joanna Gale, Narayanan Srihari, Carys Thomas, Jacob Tanguay, John Wagstaff, Prantik Das, Emma Gray, Mymoona Alzoueb, Omi Parikh, Angus Robinson, Isabel Syndikus, James Wylie, Anjali Zarkar, George Thalmann, Johann S de Bono, David P Dearnaley\*, Malcolm D Mason\*, Duncan Gilbert, Ruth E Langle, Robin Millman, David Matheson, Matthew R Sydes†, Louise C Brown†, Mahesh K B Parmar†, Nicholas D James†, on behalf of the Systemic Therapy in Advancing or Metastatic Prostate cancer: Evaluation of Drug Efficacy (STAMPEDE) investigators‡

# STAMPEDE: Progression-Free Survival

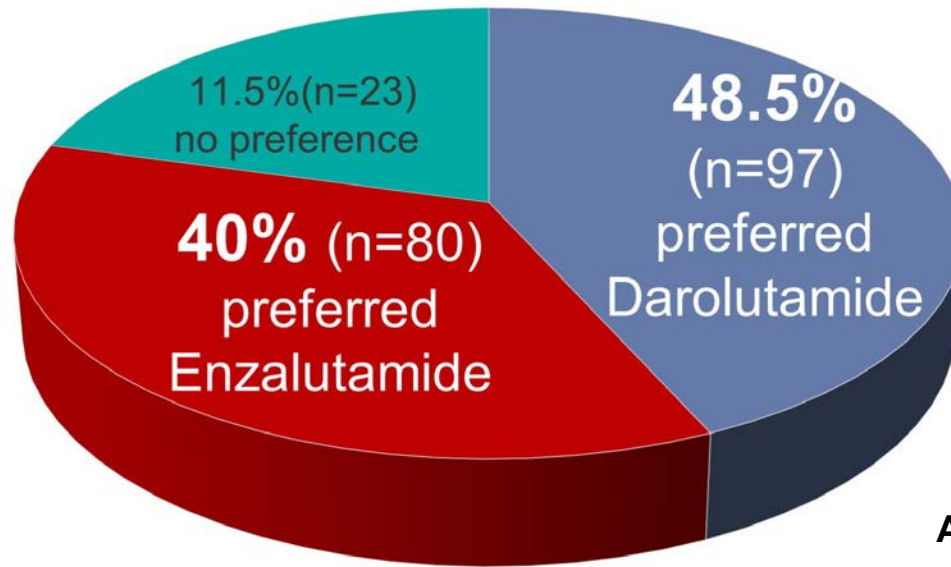


# STAMPEDE: Overall Survival

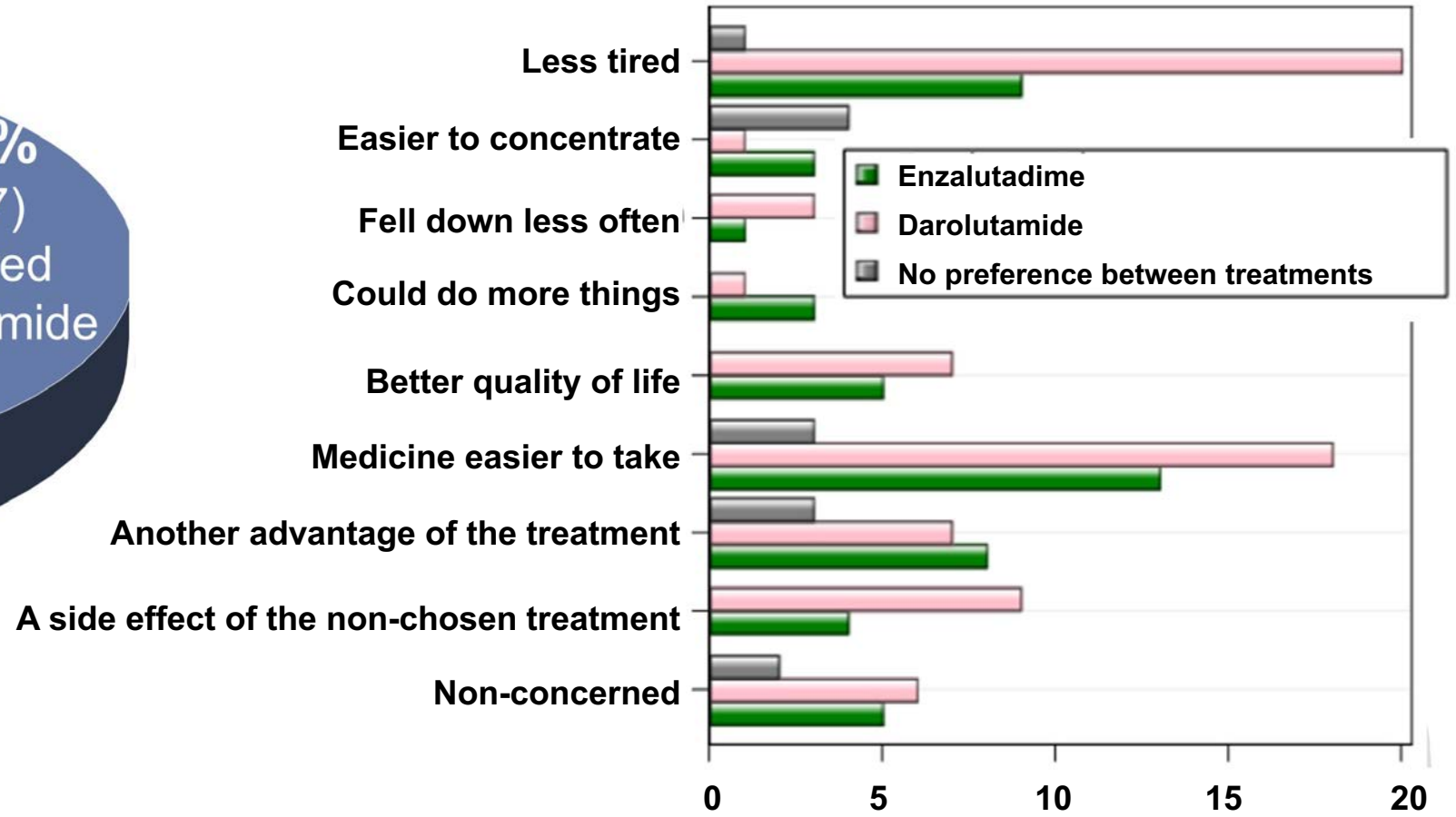




# ODENZA: A Phase II Crossover Trial Evaluating Preference Between Darolutamide and Enzalutamide Among Men with Asymptomatic or Mildly Symptomatic mCRPC



Main reasons for patient preference between treatments



# Year in Review: Prostate Cancer

**Introduction**

**MODULE 1: Endocrine Therapy**

**MODULE 2:  $^{177}\text{Lu}$ PSMA-617**

**MODULE 3: PARP Inhibitors**

**MODULE 4: Immunotherapy**

# FDA Approves <sup>177</sup>Lu-PSMA-617 for the Treatment of mCRPC

Press Release — March 23, 2022

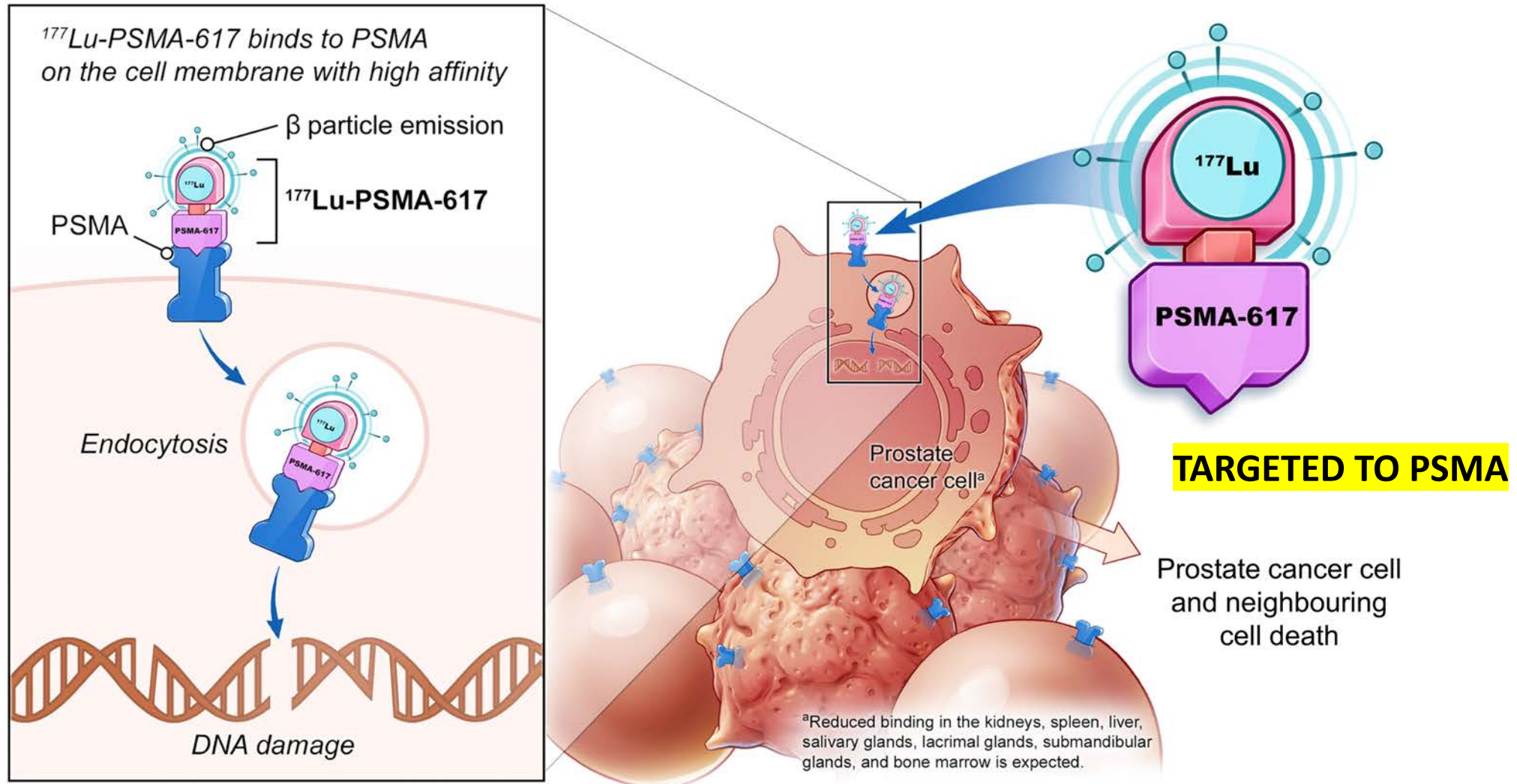
“On March 23, 2022, the Food and Drug Administration approved [the radio-ligand therapy, <sup>177</sup>Lu-PSMA-617] for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.

On the same day, the FDA approved gallium Ga 68 gozetotide, a radioactive diagnostic agent for positron emission tomography (PET) of PSMA-positive lesions, including selection of patients with metastatic prostate cancer for whom lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy is indicated. Gallium Ga 68 gozetotide is the first radioactive diagnostic agent approved for patient selection in the use of a radioligand therapeutic agent. ”

Efficacy was evaluated in the Phase III VISION trial, which demonstrated a statistically significant improvement in the primary endpoints OS and rPFS. Hazard ratio (HR) for OS was 0.62 ( $p < 0.001$ ) for the comparison of <sup>177</sup>Lu-PSMA-617 with best standard of care (BSoC) versus BSoC. Median OS was 15.3 months with <sup>177</sup>Lu-PSMA-617 and BSoC and 11.3 months with BSoC.



