Oncology Today: Recent Research Advances in Prostate Cancer and the Clinical Implications – A 2023 Post-ASCO GU Activity

A CME/MOC-Accredited Virtual Event

Wednesday, March 29, 2023
5:00 PM – 6:00 PM ET

Consulting Clinical Investigator

Daniel P Petrylak, MD

Faculty Panel

Andrew J Armstrong, MD, ScM
Rana R McKay, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Commercial Support

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

RTP
RESEARCH
TO PRACTICE

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 US Inc, Gilead Sciences Inc, Grail Inc, GSK, 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, SpringWorks Therapeutics Inc, 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.

RTP
RESEARCH
TO PRACTICE

Research To Practice CME Planning Committee Members, Staff and Reviewers

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

Dr Armstrong — Disclosures

Advisory Committee	Astellas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Clovis Oncology, Epic Sciences, Exact Sciences Corporation, Exelixis Inc, Merck, Myovant Sciences, Pfizer Inc, POINT Biopharma
Consulting Agreements	Astellas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Dendreon Pharmaceuticals Inc, Epic Sciences, Exact Sciences Corporation, Exelixis Inc, Forma Therapeutics, Janssen Biotech Inc, Merck, Myovant Sciences, Pfizer Inc, POINT Biopharma
Contracted Research	Amgen Inc, Astellas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Bristol-Myers Squibb Company, Celgene Corporation, Dendreon Pharmaceuticals Inc, Forma Therapeutics, Genentech, a member of the Roche Group, Janssen Biotech Inc, Merck, Pfizer Inc
Nonrelevant Financial Relationship	National Cancer Institute, National Institutes of Health, Prostate Cancer Foundation/Movember, US Department of Defense

RTP
RESEARCH
TO PRACTICE

Dr McKay — Disclosures

Consulting Agreements	AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, Bristol-Myers Squibb Company, Caris Life Sciences, Dendreon Pharmaceuticals Inc, Exelixis Inc, Johnson & Johnson Pharmaceuticals, Lilly, Merck, Myovant Sciences, Novartis, Pfizer Inc, Sanofi, Seagen Inc, Sorrento Therapeutics, Telix Pharmaceuticals Limited, Tempus
Contracted Research	AstraZeneca Pharmaceuticals LP, Exelixis Inc, Oncternal Therapeutics, Tempus

