Meet The Professor

Optimizing the Use of Hormonal Therapy in the Management of Prostate Cancer

Wednesday, November 9, 2022
5:00 PM – 6:00 PM ET

Faculty

Prof Karim Fizazi, MD, PhD

Stéphane Oudard, MD, PhD

Moderator

Neil Love, MD

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Commercial Support

This activity is supported by an educational grant from Bayer HealthCare Pharmaceuticals.

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 Corporation, 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, Kronos Bio Inc, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, MEI Pharma Inc, Merck, Mersana Therapeutics Inc, Mirati 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, Seagen Inc, Servier Pharmaceuticals LLC, Sumitomo Dainippon Pharma Oncology Inc, Taiho Oncology Inc, Takeda Pharmaceuticals USA Inc, TerSera Therapeutics LLC, Tesaro, A GSK Company, TG Therapeutics Inc, Turning Point Therapeutics Inc, Verastem Inc and Zymeworks Inc.

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Prof Fizazi — Disclosures

Advisory Board (Honoraria to Me)	CureVac, Orion Corporation
Advisory Board or Speaking Engagements (Honoraria Provided to My Institution)	Amgen Inc, Astellas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Clovis Oncology, Daiichi Sankyo Inc, Janssen Biotech Inc, Merck Sharp & Dohme LLC, Novartis, Pfizer Inc, Sanofi

Prof Oudard — Disclosures

No relevant conflicts of interest to disclose.

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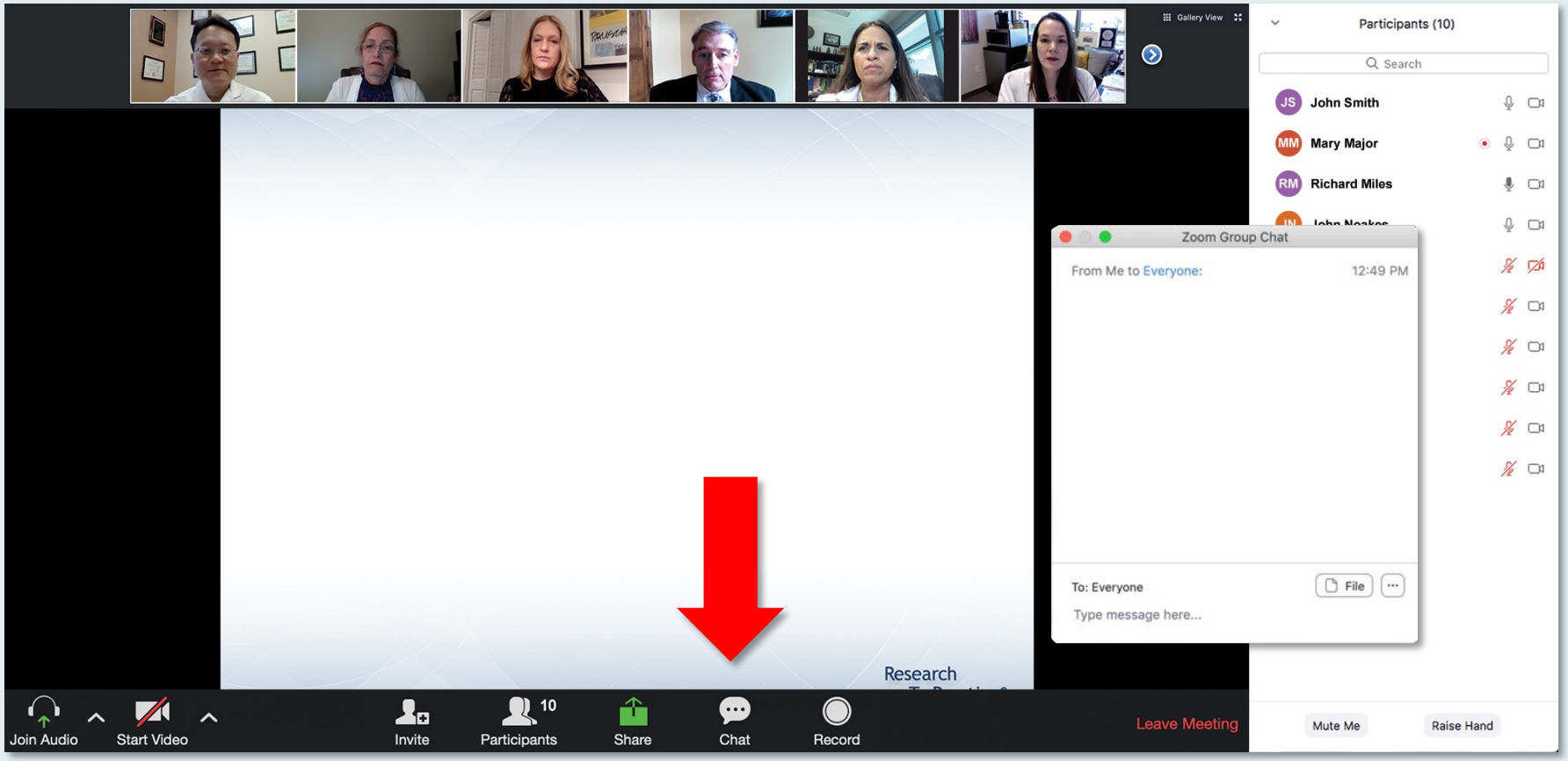
We Encourage Clinicians in Practice to Submit Questions



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

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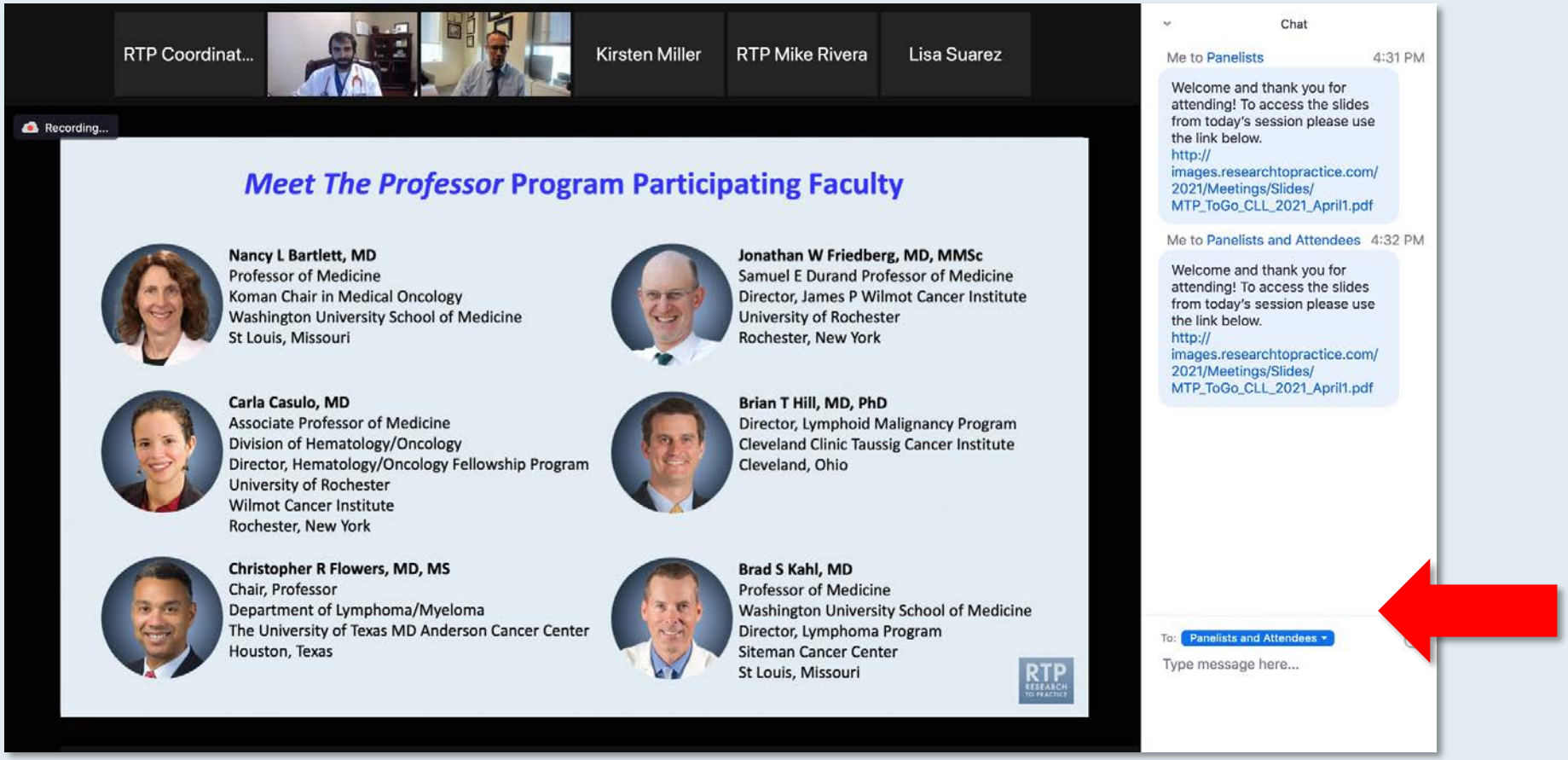
Familiarizing Yourself with the Zoom Interface

Expand chat submission box



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

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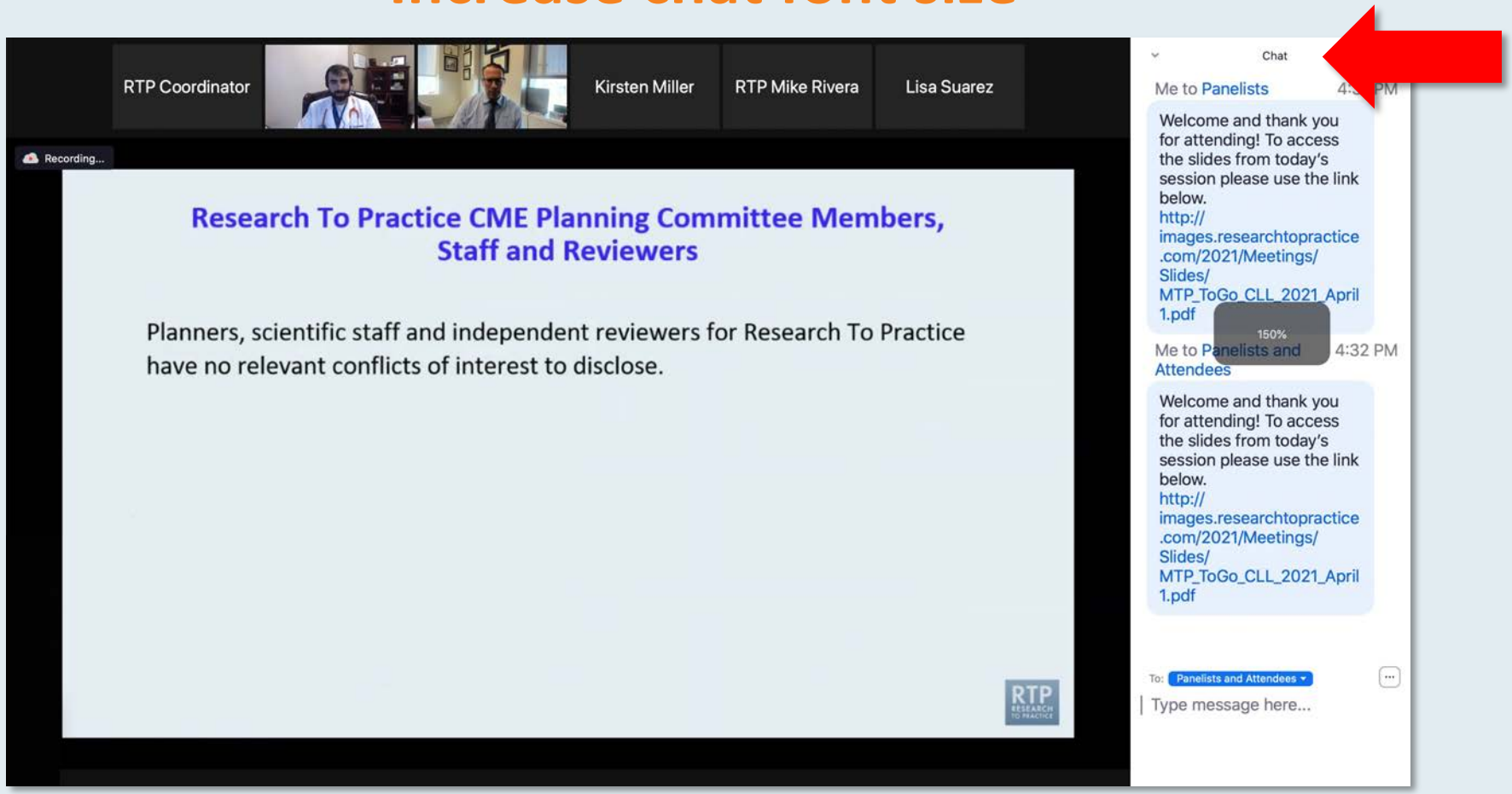
Familiarizing Yourself with the Zoom Interface

Increase chat font size



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

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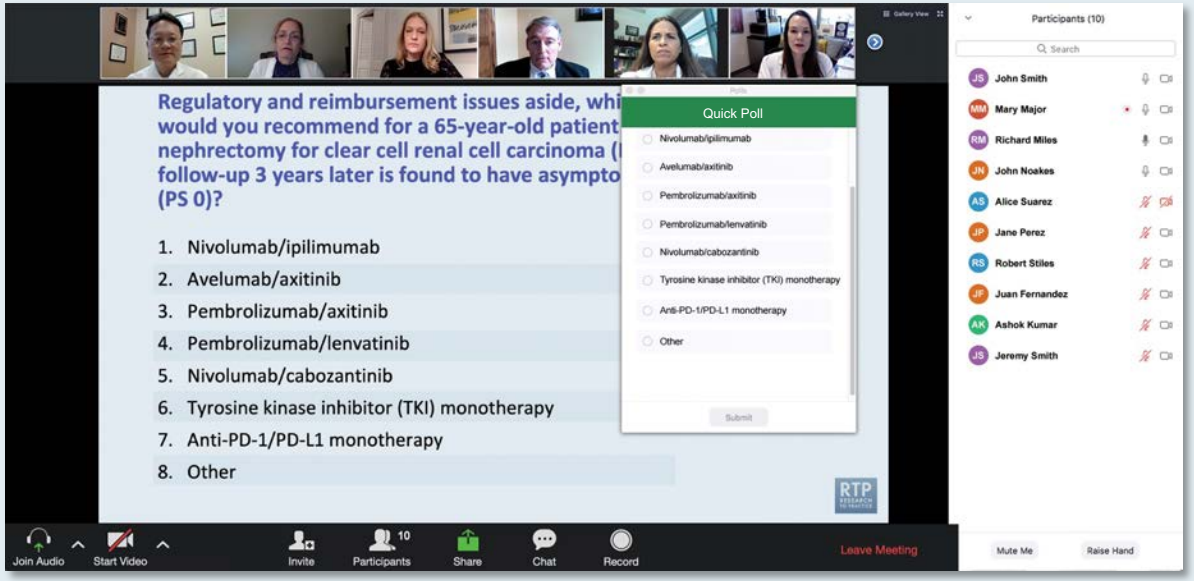

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ONCOLOGY TODAY

WITH DR NEIL LOVE

Key Presentations on Genitourinary Cancers from the 2022 ASCO Annual Meeting

DR SANDY SRINIVAS

STANFORD UNIVERSITY

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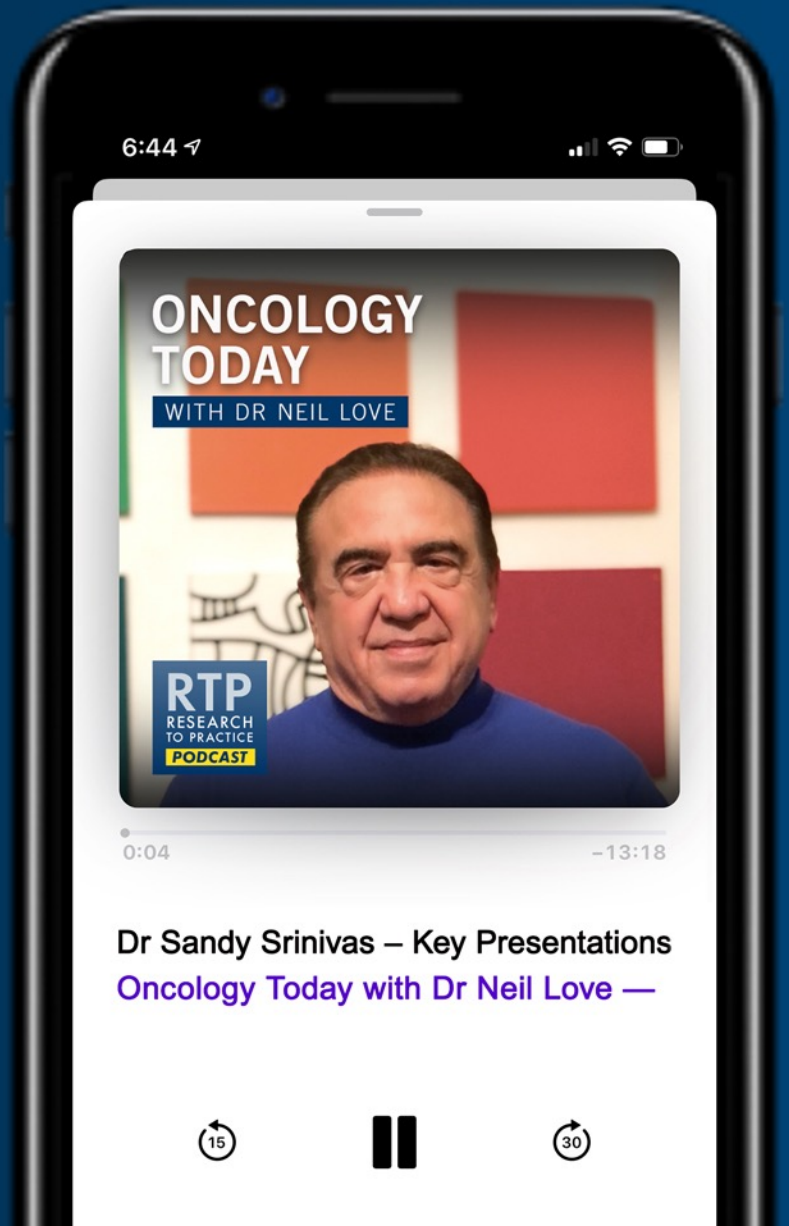

Meet The Professor
Optimizing the Management of Multiple Myeloma

Tuesday, November 15, 2022
5:00 PM – 6:00 PM ET

Faculty

Paul G Richardson, MD

Moderator

Neil Love, MD

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Oncology Today with Dr Neil Love — Novel Agents and Strategies in Acute Myeloid Leukemia

A CME/MOC-Accredited Virtual Event

Thursday, November 17, 2022
5:00 PM – 6:00 PM ET

Faculty

Daniel A Pollyea, MD, MS

Moderator

Neil Love, MD

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What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of HER2-Positive Breast Cancer

Part 1 of a 2-Part CME Satellite Symposium Series Held in Conjunction with the 2022 San Antonio Breast Cancer Symposium®

Wednesday, December 7, 2022

7:15 PM – 9:15 PM CT (8:15 PM – 10:15 PM ET)

Faculty

Erika Hamilton, MD

Sara A Hurvitz, MD

Ian E Krop, MD, PhD

Shanu Modi, MD

Sara M Tolaney, MD, MPH

Moderator

Neil Love, MD

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What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of ER-Positive Breast Cancer

Part 2 of a 2-Part CME Satellite Symposium Series Held in Conjunction with the 2022 San Antonio Breast Cancer Symposium®

Thursday, December 8, 2022

7:15 PM – 9:15 PM CT (8:15 PM – 10:15 PM ET)

Faculty

Aditya Bardia, MD, MPH

Matthew P Goetz, MD

Virginia Kaklamani, MD, DSc

Kevin Kalinsky, MD, MS

Hope S Rugo, MD

Moderator

Neil Love, MD

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Addressing Current Questions and Controversies in the Management of Chronic Lymphocytic Leukemia — What Clinicians Want to Know

Part 1 of a 3-Part CME Friday Satellite Symposium and Virtual Event Series
Preceding the 64th ASH Annual Meeting

Friday, December 9, 2022
11:30 AM – 1:30 PM CT (12:30 PM – 2:30 PM ET)

Faculty

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Matthew S Davids, MD, MMSc
Professor Dr Arnon P Kater, MD, PhD
Lindsey Roeker, MD
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Rafael Fonseca, MD
Sagar Lonial, MD
Robert Z Orlowski, MD, PhD
Noopur Raje, MD

Moderator

Neil Love, MD

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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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Meet The Professor Program Participating Faculty

Prof Karim Fizazi, MD, PhD
Head of Service and Full Professor
Institut Gustave Roussy
University of Paris Saclay
Villejuif, France

Matthew R Smith, MD, PhD
Claire and John Bertucci Endowed Chair
in Genitourinary Cancers
Professor of Medicine
Harvard Medical School
Director, Genitourinary Malignancies Program
Massachusetts General Hospital Cancer Center
Boston, Massachusetts

Stéphane Oudard, MD, PhD
Chief, Medical Oncology
Hôpital Européen Georges Pompidou
Paris, France