# $^{177}\text{Lu}$ -PSMA-617: Mechanism of Action



***N Engl J Med* 2021;385:1091-103**

*The* NEW ENGLAND JOURNAL *of* MEDICINE

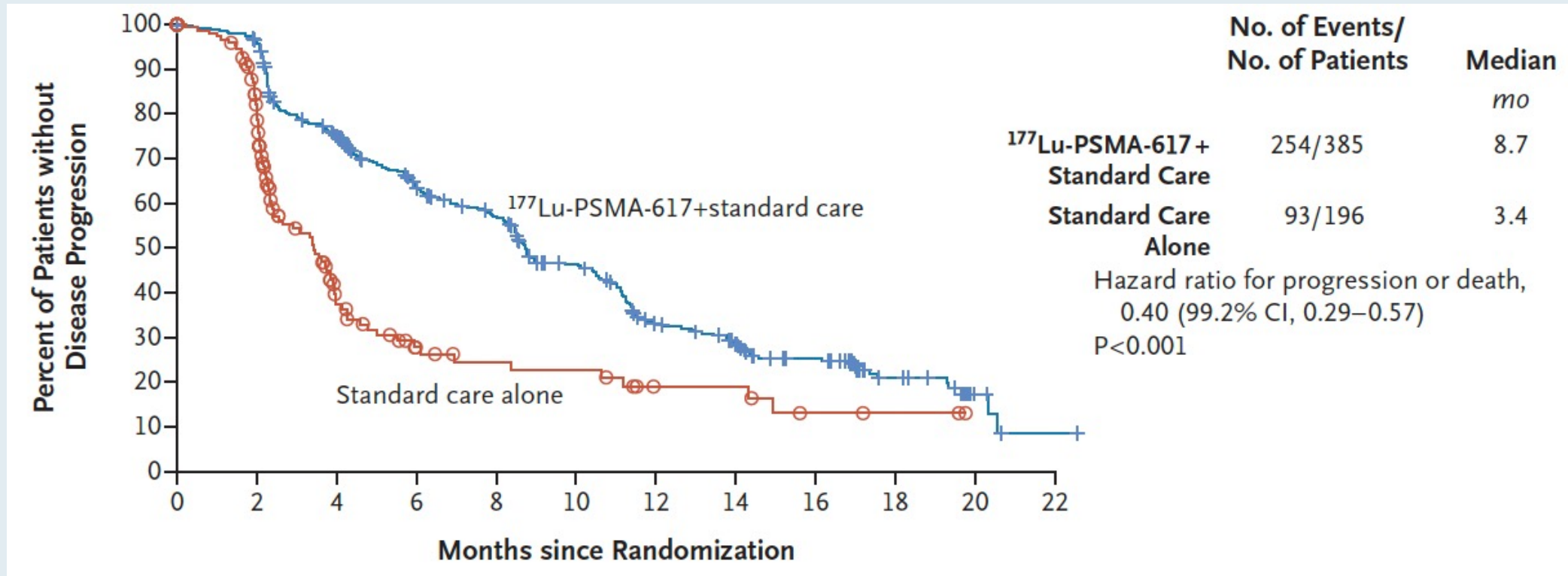
ORIGINAL ARTICLE

# Lutetium-177–PSMA-617 for Metastatic Castration-Resistant Prostate Cancer

O. Sartor, J. de Bono, K.N. Chi, K. Fizazi, K. Herrmann, K. Rahbar, S.T. Tagawa, L.T. Nordquist, N. Vaishampayan, G. El-Haddad, C.H. Park, T.M. Beer, A. Armour, W.J. Pérez-Contreras, M. DeSilvio, E. Kpamegan, G. Gericke, R.A. Messmann, M.J. Morris, and B.J. Krause, for the VISION Investigators\*

# VISION: Efficacy Summary

## Imaging-based PFS



- Median OS (<sup>177</sup>Lu-PSMA-617 vs standard therapy): 15.3 mo vs 11.3 mo (HR 0.62,  $p < 0.001$ )
- Time to first symptomatic skeletal event (<sup>177</sup>Lu-PSMA-617 vs standard therapy): 11.5 mo vs 6.8 mo (HR 0.50,  $p < 0.001$ )



# VISION: Selected Adverse Events

Event	<sup>177</sup> Lu-PSMA-617 plus Standard Care (N = 529)		Standard Care Alone (N = 205)	
	All Grades	Grade ≥3	All Grades	Grade ≥3
	<i>number of patients (percent)</i>			
Any adverse event	519 (98.1)	279 (52.7)	170 (82.9)	78 (38.0)
Adverse event that occurred in >12% of patients				
Fatigue	228 (43.1)	31 (5.9)	47 (22.9)	3 (1.5)
Dry mouth	205 (38.8)	0	1 (0.5)	0
Thrombocytopenia	91 (17.2)	42 (7.9)	9 (4.4)	2 (1.0)
Lymphopenia	75 (14.2)	41 (7.8)	8 (3.9)	1 (0.5)
Leukopenia	66 (12.5)	13 (2.5)	4 (2.0)	1 (0.5)
Adverse event that led to reduction in <sup>177</sup> Lu-PSMA-617 dose	30 (5.7)	10 (1.9)	NA	NA
Adverse event that led to interruption of <sup>177</sup> Lu-PSMA-617†	85 (16.1)	42 (7.9)	NA	NA
Adverse event that led to discontinuation of <sup>177</sup> Lu-PSMA-617†	63 (11.9)	37 (7.0)	NA	NA
Adverse event that led to death‡	19 (3.6)	19 (3.6)	6 (2.9)	6 (2.9)

Abstract 5770

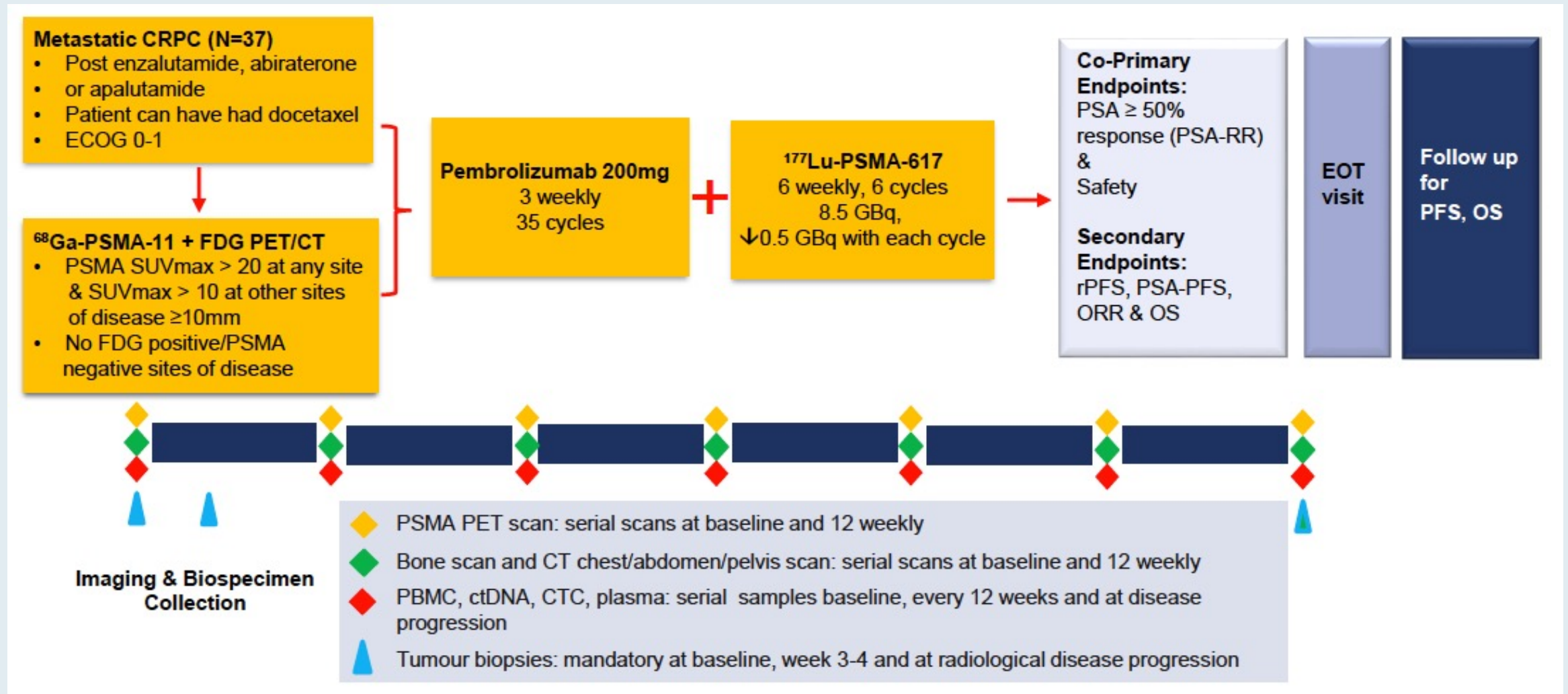
# **PRINCE: Interim Analysis of the Phase Ib Study of $^{177}\text{Lu}$ -PSMA-617 in Combination with Pembrolizumab for Metastatic Castration Resistant Prostate Cancer (mCRPC)**

Shahneen Sandhu, Anthony M. Joshua, Louise Emmett, Lavinia Spain, Lisa G. Horvath, Megan Crumbaker, Arsha Anton, Roslyn Wallace, Anupama Pasam, Mathias Bressel, Erin Cassidy, Patricia Banks, Aravind Ravi Kumar, Ramin Alipour, Tim Akhurst, Grace Kong, Ian D. Davis, Scott Williams, Rod Hicks, Michael S. Hofman