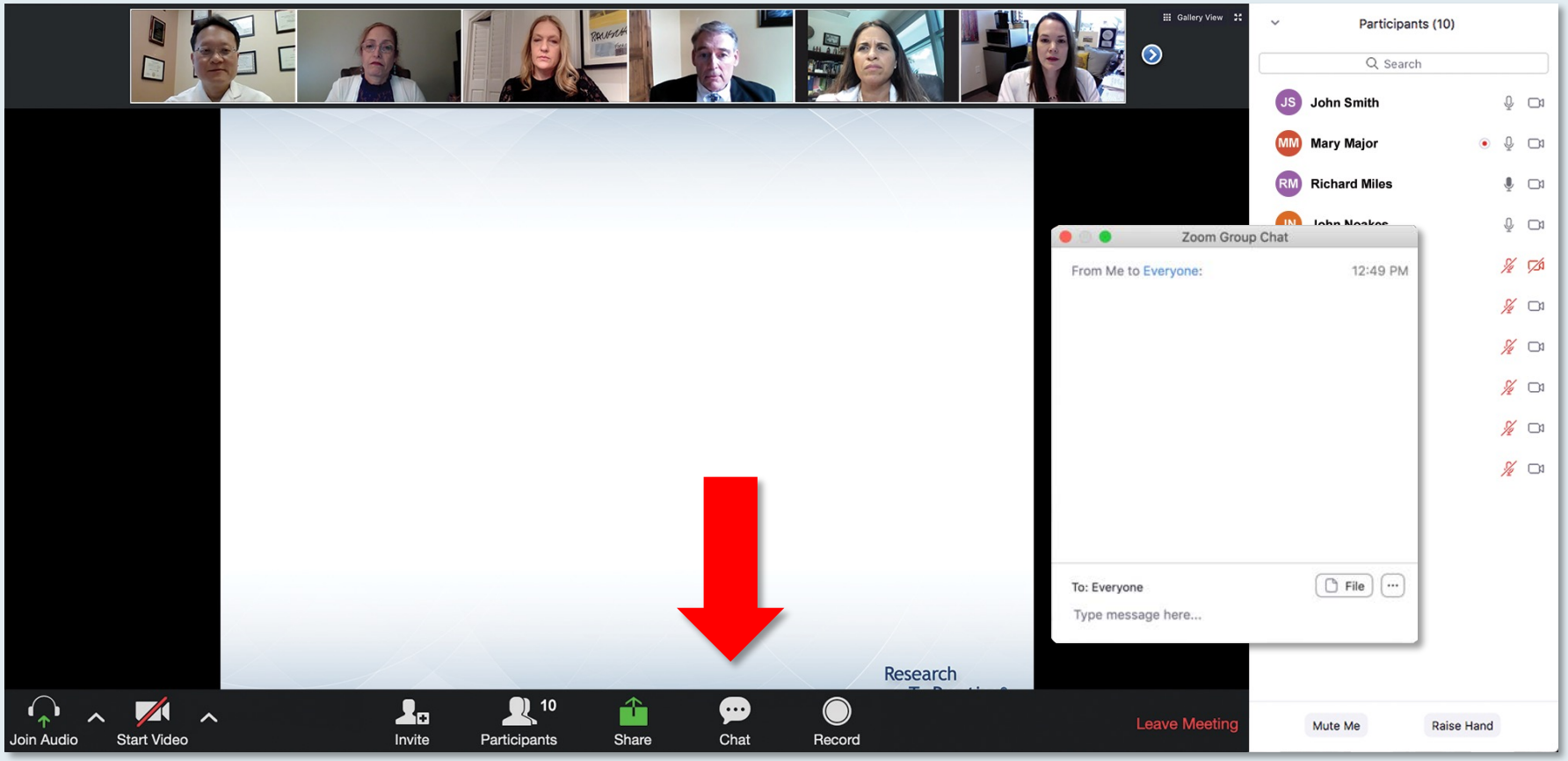
RTP
RESEARCH
TO PRACTICE

Dr Petrylak — Disclosures

Consulting Agreements	Advanced Accelerator Applications, Amgen Inc, Astellas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Bicycle Therapeutics, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Clovis Oncology, Exelixis Inc, Gilead Sciences Inc, Incyte Corporation, Infinity Pharmaceuticals Inc, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, Lilly, Merck, Mirati Therapeutics Inc, Monopteros Therapeutics, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Regeneron Pharmaceuticals Inc, Roche Laboratories Inc, Sanofi, Seagen Inc, UroGen Pharma
Contracted Research	Advanced Accelerator Applications, Agensys Inc, Arvinas, Astellas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, BioXcel Therapeutics, Bristol-Myers Squibb Company, Clovis Oncology, Daiichi Sankyo Inc, Eisai Inc, Endocyte Inc, Ferring Pharmaceuticals, Genentech, a member of the Roche Group, Gilead Sciences Inc, Innocrin Pharmaceuticals Inc, Lilly, Medivation Inc, a Pfizer Company, Merck, Mirati Therapeutics Inc, Novartis, Pfizer Inc, Progenics Pharmaceuticals Inc, Replimune, Roche Laboratories Inc, Sanofi, Seagen Inc

RTP
RESEARCH
TO PRACTICE

We Encourage Clinicians in Practice to Submit Questions

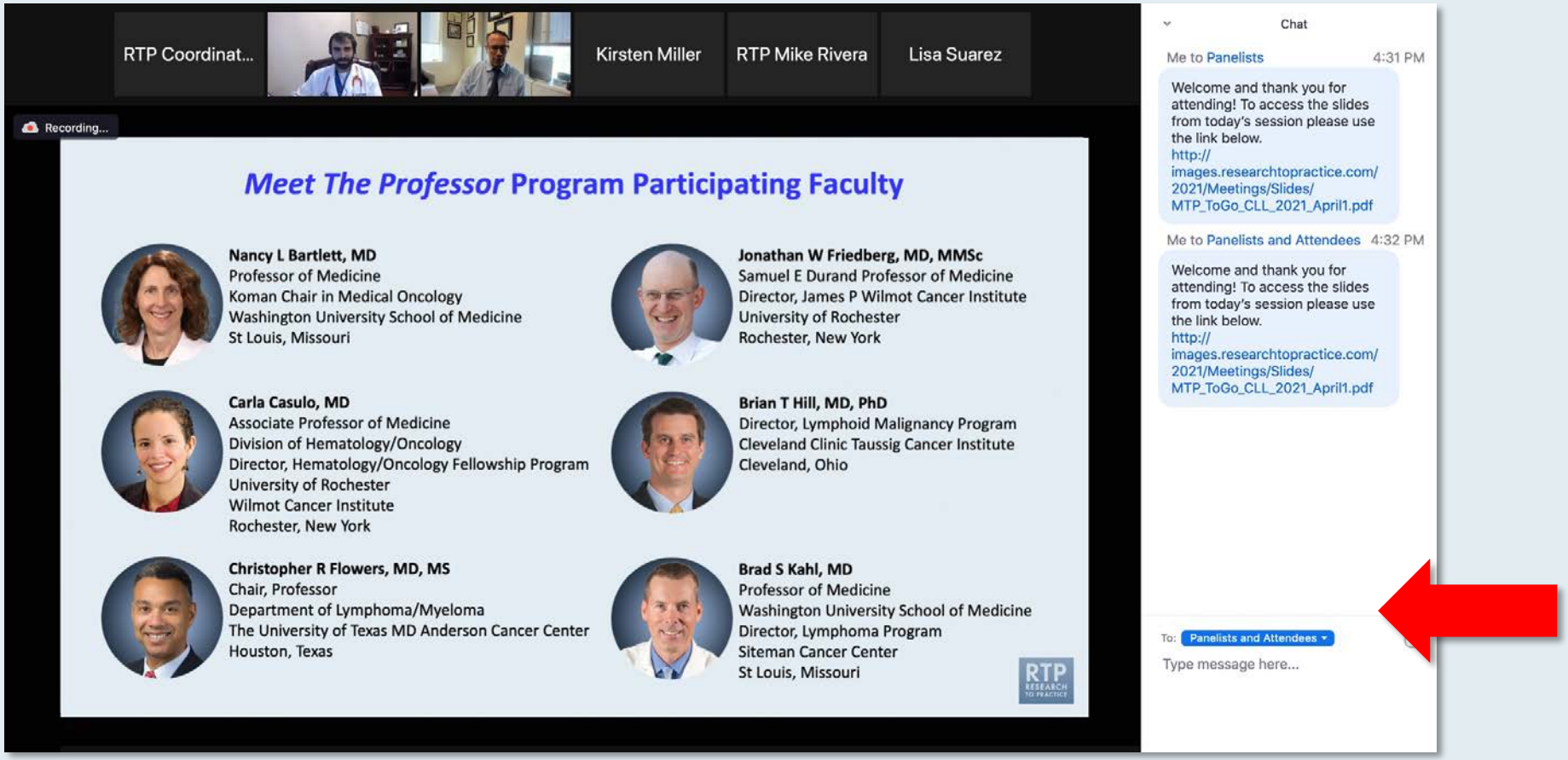


Feel free to submit questions now before the program begins and throughout the program.