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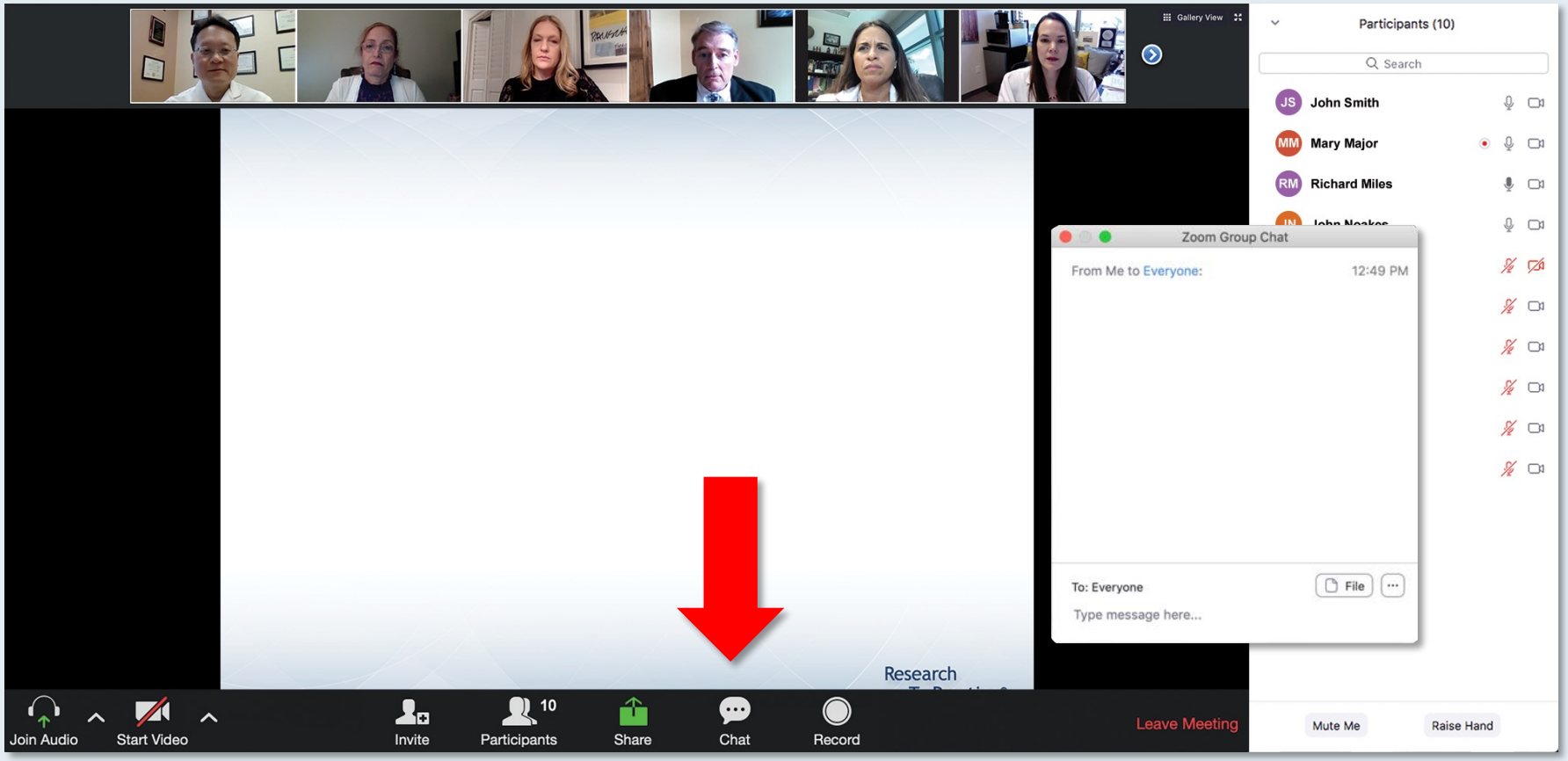

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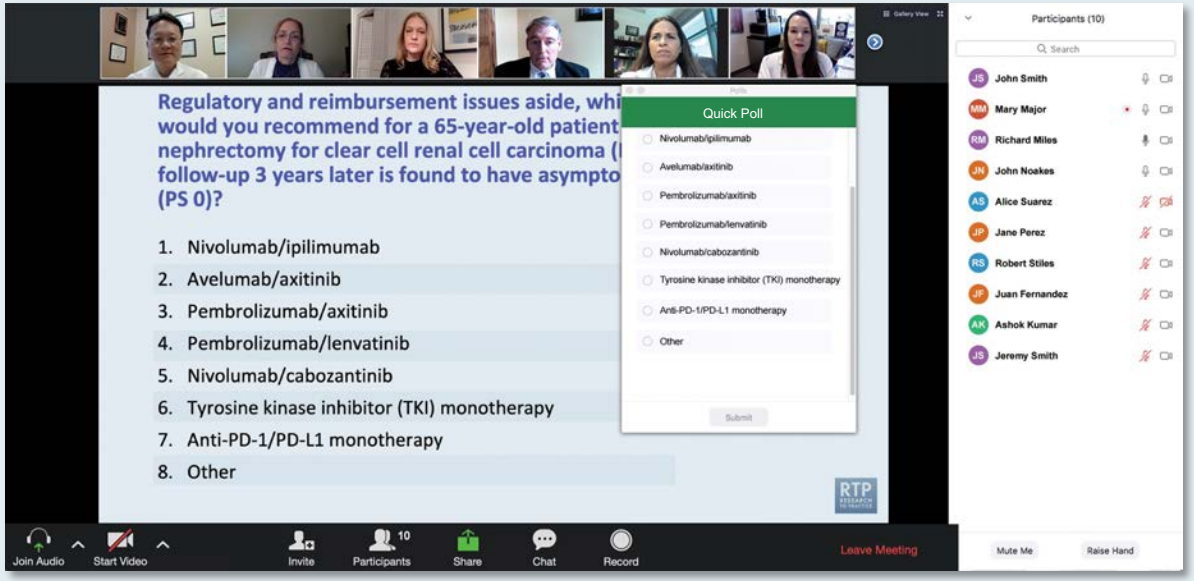

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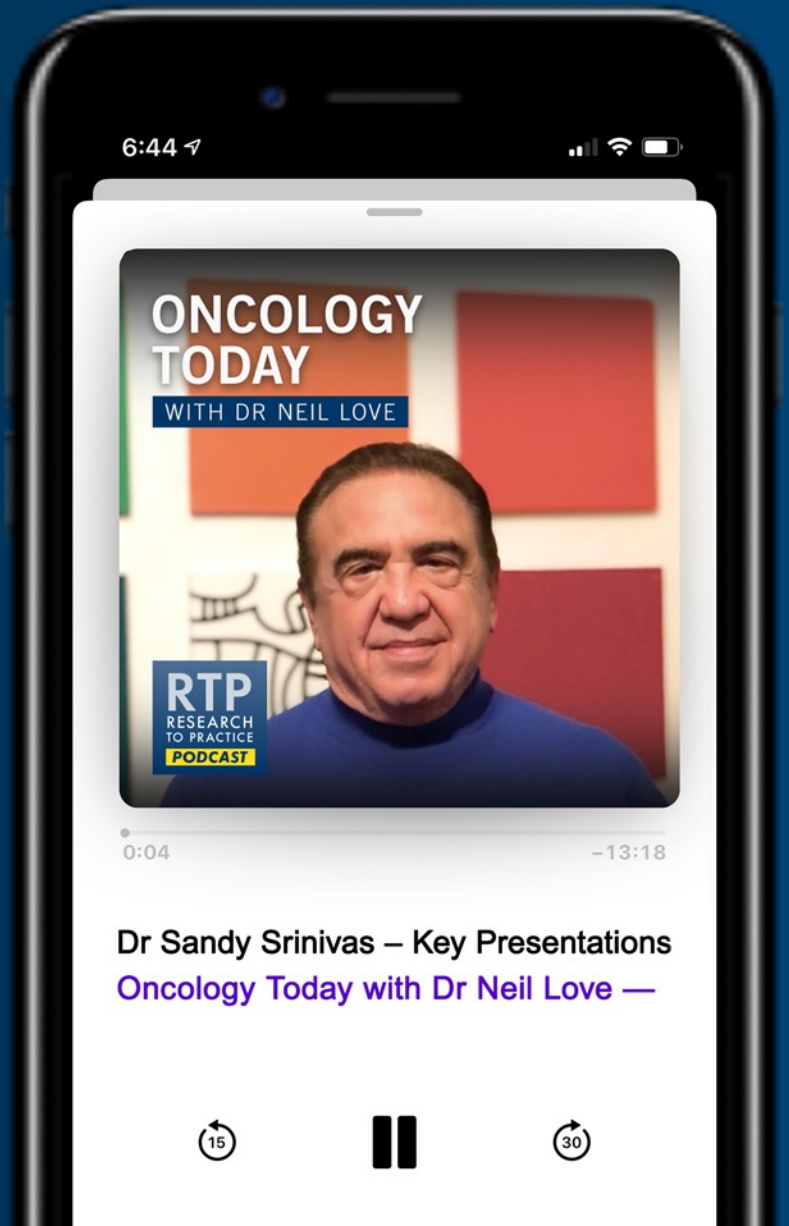

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Prof Oudard — Disclosures

No relevant conflicts of interest to disclose.

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Philip L Brooks, MD
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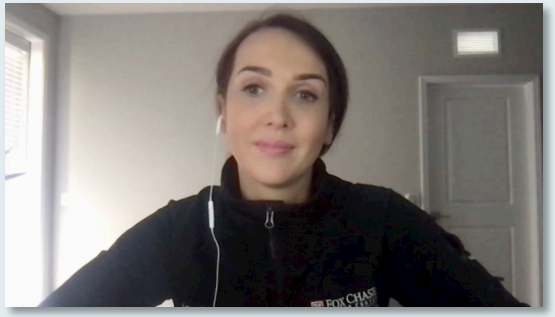
Gurveen Kaur, MD
WVU Medicine Wheeling Hospital
Wheeling, West Virginia



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Temple University School of Medicine
Philadelphia, Pennsylvania

Joanna Metzner-Sadurski, MD
Self Regional Healthcare Cancer Center
Medical University of South Carolina
Greenwood, South Carolina

Jason Hafron, MD
Oakland University William
Beaumont School of Medicine
West Bloomfield, Michigan

David S Morris, MD
Advanced Therapeutics Center
Urology Associates
Nashville, Tennessee

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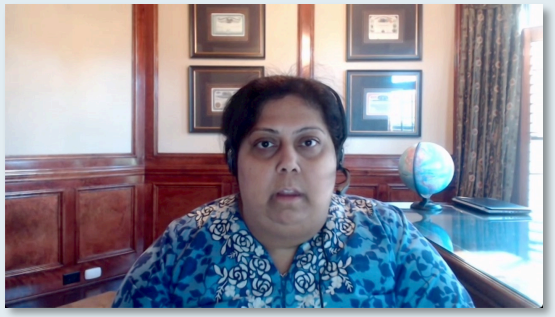

Niyati A Nathwani, MD
Carolina Blood and Cancer Care Associates
Charlotte, North Carolina

David A Taub, MD, MBA
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School of Medicine
Lynn Cancer Institute
Boca Raton, Florida

Nasfat Shehadeh, MD
Oncology Specialists of Charlotte, PA
Charlotte, North Carolina

Syed F Zafar, MD
Lee Health
Florida Cancer Specialists
Fort Myers, Florida

Meet The Professor with Prof Fizazi and Prof Oudard

Introduction: Journal Club — Profs Fizazi and Oudard

MODULE 1: Case Presentations

MODULE 2: Ongoing Trials; Reported Data; Review Articles

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Ther Adv Med Oncol 2021 October 26;13:17588359211053898.

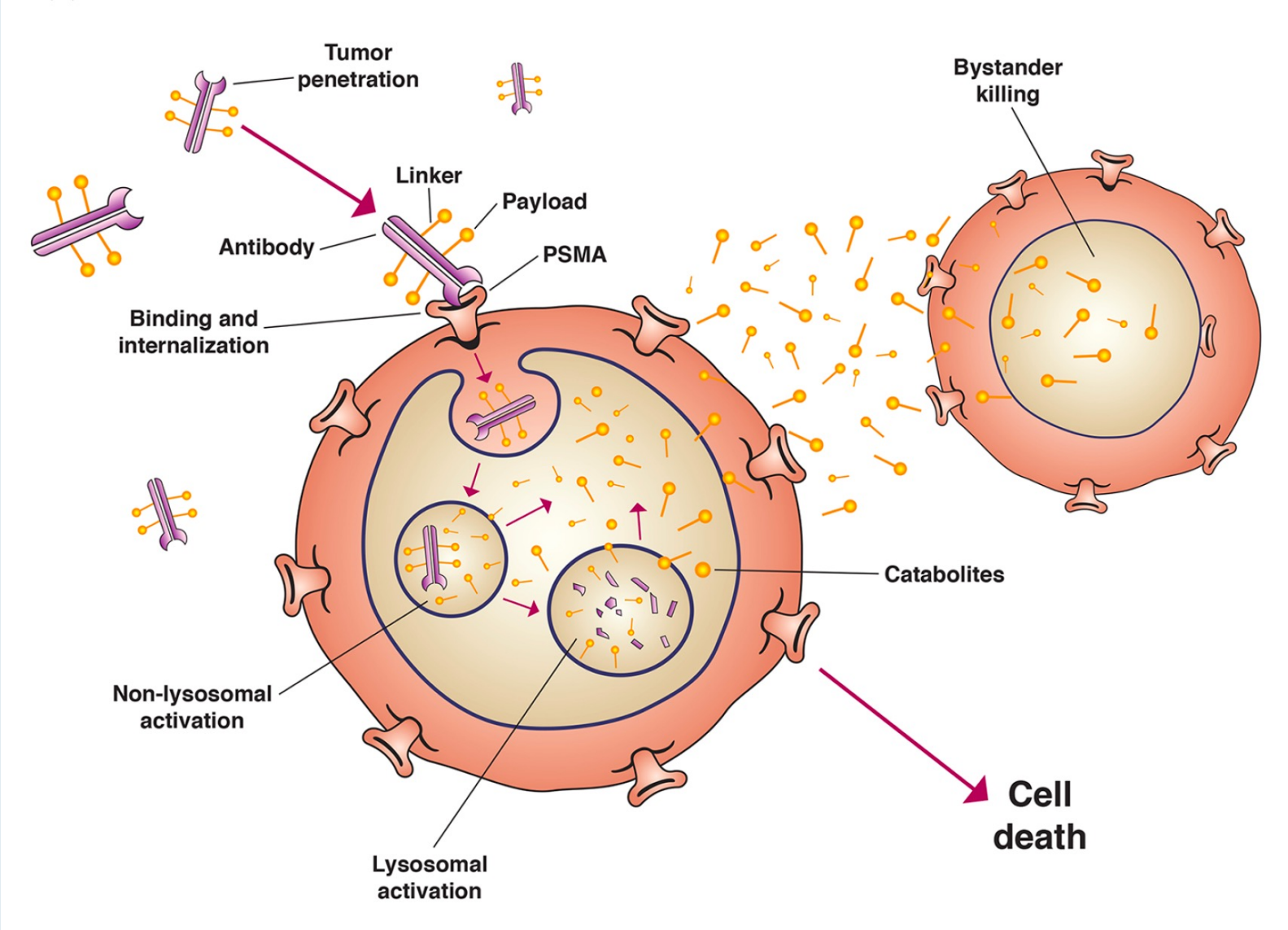
Therapeutic Advances in Medical Oncology *Review*

PSMA targeting in metastatic castration-resistant prostate cancer: where are we and where are we going?

Ther Adv Med Oncol
2021, Vol. 13: 1–14

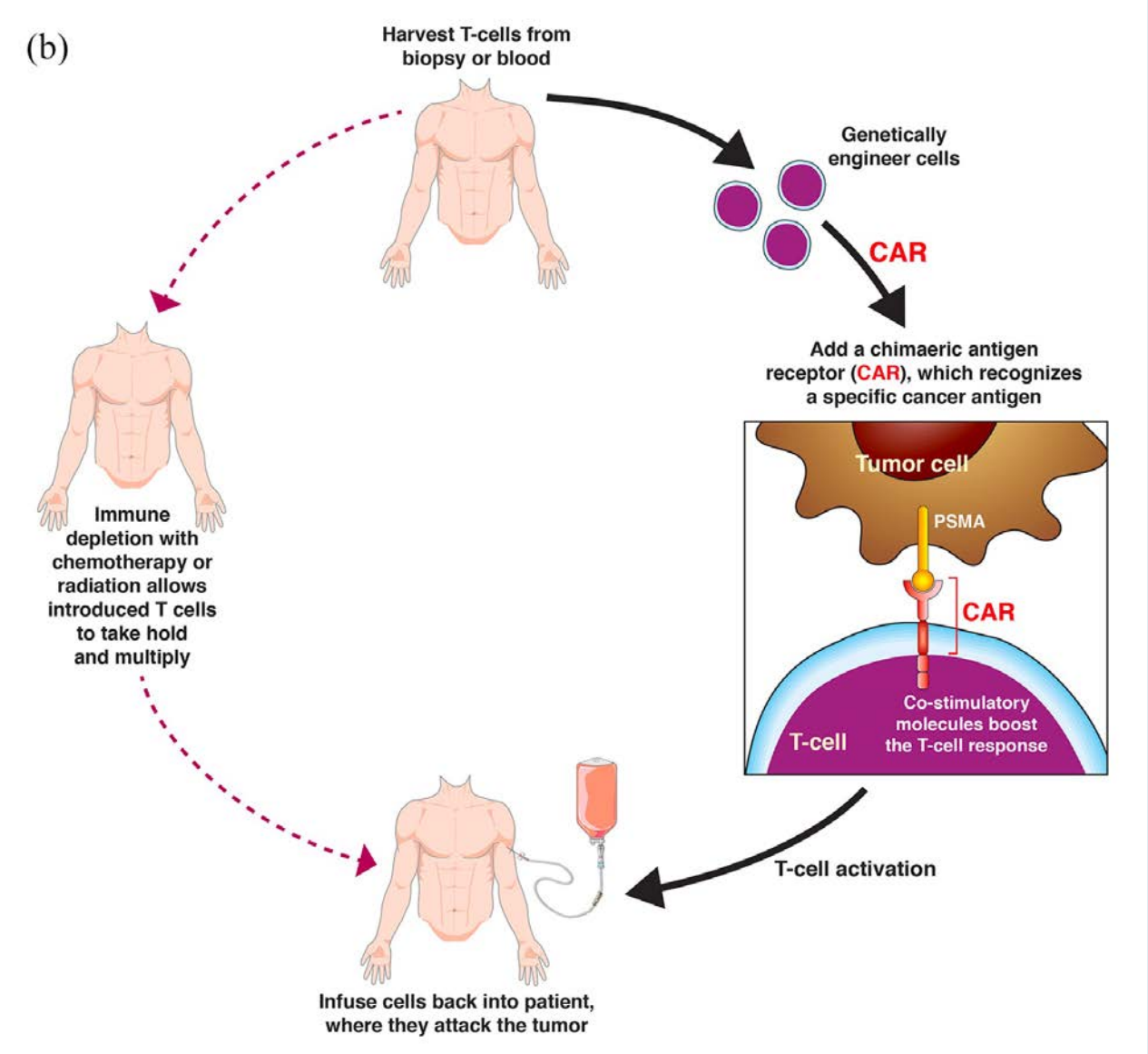
Anne-Laure Giraudet, David Kryza, Michael Hofman, Aurélie Moreau, Karim Fizazi, Aude Flechon, Rodney J. Hicks and Ben Tran

Prostate-Specific Membrane Antigen (PSMA)-Targeted Antibody-Drug Conjugates



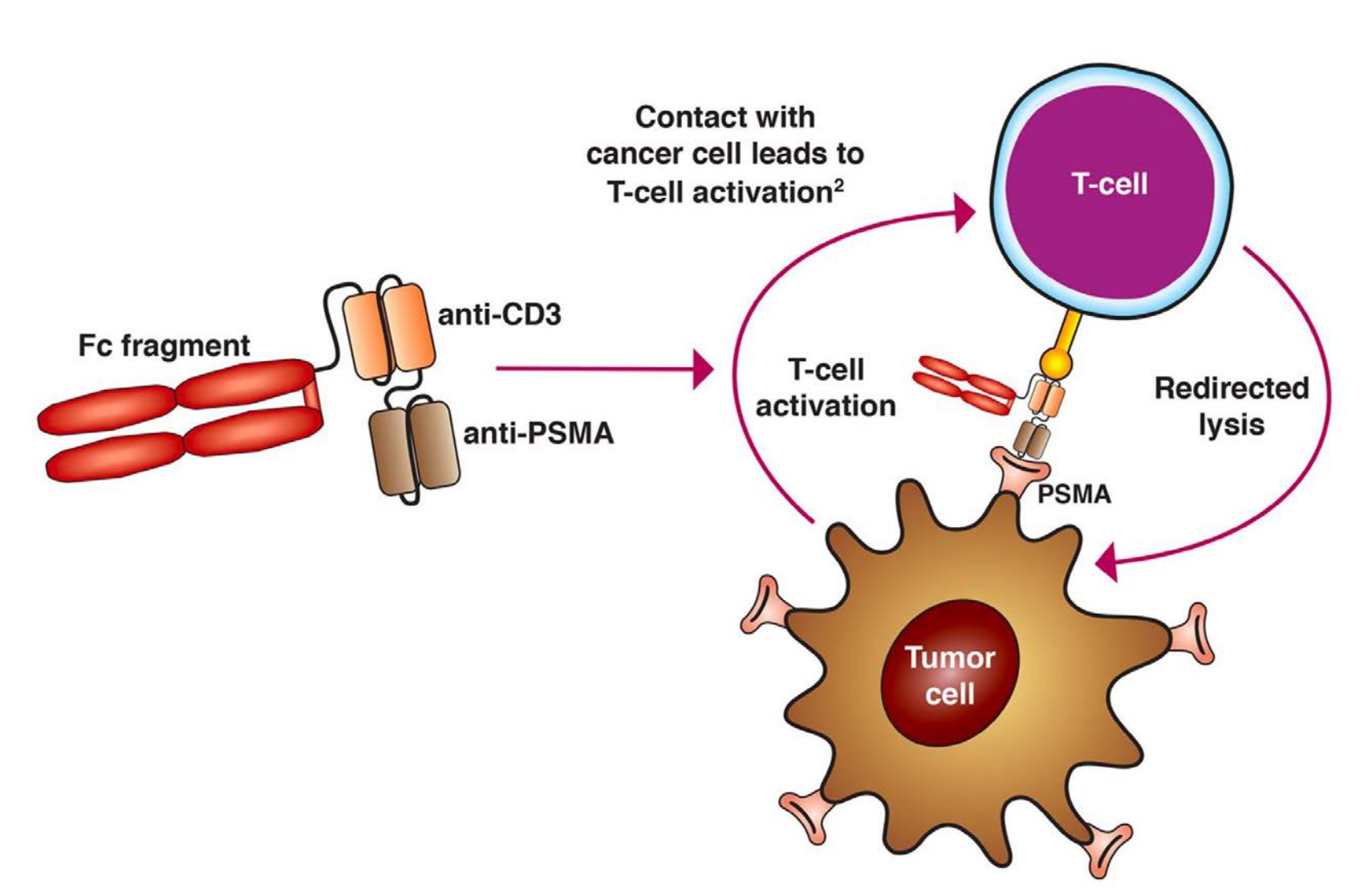
Giraudet A-L et al. *Ther Adv Med Oncol* 2021 October 26;13:17588359211053898.