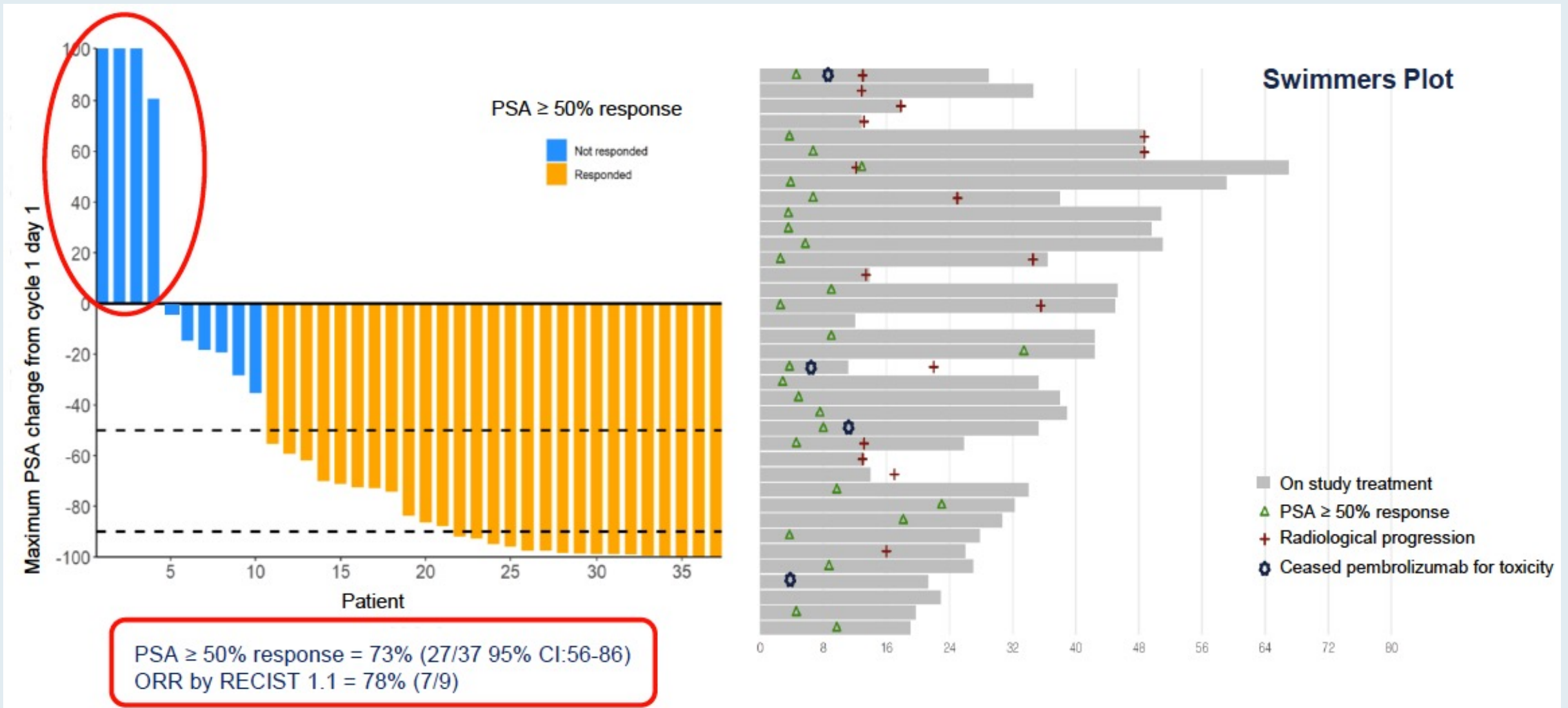
Presented by: Shahneen Sandhu

# PSMA-Lutetium Radionuclide Therapy and ImmuNotherapy for Prostate CancEr (PRINCE) Trial Schema





# PRINCE: PSA Response Rate (Primary Endpoint)



# PRINCE: Treatment-Related Adverse Events (TRAEs)

TRAE term	Grade 1 (%)	Grade 2 (%)	Grade 3 (%)	N=37 (%)
Xerostomia	21 (57%)	7 (19%)	-	28 (76%)
Fatigue	11 (29 %)	3 (8%)	2 (5%)	16 (43%)
Rash	5 (14%)	4 (11%)	-	9 (25%)
Nausea	8 (21%)	1 (3%)	-	9 (24%)
Pruritis	6 (16%)	1 (3%)	-	7 (19%)
Anorexia	3 (8%)	3 (8%)	-	6 (16%)
Thrombocytopenia	4 (11%)	1(3%)	-	5 (14%)
Bone pain (flare)	4 (11%)	-	-	4 (11%)
Aspartate aminotransferase elevation	2 (5%)	2 (5%)	-	4 (11%)
Dry eye	3 (8%)	-	-	3 (8%)
Dysgeusia	2 (5%)	1 (3%)	-	3 (8%)
Weight loss	2 (5%)	1 (3%)	-	3 (8%)
Anemia	-	2 (5%)	1(3%)	3 (8%)
Alanine aminotransferase elevation	2 (5%)	1(3%)	-	3 (8%)
Amylase elevation	1 (3%)	1 (3%)	1 (3%)	3 (8%)
Arthralgia	3 (8%)	-	-	3 (8%)
Neutropenia	1 (3%)	-	-	1 (3%)

- Treatment related adverse events (TRAEs) in by worst grade affecting > 5% and all hematological toxicity
- There were no grade 4 TRAEs or treatment related deaths

<b>Pembrolizumab cycles:</b> Median (range)	8 (1 - 22)
<b><sup>177</sup>Lu-PSMA-617 cycles:</b> Median (range)	4 (2 - 6)
<b>Discontinuation for toxicity:</b> Pembrolizumab, n (%) <sup>177</sup> Lu-PSMA-617, n (%)	4 (11%) 0 (0%)



# **<sup>177</sup>Lu-PSMA-617 (LuPSMA) versus Cabazitaxel in Metastatic Castration-Resistant Prostate Cancer (mCRPC) Progressing After Docetaxel: Updated Results Including Progression-Free Survival (PFS) and Patient-Reported Outcomes (PROs) (TheraP ANZUP 1603)<sup>1</sup>**

**[<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<sup>2</sup>**

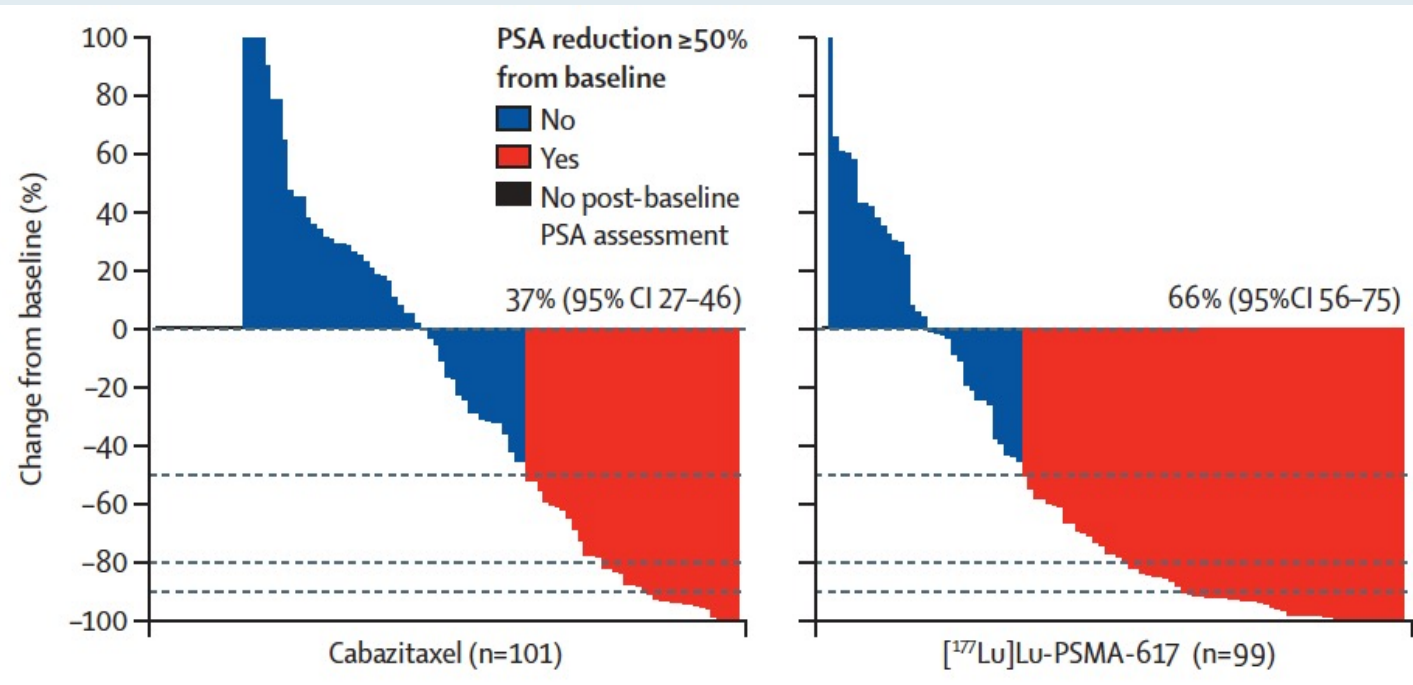
*Michael S Hofman, Louise Emmett, Shahneen Sandhu, Amir Iravani, Anthony M Joshua, Jeffrey C Goh, David A Pattison, Thean Hsiang Tan, Ian D Kirkwood, Siobhan Ng, Roslyn J Francis, Craig Gedye, Natalie K Rutherford, Andrew Weickhardt, Andrew M Scott, Sze-Ting Lee, Edmond M Kwan, Arun A Azad, Shakher Ramdave, 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†*

<sup>1</sup> Hofman MS et al. Genitourinary Cancers Symposium 2021;Abstract 6.

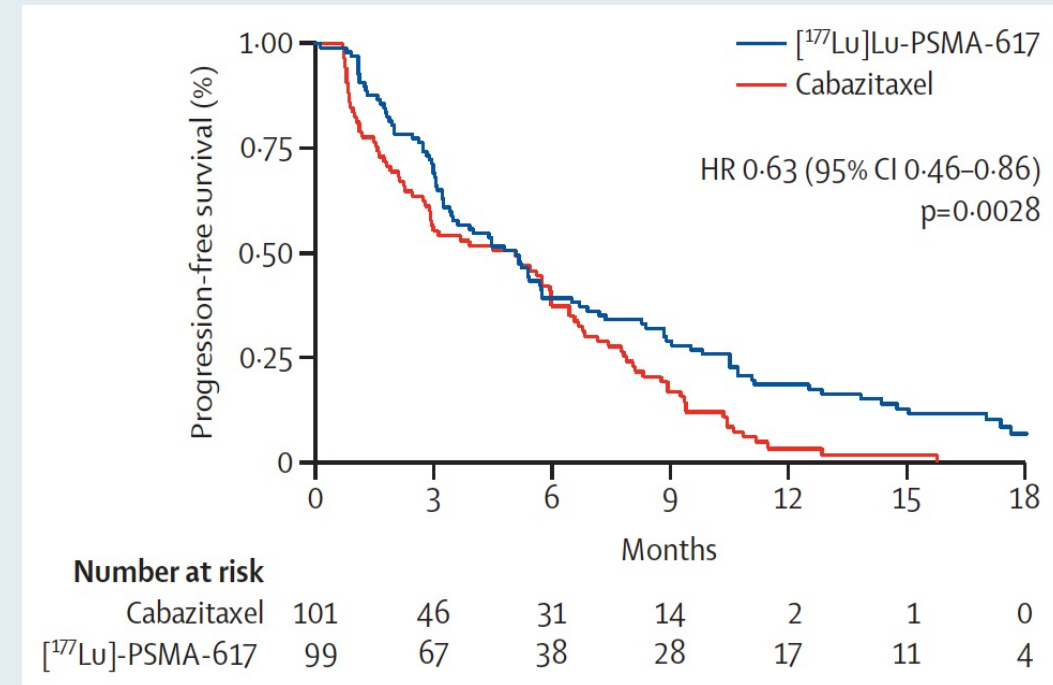
<sup>2</sup> Hofman MS et al. *Lancet* 2021;397(10276):797-804.

# TheraP ANZUP 1603: PSA Response and PFS

## PSA response



## Radiographic or PSA progression-free survival



# Year in Review: Prostate Cancer

**Introduction**

**MODULE 1: Endocrine Therapy**

**MODULE 2:  $^{177}\text{Lu}$  Lutetium-PSMA-617**

**MODULE 3: PARP Inhibitors**

**MODULE 4: Immunotherapy**



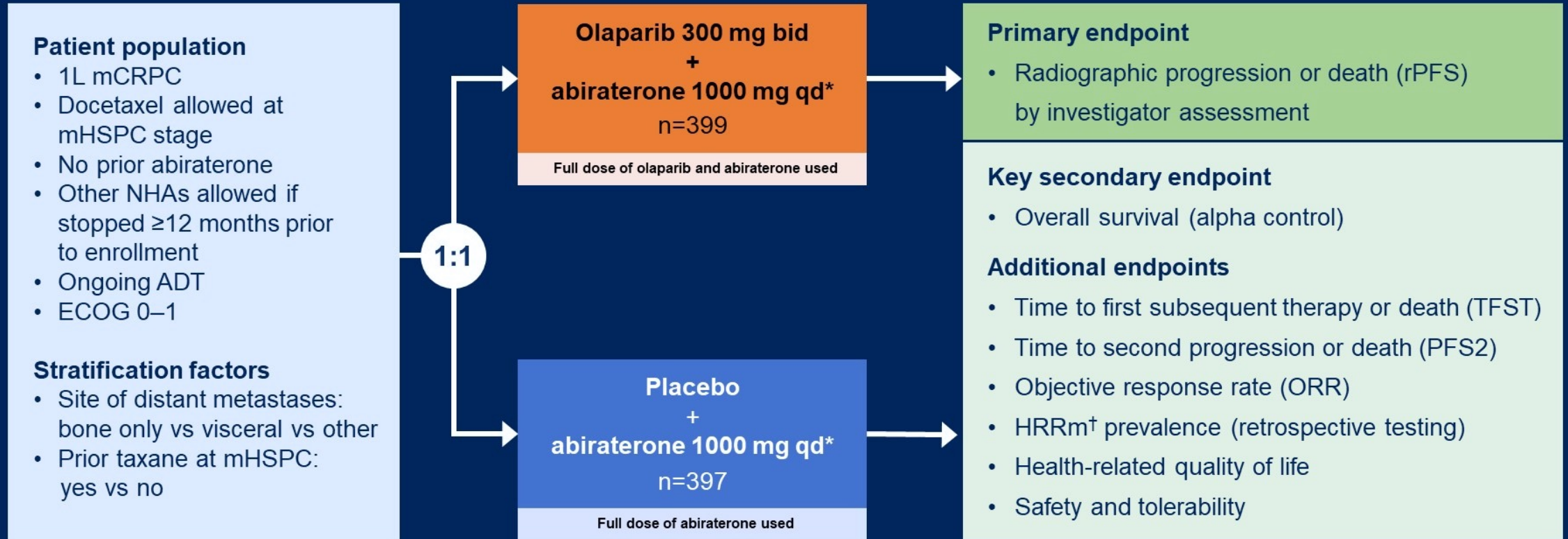
# **PROpel: phase III trial of olaparib and abiraterone versus placebo and abiraterone as first-line therapy for patients with metastatic castration-resistant prostate cancer**

Fred Saad, Andrew J. Armstrong, Antoine Thiery-Vuillemin, Mototsugu Oya, Eugenia Loredi, Giuseppe Procopio, Juliana de Menezes, Gustavo Giroto, Cagatay Arslan, Niven Mehra, Francis Parnis, Emma Brown, Friederike Schlürmann, Jae Young Joung, Mikio Sugimoto, Christian Poehlein, Elizabeth A. Harrington, Chintu Desai, Jinyu Kang, and Noel Clarke

ClinicalTrials.gov identifier: NCT03732820.