RTP RESEARCH TO PRACTICE

Familiarizing Yourself with the Zoom Interface

Expand chat submission box

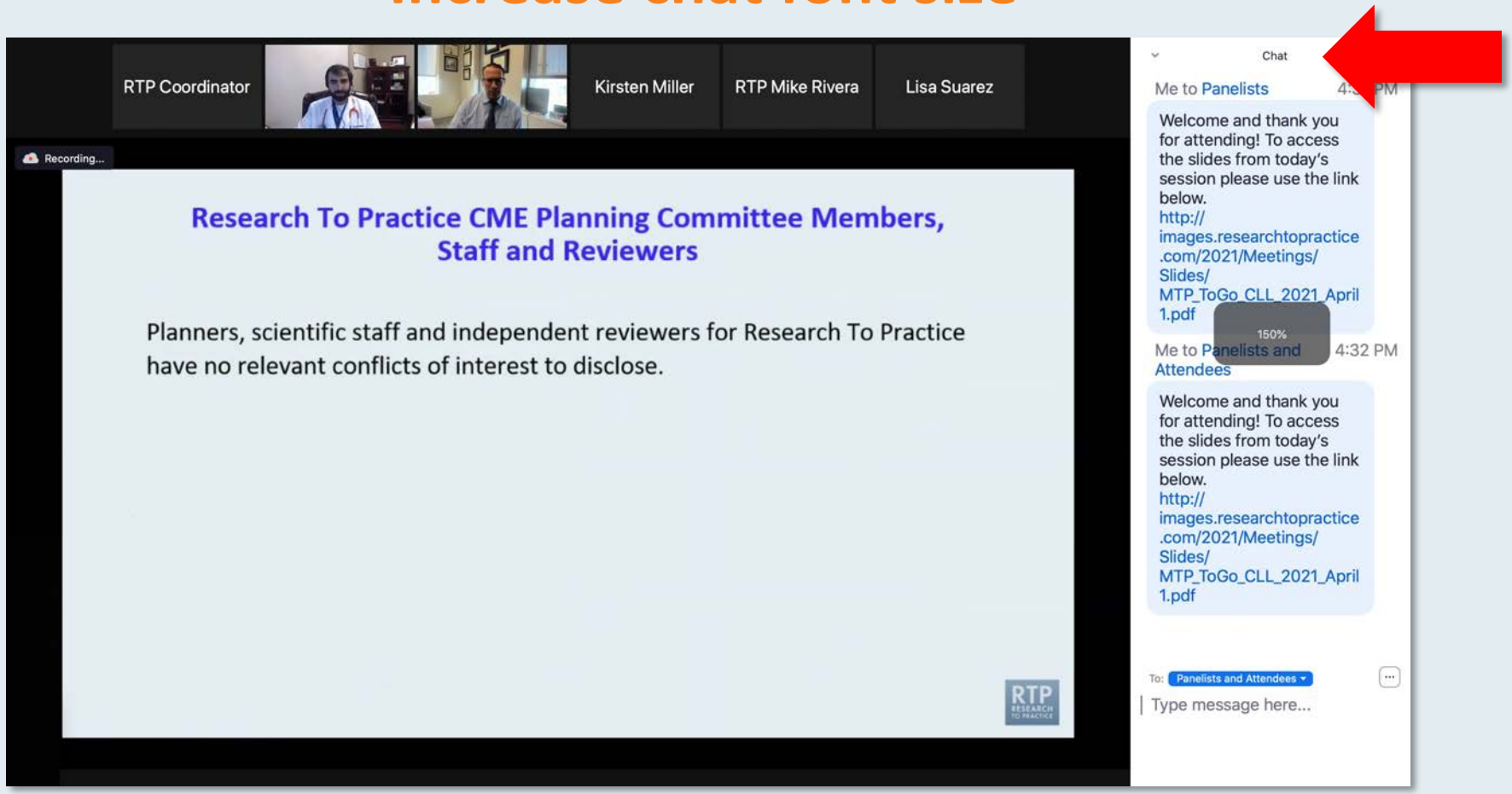


Drag the white line above the submission box up to create more space for your message.

RTP RESEARCH TO PRACTICE

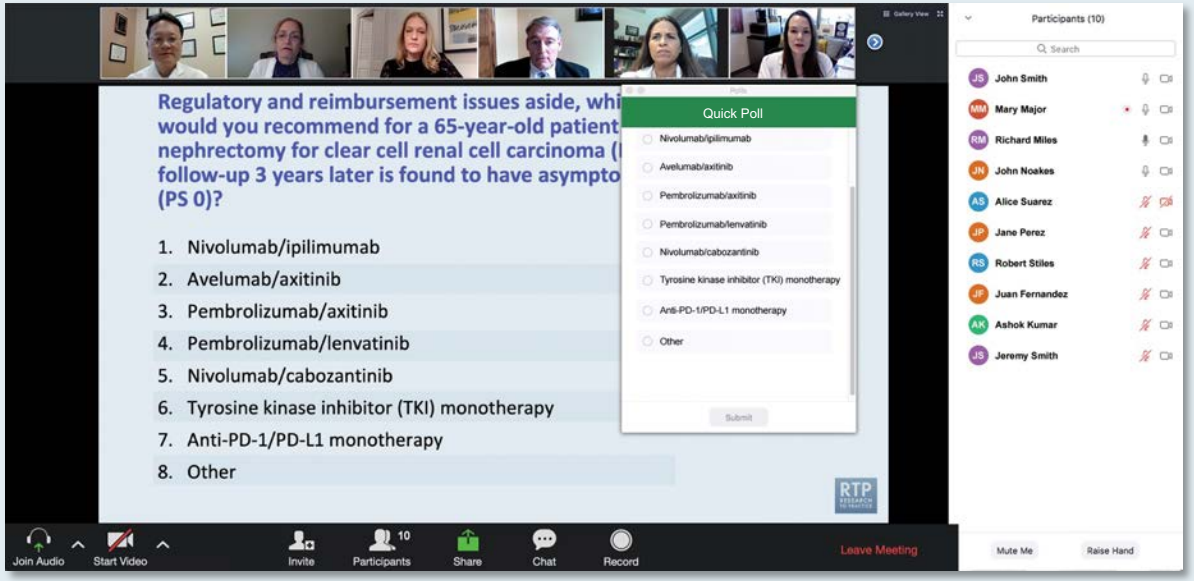
Familiarizing Yourself with the Zoom Interface

Increase chat font size



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

Clinicians in the Audience, Please Complete the Pre- and Postmeeting Surveys



RTP RESEARCH TO PRACTICE

ONCOLOGY TODAY

WITH DR NEIL LOVE

Managing Metastatic Urothelial Bladder Cancer

DR SCOTT TAGAWA

WEILL CORNELL MEDICINE

Listen on Apple Podcasts

Spotify

Listen on Google Podcasts

Year in Review: Clinical Investigator Perspectives on the Most Relevant New Data Sets and Advances in Oncology