PSMA-Targeted Chimeric Antigen Receptor (CAR) T-Cell Therapy



Giraudet A-L et al. *Ther Adv Med Oncol* 2021 October 26;13:17588359211053898.

PSMA-Targeted Bispecific T Cell-Redirected Therapy



Giraudet A-L et al. *Ther Adv Med Oncol* 2021 October 26;13:17588359211053898.

CYCLONE 1: A Phase 2 Study of Abemaciclib in Patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC) Previously Treated with a Novel Hormonal Agent and Taxane-Based Chemotherapy

Agarwal N et al.

ASCO 2021;Abstract TPS5086.

CYCLONE 1: Eligibility and Study Design

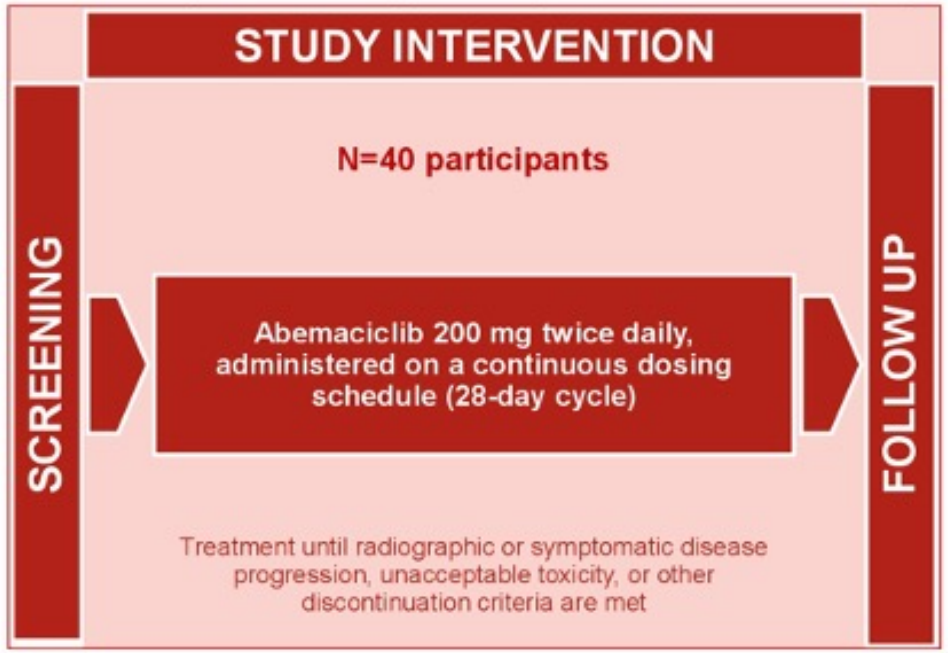
Key eligibility criteria *Additional screening criteria will be assessed prior to trial enrollment*

- mCRPC with at least 1 measurable lesion per RECIST v1.1
- Progressive disease at study entry in the setting of medical or surgical castration, defined as at least one of the following:
  - PSA progression (per PCWG3)
  - Radiographic progression (per RECIST v1.1 for soft tissue and/or PCWG3 for bone)
- Prior treatments:
  - ≥1 NHA (abiraterone acetate, apalutamide, darolutamide or enzalutamide, in any setting)
  - 2 taxane regimens[b] (docetaxel and cabazitaxel, ≥2 cycles each, in any setting)
  - ≤3 prior systemic therapy regimens for mCRPC
- Amenable to metastatic biopsy or availability of adequate archival metastatic tissue
- No prior treatment with abemaciclib or any CDK4 and/or CDK6 inhibitors
- Participants with serious and/or uncontrolled preexisting medical condition(s) (e.g. interstitial lung disease/pneumonitis), known/suspected brain metastasis or untreated (or risk of) spinal cord compression are not eligible

[b] *if a patient has received only 1 taxane regimen, he may be eligible ONLY if the second taxane regimen is deemed unsuitable (e.g. intolerance or contraindication). This requires sponsor approval,*

Study Design

Phase 2, open label, single-arm, global multi-center study



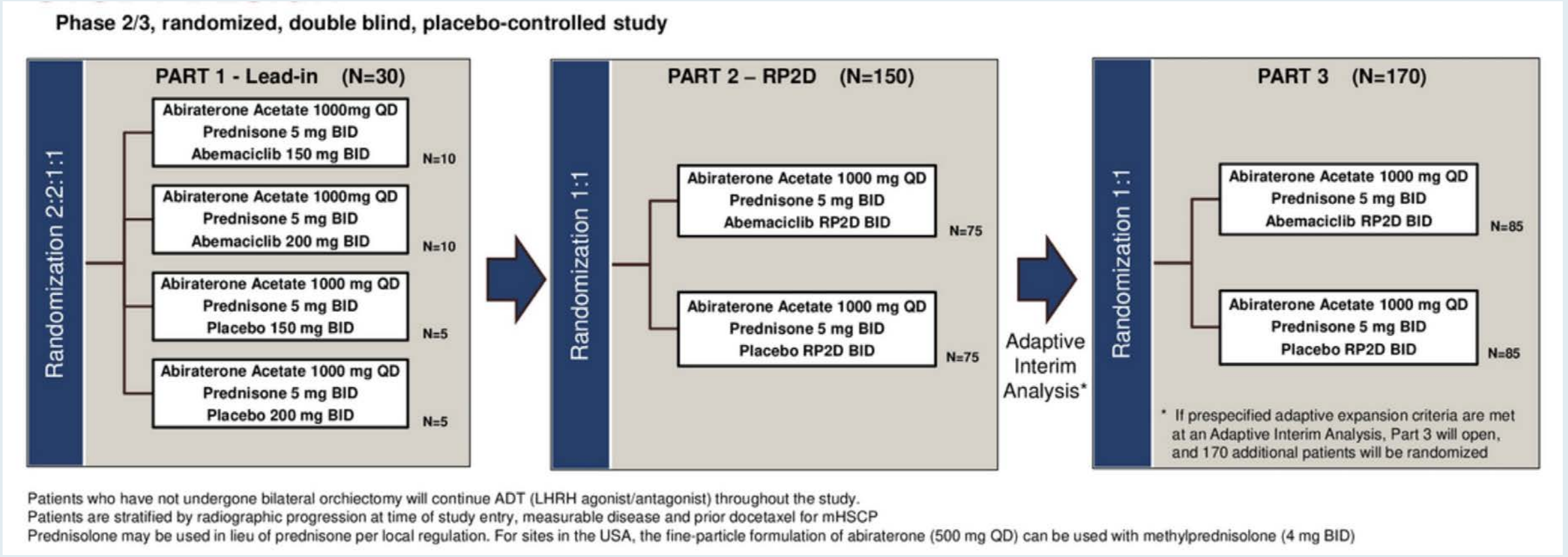
Agarwal N et al. ASCO 2021;Abstract TPS5086.

CYCLONE 2: A Phase 2/3, Randomized, Placebo-Controlled Study of Abiraterone Acetate plus Prednisone with or without Abemaciclib in Patients with Metastatic Castration-Resistant Prostate Cancer

Smith MR et al.

Genitourinary Cancers Symposium 2022;Abstract TPS198.

CYCLONE 2 Phase II/III Study Design



Patients who have not undergone bilateral orchiectomy will continue ADT (LHRH agonist/antagonist) throughout the study.
Patients are stratified by radiographic progression at time of study entry, measurable disease and prior docetaxel for mHSCP
Prednisolone may be used in lieu of prednisone per local regulation. For sites in the USA, the fine-particle formulation of abiraterone (500 mg QD) can be used with methylprednisolone (4 mg BID)

Smith MR et al. Genitourinary Cancers Symposium 2022;Abstract TPS198.

Meet The Professor with Prof Fizazi and Prof Oudard

MODULE 1: Case Presentations

- Dr Brooks: 59-year-old man with Gleason 7 prostate cancer s/p prostatectomy/RT/ADT experiences biochemical recurrence 2 years later (PSA 0.5; doubling time 9 months)
- Dr Shehadeh: 70-year-old man, pacemaker, s/p CVA presents with de novo mHSPC
- Dr Kaur: 49-year-old man with multiple medical comorbidities presents with de novo mHSPC (PSA 19.4) and responds to ADT/docetaxel
- Dr Metzner-Sadurski: 65-year-old man with de novo mHSPC receives leuprolide, and PSA levels decrease from 865 ng/mL to 1.34 ng/mL
- Dr Nathwani: 58-year-old man with mHSPC receives leuprolide with progression 1.5 years later and responds to abiraterone/prednisone but on liquid biopsy is found to have an AR T878 mutation
- Dr Morris: 76-year-old man s/p radical prostatectomy, salvage RT now has osseous metastases on a clinical trial of enzalutamide/IO
- Dr Zafar: 65-year-old man presents with de novo metastatic prostate cancer and has disease progression on ADT + docetaxel, now with PD on abiraterone/prednisone – germline CHEK2 mutation
- Dr Hafron: 86-year-old man received cryoablation for Stage IIB PCA; s/p apalutamide for M0 recurrence. MRI reveals diffuse abnormal signal entire prostate
- Dr Bukavina: 72-year-old man with primary PCA and PSA 160 ng/mL. Scans show only disease in prostate
- Dr Taub: 82-year-old man with a prior history of prostate and bladder cancer now has elevated alkaline phosphatase (685), PSA 43 and widespread osseous metastases

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Case Presentation: 59-year-old man with Gleason 7 prostate cancer s/p prostatectomy/RT/ADT experiences biochemical recurrence 2 years later (PSA 0.5; doubling time 9 months)

Dr Philip Brooks (Brewer, Maine)

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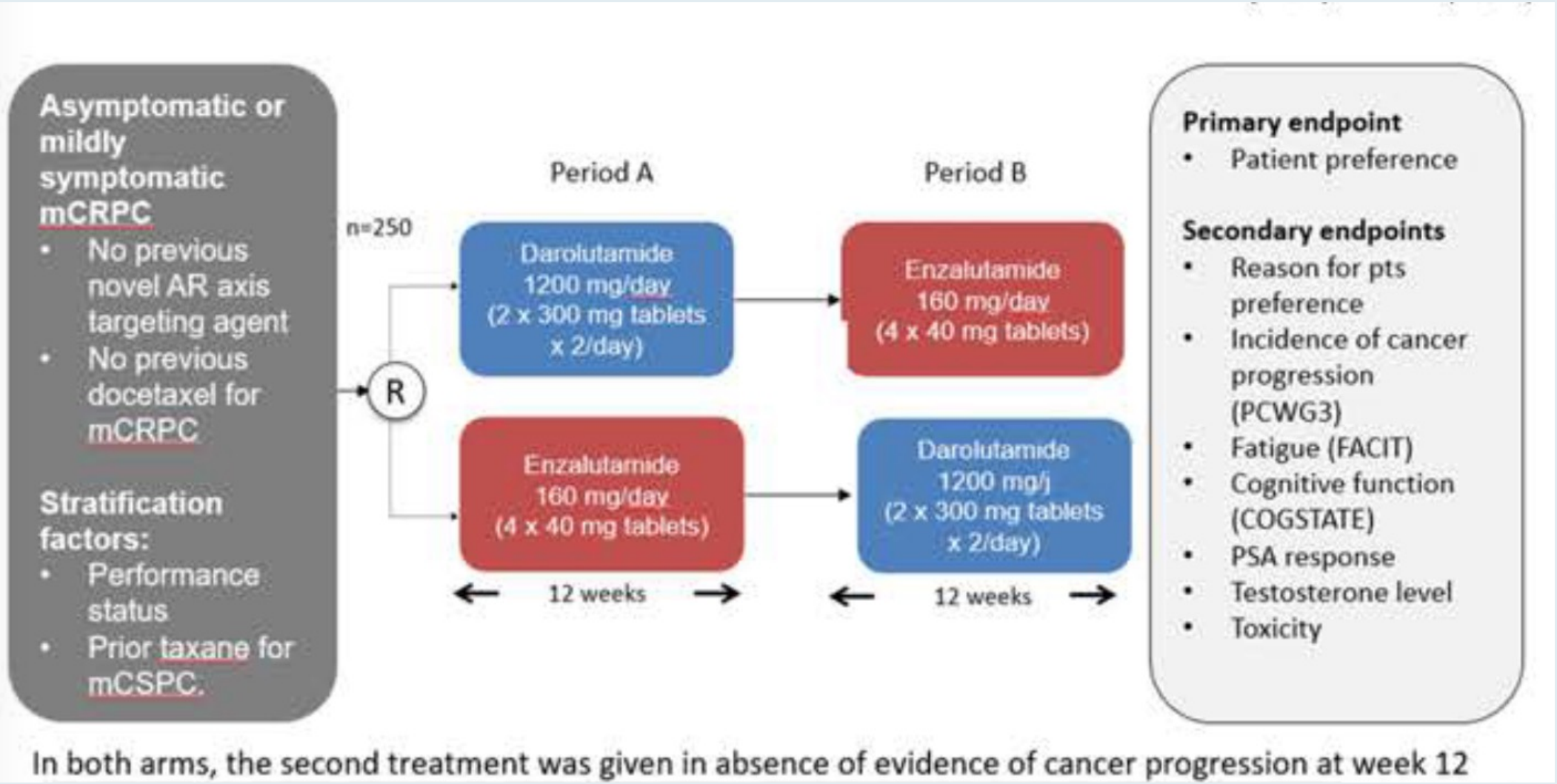
ODENZA: A French Prospective, Randomized, Open-Label, Multicenter, Cross-Over Phase II Trial of Preference Between Darolutamide and Enzalutamide in Men with Asymptomatic or Mildly Symptomatic Metastatic Castrate-Resistant Prostate Cancer (CRPC)

Colombo E et al.

ASCO 2021;Abstract 5046.

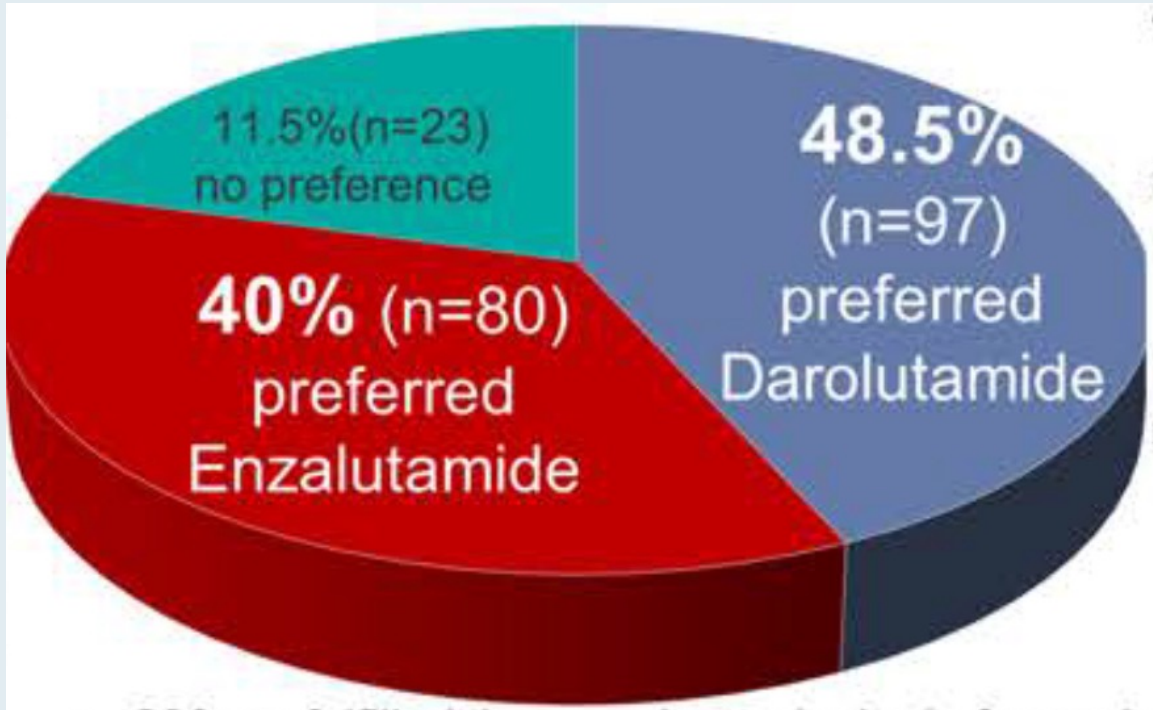
ODENZA Trial Design

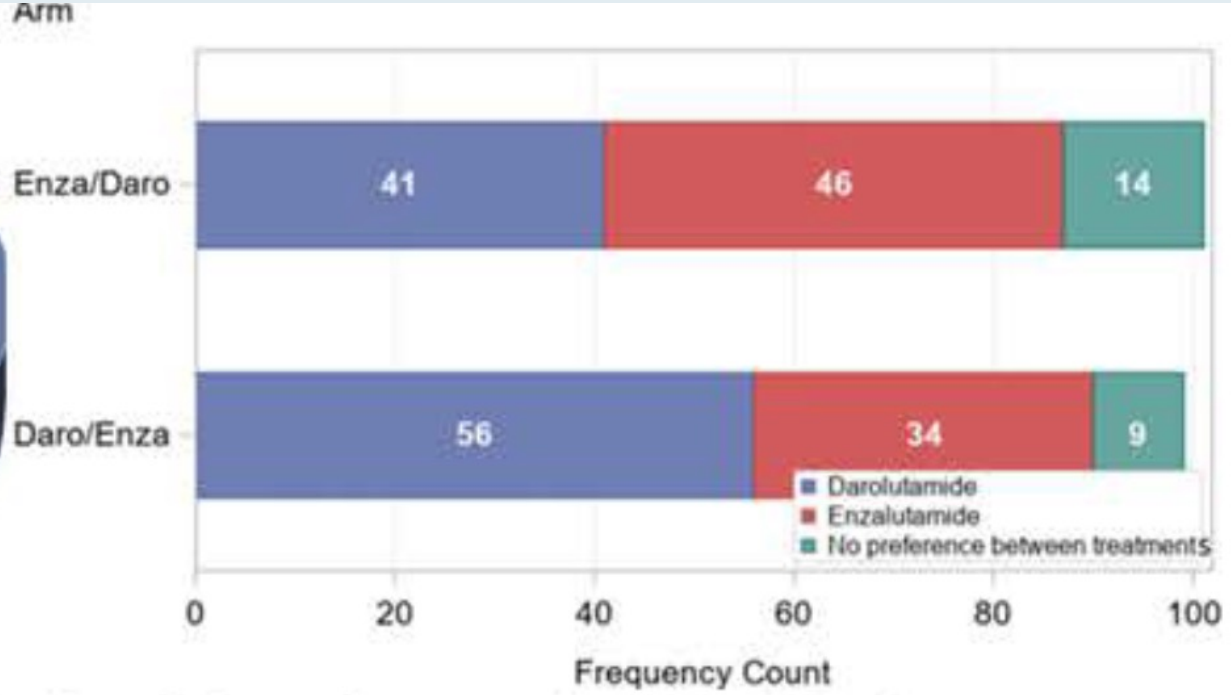


In both arms, the second treatment was given in absence of evidence of cancer progression at week 12

Colombo E et al. ASCO 2021;Abstract 5046.

ODENZA Primary Endpoint: Patient Preference

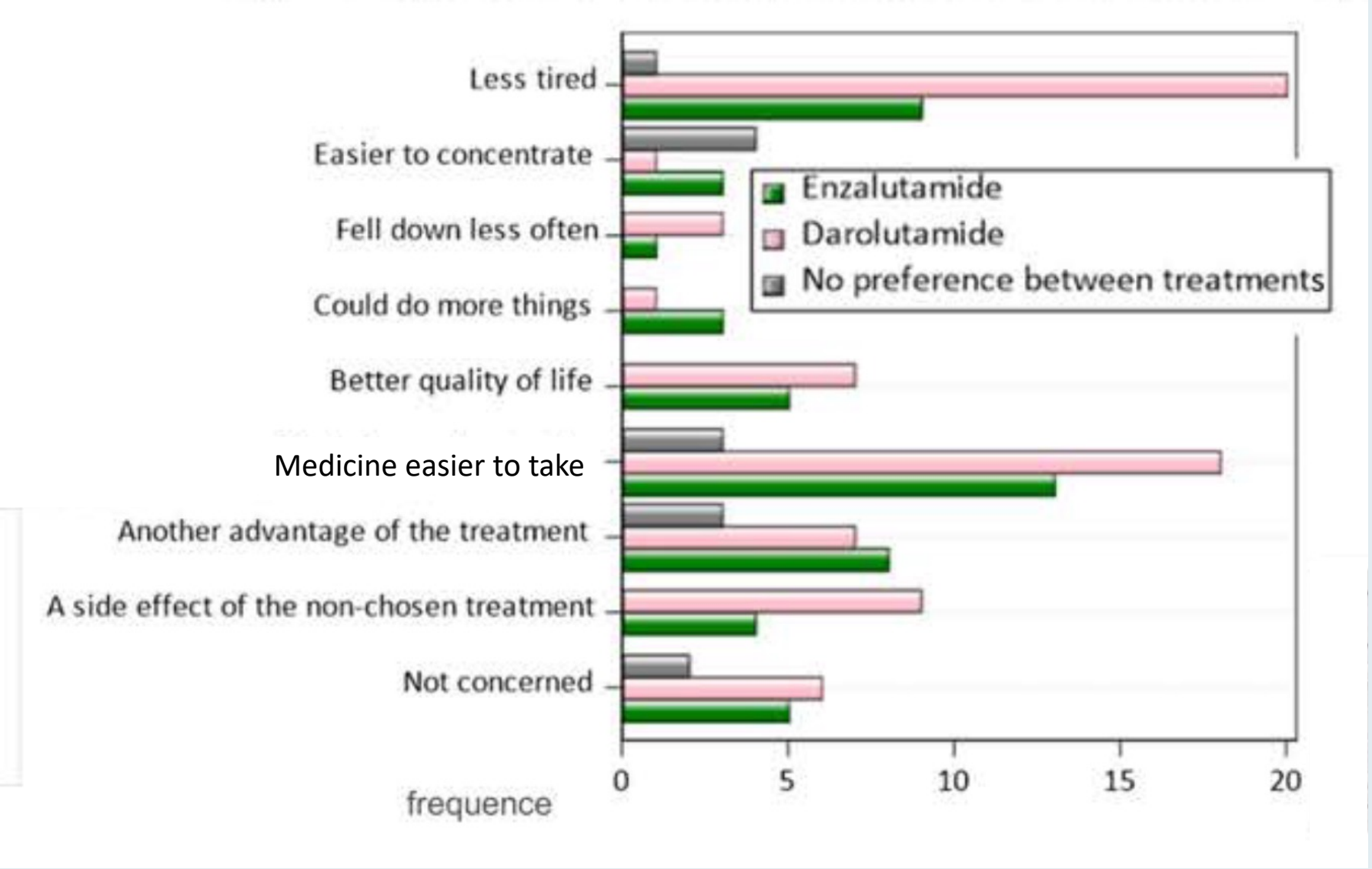




- 200 pts fulfilled the pre-planned criteria for evaluation of the preference primary endpoint (exposure to both treatments, no progression at week 12, and completion of the preference questionnaire). Overall, 97 (**48.5%** [41.3;55.7]), 80 (**40.0%** [33.0;47.0]), and 23 (11.5% [6.8;16.2]) chose **Daro, Enza,** and had no preference, respectively (unilateral p-value of 0.92).