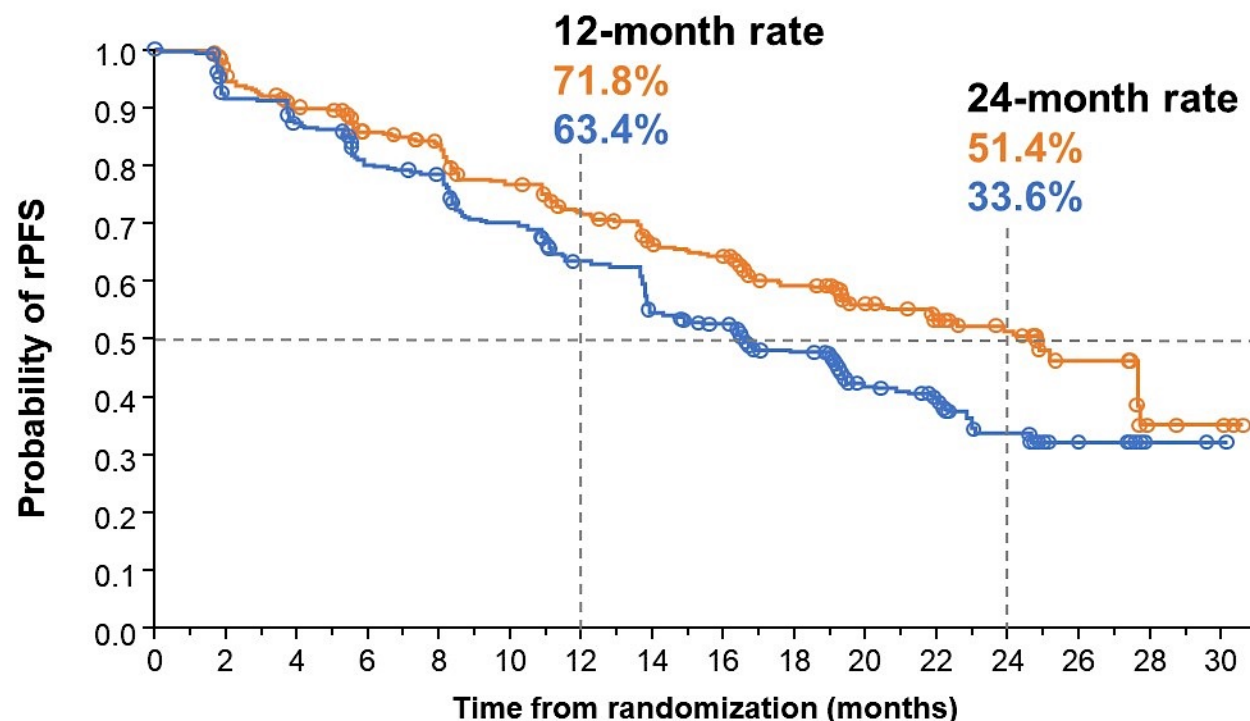
# PROpel: Study Design



First patient randomized: Nov 2018; Last patient randomized: Mar 2020; DCO1: July 30, 2021, for interim analysis of rPFS and OS.  
Multiple testing procedure is used in this study: 1-sided alpha of 0.025 fully allocated to rPFS. If the rPFS result is statistically significant, OS to be tested in a hierarchical fashion with alpha passed on to OS.  
Please access the **Supplement** via the QR code at the end of this presentation for more details.  
\*In combination with prednisone or prednisolone 5 mg bid. <sup>†</sup>HRRm, homologous recombination repair mutation, including 14 genes panel.  
ADT, androgen deprivation therapy; bid, twice daily; ECOG, Eastern Cooperative Oncology Group; mHSPC, metastatic hormone sensitive prostate cancer; qd, daily

# PROpel Primary Endpoint: Investigator-Assessed rPFS

34% risk reduction of progression or death with olaparib + abiraterone



No. at risk

**Olaparib + abiraterone** 399 395 367 354 340 337 313 309 301 277 274 265 251 244 277 221 219 170 167 163 104 100 87 59 57 28 26 25 5 4 4 0  
**Placebo + abiraterone** 397 393 359 356 338 334 306 303 297 266 264 249 232 228 198 190 186 143 141 137 87 84 73 45 43 21 17 16 2 2 1 0

	Olaparib + abiraterone (n=399)	Placebo + abiraterone (n=397)
Events, n (%)	168 (42.1)	226 (56.9)
Median rPFS (months)	24.8	16.6
HR (95% CI)	0.66 (0.54–0.81); P<0.0001	

Pre-specified 2-sided alpha: 0.0324

**Median rPFS improvement of 8.2 months favors olaparib + abiraterone\***

Events: 394; Maturity 49.5%

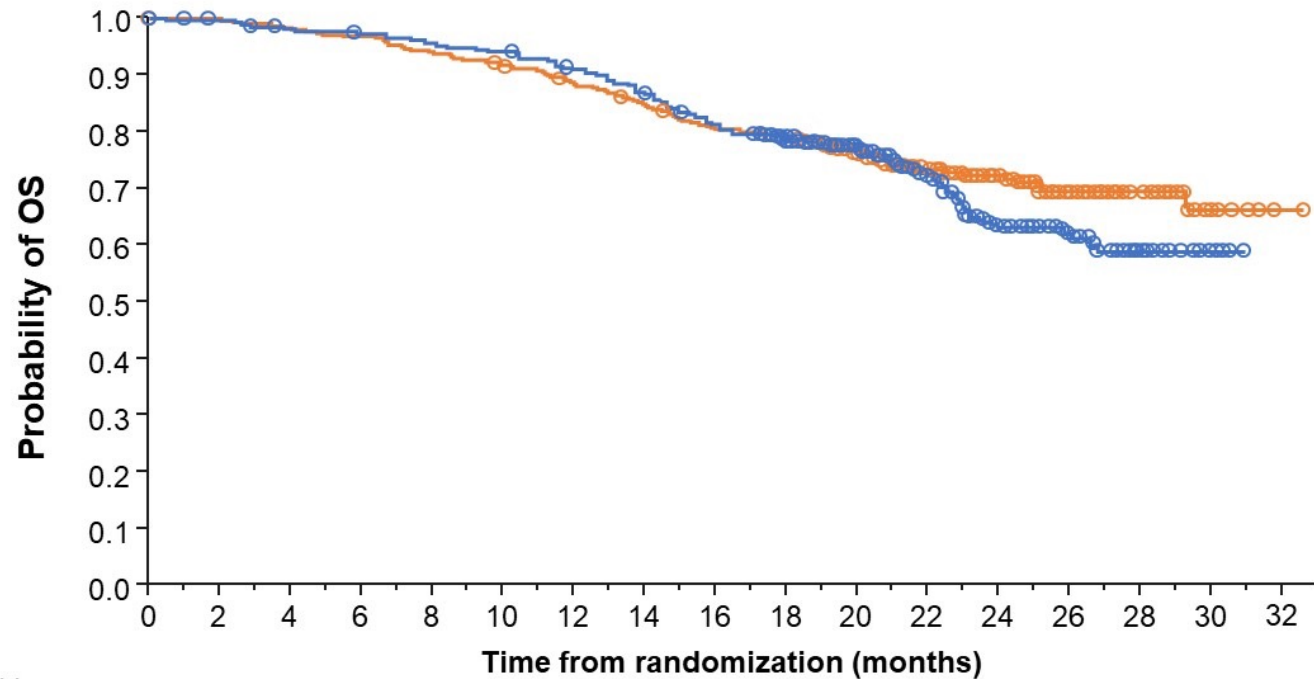
\*In combination with prednisone or prednisolone

CI, confidence interval; HR, hazard ratio.



# PROpel: Overall Survival

28.6% maturity; trend towards improved OS with olaparib + abiraterone



No. at risk

Olaparib + abiraterone 399 398 398 394 391 387 385 379 374 369 364 359 349 343 333 322 316 313 290 263 231 193 159 135 116 92 73 51 37 24 11 4 1 0  
Placebo + abiraterone 397 394 392 386 385 383 381 377 374 371 368 363 353 345 335 322 314 308 286 258 223 186 151 121 104 88 63 44 22 13 6 0 0 0

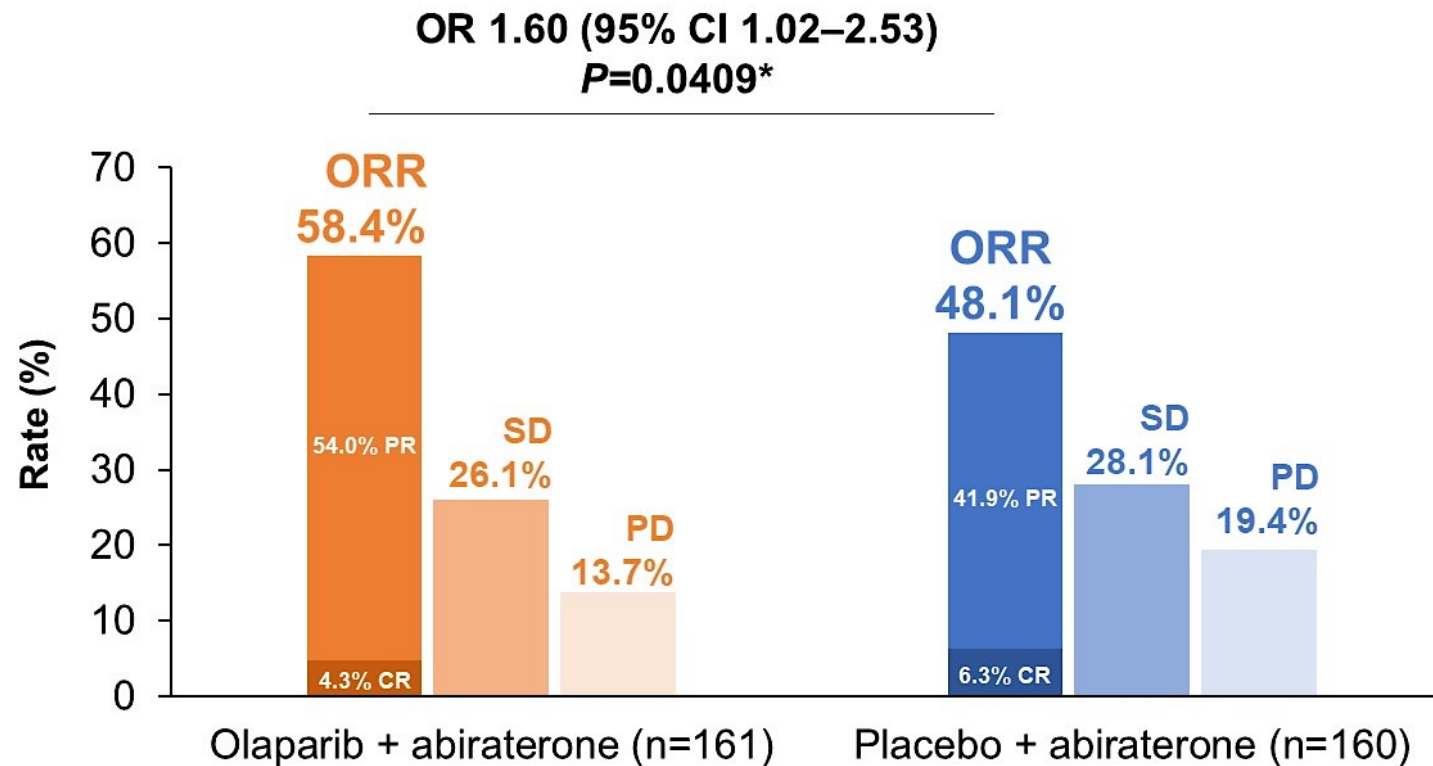
	Olaparib + abiraterone (n=399)	Placebo + abiraterone (n=397)
Events, n (%)	107 (26.8)	121 (30.5)
Median OS (months)	NR	NR
HR (95% CI)	0.86 (0.66–1.12) P=0.29	

Pre-specified 2-sided alpha: 0.001

Events: 228  
NR, not reached.