A Multitumor CME/MOC-Accredited Live Webinar Series

Acute Myeloid Leukemia and Myelodysplastic Syndromes

Tuesday, April 4, 2023
5:00 PM – 6:00 PM ET

Faculty

Uma Borate, MD, MS

Andrew H Wei, MBBS, PhD

Moderator

Neil Love, MD

RTP Year in Review 2023

Meet The Professor

Optimizing the Management of ER-Positive and Triple-Negative Breast Cancer

Wednesday, April 12, 2023
5:00 PM – 6:00 PM ET

Faculty

Sara A Hurvitz, MD

Moderator

Neil Love, MD

RTP
RESEARCH
TO PRACTICE

Year in Review: Clinical Investigator Perspectives on the Most Relevant New Data Sets and Advances in Oncology

A Multitumor CME/MOC-Accredited Live Webinar Series

Immunotherapy and Other Nontargeted Approaches for Lung Cancer

Thursday, April 13, 2023
5:00 PM – 6:00 PM ET

Faculty

Luis Paz-Ares, MD, PhD

Heather Wakelee, MD

Moderator

Neil Love, MD

RTP Year in Review 2023

Year in Review: Clinical Investigator Perspectives on the Most Relevant New Data Sets and Advances in Oncology

A Multitumor CME/MOC-Accredited Live Webinar Series

Colorectal Cancer

Wednesday, April 19, 2023
5:00 PM – 6:00 PM ET

Faculty

Pashtoon M Kasi, MD, MS

Wells A Messersmith, MD

Moderator

Neil Love, MD

RTP Year in Review 2023

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 48th Annual ONS Congress

Cervical and Endometrial Cancer

Wednesday, April 26, 2023
11:15 AM – 12:45 PM CT (12:15 PM – 1:45 PM ET)

Faculty
Paula J Anastasia, MN, RN, AOCN
Michael J Birrer, MD, PhD
Jennifer Filipi, MSN, NP
Brian M Slomovitz, MD

Breast Cancer

Wednesday, April 26, 2023
6:00 PM – 8:00 PM CT (7:00 PM – 9:00 PM ET)

Faculty
Jamie Carroll, APRN, MSN, CNP
Virginia Kaklamani, MD, DSc
Joyce O'Shaughnessy, MD
Ronald Stein, JD, MSN, NP-C, AOCNP

Diffuse Large B-Cell Lymphoma

Thursday, April 27, 2023
6:00 AM – 7:30 AM CT (7:00 AM – 8:30 AM ET)

Faculty
Christopher R Flowers, MD, MS
Amy Goodrich, CRNP
Robin Klebig, APRN, CNP, AOCNP
Matthew Lunning, DO

Chronic Lymphocytic Leukemia

Thursday, April 27, 2023
12:15 PM – 1:45 PM CT (1:15 PM – 2:45 PM ET)

Faculty
John N Allan, MD
Jacqueline Broadway-Duren, PhD, DNP, APRN, FNP-BC
Corinne Hoffman, MS, APRN-CNP, AOCNP
Additional faculty to be announced

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 48th Annual ONS Congress

HER2-Targeted Antibody-Drug Conjugates

Thursday, April 27, 2023
6:00 PM – 7:30 PM CT (7:00 PM – 8:30 PM ET)
Faculty
Kelly EH Goodwin, MSN, RN, ANP-BC
Zev Wainberg, MD, MSc
Additional faculty to be announced

Ovarian Cancer

Friday, April 28, 2023
12:15 PM – 1:45 PM CT (1:15 PM – 2:45 PM ET)
Faculty
Courtney Arn, CNP
David M O'Malley, MD
Richard T Penson, MD, MRCP
Jaclyn Shaver, MS, APRN, CNP, WHNP

Hepatobiliary Cancers

Friday, April 28, 2023
6:00 AM – 7:30 AM CT (7:00 AM – 8:30 AM ET)
Faculty
Blanca Ledezma, MSN, NP, AOCNP
Amanda K Wagner, APRN-CNP, AOCNP
Additional faculty to be announced

Lung Cancer

Friday, April 28, 2023
6:00 PM – 8:00 PM CT (7:00 PM – 9:00 PM ET)
Faculty
Tara Plues, APRN, MSN
Jillian Thompson, MSN, ANP-BC, AOCNP
Additional faculty to be announced

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 48th Annual ONS Congress

Prostate Cancer

Saturday, April 29, 2023

12:15 PM – 1:45 PM CT (1:15 PM – 2:45 PM ET)

Faculty

Neeraj Agarwal, MD

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

Susan K Roethke, MSN, CRNP, AOCNP, ANP-BC

Additional faculty to be announced

Oncology Today: Recent Research Advances in Prostate Cancer and the Clinical Implications – A 2023 Post-ASCO GU Activity

A CME/MOC-Accredited Virtual Event

Wednesday, March 29, 2023
5:00 PM – 6:00 PM ET

Consulting Clinical Investigator

Daniel P Petrylak, MD

Faculty Panel

Andrew J Armstrong, MD, ScM
Rana R McKay, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Agenda

- Intensification of endocrine therapy: Emerging role in nonmetastatic disease; choice of androgen deprivation therapy
- Management of castration-resistant M0 disease; PROTACs, CDK4/6 inhibitors and other new endocrine approaches
- Hormone-sensitive metastatic disease – Choice of antiandrogen
- Castration-resistant metastatic disease
- Genomic evaluation; PARP inhibitors for metastatic disease
- Ideal sequencing of PARP inhibitors; management of associated side effects
- Biomarker testing; MSI-high disease; TKIs with immunotherapy; bispecific antibodies?

Thank you for joining us!