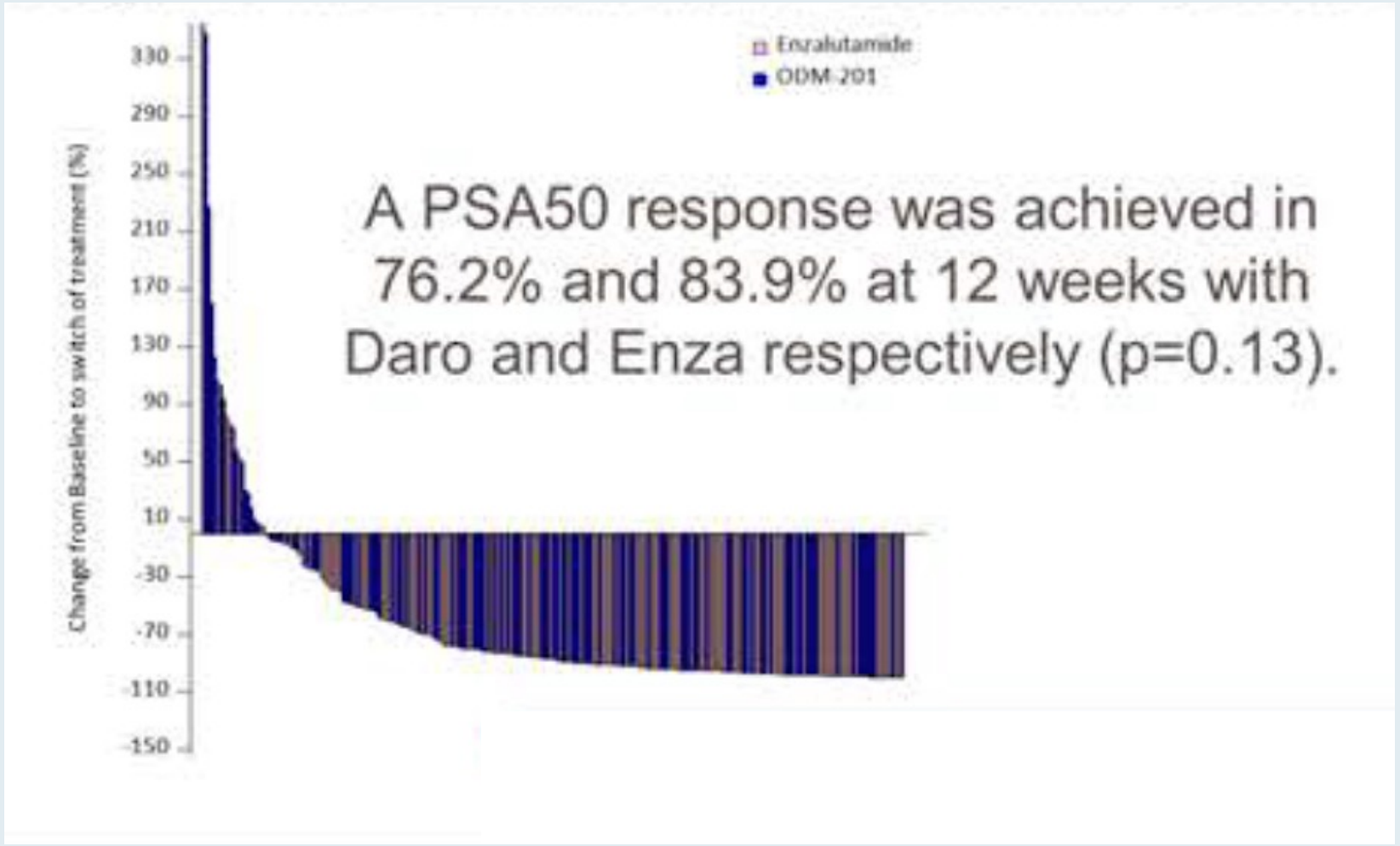
Colombo E et al. ASCO 2021;Abstract 5046.

ODENZA: Main Reasons for Patient Preference Between Treatments



Colombo E et al. ASCO 2021;Abstract 5046.

ODENZA: PSA Response with Enzalutamide and Darolutamide at Week 12



Colombo E et al. ASCO 2021;Abstract 5046.

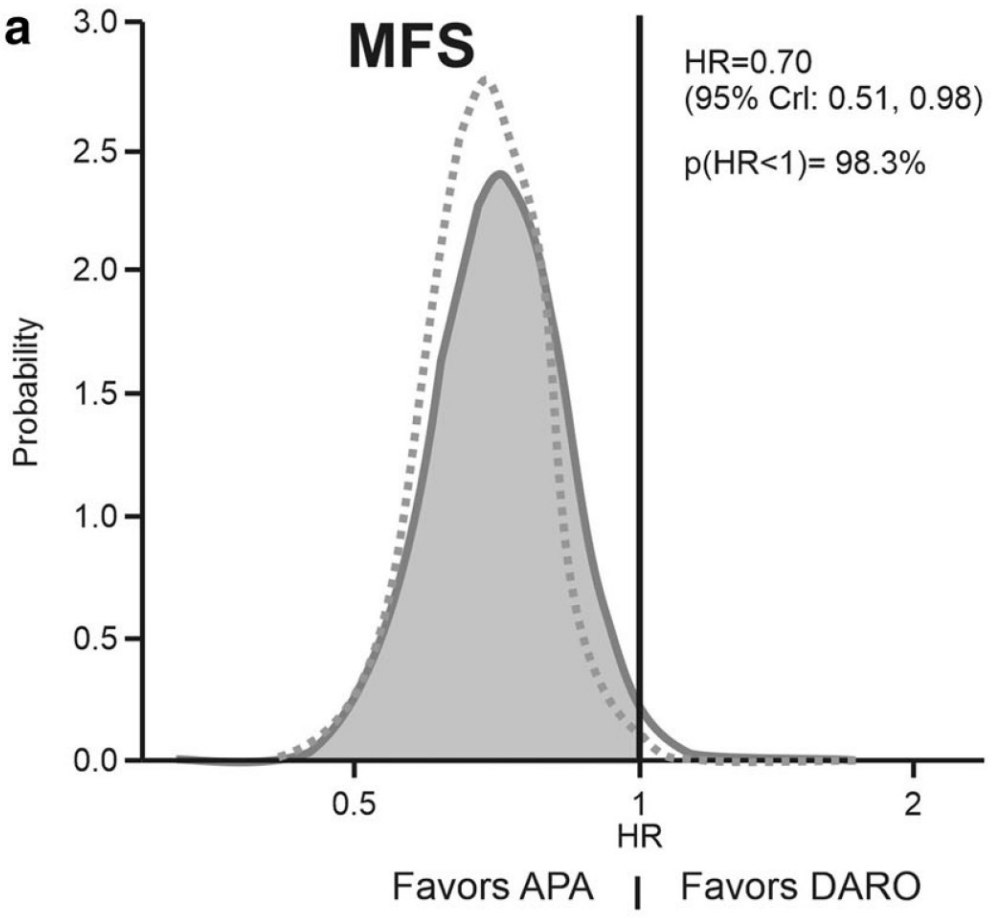
Adv Ther (2022) 39:518–531
https://doi.org/10.1007/s12325-021-01885-6

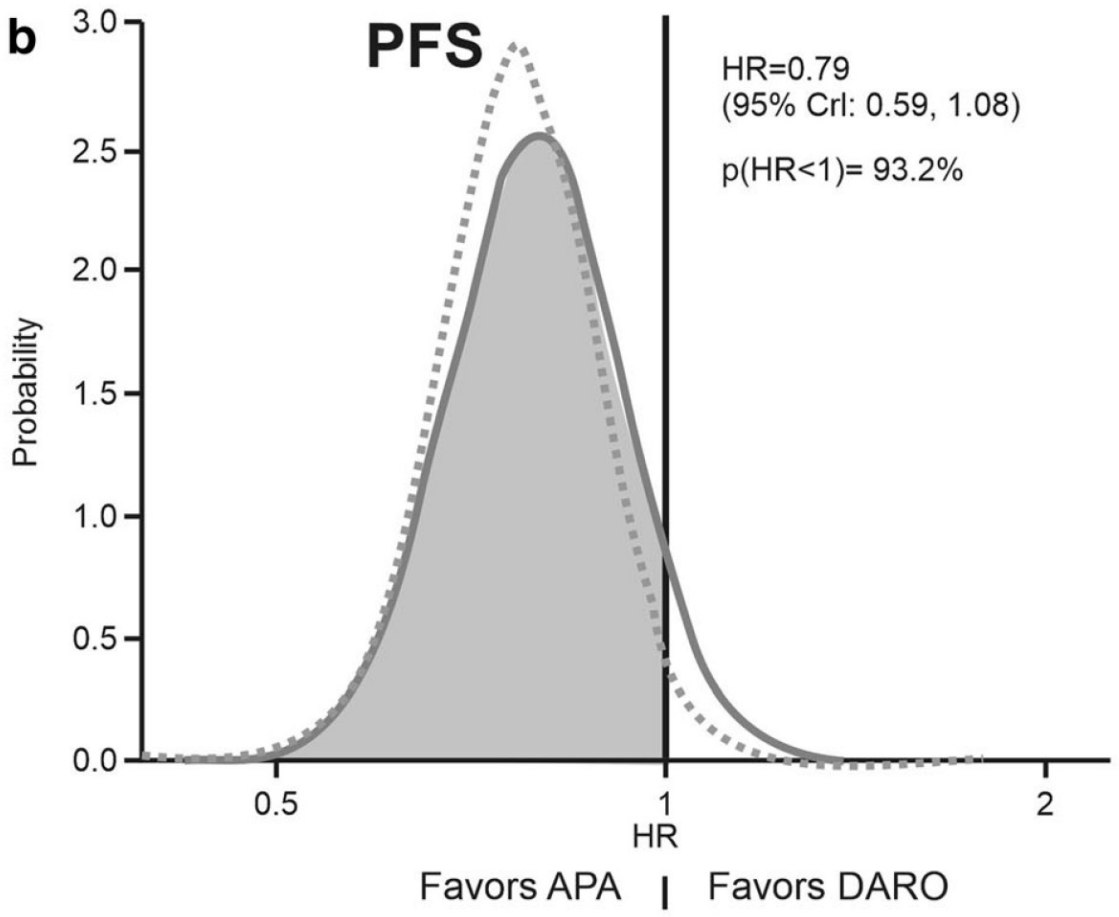
ORIGINAL RESEARCH

Apalutamide Compared with Darolutamide for the Treatment of Non-metastatic Castration-Resistant Prostate Cancer: Efficacy and Tolerability in a Matching-Adjusted Indirect Comparison

Simon Chowdhury · Stephane Oudard · Hiroji Uemura · Steven Joniau · Lindsay Dearden · Camille Capone · Suzy Van Sanden · Joris Diels · Boris A. Hadaschik

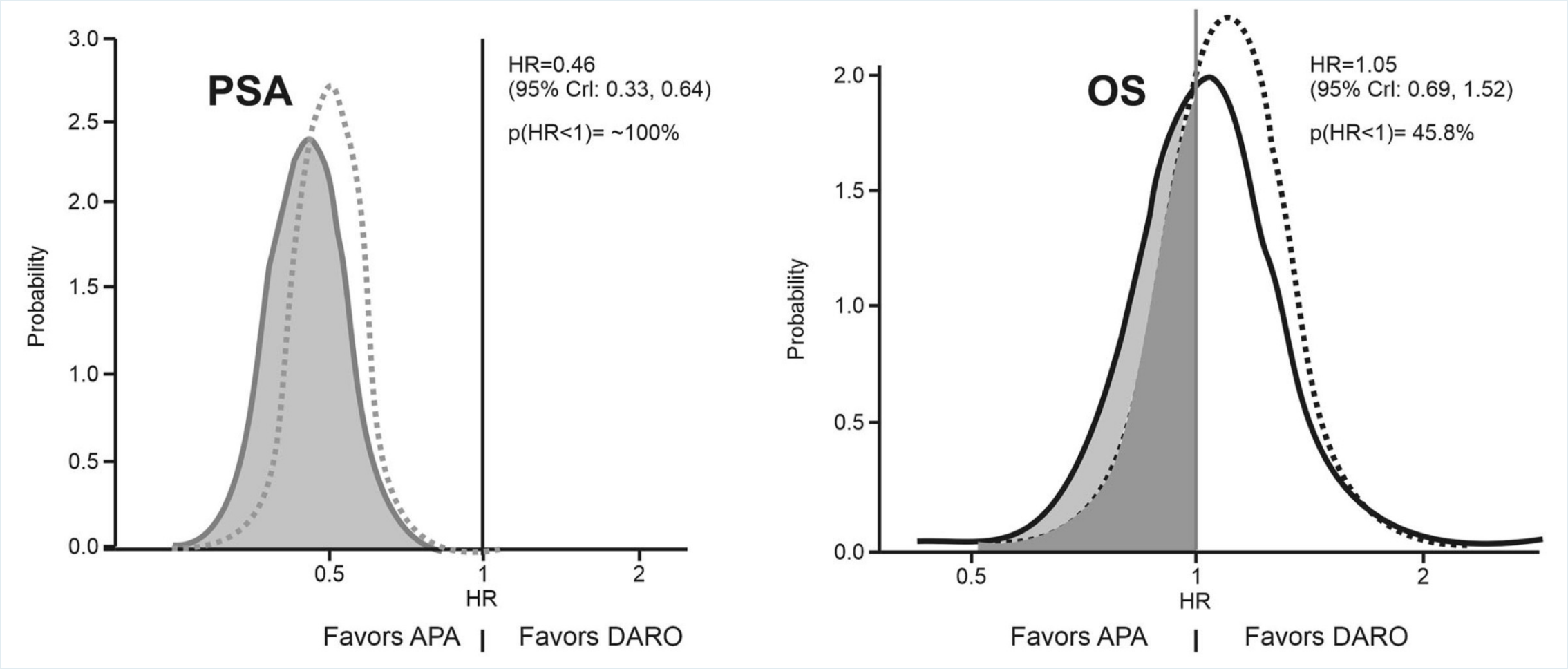
Posterior Distribution of Hazard Ratio for Metastasis-Free and Progression-Free Survival





Chowdhury S et al. *Adv Ther* 2022;39:518-31.

Posterior Distribution of Hazard Ratio for PSA Progression and Overall Survival



Chowdhury S et al. *Adv Ther* 2022;39:518-31.

Eur Urol 2022 September 8;[Online ahead of print].

available at www.sciencedirect.com
journal homepage: www.europeanurology.com

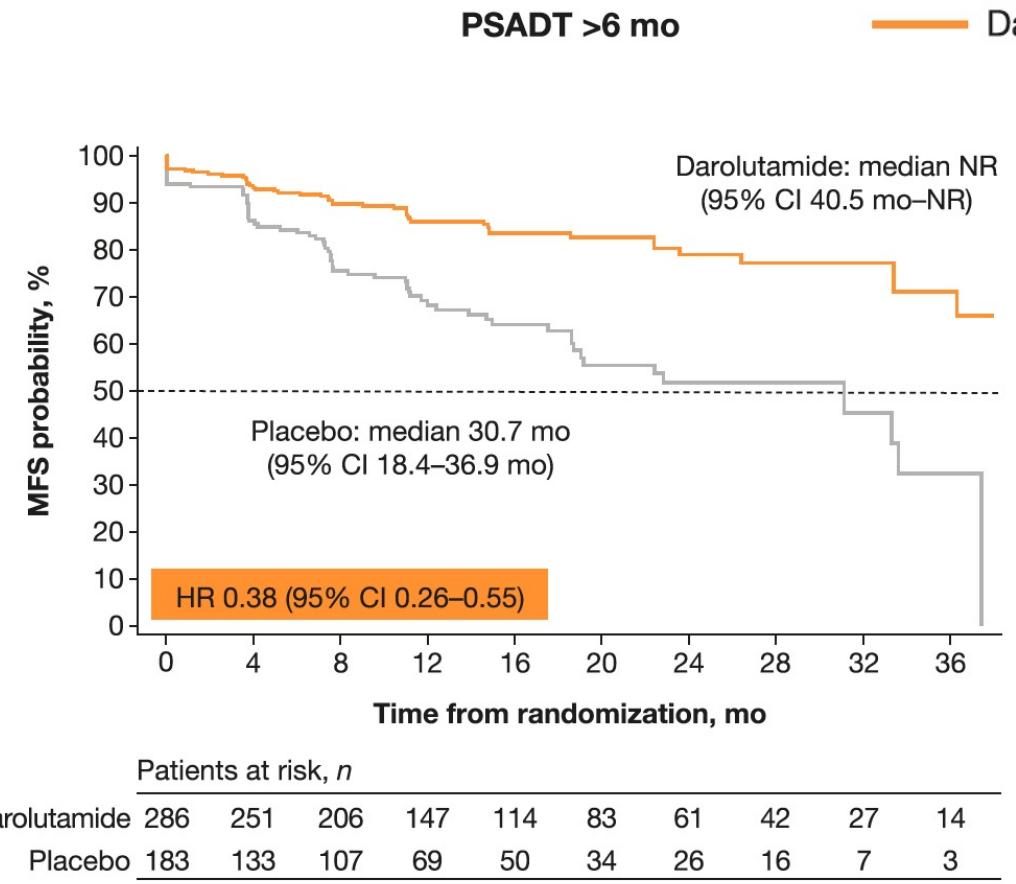
European Association of Urology

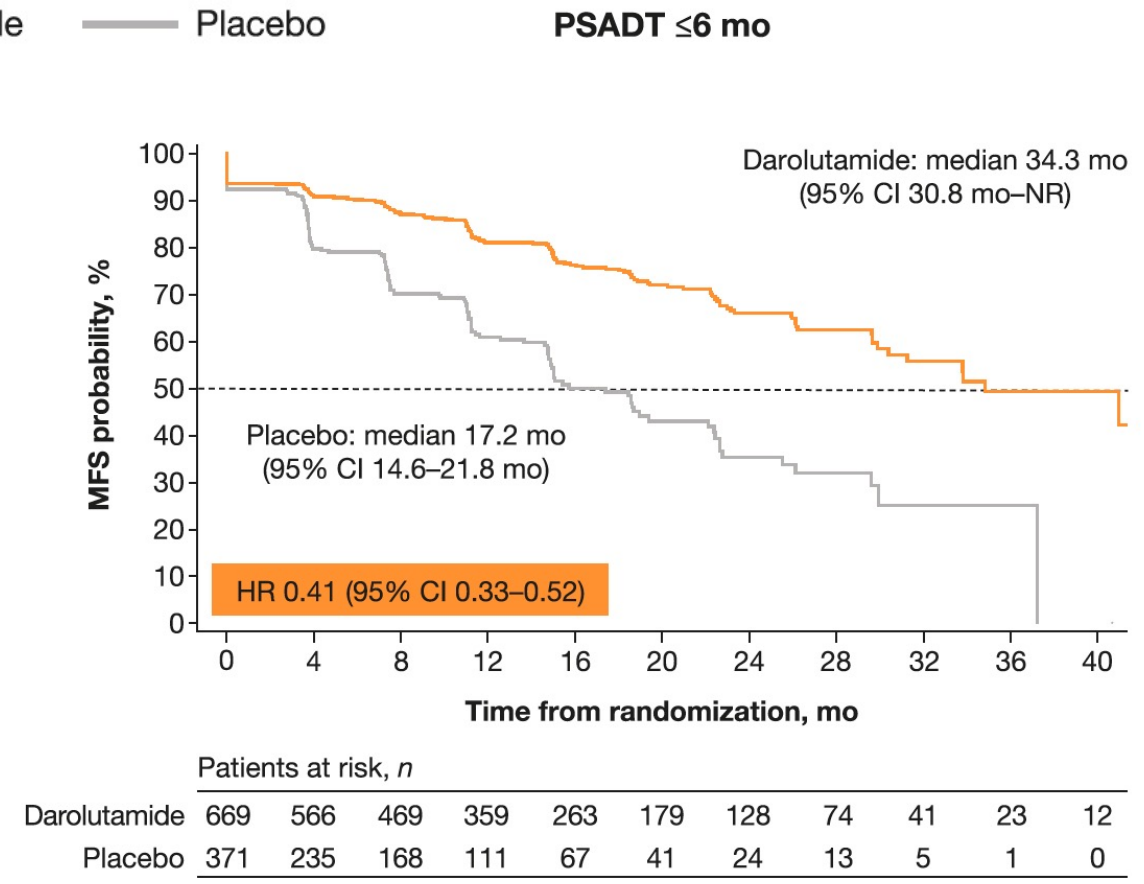
Prostate Cancer

Efficacy and Safety of Darolutamide in Patients with Nonmetastatic Castration-resistant Prostate Cancer Stratified by Prostate-specific Antigen Doubling Time: Planned Subgroup Analysis of the Phase 3 ARAMIS Trial