# PROpel: ORR for Patients with Measurable Disease

10% improvement in ORR with olaparib + abiraterone



321/796 patients (40.3%)  
had measurable disease  
by RECIST v1.1 criteria  
at baseline

\*Nominal.

CR, complete response; OR, odds ratio; ORR, overall response rate; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.

# PROpel: Cardiac and Thromboembolic Adverse Events

n (%)	Olaparib + abiraterone (n=399)	Placebo + abiraterone (n=397)
<b>Cardiac failure SMQ</b>	6 (1.5)	5 (1.3)
<b>Embolic and thrombotic events, arterial SMQ</b>	8 (2.0)	10 (2.5)
<b>Embolic and thrombotic events, venous SMQ</b>	29 (7.3)	13 (3.3)
Pulmonary embolism	26 (6.5)	7 (1.8)

CT, computerized tomography; SMQ, Standardised MedDRA Query.



## Phase 3 MAGNITUDE study: First results of niraparib (NIRA) with abiraterone acetate and prednisone (AAP) as first-line therapy in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) with and without homologous recombination repair (HRR) gene alterations

**Kim N. Chi,**<sup>1</sup> Dana E. Rathkopf,<sup>2</sup> Matthew R. Smith,<sup>3</sup> Eleni Efstathiou,<sup>4</sup> Gerhardt Attard,<sup>5</sup> David Olmos,<sup>6</sup> Ji Youl Lee,<sup>7</sup> Eric J. Small,<sup>8</sup> Andrea J. Pereira de Santana Gomes,<sup>9</sup> Guilhem Roubaud,<sup>10</sup> Marniza Saad,<sup>11</sup> Bogdan Zurawski,<sup>12</sup> Valerii Sakalo,<sup>13</sup> Gary E. Mason,<sup>14</sup> Adam del Corral,<sup>15</sup> George Wang,<sup>14</sup> Daphne Wu,<sup>16</sup> Brooke Diorio,<sup>17</sup> Angela Lopez-Gitlitz,<sup>16</sup> Shahneen Sandhu<sup>18</sup>

<sup>1</sup>University of British Columbia, BC Cancer – Vancouver Center, Vancouver, BC, Canada; <sup>2</sup>Memorial Sloan Kettering Cancer Center and Weill Cornell Medicine, New York, NY, USA; <sup>3</sup>Massachusetts General Hospital Cancer Center and Harvard Medical School, Boston, MA, USA; <sup>4</sup>Houston Methodist Cancer Center, Houston, TX, USA; <sup>5</sup>University College London, London, UK; <sup>6</sup>Department of Medical Oncology, Hospital Universitario 12 de Octubre, Instituto de Investigación Sanitaria Hospital 12 de Octubre (imas12), Madrid, Spain; <sup>7</sup>Department of Urology Cancer Center, Seoul St. Mary's Hospital, The Catholic University of Korea, Seoul, South Korea; <sup>8</sup>Helen Diller Family Comprehensive Cancer Center, University of California San Francisco, San Francisco, CA, USA; <sup>9</sup>Liga Norte Riograndense Contra o Câncer, Natal, Brazil; <sup>10</sup>Department of Medical Oncology, Institut Bergonié, Bordeaux, France; <sup>11</sup>Department of Clinical Oncology, Faculty of Medicine, University of Malaya, Kuala Lumpur, Malaysia; <sup>12</sup>Department of Outpatient Chemotherapy, Professor Franciszek Lukaszczyk Oncology Center, Bydgoszcz, Poland; <sup>13</sup>Institute of Urology named after Academician OF Vozianov of NAMS of Ukraine, Kyiv, Ukraine; <sup>14</sup>Janssen Research & Development, Spring House, PA, USA; <sup>15</sup>Janssen Research & Development, Bridgewater, NJ, USA; <sup>16</sup>Janssen Research & Development, Los Angeles, CA, USA; <sup>17</sup>Janssen Research & Development, Titusville, NJ, USA; <sup>18</sup>Peter MacCallum Cancer Center and the University of Melbourne, Melbourne, Australia

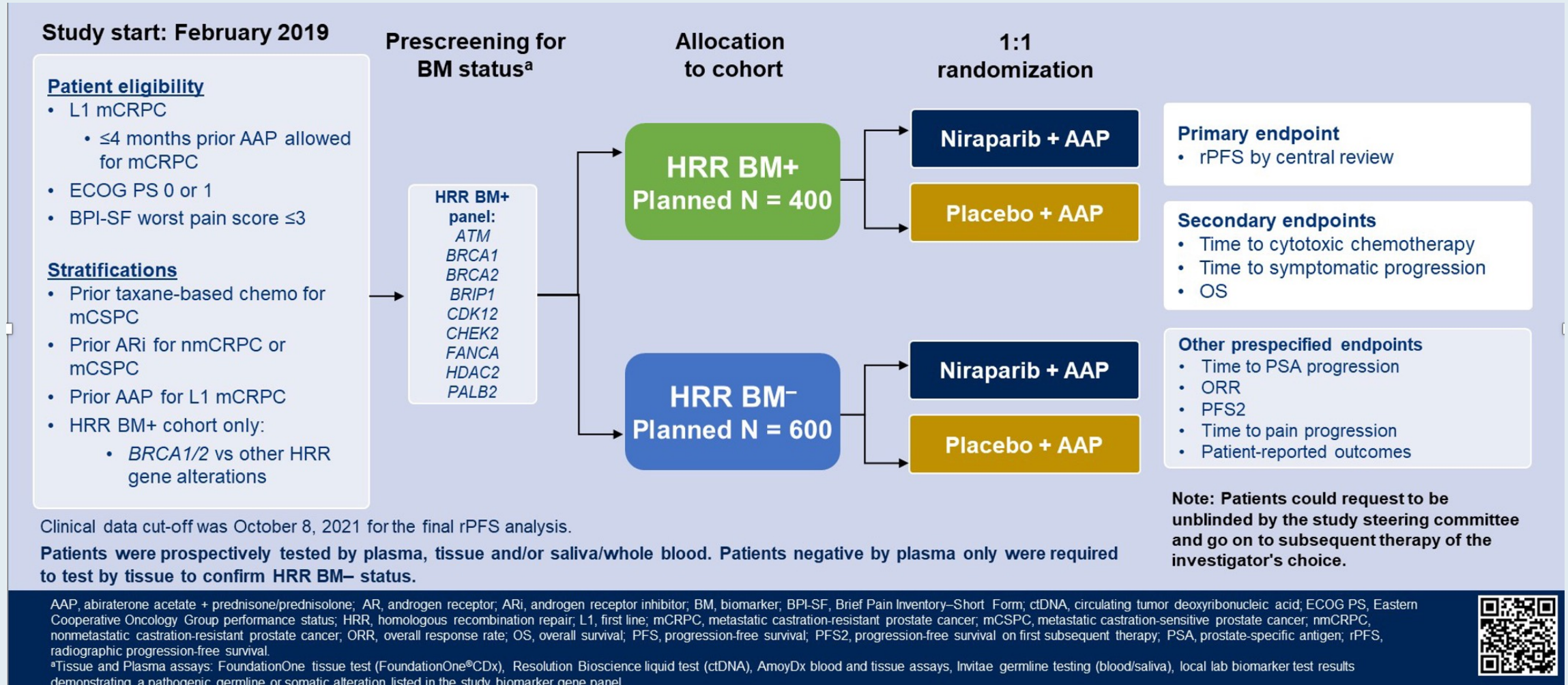
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# MAGNITUDE: Randomized, Double-Blind, Placebo-Controlled Study

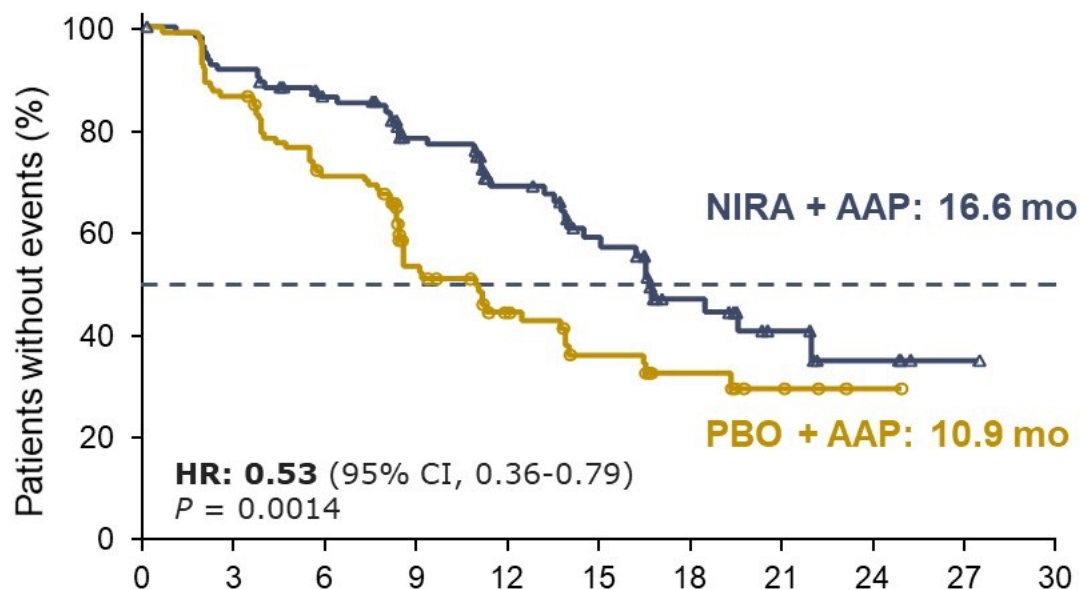
## Prospectively Selected Biomarker (BM) Cohorts Designed to Test HRR BM+ and HRR BM-



# MAGNITUDE BRCA1/2 Mutations: Primary Endpoint

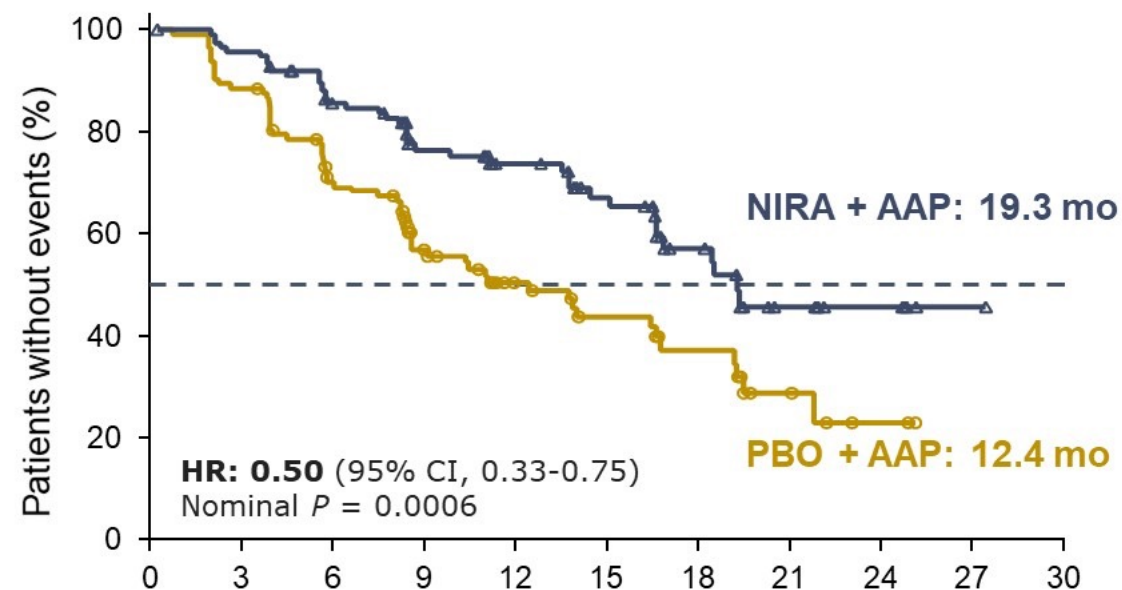
## NIRA + AAP Significantly Reduced the Risk of Disease Progression or Death by 47%

rPFS assessed by central review



No. at risk	Months from randomization										
NIRA + AAP	113	103	90	65	45	31	18	9	4	1	0
PBO + AAP	112	97	77	43	28	20	11	5	2	0	0