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

RTP
RESEARCH
TO PRACTICE

Oncology Today: Recent Research Advances in Prostate Cancer and the Clinical Implications – A 2023 Post-ASCO GU Activity

A CME/MOC-Accredited Virtual Event

Wednesday, March 29, 2023
5:00 PM – 6:00 PM ET

Consulting Clinical Investigator

Daniel P Petrylak, MD

Faculty Panel

Andrew J Armstrong, MD, ScM
Rana R McKay, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Consulting Clinical Investigator

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

Moderator
Neil Love, MD
Research To Practice

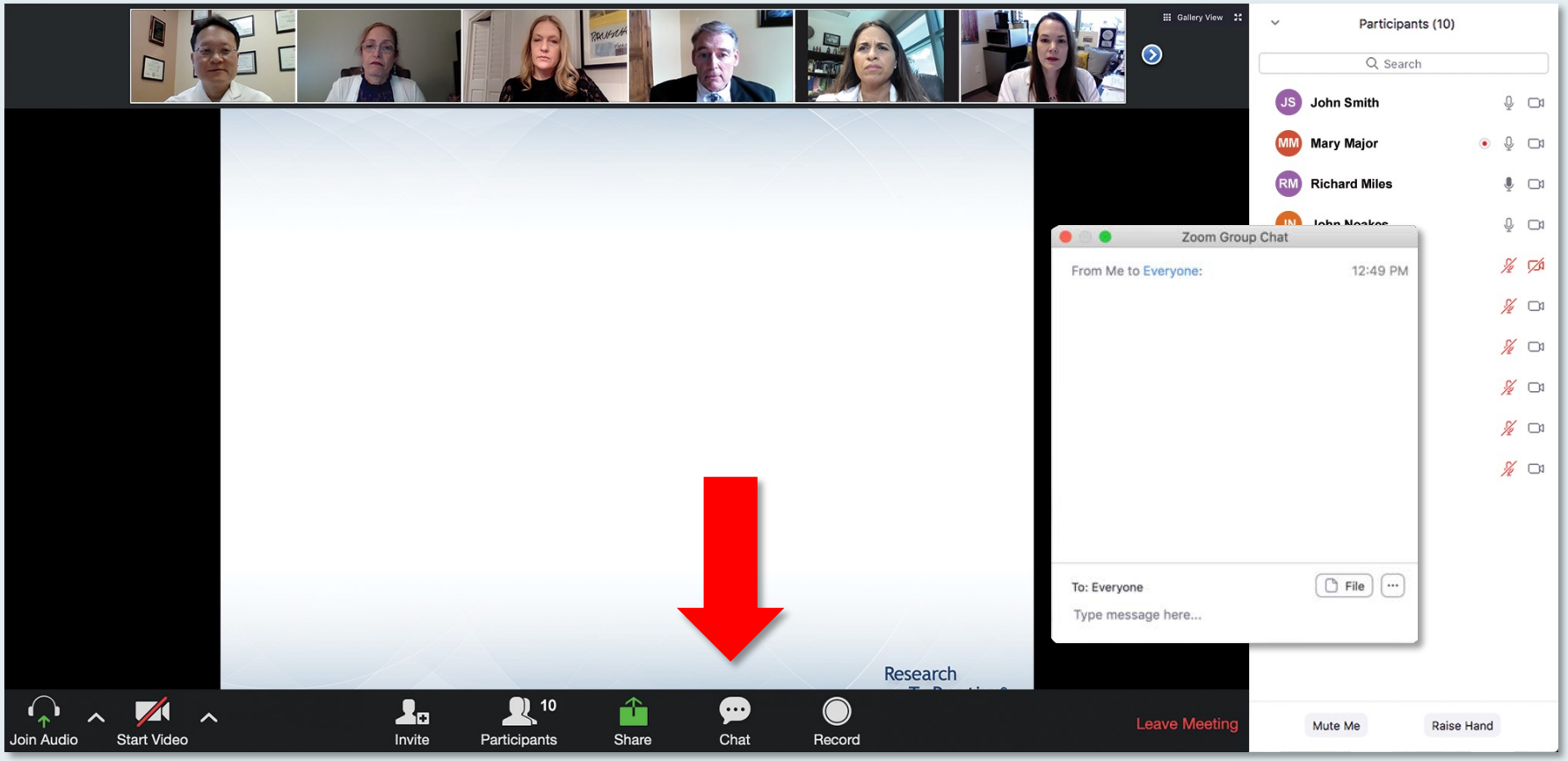
Faculty Panel

Andrew J Armstrong, MD, ScM
Professor of Medicine, Surgery, Pharmacology and Cancer Biology
Director of Research
Duke Cancer Institute Center for Prostate and Urologic Cancers
Divisions of Medical Oncology and Urology
Duke University
Durham, North Carolina

Rana R McKay, MD
Associate Professor of Medicine and Urology
Associate Director, Translational Sciences
Co-Lead, Genitourinary Oncology Program
University of California San Diego
Moores Cancer Center
La Jolla, California

RTP RESEARCH TO PRACTICE

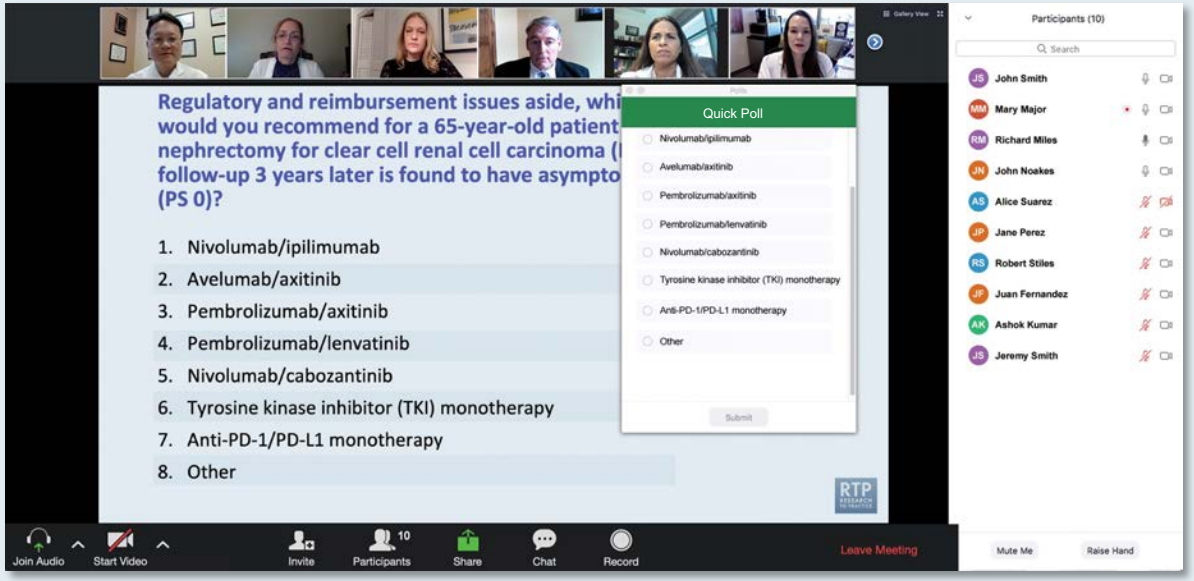
We Encourage Clinicians in Practice to Submit Questions