Martin Bögemann[a,], Neal D. Shore[b], Matthew R. Smith[c], Teuvo L.J. Tammela[d], Albertas Ulys[e], Egils Vjaters[f], Sergey Polyakov[g], Mindaugas Jievaltas[h], Murilo Luz[i], Boris Alekseev[j], Thierry Lebret[k], Martin Schostak[l], Frank Verholen[m], Marie-Aude Le Berre[n], Shankar Srinivasan[o], Jorge Ortiz[o], Ateesha F. Mohamed[o], Toni Sarapohja[p], Karim Fizazi[q]*

ARAMIS: Metastasis-Free Survival (MFS) by PSADT Subgroup

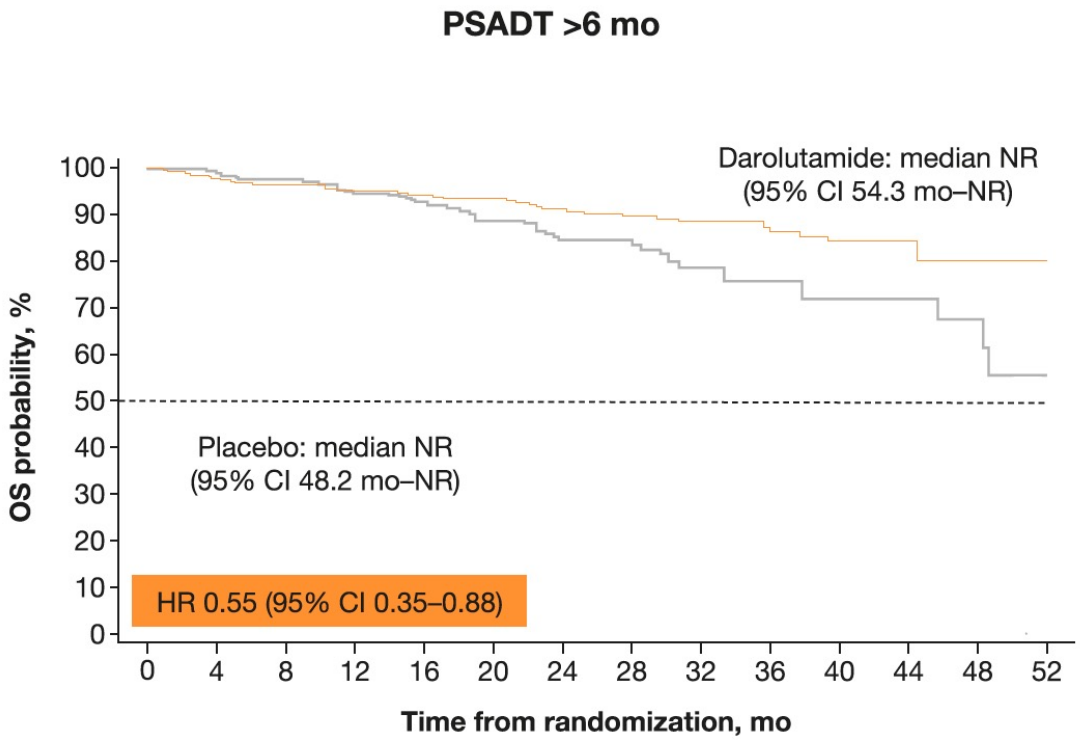




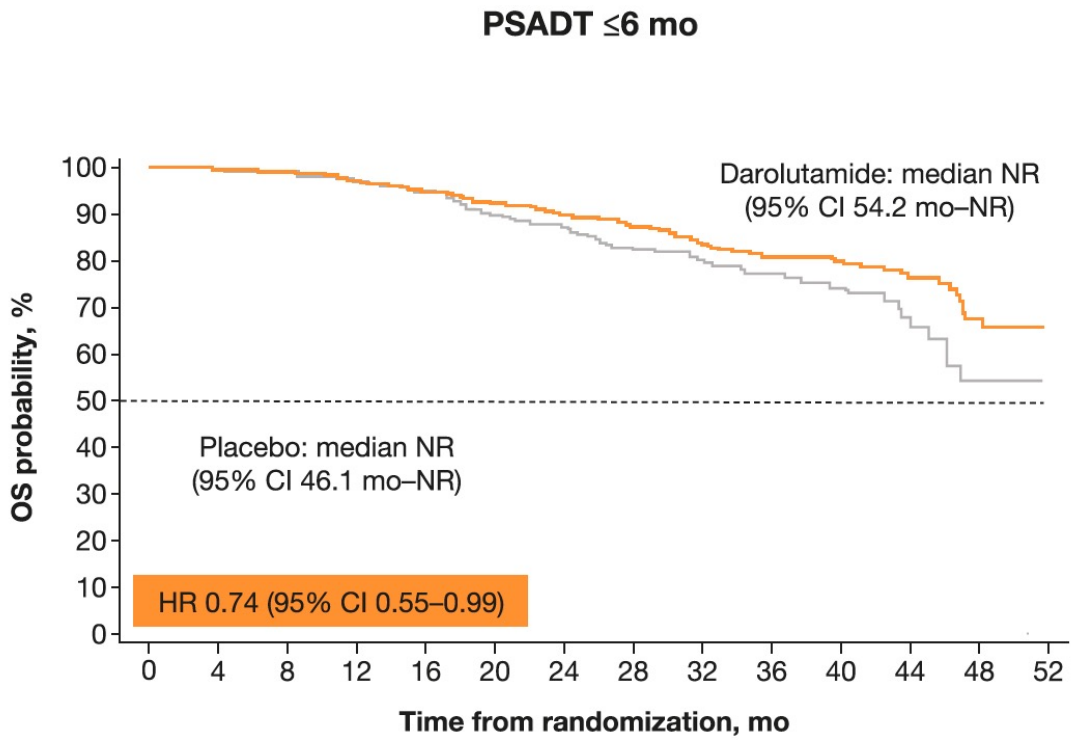
PSADT = prostate-specific antigen doubling time

Bogemann M et al. *Eur Urol* 2022 September 8;[Online ahead of print].

ARAMIS: Overall Survival (OS) by PSADT Subgroup



Patients at risk, *n*													
Darolutamide	286	277	268	260	241	232	203	154	126	89	64	43	26	13
Placebo	183	178	164	153	146	133	114	87	56	41	30	22	11	8



Patients at risk, *n*													
Darolutamide	669	655	640	603	575	539	477	395	299	204	150	86	43	24
Placebo	371	352	333	307	286	261	219	174	126	89	63	32	17	8

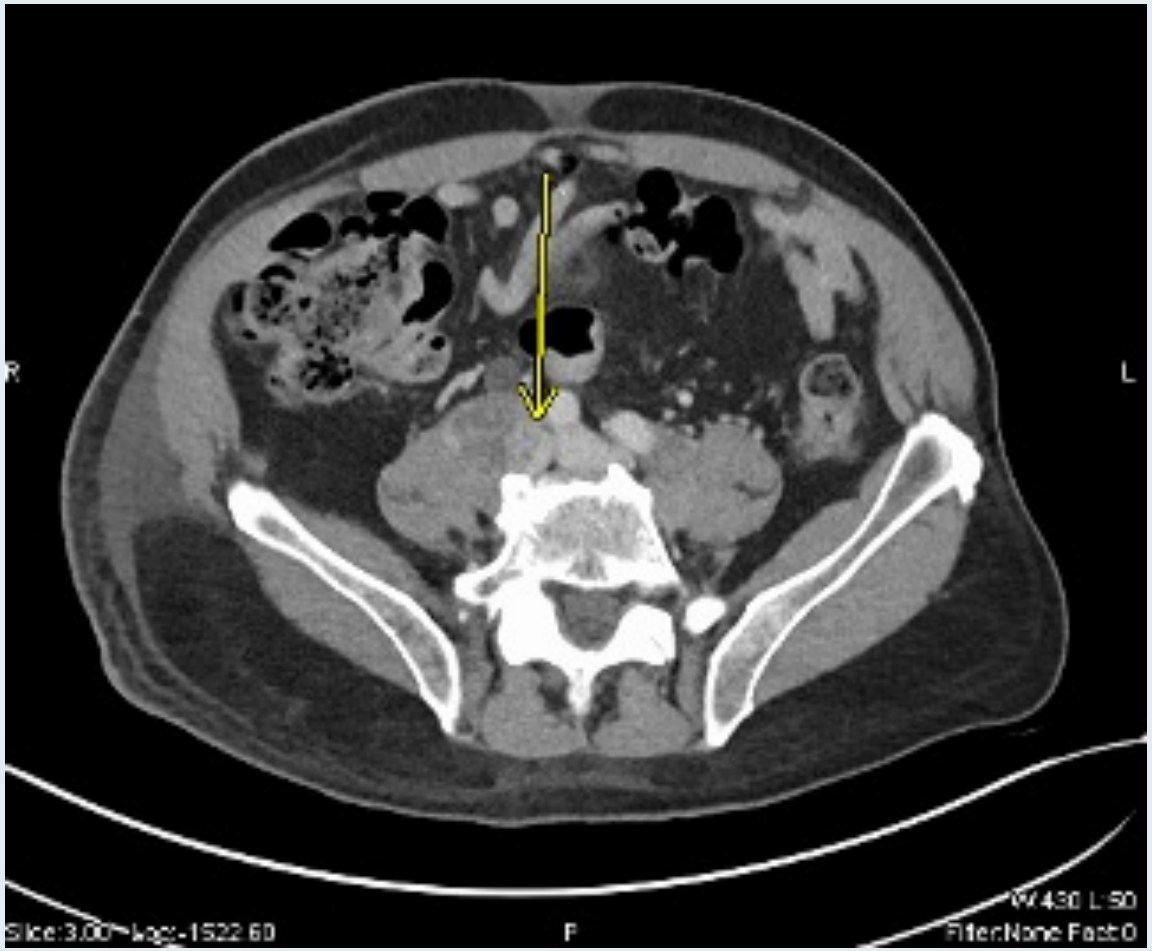
Darolutamide Placebo

Bogemann M et al. *Eur Urol* 2022 September 8;[Online ahead of print].

Case Presentation: 70-year-old man, pacemaker, S/P CVA presents with de novo mHSPC

Dr Nasfat Shehadeh (Charlotte, North Carolina)

RTP
RESEARCH
TO PRACTICE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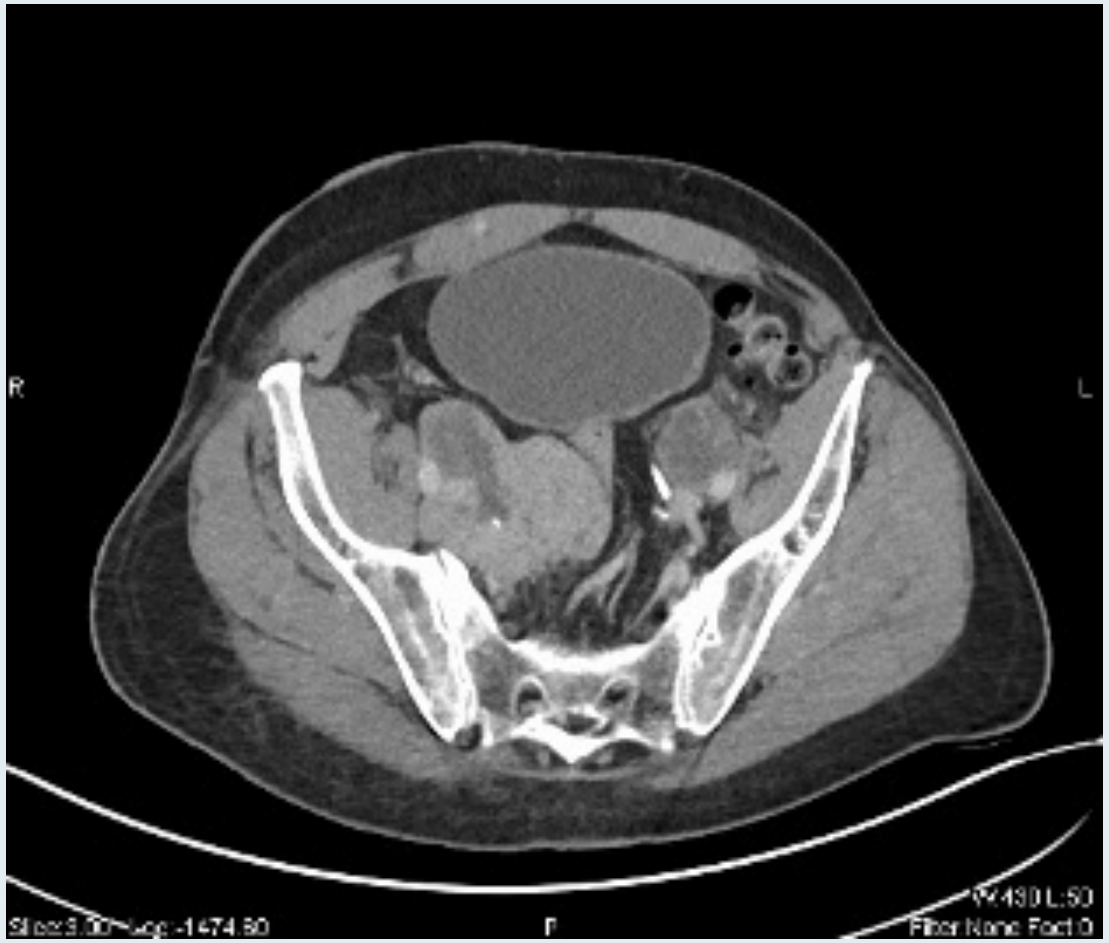
R
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W:430 L:50
Filter:None Fact:0

J Clin Oncol 2022;40(31):3573-6.

Management of Metastatic Hormone-Sensitive Prostate Cancer: Is Docetaxel Needed?

Adi Kartolo, MD[1]; Ian F. Tannock, MD, PhD, DSc[2]; and Francisco E. Vera Badillo, MD, MSc[1]

“In summary, triplet therapy may be a viable option for men with mHSPC who would otherwise have been offered ADT plus docetaxel. The benefits of triplet therapy over ADT plus an ASI remain questionable, because of the lack of head-to-head comparisons. In the absence of definitive evidence of benefit, particularly in men with lower-grade, low-volume mHSPC, the default should be to simpler, less toxic treatment.”

Kartolo A et al. *J Clin Oncol* 2022;40(31):3573-6.

European Journal of Cancer 173 (2022) 276–284

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.ejcancer.com

Original Research

Triplet therapy with androgen deprivation, docetaxel, and androgen receptor signalling inhibitors in metastatic castration-sensitive prostate cancer: A meta-analysis

Chiara Ciccarese [a], Roberto Iacovelli [a,*], Cora N. Sternberg [b], Silke Gillessen [c,d,e], Giampaolo Tortora [a,f,1], Karim Fizazi [g,1]

Lancet 2022;399:1695-07.

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 Kacso, 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**

N Engl J Med 2022;386:1132-42

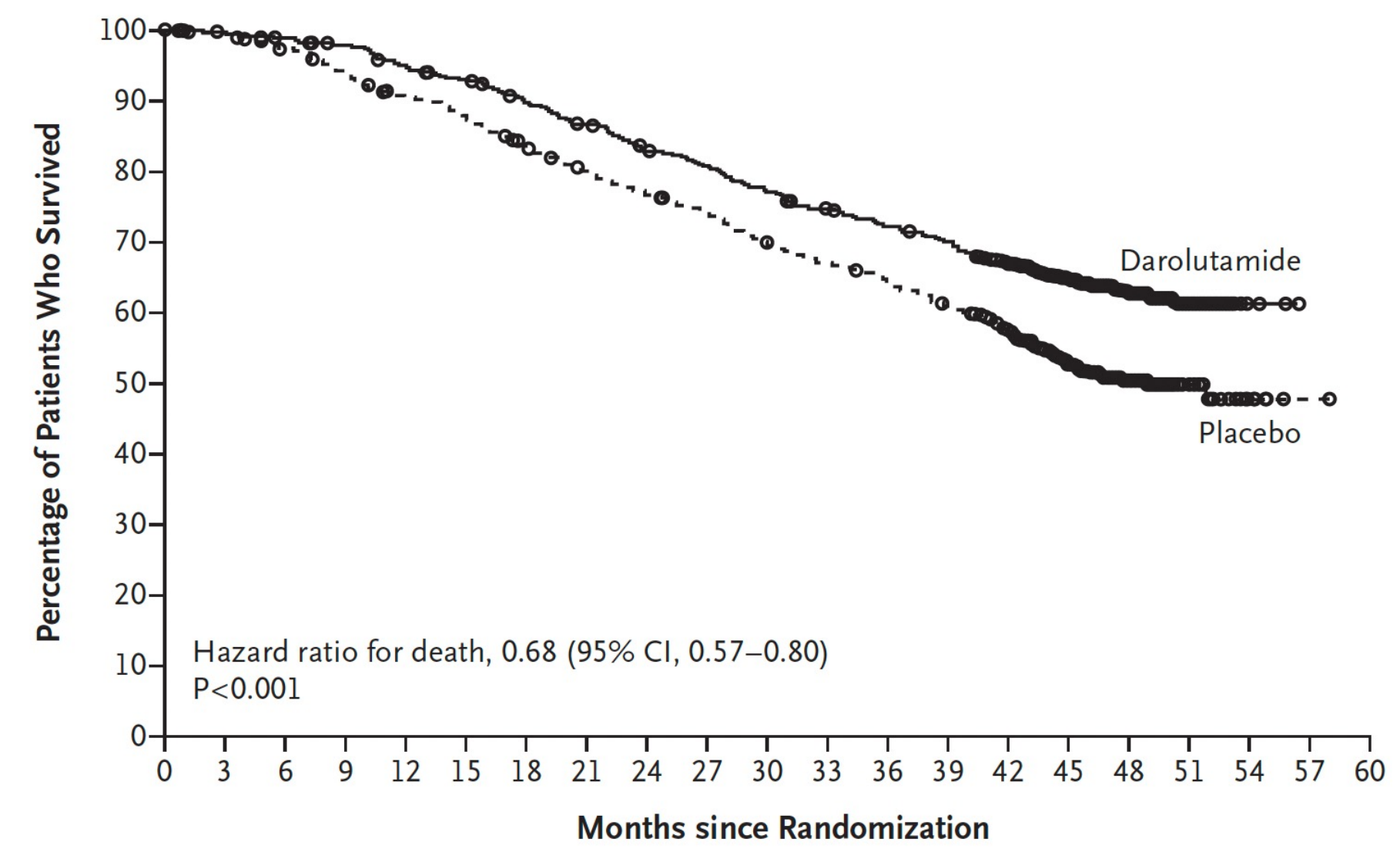
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Darolutamide and Survival in Metastatic, Hormone-Sensitive Prostate Cancer

Matthew R. Smith, M.D., Ph.D., Maha Hussain, M.D., Fred Saad, M.D., Karim Fizazi, M.D., Ph.D., Cora N. Sternberg, M.D., E. David Crawford, M.D., Evgeny Kopyltsov, M.D., Chandler H. Park, M.D., Boris Alekseev, M.D., Álvaro Montesa-Pino, M.D., Dingwei Ye, M.D., Francis Parnis, M.B., B.S., Felipe Cruz, M.D., Teuvo L.J. Tammela, M.D., Ph.D., Hiroyoshi Suzuki, M.D., Ph.D., Tapio Utriainen, M.D., Cheng Fu, M.D., Motohide Uemura, M.D., Ph.D., María J. Méndez-Vidal, M.D., Benjamin L. Maughan, M.D., Pharm.D., Heikki Joensuu, M.D., Silke Thiele, M.D., Rui Li, M.S., Iris Kuss, M.D., and Bertrand Tombal, M.D., Ph.D., for the ARASENS Trial Investigators*

ARASENS: Overall Survival (Primary Endpoint)



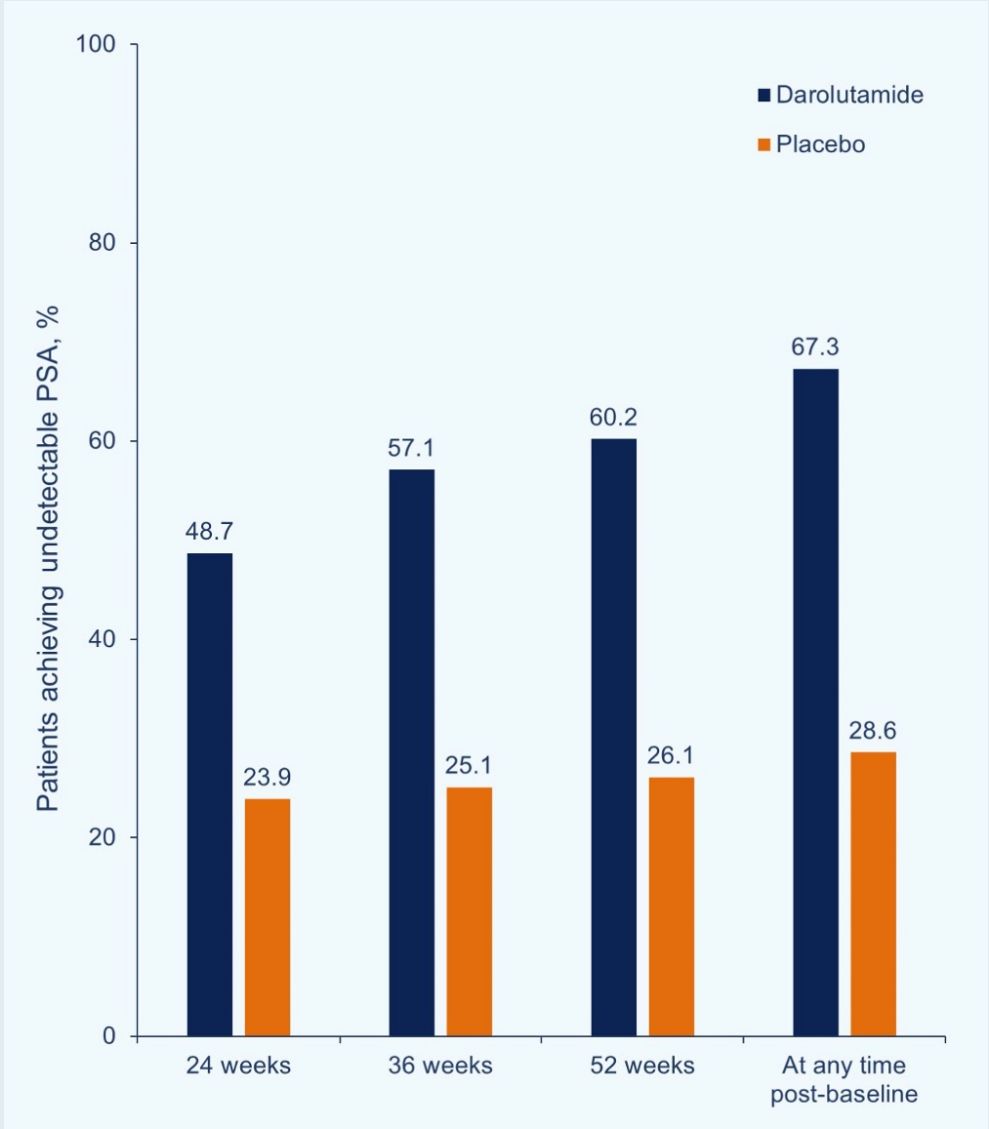
Smith MR et al. *N Engl J Med* 2022;386(12):1132-42.