rPFS assessed by investigator

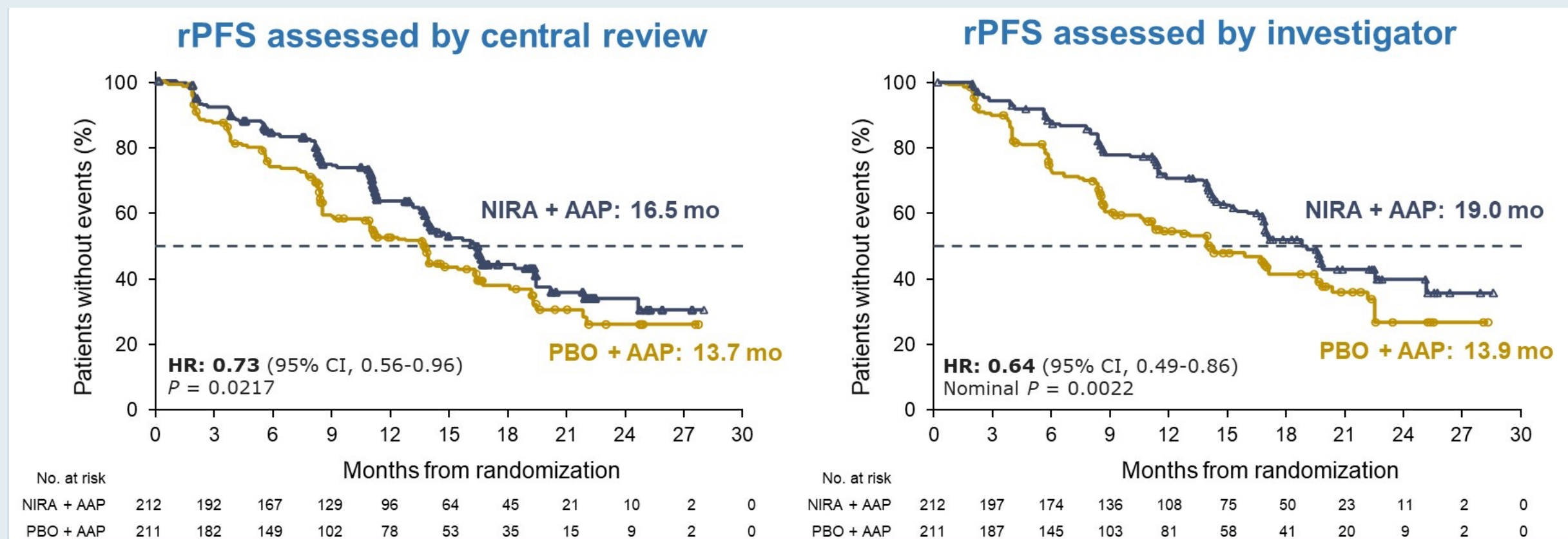


No. at risk	Months from randomization										
NIRA + AAP	113	107	90	64	49	36	23	10	5	1	0
PBO + AAP	112	99	73	45	32	23	14	6	2	0	0

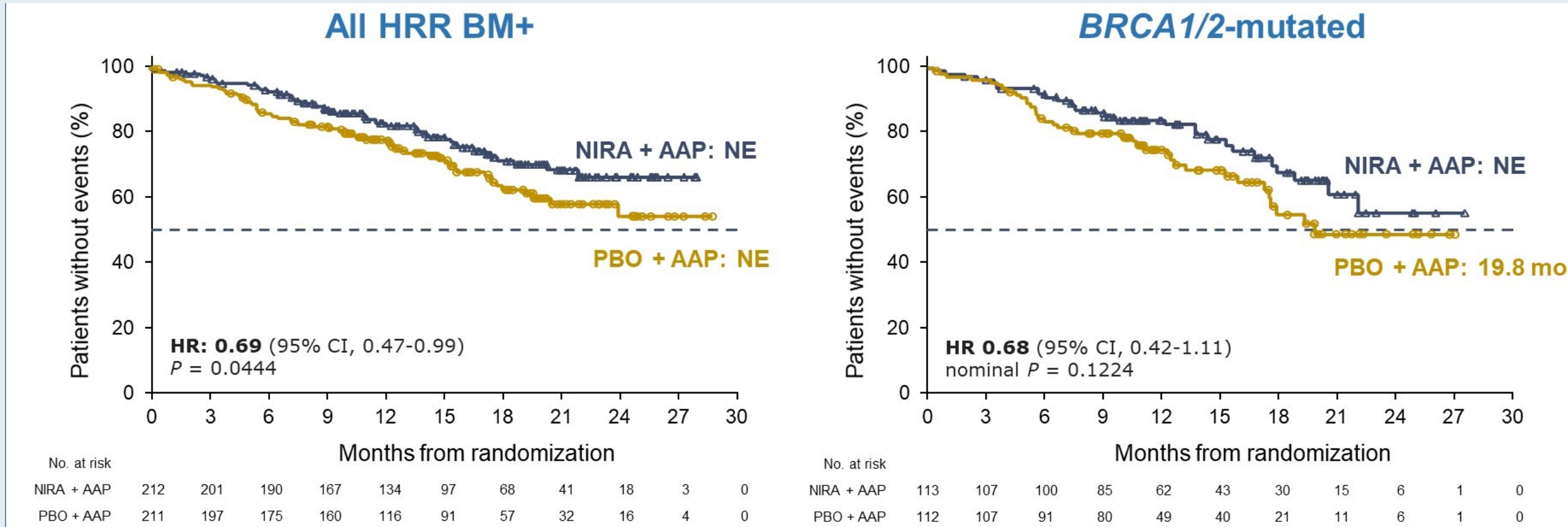


# MAGNITUDE All HRR Biomarker-Positive: Primary Endpoint

## NIRA + AAP Significantly Reduced the Risk of Disease Progression or Death by 27%



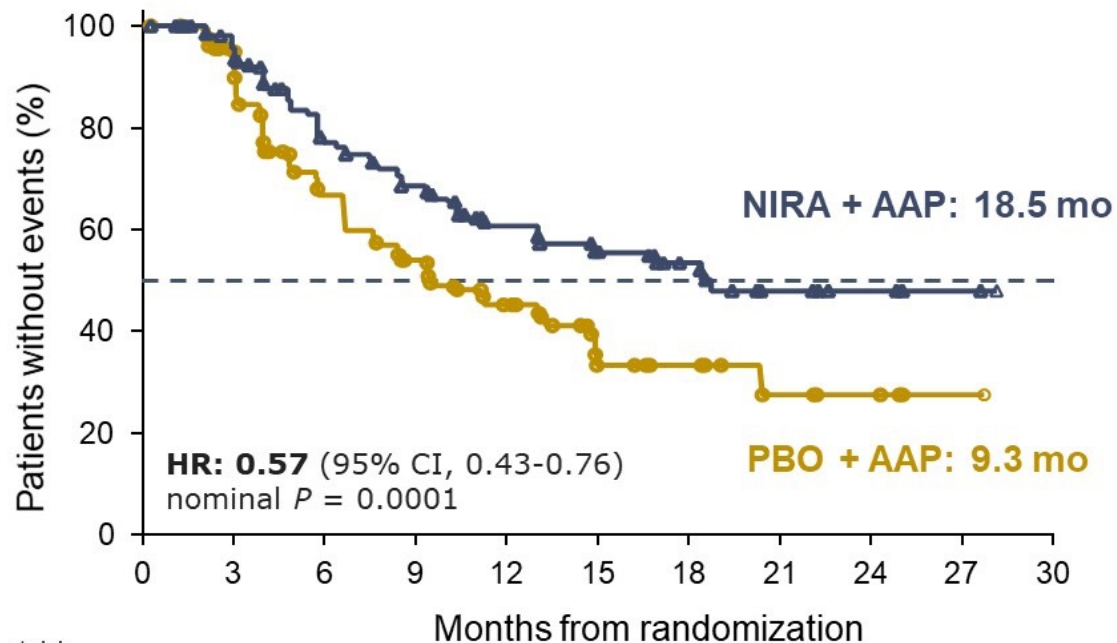
# MAGNITUDE: NIRA + AAP Delays Time to Symptomatic Progression Across Gene Alterations



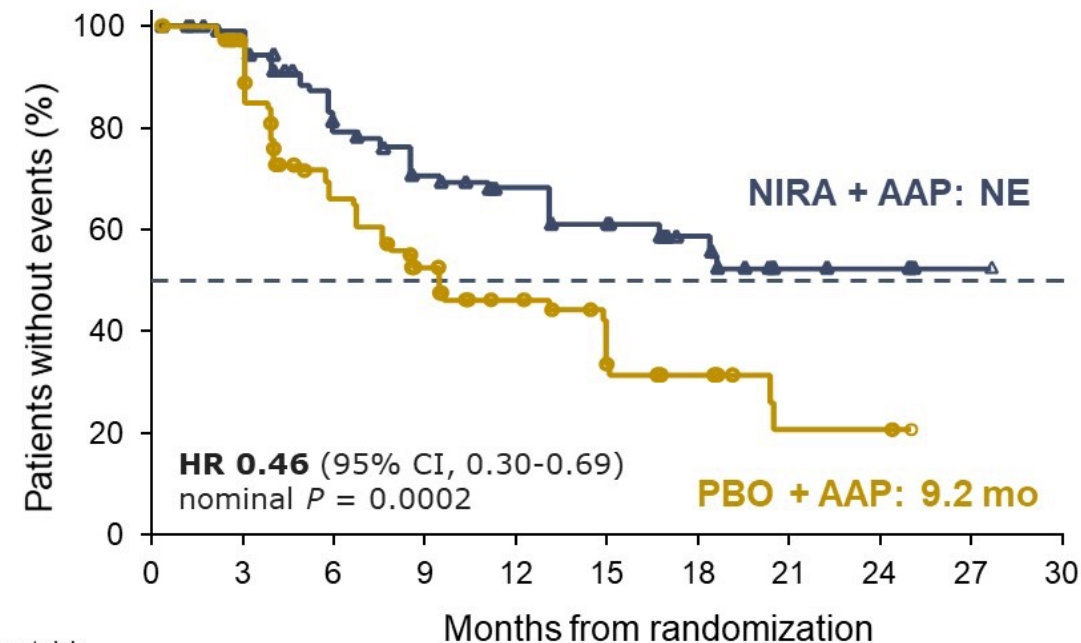
**NIRA + AAP provides >30% improvement in time to symptomatic progression in evaluated groups**