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

RTP RESEARCH TO PRACTICE

Clinicians in the Audience, Please Complete the Pre- and Postmeeting Surveys



RTP RESEARCH TO PRACTICE

Year in Review: Clinical Investigator Perspectives on the Most Relevant New Data Sets and Advances in Oncology

A Multitumor CME/MOC-Accredited Live Webinar Series

Acute Myeloid Leukemia and Myelodysplastic Syndromes

Tuesday, April 4, 2023
5:00 PM – 6:00 PM ET

Faculty

Uma Borate, MD, MS

Andrew H Wei, MBBS, PhD

Moderator

Neil Love, MD

RTP Year in Review 2023

Meet The Professor

Optimizing the Management of ER-Positive and Triple-Negative Breast Cancer

Wednesday, April 12, 2023
5:00 PM – 6:00 PM ET

Faculty

Sara A Hurvitz, MD

Moderator

Neil Love, MD

RTP
RESEARCH
TO PRACTICE

Year in Review: Clinical Investigator Perspectives on the Most Relevant New Data Sets and Advances in Oncology

A Multitumor CME/MOC-Accredited Live Webinar Series

Immunotherapy and Other Nontargeted Approaches for Lung Cancer

Thursday, April 13, 2023
5:00 PM – 6:00 PM ET

Faculty

Luis Paz-Ares, MD, PhD

Heather Wakelee, MD

Moderator

Neil Love, MD

RTP Year in Review 2023

Year in Review: Clinical Investigator Perspectives on the Most Relevant New Data Sets and Advances in Oncology

A Multitumor CME/MOC-Accredited Live Webinar Series

Colorectal Cancer

Wednesday, April 19, 2023
5:00 PM – 6:00 PM ET

Faculty

Pashtoon M Kasi, MD, MS

Wells A Messersmith, MD

Moderator

Neil Love, MD

RTP Year in Review 2023

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 48th Annual ONS Congress

Cervical and Endometrial Cancer

Wednesday, April 26, 2023
11:15 AM – 12:45 PM CT (12:15 PM – 1:45 PM ET)

Faculty
Paula J Anastasia, MN, RN, AOCN
Michael J Birrer, MD, PhD
Jennifer Filipi, MSN, NP
Brian M Slomovitz, MD

Breast Cancer

Wednesday, April 26, 2023
6:00 PM – 8:00 PM CT (7:00 PM – 9:00 PM ET)

Faculty
Jamie Carroll, APRN, MSN, CNP
Virginia Kaklamani, MD, DSc
Joyce O'Shaughnessy, MD
Ronald Stein, JD, MSN, NP-C, AOCNP

Diffuse Large B-Cell Lymphoma

Thursday, April 27, 2023
6:00 AM – 7:30 AM CT (7:00 AM – 8:30 AM ET)

Faculty
Christopher R Flowers, MD, MS
Amy Goodrich, CRNP
Robin Klebig, APRN, CNP, AOCNP
Matthew Lunning, DO

Chronic Lymphocytic Leukemia

Thursday, April 27, 2023
12:15 PM – 1:45 PM CT (1:15 PM – 2:45 PM ET)

Faculty
John N Allan, MD
Jacqueline Broadway-Duren, PhD, DNP, APRN, FNP-BC
Corinne Hoffman, MS, APRN-CNP, AOCNP
Additional faculty to be announced

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 48th Annual ONS Congress

HER2-Targeted Antibody-Drug Conjugates

Thursday, April 27, 2023
6:00 PM – 7:30 PM CT (7:00 PM – 8:30 PM ET)
Faculty
Kelly EH Goodwin, MSN, RN, ANP-BC
Zev Wainberg, MD, MSc
Additional faculty to be announced

Ovarian Cancer

Friday, April 28, 2023
12:15 PM – 1:45 PM CT (1:15 PM – 2:45 PM ET)
Faculty
Courtney Arn, CNP
David M O'Malley, MD
Richard T Penson, MD, MRCP
Jaclyn Shaver, MS, APRN, CNP, WHNP

Hepatobiliary Cancers

Friday, April 28, 2023
6:00 AM – 7:30 AM CT (7:00 AM – 8:30 AM ET)
Faculty
Blanca Ledezma, MSN, NP, AOCNP
Amanda K Wagner, APRN-CNP, AOCNP
Additional faculty to be announced

Lung Cancer

Friday, April 28, 2023
6:00 PM – 8:00 PM CT (7:00 PM – 9:00 PM ET)
Faculty
Tara Plues, APRN, MSN
Jillian Thompson, MSN, ANP-BC, AOCNP
Additional faculty to be announced

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 48th Annual ONS Congress

Prostate Cancer

Saturday, April 29, 2023

12:15 PM – 1:45 PM CT (1:15 PM – 2:45 PM ET)

Faculty

Neeraj Agarwal, MD

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

Susan K Roethke, MSN, CRNP, AOCNP, ANP-BC

Additional faculty to be announced

ONCOLOGY TODAY

WITH DR NEIL LOVE

Managing Metastatic Urothelial Bladder Cancer

DR SCOTT TAGAWA

WEILL CORNELL MEDICINE

Listen on Apple Podcasts

Spotify

Listen on Google Podcasts

Oncology Today: Recent Research Advances in Prostate Cancer and the Clinical Implications – A 2023 Post-ASCO GU Activity

A CME/MOC-Accredited Virtual Event

Wednesday, March 29, 2023
5:00 PM – 6:00 PM ET

Consulting Clinical Investigator

Daniel P Petrylak, MD

Faculty Panel

Andrew J Armstrong, MD, ScM
Rana R McKay, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Commercial Support

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

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 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 US Inc, Gilead Sciences Inc, Grail Inc, GSK, 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, SpringWorks Therapeutics Inc, 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.