Association of Prostate-Specific Antigen (PSA) Response and Overall Survival (OS) in Patients with Metastatic Hormone-Sensitive Prostate Cancer (mHSPC) from the Phase 3 ARASENS Trial

Saad F et al.

ASCO 2022;Abstract 5078.

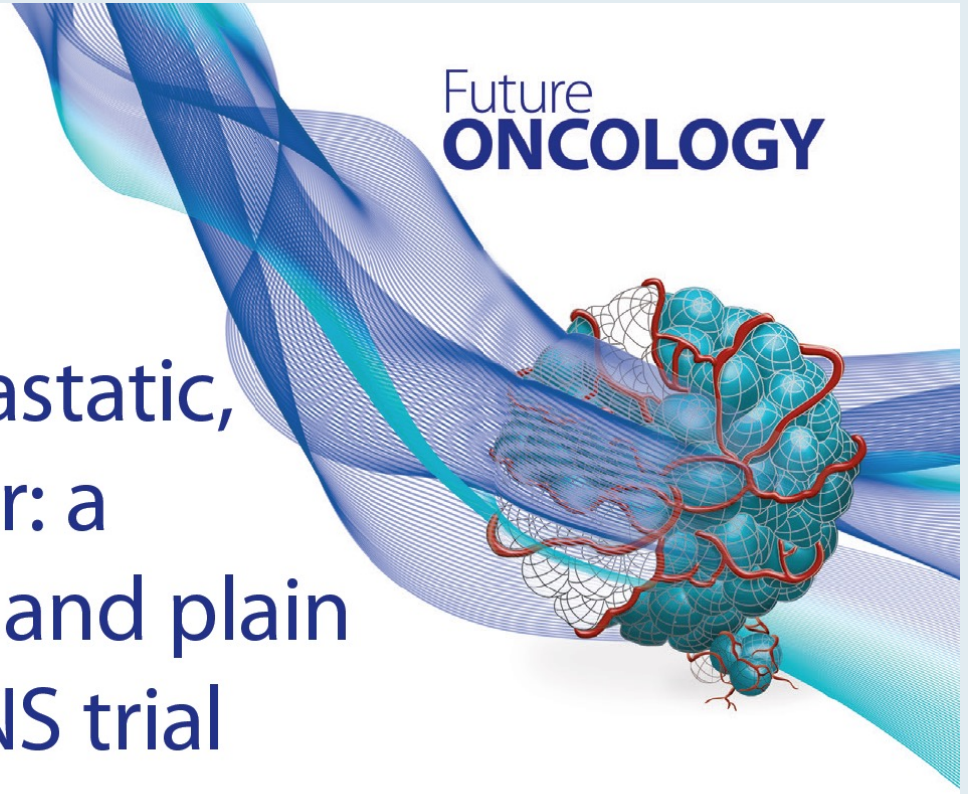
Undetectable PSA (<0.2 ng/mL) Achieved in More than Twice the Number of Patients Receiving Darolutamide versus Placebo



Saad F et al. ASCO 2022;Abstract 5078.

Future Oncol 2022;18(21):2585-97.

Plain Language Summary of Publication

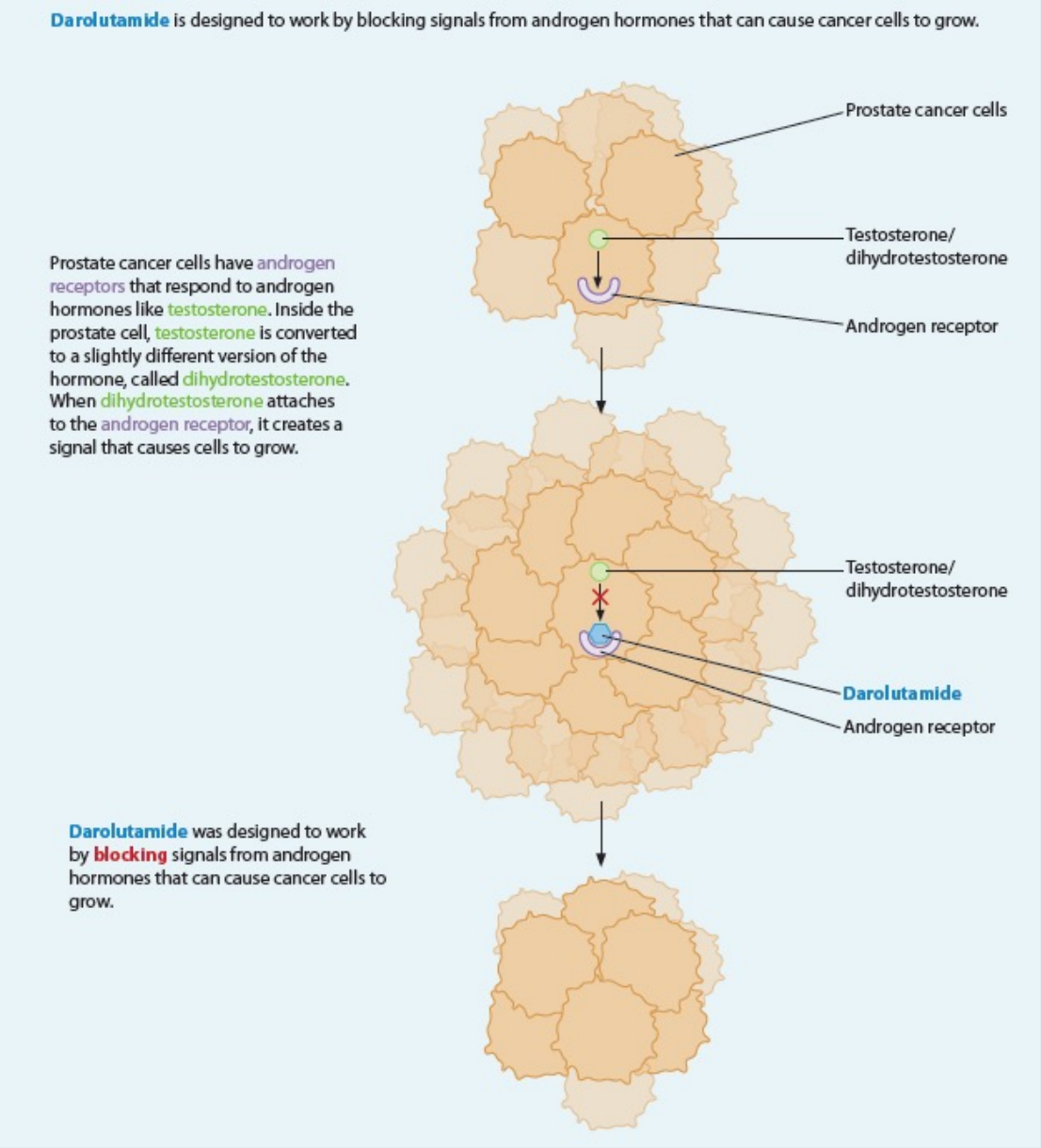


Darolutamide and survival in metastatic, hormone-sensitive prostate cancer: a patient and caregiver perspective and plain language summary of the ARASENS trial

Matthew R Smith*[,1], Maha Hussain[2], Fred Saad[3], Karim Fizazi[4], Cora N Sternberg[5], David Crawford[6], Jan Manarite[7,8], David Muslin[9], Thomas Farrington[9,10] & Bertrand Tombal[11]

[1]Massachusetts General Hospital Cancer Center, Boston, MA, USA; [2]Northwestern University, Feinberg School of Medicine, Chicago, IL, USA; [3]University of Montreal Hospital Center, Montreal, Quebec, Canada; [4]Institut Gustave Roussy, University of Paris-Saclay, Villejuif, France; [5]Englander Institute for Precision Medicine, Weill Cornell Department of Medicine, Meyer Cancer Center, New York-Presbyterian Hospital, New York, NY, USA; [6]UC San Diego School of Medicine, San Diego, CA, USA; [7]Caregiver Author; [8]Cancer ABCs, Brooklyn, NY, USA; [9]Patient Author; [10]Prostate Health Education Network, Quincy, MA, USA; [11]Division of Urology, IREC, Cliniques Universitaires Saint Luc, UCLouvain, Brussels, Belgium

How Is Darolutamide Designed to Work?



Smith MR et al. *Future Oncol* 2022;18(21):2585-97.

About the ARASENS trial

started in November 2016 and is still ongoing as of April 2022.

Placebo-controlled
A placebo looks like a trial treatment but does not have any medicine in it. Researchers use a **placebo** to make sure the effects of the trial treatment are actually caused by the trial treatment. In this trial, in addition to **ADT** and **docetaxel**, about half of trial patients received a placebo and the other half received **darolutamide**.

includes 1,306 patients with mHSPC.

Double-blinded
None of the trial patients, researchers, or doctors knew what treatment each patient received. This means they were "blind" to this information.

Randomized
Random chance was used by a computer to place trial patients into different equally sized groups. This is similar to flipping a coin.

Smith MR et al. *Future Oncol* 2022;18(21):2585-97.

What happened in the ARASENS trial?

1,306
patients were split into
2 groups

651
patients were put into the
darolutamide group
and received these treatments:

655
patients were put into the
placebo group
and received these treatments:

Docetaxel
6 cycles of 75 mg per 1 square meter of body-surface area on day 1 and every 21 days

ADT
As prescribed, throughout the entire trial

Darolutamide
600 mg taken twice a day, throughout the entire trial

Docetaxel
6 cycles of 75 mg per 1 square meter of body-surface area on day 1 and every 21 days

ADT
As prescribed, throughout the entire trial

Placebo
Taken twice a day, throughout the entire trial

The patients received **darolutamide** or the **placebo**, in addition to **ADT** and **docetaxel,** until any of the following happened:

- Their cancer got worse
- They had a change in chemotherapy
- They had treatment effects that were too toxic
- They or their doctor decided to stop treatment for a different reason

Smith MR et al. *Future Oncol* 2022;18(21):2585-97.

What were the results?

The purpose of the ARASENS trial was to learn if combining **darolutamide** with **ADT** and **docetaxel** could help treat patients with mHSPC better than **placebo** with **ADT** and **docetaxel**.

The researchers wanted to learn the answers to several questions to determine if combining **darolutamide** was working better than the **placebo**. To answer these questions, the researchers collected data from the trial patients until October 2021.

They compared the results of the patients who received **darolutamide** to the patients who received the **placebo**. The results below were similar in all race groups.

Below are the answers to these questions.

Compared to the **placebo**, did adding **darolutamide** to **ADT** and **docetaxel** help…

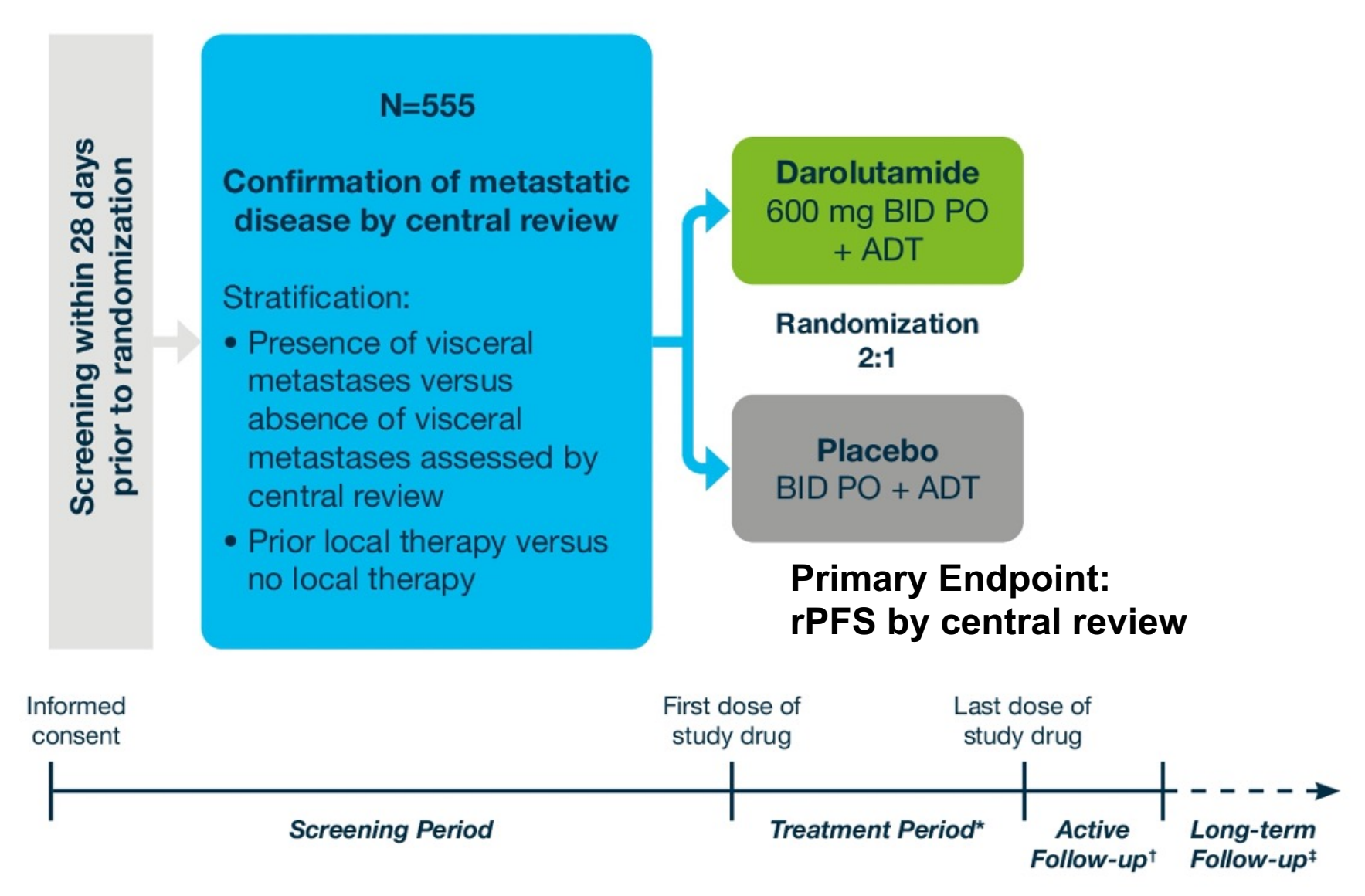
		Risk reduction	After 4 years of receiving trial treatment
trial patients live longer?	Yes	Overall, treatment with **darolutamide** increased the chance of survival and reduced the risk of dying by **32.5%** compared to the **placebo**.	 **62.7%** of patients in the **darolutamide group** were still alive  **50.4%** of patients in the **placebo group** were still alive

As of October 2021

delay castration-resistant cancer? When prostate cancer becomes castration-resistant, it means it is no longer responding to treatment with ADT and the growth of cancer cells may increase.	Yes	Overall, treatment with **darolutamide** increased the length of time patients continued to respond to ADT and didn't require treatment change. It also reduced the risk of cancer becoming castration-resistant by **64%** compared to the **placebo**.	 **35%** of patients in the **darolutamide group** had castration-resistant cancer  **60%** of patients in the **placebo group** had castration-resistant cancer
delay worsening pain? Severity of pain was measured using a survey called the Brief Pain Inventory (Short Form) that was completed by trial patients.	Yes	Overall, treatment with **darolutamide** increased the length of time patients remained alive without worsening of pain and reduced the risk of pain becoming worse by **21%** compared to the **placebo**.	 **34%** of patients in the **darolutamide group** had worsening pain  **38%** of patients in the **placebo group** had worsening pain

Smith MR et al. *Future Oncol* 2022;18(21):2585-97.

ARANOTE Phase III Study Design



Haresh KP et al. ASCO 2022;Abstract TPS200.

Case Presentation: 49-year-old man with multiple medical comorbidities presents with de novo mHSPC (PSA 19.4) and responds to ADT/docetaxel

Dr Gurveen Kaur (Wheeling, West Virginia)

RTP RESEARCH TO PRACTICE

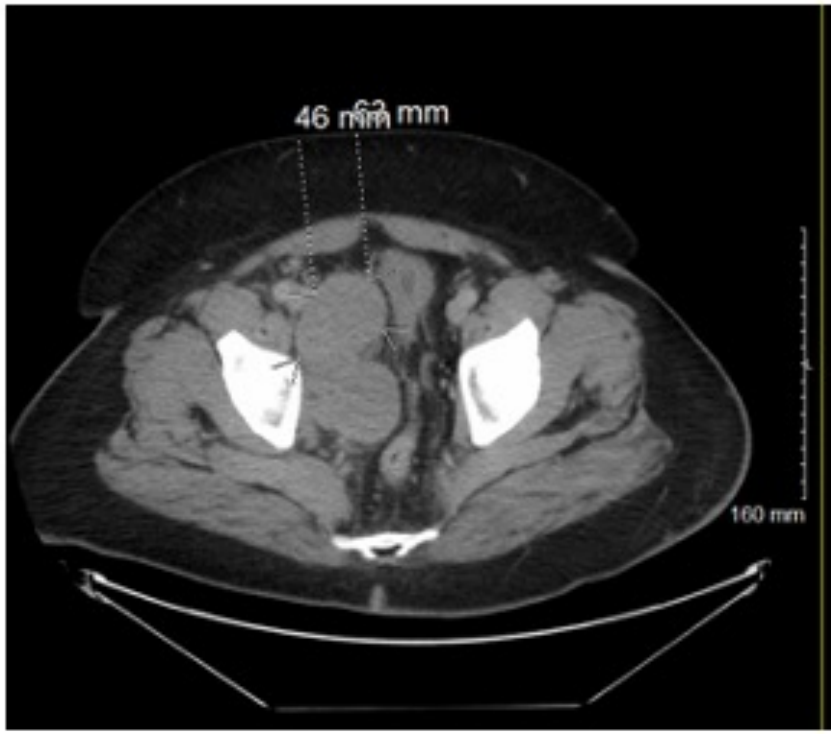
Case Presentation: 65-year-old man with de novo mHSPC receives leuprolide, and PSA levels decrease from 865 ng/mL to 1.34 ng/mL

Dr Joanna Metzner-Sadurski (Greenwood, South Carolina)

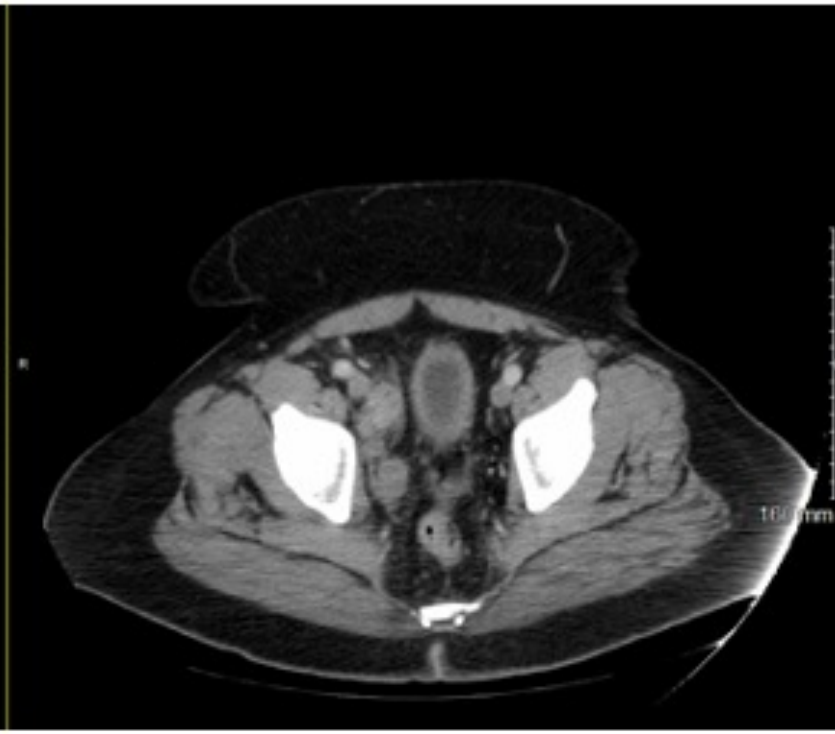
RTP
RESEARCH
TO PRACTICE

CT Pelvis - Comparison

1/20/22



10/29/21



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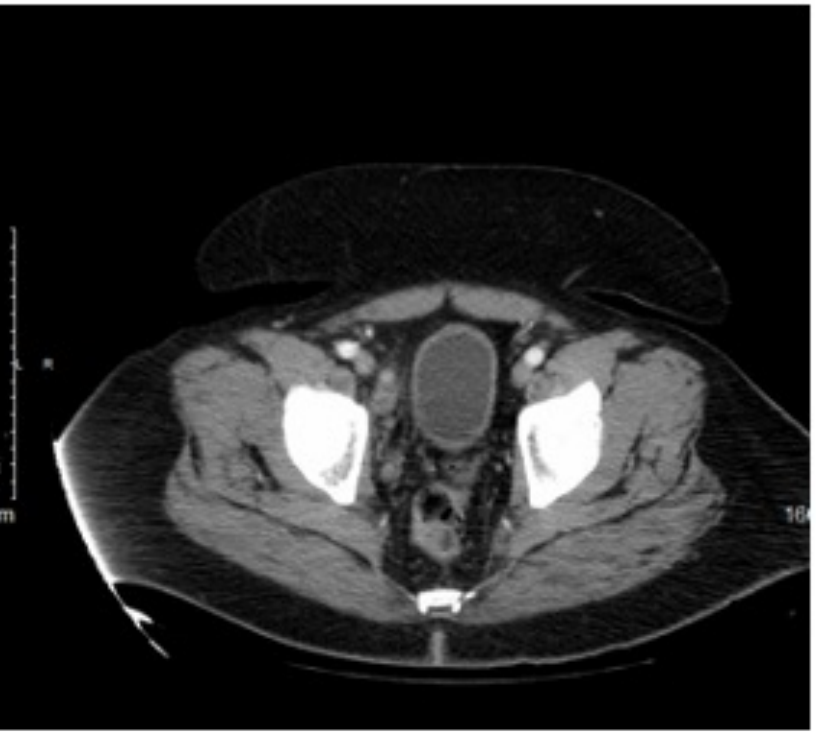