# MAGNITUDE: NIRA + AAP Consistently Prolongs Time to PSA Progression Across Gene Alterations

All HRR BM+

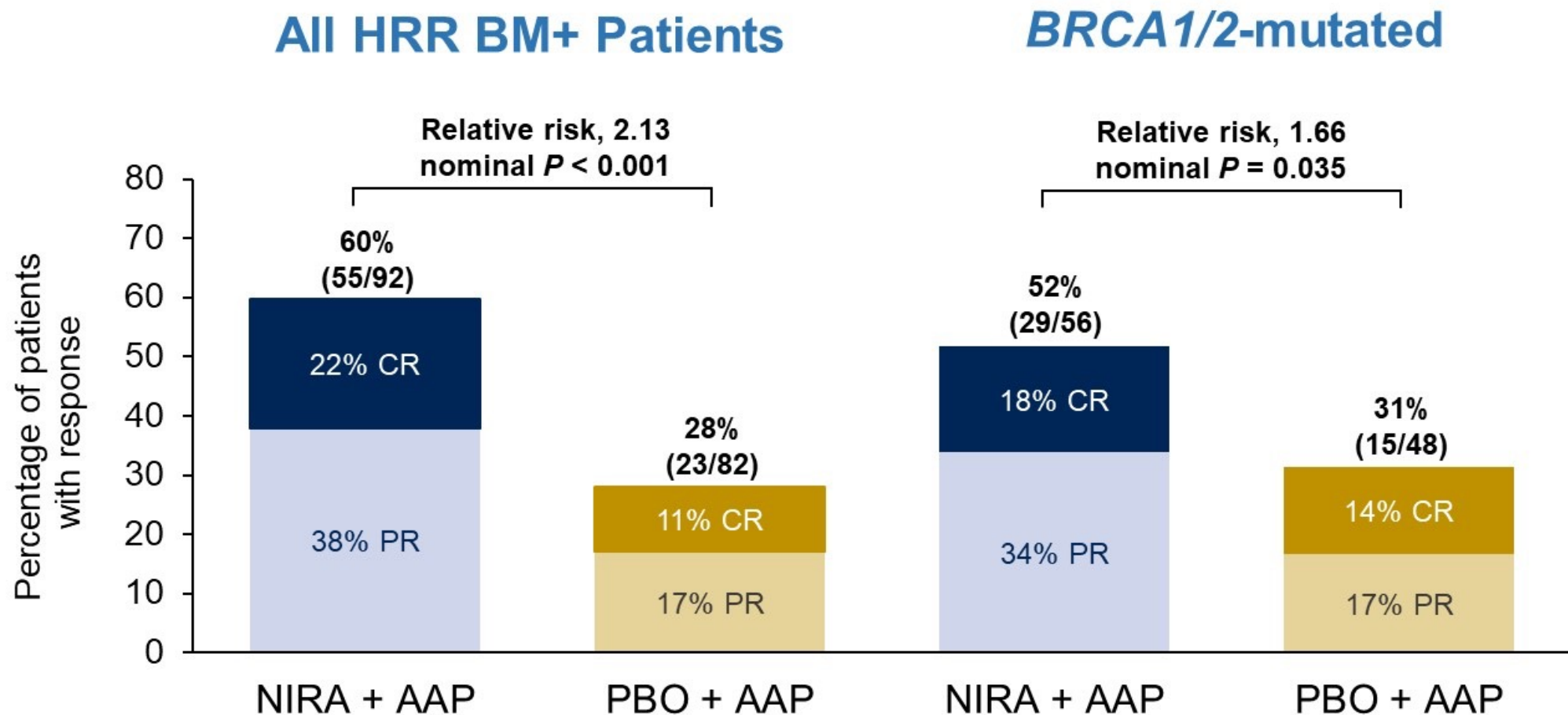


BRCA1/2-mutated



**NIRA + AAP nearly doubles the median time to PSA progression with 43% improvement**

# MAGNITUDE: NIRA + AAP Improves Overall Response Rate Consistently Across Gene Alterations



NIRA + AAP nearly doubles ORR rate and provides deeper response in patients with measurable disease

# Year in Review: Prostate Cancer

**Introduction**

**MODULE 1: Endocrine Therapy**

**MODULE 2:  $^{177}$ Lutetium-PSMA-617**

**MODULE 3: PARP Inhibitors**

**MODULE 4: Immunotherapy**



# Cabozantinib in combination with atezolizumab in patients with metastatic castration-resistant prostate cancer (mCRPC): results of expanded cohort 6 of the COSMIC-021 Study

Neeraj Agarwal,<sup>1</sup> Bradley McGregor,<sup>2</sup> Benjamin L. Maughan,<sup>1</sup> Tanya B. Dorff,<sup>3</sup> William Kelly,<sup>4</sup> Bruno Fang,<sup>5</sup> Rana R. McKay,<sup>6</sup> Parminder Singh,<sup>7</sup> Lance Pagliaro,<sup>8</sup> Robert Dreicer,<sup>9</sup> Sandy Srinivas,<sup>10</sup> Yohann Loriot,<sup>11</sup> Ulka Vaishampayan,<sup>12</sup> Sanjay Goel,<sup>13</sup> Dominic Curran,<sup>14</sup> Ashok Panneerselvam,<sup>14</sup> Li-Fen Liu,<sup>14</sup> Toni K. Choueiri,<sup>2\*</sup> Sumanta Pal<sup>3\*</sup>

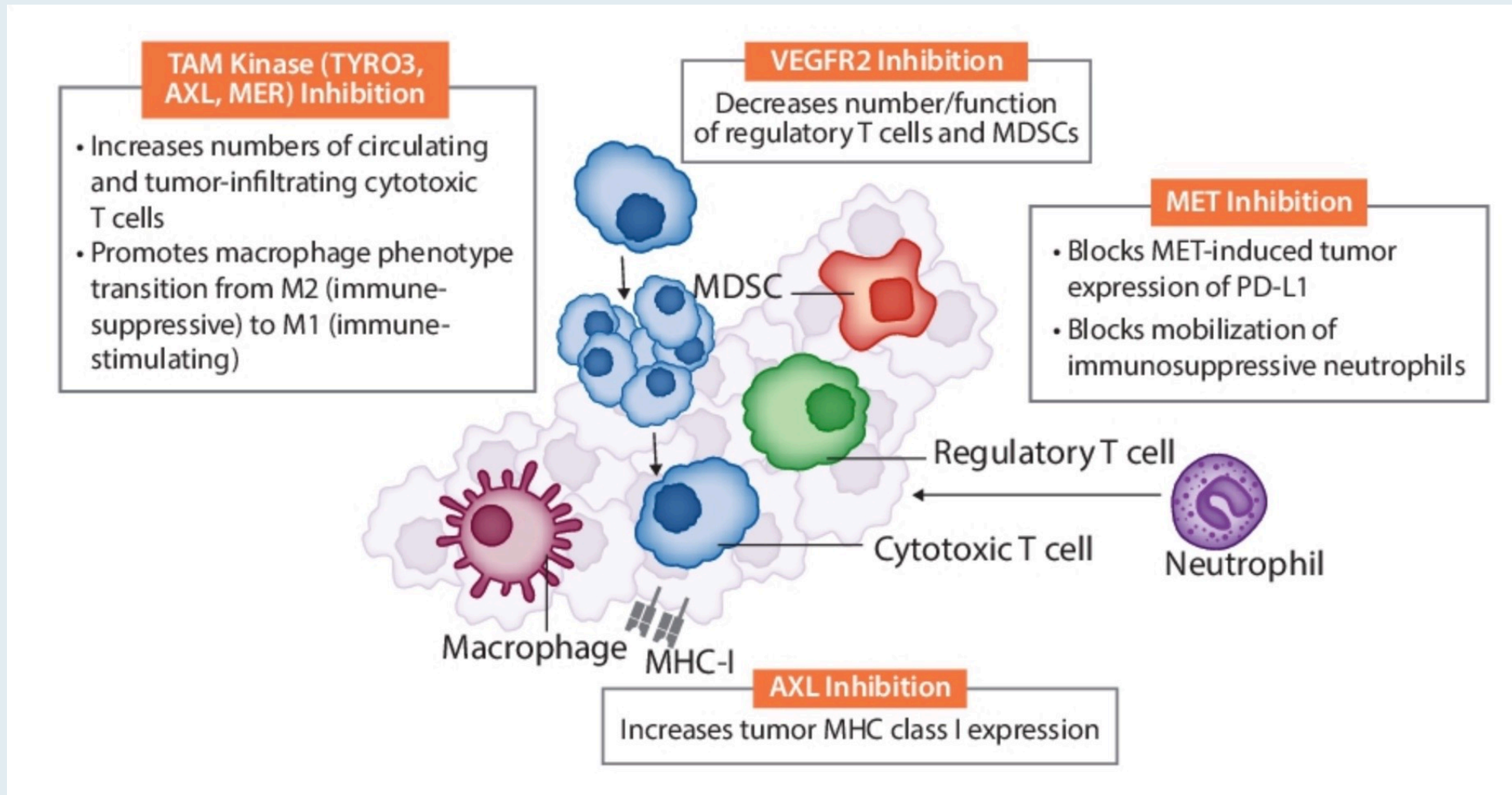
<sup>1</sup>Huntsman Cancer Institute, University of Utah, Salt Lake City, UT, USA; <sup>2</sup>Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA, USA; <sup>3</sup>City of Hope Comprehensive Cancer Center, Duarte, CA, USA; <sup>4</sup>Sidney Kimmel Cancer Center, Thomas Jefferson University, Philadelphia, PA, USA; <sup>5</sup>Regional Cancer Care Associates, East Brunswick, NJ, USA; <sup>6</sup>University of California San Diego, San Diego, CA, USA; <sup>7</sup>Department of Oncology, Mayo Clinic, Scottsdale, AZ, USA; <sup>8</sup>Department of Oncology, Mayo Clinic, Rochester, MN, USA; <sup>9</sup>University of Virginia Cancer Center, Charlottesville, VA, USA; <sup>10</sup>Division of Medical Oncology, Stanford University Medical Center, Stanford, CA, USA; <sup>11</sup>Department of Cancer Medicine, Gustave Roussy Institute, INSERM 981, University Paris-Saclay, Villejuif, France; <sup>12</sup>Karmanos Cancer Center, Wayne State University, Detroit, MI, USA (Current affiliation: Division of Hematology/Oncology, University of Michigan, Ann Arbor, MI, USA); <sup>13</sup>Department of Medical Oncology, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY, USA; <sup>14</sup>Exelixis, Inc., Alameda, CA, USA