RTP
RESEARCH
TO PRACTICE

Dr Armstrong — Disclosures

Advisory Committee	Astellas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Clovis Oncology, Epic Sciences, Exact Sciences Corporation, Exelixis Inc, Merck, Myovant Sciences, Pfizer Inc, POINT Biopharma
Consulting Agreements	Astellas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Dendreon Pharmaceuticals Inc, Epic Sciences, Exact Sciences Corporation, Exelixis Inc, Forma Therapeutics, Janssen Biotech Inc, Merck, Myovant Sciences, Pfizer Inc, POINT Biopharma
Contracted Research	Amgen Inc, Astellas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Bristol-Myers Squibb Company, Celgene Corporation, Dendreon Pharmaceuticals Inc, Forma Therapeutics, Genentech, a member of the Roche Group, Janssen Biotech Inc, Merck, Pfizer Inc
Nonrelevant Financial Relationship	National Cancer Institute, National Institutes of Health, Prostate Cancer Foundation/Movember, US Department of Defense

RTP
RESEARCH
TO PRACTICE

Dr McKay — Disclosures

Consulting Agreements	AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, Bristol-Myers Squibb Company, Caris Life Sciences, Dendreon Pharmaceuticals Inc, Exelixis Inc, Johnson & Johnson Pharmaceuticals, Lilly, Merck, Myovant Sciences, Novartis, Pfizer Inc, Sanofi, Seagen Inc, Sorrento Therapeutics, Telix Pharmaceuticals Limited, Tempus
Contracted Research	AstraZeneca Pharmaceuticals LP, Exelixis Inc, Oncternal Therapeutics, Tempus

RTP
RESEARCH
TO PRACTICE

Dr Petrylak — Disclosures

Consulting Agreements	Advanced Accelerator Applications, Amgen Inc, Astellas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Bicycle Therapeutics, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Clovis Oncology, Exelixis Inc, Gilead Sciences Inc, Incyte Corporation, Infinity Pharmaceuticals Inc, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, Lilly, Merck, Mirati Therapeutics Inc, Monopteros Therapeutics, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Regeneron Pharmaceuticals Inc, Roche Laboratories Inc, Sanofi, Seagen Inc, UroGen Pharma
Contracted Research	Advanced Accelerator Applications, Agensys Inc, Arvinas, Astellas, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, BioXcel Therapeutics, Bristol-Myers Squibb Company, Clovis Oncology, Daiichi Sankyo Inc, Eisai Inc, Endocyte Inc, Ferring Pharmaceuticals, Genentech, a member of the Roche Group, Gilead Sciences Inc, Innocrin Pharmaceuticals Inc, Lilly, Medivation Inc, a Pfizer Company, Merck, Mirati Therapeutics Inc, Novartis, Pfizer Inc, Progenics Pharmaceuticals Inc, Replimune, Roche Laboratories Inc, Sanofi, Seagen Inc

RTP
RESEARCH
TO PRACTICE

Cases from the Community: Investigators Discuss Available Research Guiding the Care of Patients with Prostate Cancer

Part 2 of a 3-Part CME Symposium Series Held in Conjunction with the 2023 ASCO Genitourinary Cancers Symposium

Thursday, February 16, 2023
7:15 PM – 9:15 PM PT

Faculty

Emmanuel S Antonarakis, MD
Prof Karim Fizazi, MD, PhD
Maha Hussain, MD, FACP, FASCO
Matthew R Smith, MD, PhD

Moderator

Alan H Bryce, MD

RTP RESEARCH TO PRACTICE

Agenda

- Intensification of endocrine therapy: Emerging role in nonmetastatic disease; choice of androgen deprivation therapy
- Management of castration-resistant M0 disease; PROTACs, CDK4/6 inhibitors and other new endocrine approaches
- Hormone-sensitive metastatic disease – Choice of antiandrogen
- Castration-resistant metastatic disease
- Genomic evaluation; PARP inhibitors for metastatic disease
- Ideal sequencing of PARP inhibitors; management of associated side effects
- Biomarker testing; MSI-high disease; TKIs with immunotherapy; bispecific antibodies?

Positive Topline Results from the Phase III EMBARK Study of Enzalutamide with Leuprolide for Nonmetastatic Prostate Cancer

Press Release – March 16, 2023

"[Today positive topline results were announced] from the Phase 3 EMBARK trial evaluating enzalutamide in men with non-metastatic hormone-sensitive prostate cancer (nmHSPC; also known as non-metastatic castration-sensitive prostate cancer or nmCSPC) with high-risk biochemical recurrence (BCR). Patients enrolled in the trial were randomized to one of three study arms: enzalutamide plus leuprolide, placebo plus leuprolide, or enzalutamide monotherapy. The study met its primary endpoint with a statistically significant and clinically meaningful improvement in metastasis-free survival (MFS) for patients treated with enzalutamide plus leuprolide versus placebo plus leuprolide.

At the time of the analysis, a positive trend in the key secondary endpoint of overall survival (OS) was also observed, but these data were not yet mature. Patients in the trial will be followed for a subsequent final OS analysis. The study also met a key secondary endpoint with a statistically significant and clinically meaningful improvement in MFS for patients treated with enzalutamide monotherapy versus placebo plus leuprolide. Additional key secondary endpoints reached statistical significance, including time to prostate-specific antigen (PSA) progression and time to first use of new antineoplastic therapy. Other secondary endpoints are being analyzed. No new safety signals have been observed to date in the preliminary safety analysis. Detailed results from EMBARK will be presented at a future medical meeting."

https://www.pfizer.com/news/press-release/press-release-detail/phase-3-study-shows-xtandir-enzalutamide-plus-leuprolide

RTP RESEARCH TO PRACTICE

EMBARK: A Phase 3 Randomized Study of Enzalutamide or Placebo plus Leuprolide Acetate and Enzalutamide Monotherapy in High-Risk Biochemically Recurrent Prostate Cancer

Shore ND et al.

AUA 2023.