Case Presentation: 58-year-old man with mHSPC receives leuprolide with progression 1.5 years later and responds to abiraterone/prednisone but on liquid biopsy is found to have an AR T878 mutation

Dr Niyati Nathwani (Charlotte, North Carolina)

RTP
RESEARCH
TO PRACTICE

Case Presentation: 76-year-old man s/p radical prostatectomy, salvage RT now has osseous metastases on a clinical trial of enzalutamide/IO

Dr David Morris (Nashville, Tennessee)

RTP
RESEARCH
TO PRACTICE

Case Presentation: 65-year-old man presents with de novo metastatic prostate cancer and has disease progression on ADT + docetaxel, now with PD on abiraterone/prednisone – germline CHEK2 mutation

Dr Syed Zafar (Fort Myers, Florida)

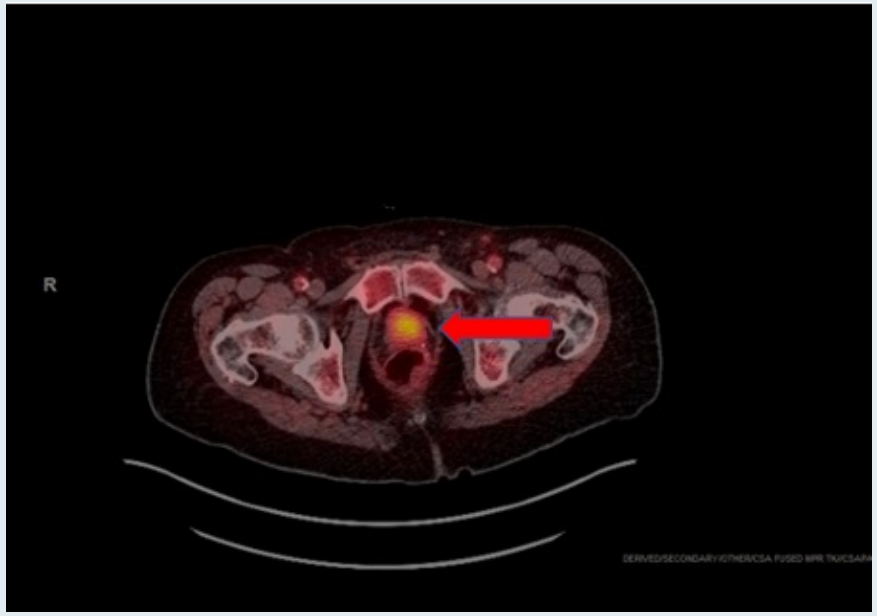
RTP
RESEARCH
TO PRACTICE

Case Presentation: 86-year-old man received cryoablation for Stage IIB PCA; s/p apalutamide for M0 recurrence. MRI reveals diffuse abnormal signal entire prostate

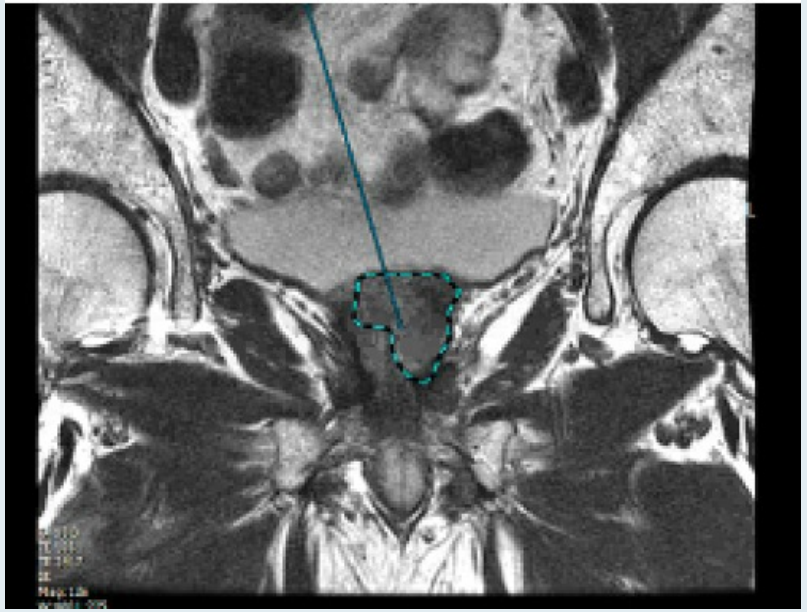
Dr Jason Hafron (West Bloomfield, Michigan)

RTP
RESEARCH
TO PRACTICE

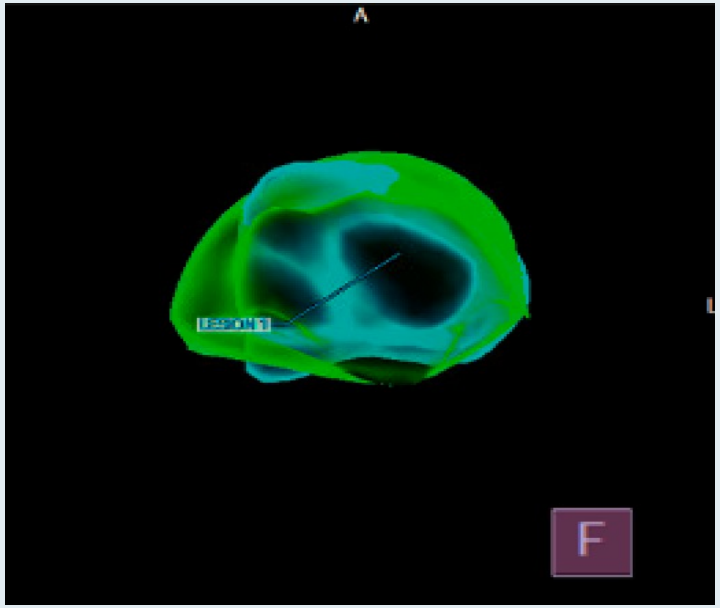
Fluciclovine F 18 PET/CT



MRI of Prostate with PI-RADS 5 Lesion

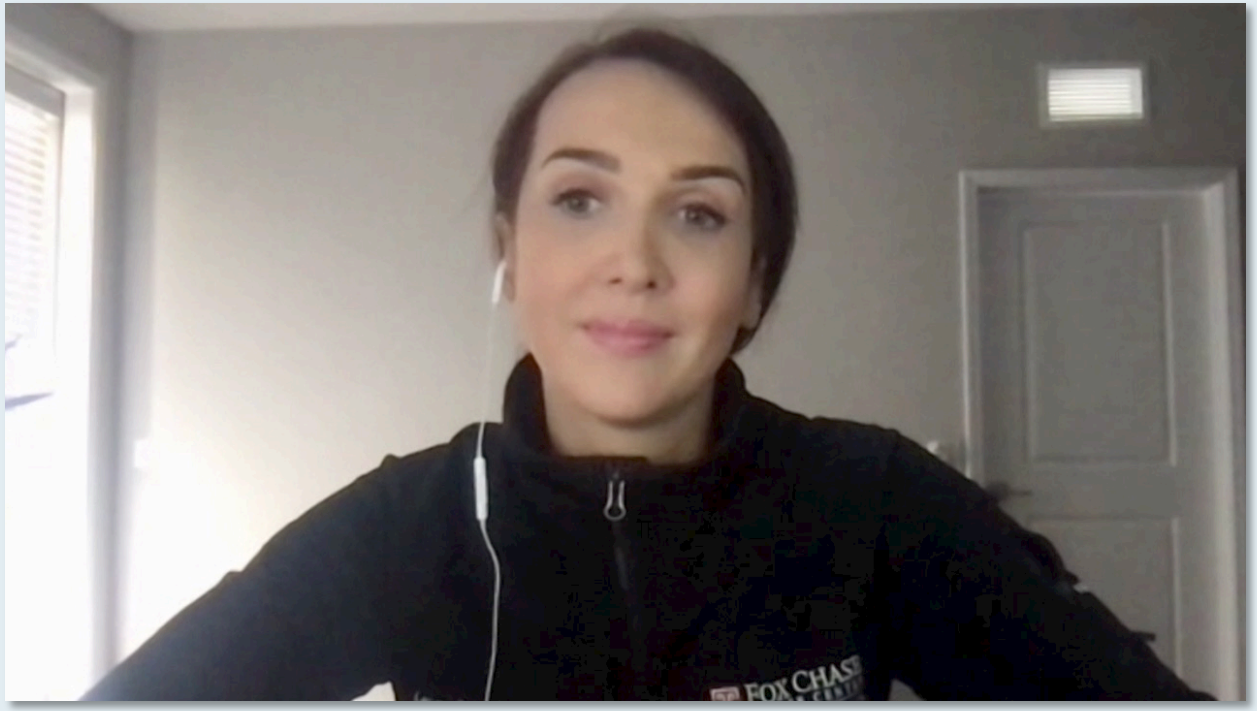


Dynacad Reconstruction of Prostate PI-RADS Lesion



RTP RESEARCH TO PRACTICE

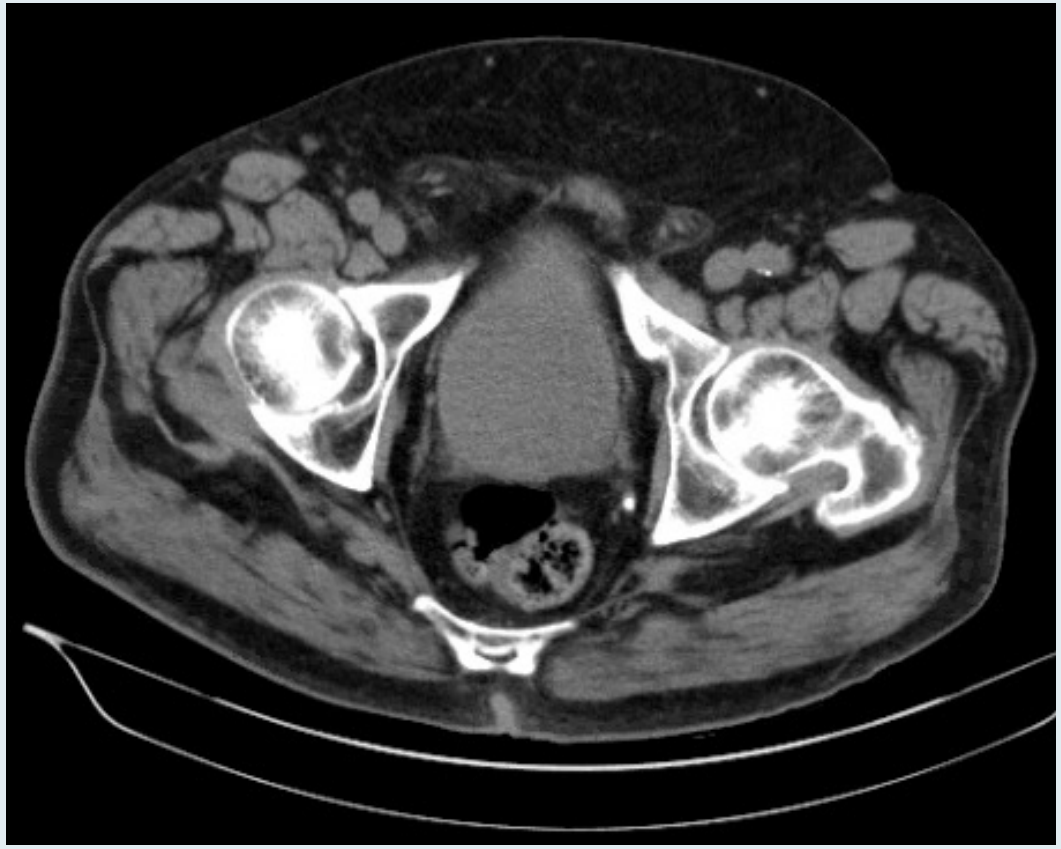
Case Presentation: 72-year-old man with primary PCA and PSA 160 ng/mL. Scans show only disease in prostate



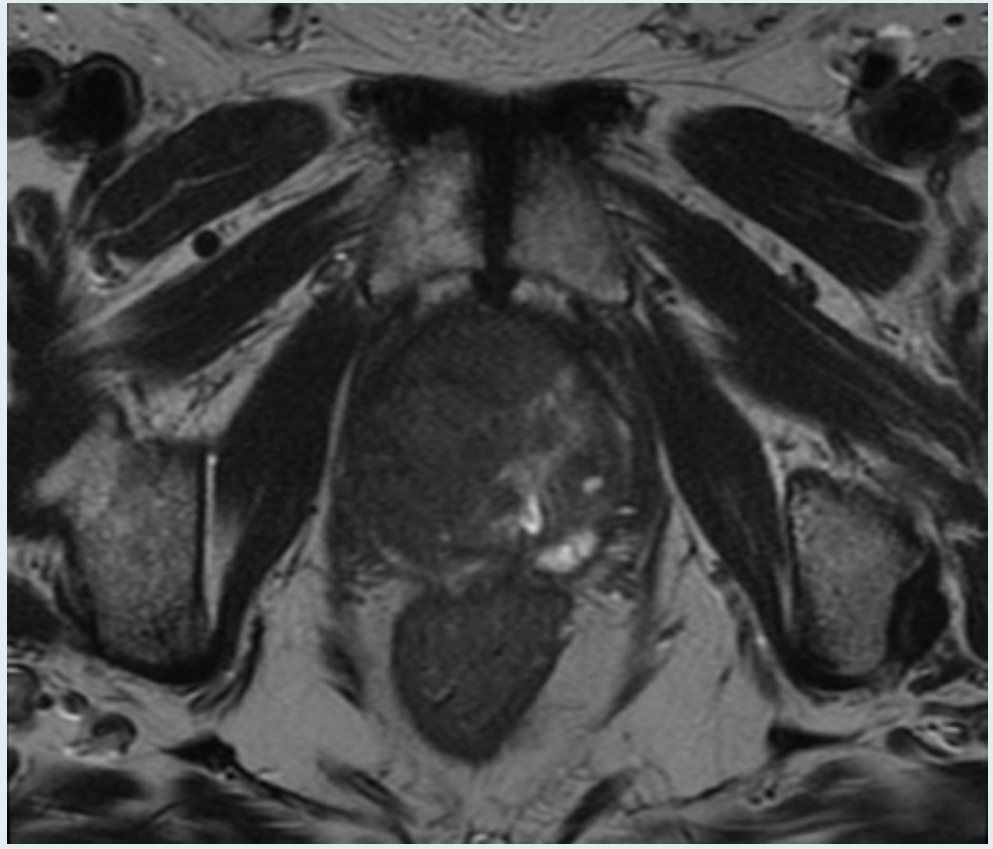
Dr Laura Bukavina (Philadelphia, Pennsylvania)

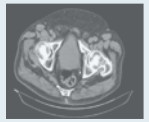
RTP
RESEARCH
TO PRACTICE

CT Scan
Prostate Size 220g



MRI PI-RADS 5 Lesion
Prostate Size 97g

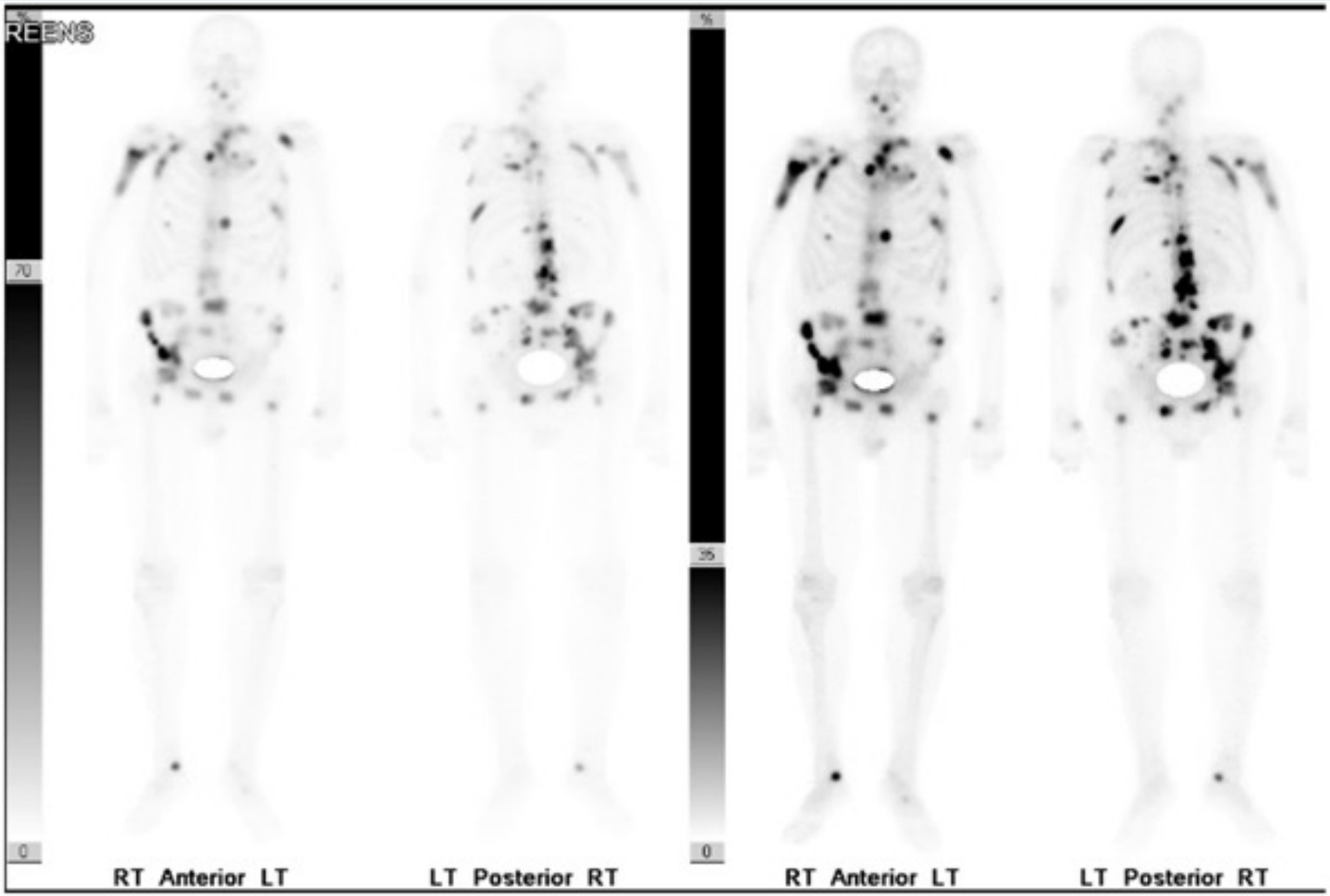




Case Presentation: 82-year-old man with a prior history of prostate and bladder cancer now has elevated alkaline phosphatase (685), PSA 43 and widespread osseous metastases

Dr David Taub (Boca Raton, Florida)

RTP
RESEARCH
TO PRACTICE


REENS
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Meet The Professor with Prof Fizazi and Prof Oudard

Introduction: Journal Club — Profs Fizazi and Oudard

MODULE 1: Case Presentations

MODULE 2: Ongoing Trials; Reported Data; Review Articles

RTP
RESEARCH
TO PRACTICE

PARIS 2022 ESMO congress

Abstract LBA9

Duration of androgen deprivation therapy (ADT) with post-operative radiotherapy (RT) for prostate cancer: first results of the RADICALS-HD trial

C.C. Parker

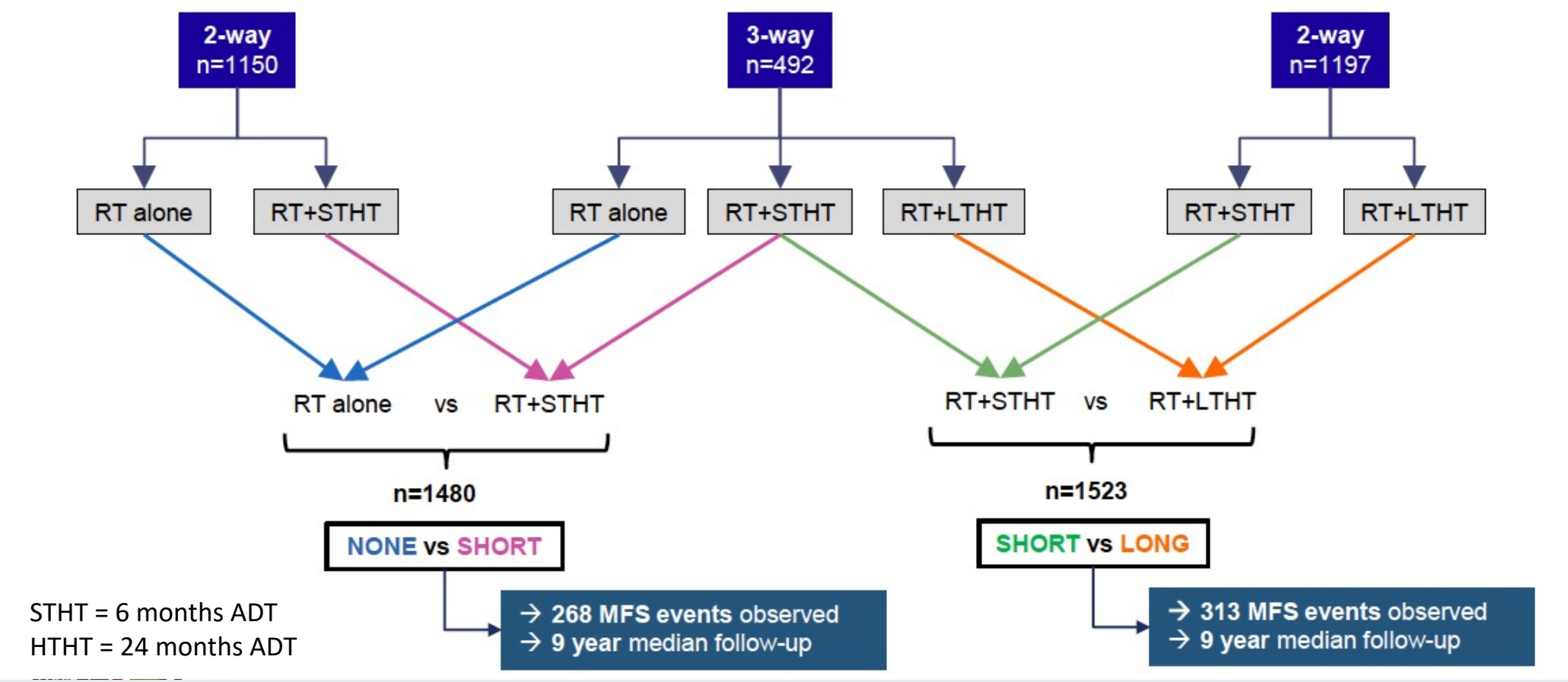
N.W. Clarke, A. Cook, C. Catton, W. Cross, H. Kynaston, J. Logue, P.M. Petersen, P. Neville, R. Persad, H. Payne, F. Saad, A. Stirling, W.R. Parulekar, M.K.B. Parmar, M.R. Sydes