\*Co-senior authors

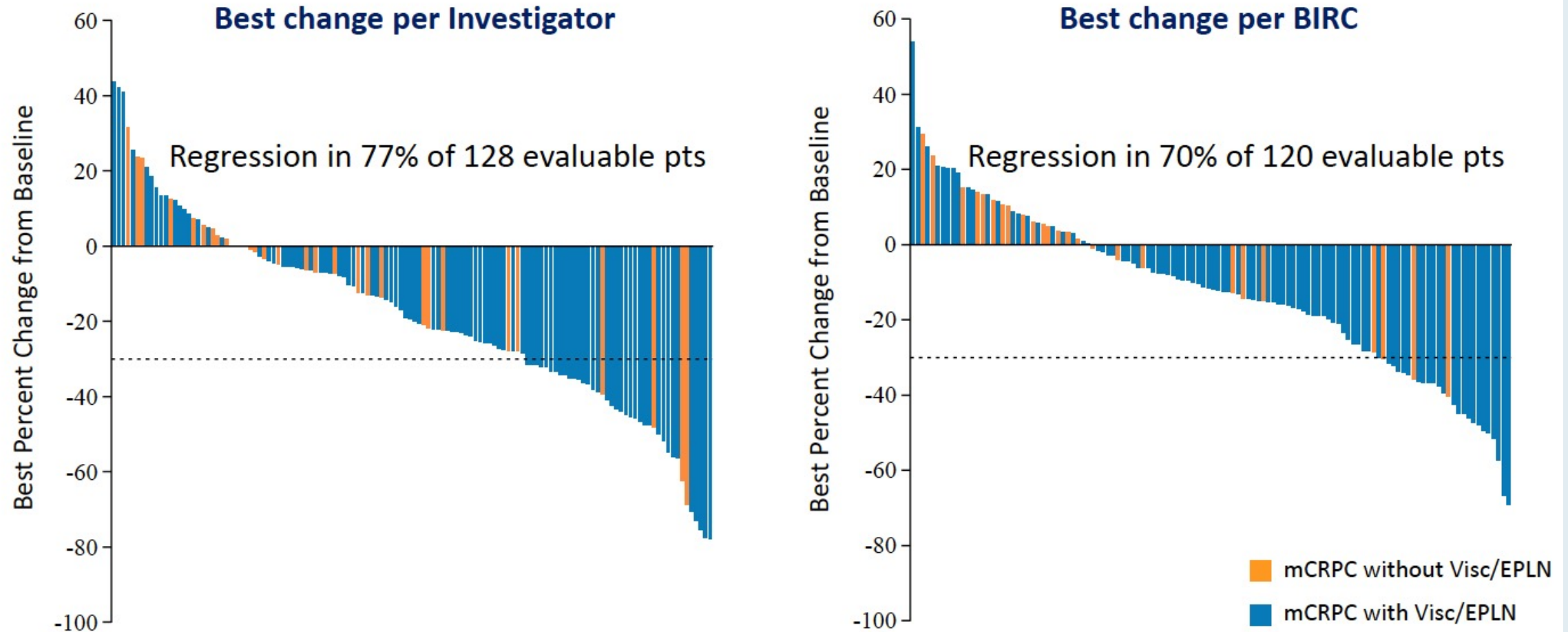




# Cabozantinib Targets Pathways Associated with Tumor Immune Suppression

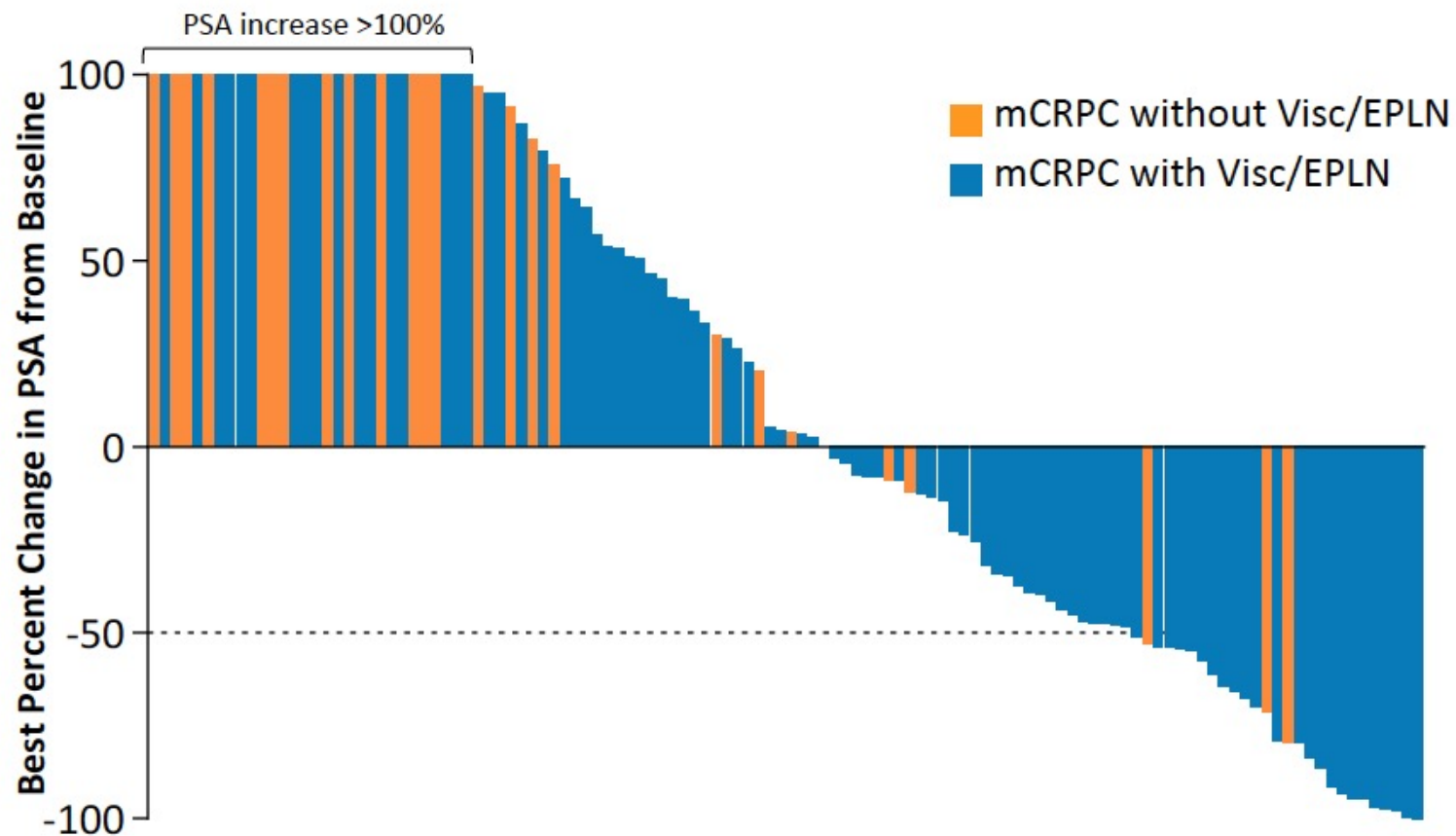


# COSMIC-021: Best Change from Baseline in Sum of Target Lesions



Evaluable patients (pts) had measurable disease and at least one post-baseline scan; the three patients with complete responses per investigator had lymph node metastases as target lesions.

# COSMIC-021: Best Change in PSA from Baseline



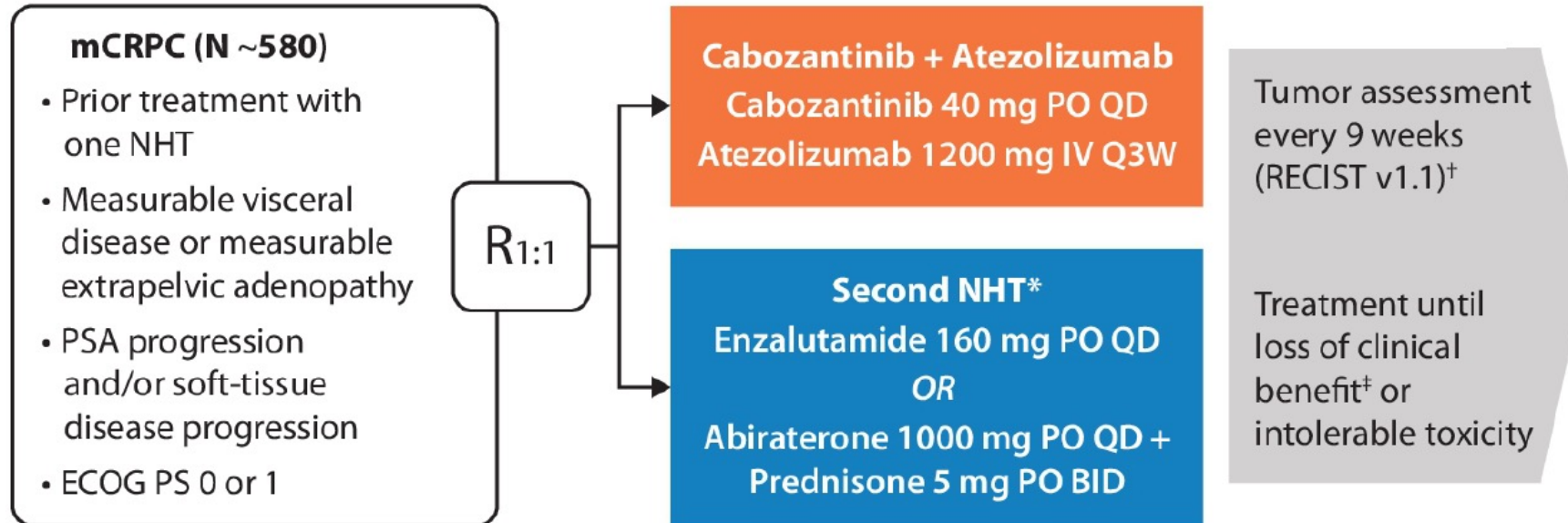
- In 118 patients with post-baseline assessments, 55 (47%) had a decrease in PSA, and 27 (23%) had a decrease  $\geq 50\%$
- In 92 patients with Visc/EPLN, 50 (54%) had a decrease in PSA, and 24 (26%) had a decrease  $\geq 50\%$

# COSMIC-021: Select Treatment-Related Adverse Events

	mCRPC (N=132)	
	Any Grade	Grade 3/4
Any AE, %	95	55
Diarrhea	55	6.8
Fatigue	43	6.8
Nausea	42	0.8
Decreased appetite	34	1.5
Dysgeusia	27	0
Palmar-plantar erythrodysesthesia	25	2.3
Vomiting	23	1.5
Weight decreased	23	1.5
Aspartate aminotransferase increased	20	3.0
Stomatitis	16	0.8
Hypertension	14	6.8
Alanine aminotransferase increased	14	3
Dysphonia	13	0
Hypothyroidism	12	0
Pulmonary embolism	11	8.3



# CONTACT-02: Phase III Trial Schema



## Primary Endpoints:

- PFS per RECIST v1.1 by BIRC
- OS

## Secondary Endpoint:

- ORR per RECIST v1.1 by BIRC

## Stratification

- Liver metastasis (yes, no)
- Prior docetaxel treatment for mCSPC (yes, no)
- Disease stage for which the first NHT was given (mCSPC, M0 CRPC, mCRPC)

\*Second NHT must differ from previous NHT taken

<sup>†</sup>Tumor assessment (RECIST v1.1) every 9 weeks for the first 28 weeks then every 12 weeks thereafter

<sup>‡</sup>Patients may be treated beyond progression if there is a clinical benefit in the opinion of the investigator



## Immune Checkpoint Inhibitors in mCRPC

Therapy	Disease state	Disease response
Pembrolizumab monotherapy <sup>a</sup>	Postchemotherapy	ORR 9% PSA RR 14%
Pembrolizumab + enzalutamide <sup>b</sup>	Prechemotherapy, progressing on enzalutamide	ORR 12% PSA RR 14%
Atezolizumab + enzalutamide <sup>c</sup>	Pre- and postchemotherapy, s/p abiraterone	ORR 14% PSA RR 26%
Atezolizumab + cabozantinib <sup>d</sup>	Prechemotherapy, s/p enzalutamide or abiraterone	ORR 34% PSA RR 29%

<sup>a</sup>JCO 2020;38(5):395-405. <sup>b</sup>Presented at the 2021 ASCO Annual Meeting – Virtual; June 4-8, 2021. <sup>c</sup>Sweeney C. AACR 2020. IMbassador250. <sup>d</sup>Agarwal ASCO 2020. COSMIC-021

# **Year in Review: Hepatobiliary and Pancreatic Cancers**

**Wednesday, April 13, 2022  
5:00 PM – 6:00 PM ET**

## **Faculty**

**Tanios Bekaii-Saab, MD  
Philip A Philip, MD, PhD, FRCP**

## **Special Topics**

- **HIMALAYA trial**

# What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

*A Complimentary NCPD Hybrid Symposium Series Held During the 47<sup>th</sup> Annual ONS Congress*

## Prostate Cancer

**Thursday, April 28, 2022**

6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)

### Faculty

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

Robert Dreicer, MD, MS

Sandy Srinivas, MD

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

## Non-Small Cell Lung Cancer

**Thursday, April 28, 2022**

6:00 PM – 8:00 PM PT (9:00 PM – 11:00 PM ET)

### Faculty

Edward B Garon, MD, MS

Kelly EH Goodwin, MSN, RN, ANP-BC

Tara Plues, APRN, MSN

Anne S Tsao, MD, MBA

## Ovarian Cancer

**Thursday, April 28, 2022**

12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)

### Faculty

Jennifer Filipi, MSN, NP

Kathleen N Moore, MD, MS

Krishnansu S Tewari, MD

Deborah Wright, MSN, APRN, AGCNS-BC

## Hepatobiliary Cancers

**Thursday, April 28, 2022**

8:20 PM – 9:20 PM PT (11:20 PM – 12:20 AM ET)

### Faculty

Richard S Finn, MD

Amanda K Wagner, APRN-CNP, AOCNP

# What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

*A Complimentary NCPD Hybrid Symposium Series Held During the 47<sup>th</sup> Annual ONS Congress*

## Small Cell Lung Cancer

**Friday, April 29, 2022**

6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)

### Faculty

Marianne J Davies, DNP, MSN, RN, APRN

Matthew Gubens, MD, MS

Lowell L Hart, MD

Chaely J Medley, MSN, AGNP

## Breast Cancer

**Friday, April 29, 2022**

6:00 PM – 8:00 PM PT (9:00 PM – 11:00 PM ET)

### Faculty

Jamie Carroll, APRN, MSN, CNP

Sara A Hurvitz, MD

Kelly Leonard, MSN, FNP-BC

Hope S Rugo, MD

## Chronic Lymphocytic Leukemia

**Friday, April 29, 2022**

12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)

### Faculty

Lesley Camille Ballance, MSN, FNP-BC

Amy Goodrich, CRNP

Anthony R Mato, MD, MSCE

Susan O'Brien, MD

## Acute Myeloid Leukemia and Myelodysplastic Syndromes

**Friday, April 29, 2022**

8:20 PM – 9:20 PM PT (11:20 PM – 12:20 AM ET)

### Faculty

Ilene Galinsky, NP

Eunice S Wang, MD

# What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

*A Complimentary NCPD Hybrid Symposium Series Held During the 47<sup>th</sup> Annual ONS Congress*

## **Cervical and Endometrial Cancer**

**Saturday, April 30, 2022**

6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)

### **Faculty**

Paula J Anastasia, MN, RN, AOCN

Robert L Coleman, MD

David M O'Malley, MD

Jaclyn Shaver, MS, APRN, CNP, WHNP

## **Bladder Cancer**

**Saturday, April 30, 2022**

12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)

### **Faculty**

Monica Averia, MSN, AOCNP, NP-C

Shilpa Gupta, MD

Brenda Martone, MSN, NP-BC, AOCNP

Sumanta Kumar Pal, MD



*Thank you for joining us!*

*CME and MOC credit information will be emailed to each participant within 5 business days.*