Paris, September 2022

RTP RESEARCH TO PRACTICE

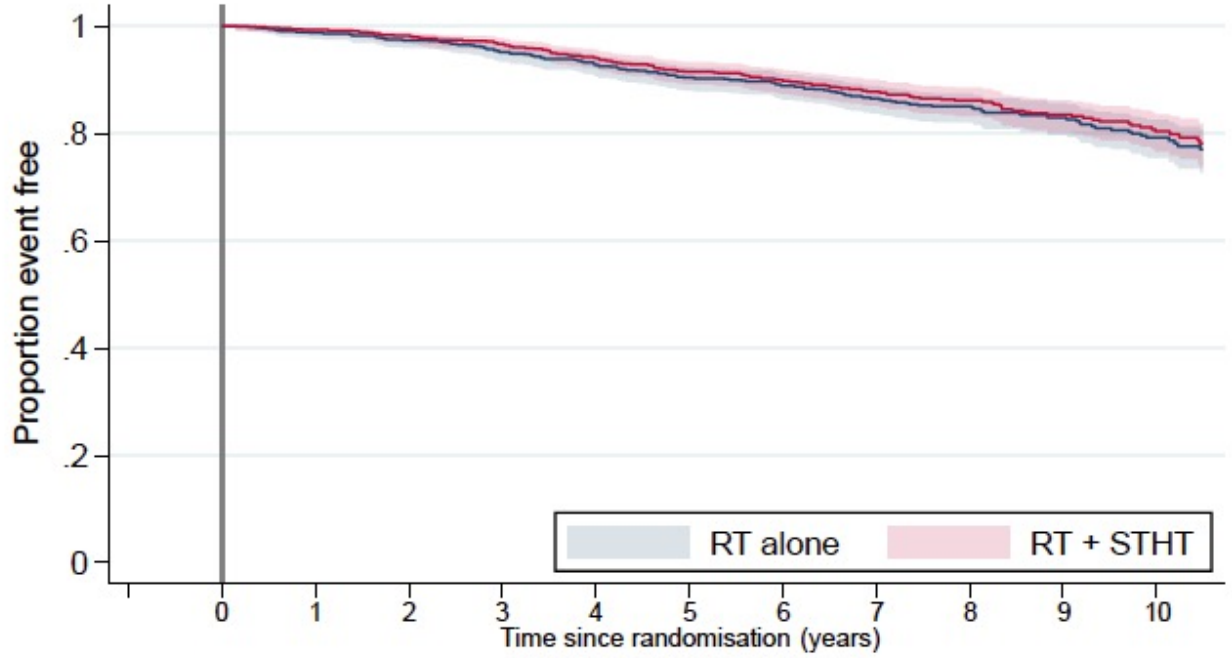
RADICALS-HD Phase III Trial: Recruitment and Randomization

- RADICALS-HD is part of the RADICALS protocol and was designed to assess the use and duration of ADT with postoperative radiation therapy (RT) for prostate cancer
- Key eligibility criteria were indication for RT after previous radical prostatectomy and no previous post-operative ADT



Parker CC et al. ESMO 2022;Abstract LBA9.

RADICALS-HD Metastasis-Free Survival: None versus Short ADT



NONE vs SHORT

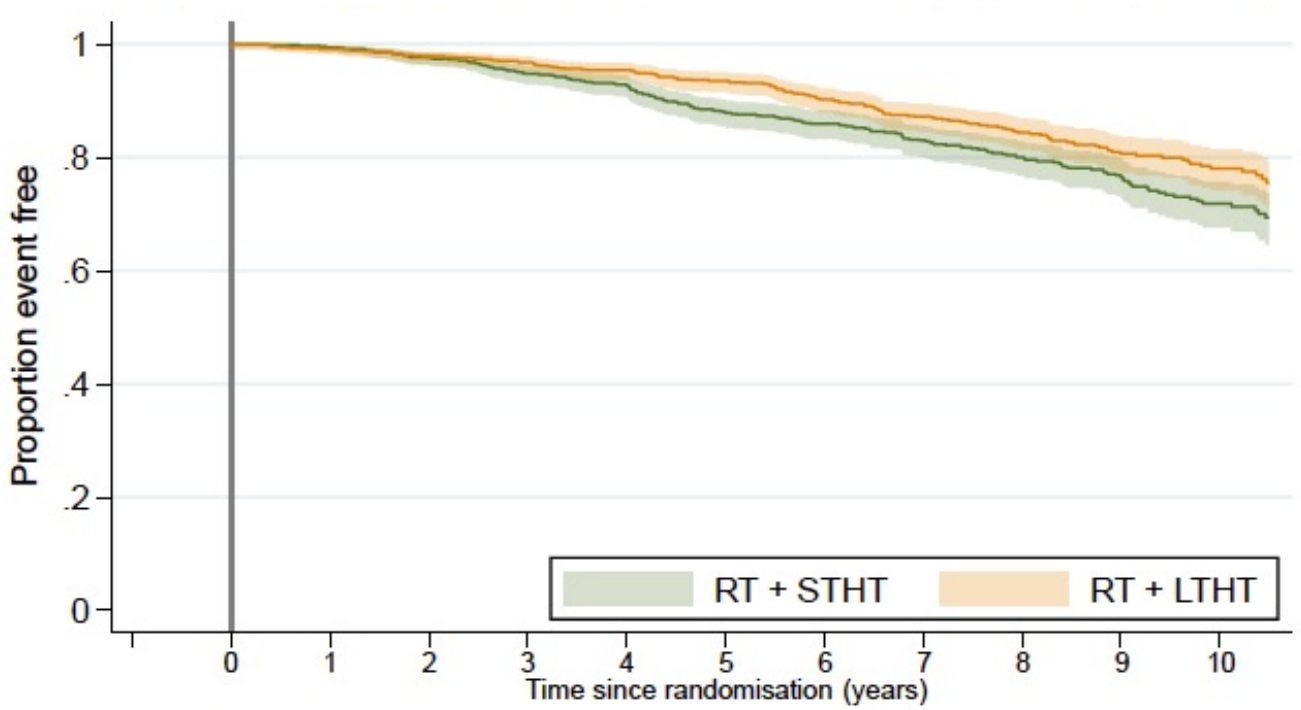
	RT alone (n=737)	RT+STHT (n=743)
Events	142	126
HR (95%CI)	0.89 (0.69 to 1.14)	
P-value	0.35	
10yr event free	79%	80%

Note: HR < 1 favour RT+STHT
Note: predicted 10yr MFS = 80%

Parker CC et al. ESMO 2022;Abstract LBA9.

RTP RESEARCH TO PRACTICE

RADICALS-HD Metastasis-Free Survival: Short versus Long ADT



SHORT vs LONG

	RT+STHT (n=761)	RT+LTHT (n=762)
Events	174	139
HR (95%CI)	**0.77** (0.61 to 0.97)	
P-value	0.03	
10yr event free	72%	78%

Note: HR < 1 favour RT+LTHT
Note: predicted 10yr MFS = 75%

Parker CC et al. ESMO 2022;Abstract LBA9.

RTP RESEARCH TO PRACTICE

RADICALS-HD: Adverse Events

	NONE vs SHORT			SHORT vs LONG		
Maximum grade	**RT alone**	**RT+STHT**	**p**	**RT+STHT**	**RT+LTHT**	**p**
0-2	612 (83%)	635 (85%)	0.25	650 (85%)	615 (81%)	0.06
3	114 (16%)	90 (12%)		99 (13%)	138 (18%)	
4*	7 (1%)	10 (1%)		6 (1%)	4 (1%)	

* No grade 5 events

Most common grade 3+ adverse events reported within 2 years after randomisation:

6% - Urethral stricture
4% - Haematuria

Parker CC et al. ESMO 2022;Abstract LBA9.

Oral Relugolix for Androgen Deprivation Therapy in Advanced Prostate Cancer: Detailed Safety Analysis from the Randomized Phase 3 HERO Study

Mehlhaff B et al.

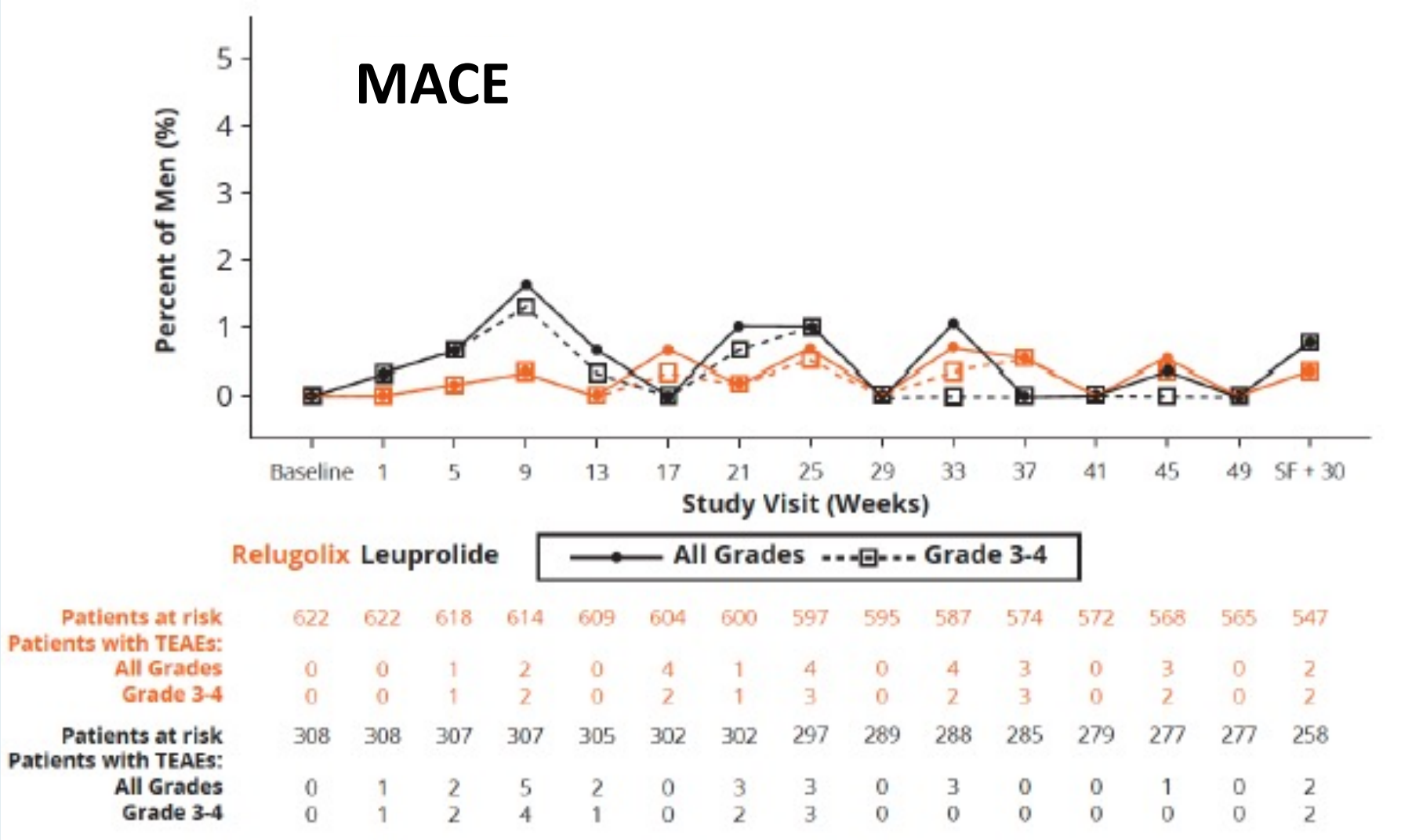
AUA 2022;Abstract MP27-16.

HERO: Onset and Duration of Adverse Events (AEs) with Relugolix for Advanced Prostate Cancer

	Relugolix (N = 622)			Leuprolide (N = 308)		
	AE n (%)	Onset (Days)[a] Median (min, max)	Duration (Days)[b] Median (min, max)	AE n (%)	Onset (Days)[a] Median (min, max)	Duration (Days)[b] Median (min, max)
AEs in > 10% of men						
Hot flash	338 (54.3)	19 (1, 343)	342 (15, 477)	159 (51.6)	33 (1, 200)	331 (1, 428)
Fatigue	134 (21.5)	46 (1, 342)	289 (2, 429)	57 (18.5)	41 (1, 326)	274 (3, 426)
Constipation	76 (12.2)	128 (1, 359)	67 (2, 409)	30 (9.7)	61 (1, 273)	92 (3, 410)
Diarrhea[d]	76 (12.2)	76 (1, 338)	9 (1, 370)	21 (6.8)	133 (2, 313)	3 (1, 224)
Arthralgia	75 (12.1)	142 (1, 355)	160 (1, 495)	28 (9.1)	189 (1, 370)	130 (2, 589)
Grade ≥ 3 AEs in ≥ 1% men						
Hypertension[e]	10 (1.6)	206 (15, 334)	15 (1, 328)	2 (0.6)	55 (21, 89)	27 (2, 51)
Diabetes	6 (1.0)	203 (85, 338)	118 (1, 204)	2 (0.6)	32 (29, 34)	192 (53, 330)
Syncope	6 (1.0)	163 (79, 315)	N/A	3 (1.0)	83 (45, 214)	N/A
MACE[c]	18 (2.9)	177 (38, 343)	N/A	19 (6.2)	132 (8, 352)	N/A

Mehlhaff B et al. AUA 2022;Abstract MP27-16.

HERO: MACE by Week During the Study



Patients at risk	622	622	618	614	609	604	600	597	595	587	574	572	568	565	547
Patients with TEAEs:															
All Grades	0	0	1	2	0	4	1	4	0	4	3	0	3	0	2
Grade 3-4	0	0	1	2	0	2	1	3	0	2	3	0	2	0	2
Patients at risk	308	308	307	307	305	302	302	297	289	288	285	279	277	277	258
Patients with TEAEs:															
All Grades	0	1	2	5	2	0	3	3	0	3	0	0	1	0	2
Grade 3-4	0	1	2	4	1	0	2	3	0	0	0	0	0	0	2

Mehlhaff B et al. AUA 2022;Abstract MP27-16.

EUROPEAN UROLOGY 82 (2022) 115–141

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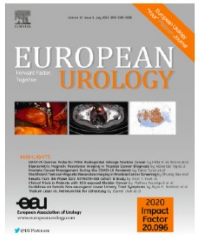

European Association of Urology

Prostate Cancer

Management of Patients with Advanced Prostate Cancer: Report from the Advanced Prostate Cancer Consensus Conference 2021

Silke Gillessen[a,b,c,d,*], *Andrew Armstrong*[e], *Gert Attard*[f], *Tomasz M. Beer*[g], *Himisha Beltran*[h], *Anders Bjartell*[i], *Alberto Bossi*[j], *Alberto Briganti*[k], *Robert G. Bristow*[d,l], *Muhammad Bulbul*[m], *Orazio Caffo*[n], *Kim N. Chi*[o], *Caroline S. Clarke*[p], *Noel Clarke*[q], *Ian D. Davis*[r], *Johann S. de Bono*[s], *Ignacio Duran*[t], *Ros Eeles*[s], *Eleni Efstathiou*[u], *Jason Efstathiou*[v], *Onyeanunam Ngozi Ekeke*[w], *Christopher P. Evans*[x], *Stefano Fanti*[y], *Felix Y. Feng*[z], *Karim Fizazi*[aa], *Mark Frydenberg*[ab], *Dan George*[ac], *Martin Gleave*[ad], *Susan Halabi*[ae], *Daniel Heinrich*[af], *Celesta Higano*[ag], *Michael S. Hofman*[ah], *Maha Hussain*[ai], *Nick James*[s], *Robert Jones*[aj], *Ravindran Kanesvaran*[ak], *Raja B. Khauli*[al], *Laurence Klotz*[am], *Raya Leibowitz*[an], *Chris Logothetis*[ao,ap], *Fernando Maluf*[aq,ar], *Robin Millman*[as], *Alicia K. Morgans*[h], *Michael J. Morris*[at], *Nicolas Mottet*[au], *Hind Mrabti*[av], *Declan G. Murphy*[aw,ax], *Vedang Murthy*[ay], *William K. Oh*[az], *Piet Ost*[ba,bb], *Joe M. O'Sullivan*[bc], *Anwar R. Padhani*[s,bd], *Chris Parker*[s], *Darren M.C. Poon*[be], *Colin C. Pritchard*[bf], *Danny M. Rabah*[bg], *Dana Rathkopf*[at], *Rob E. Reiter*[bh], *Mark Rubin*[bi], *Charles J. Ryan*[bj], *Fred Saad*[bk], *Juan P. Sade*[bl], *Oliver Sartor*[bm], *Howard I. Scher*[at,bn], *Neal Shore*[bo], *Iwona Skoneczna*[bp], *Eric Small*[z], *Matthew Smith*[bq], *Howard Soule*[br], *Daniel E. Spratt*[bs], *Cora N. Sternberg*[bt], *Hiroyoshi Suzuki*[bu], *Christopher Sweeney*[h], *Matthew R. Sydes*[bv], *Mary-Ellen Taplin*[h], *Derya Tilki*[bw,bx,by], *Bertrand Tombal*[bz], *Levent Türkeri*[ca], *Hiroji Uemura*[cb], *Hirotsugu Uemura*[cc], *Inge van Oort*[cd], *Kosj Yamoah*[ce], *Dingwei Ye*[cf,cg], *Almudena Zapatero*[ch], *Aurelius Omlin*[ci]

Open access Original research

Journal for ImmunoTherapy of Cancer

Immune system and intestinal microbiota determine efficacy of androgen deprivation therapy against prostate cancer

Safae Terrisse ,[1,2] Anne-Gaelle Goubet,[1] Kousuke Ueda,[3] Andrew Maltez Thomas,[4] Valentin Quiniou,[5] Cassandra Thelemaque,[1] Garett Dunsmore,[1] Emmanuel Clave ,[6] Melissa Gamat-Huber ,[7] Satoru Yonekura,[1] Gladys Ferrere,[1] Conrad Rauber,[1] Hang Phuong Pham,[5] Jean-Eudes Fahrner,[1,8] Eugenie Pizzato,[1] Pierre Ly,[1] Marine Fidelle,[1] Marine Mazzenga,[1] Carolina Alves Costa Silva,[1,8] Federica Armanini,[4] Federica Pinto,[4] Francesco Asnicar,[4] Romain Daillère,[9,10] Lisa Derosa,[1,11] Corentin Richard,[12] Pierre Blanchard,[13] Bertrand Routy,[12,14] Stéphane Culine,[2,15] Paule Opolon,[16] Aymeric Silvin,[1] Florent Ginhoux,[1] Antoine Toubert,[17,18] Nicola Segata ,[4] Douglas G McNeel ,[19] Karim Fizazi ,[8,20] Guido Kroemer,[9,21] Laurence Zitvogel[22,23]

J Immunother Cancer 2022 March;10(3):e004191.

Evolving Role of Prostate-Specific Membrane Antigen-Positron Emission Tomography in Metastatic Hormone-Sensitive Prostate Cancer: More Questions than Answers?

Maha Hussain, MD[1]; Michael A. Carducci, MD[2]; Noel Clarke, MBBS[3]; Sarah E. Fenton, MD, PhD[1]; Karim Fizazi, MD, PhD[4]; Silke Gillessen, MD, PhD[5,6,7]; Heather Jacene, MD[8]; Michael J. Morris, MD[9]; Fred Saad, MD[10]; Oliver Sartor, MD[11]; Mary-Ellen Taplin, MD[12]; Neha Vapiwala, MD[13]; Scott Williams, MD[14]; and Christopher Sweeney, MD[12]

J Clin Oncol 2022;40(26):3011-6.

Clin Cancer Res 2021 August 15;27(16):4539-48.

CLINICAL CANCER RESEARCH | CLINICAL TRIALS: TARGETED THERAPY

Blood Biomarker Landscape in Patients with High-risk Nonmetastatic Castration-Resistant Prostate Cancer Treated with Apalutamide and Androgen-Deprivation Therapy as They Progress to Metastatic Disease

Matthew R. Smith[1], Shibu Thomas[2], Michael Gormley[2], Simon Chowdhury[3], David Olmos[4], Stéphane Oudard[5], Felix Y. Feng[6], Yashoda Rajpurohit[2], Karen Urtishak[2], Deborah S. Ricci[2], Brendan Rooney[7], Angela Lopez-Gitlitz[8], Margaret Yu[8], Alexander W. Wyatt[9], Mark Li[10], Gerhardt Attard[11], and Eric J. Small[6]

Meet The Professor
Optimizing the Management of Multiple Myeloma

Tuesday, November 15, 2022
5:00 PM – 6:00 PM ET

Faculty

Paul G Richardson, MD

Moderator

Neil Love, MD

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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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