Session: Plenary: Saturday Morning

April 29, 2023

9:45 AM – 10:00 AM CT (10:45 AM – 11:00 AM ET)

Location: Hall B1

RTP
RESEARCH
TO PRACTICE

Intensification of endocrine therapy: Emerging role in nonmetastatic disease; choice of androgen deprivation therapy

Dr Daniel Petrylak (New Haven, Connecticut)

RTP
RESEARCH
TO PRACTICE

Management of castration-resistant M0 disease; PROTACs, CDK4/6 inhibitors and other new endocrine approaches

Dr Daniel Petrylak (New Haven, Connecticut)

RTP
RESEARCH
TO PRACTICE

Hormone-sensitive metastatic disease – Choice of antiandrogen

Dr Daniel Petrylak (New Haven, Connecticut)

RTP
RESEARCH
TO PRACTICE

Castration-resistant metastatic disease

Dr Daniel Petrylak (New Haven, Connecticut)

RTP
RESEARCH
TO PRACTICE

Genomic evaluation; PARP inhibitors for metastatic disease

Dr Daniel Petrylak (New Haven, Connecticut)

RTP
RESEARCH
TO PRACTICE

Ideal sequencing of PARP inhibitors; management of associated side effects

Dr Daniel Petrylak (New Haven, Connecticut)

RTP
RESEARCH
TO PRACTICE

Biomarker testing; MSI-high disease; TKIs with immunotherapy; bispecific antibodies?

Dr Daniel Petrylak (New Haven, Connecticut)

RTP
RESEARCH
TO PRACTICE

Year in Review: Clinical Investigator Perspectives on the Most Relevant New Data Sets and Advances in Oncology

A Multitumor CME/MOC-Accredited Live Webinar Series

Acute Myeloid Leukemia and Myelodysplastic Syndromes

Tuesday, April 4, 2023
5:00 PM – 6:00 PM ET

Faculty

Uma Borate, MD, MS

Andrew H Wei, MBBS, PhD

Moderator

Neil Love, MD

RTP Year in Review 2023

Thank you for joining us!

Please take a moment to complete the survey currently up on Zoom. Your feedback is very important to us. The survey will remain open up to 5 minutes after the meeting ends.

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

RTP
RESEARCH
TO PRACTICE

Supplementary slides

Oncology Today: Recent Research Advances in Prostate Cancer and the Clinical Implications – A 2023 Post-ASCO GU Activity

A CME/MOC-Accredited Virtual Event

Wednesday, March 29, 2023
5:00 PM – 6:00 PM ET

Consulting Clinical Investigator

Daniel P Petrylak, MD

Faculty Panel

Andrew J Armstrong, MD, ScM
Rana R McKay, MD

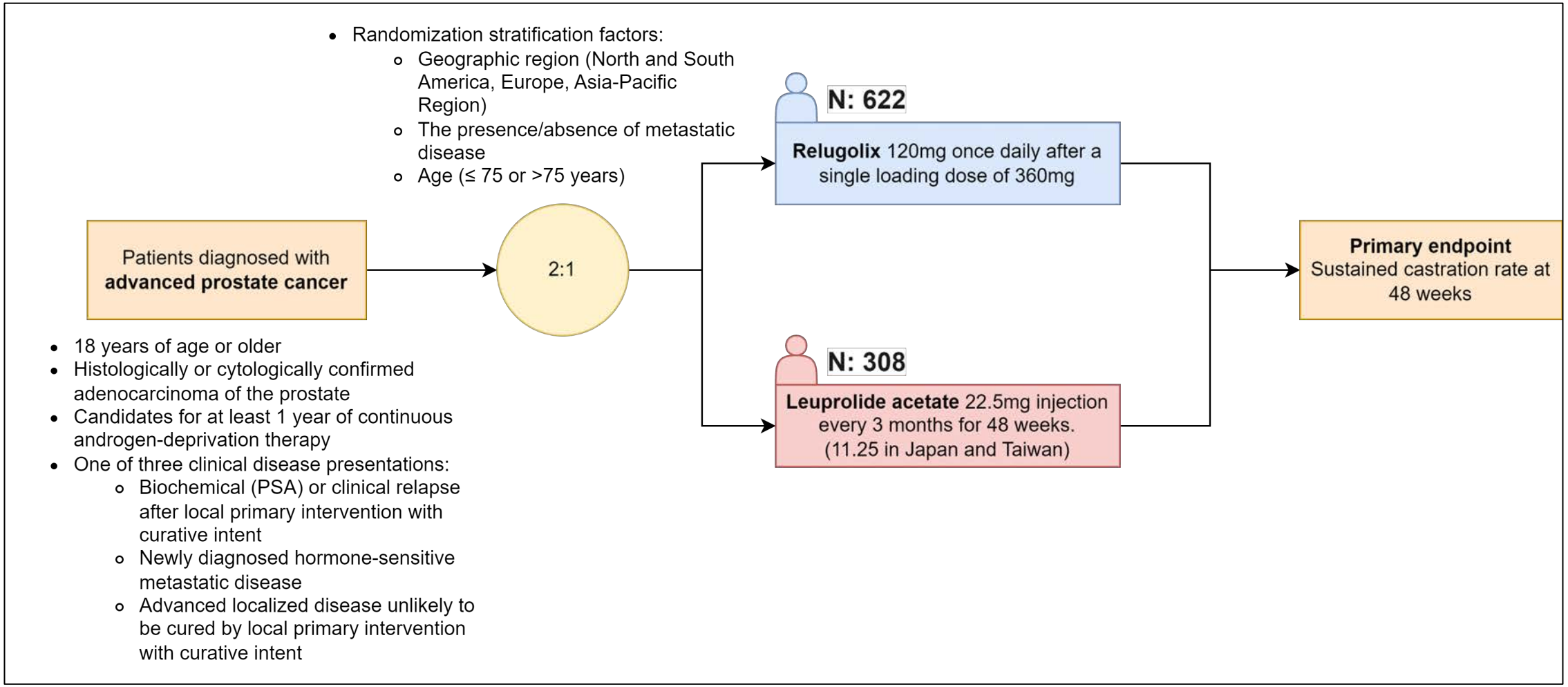
Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

PHASE III HERO TRIAL

STUDY DESIGN

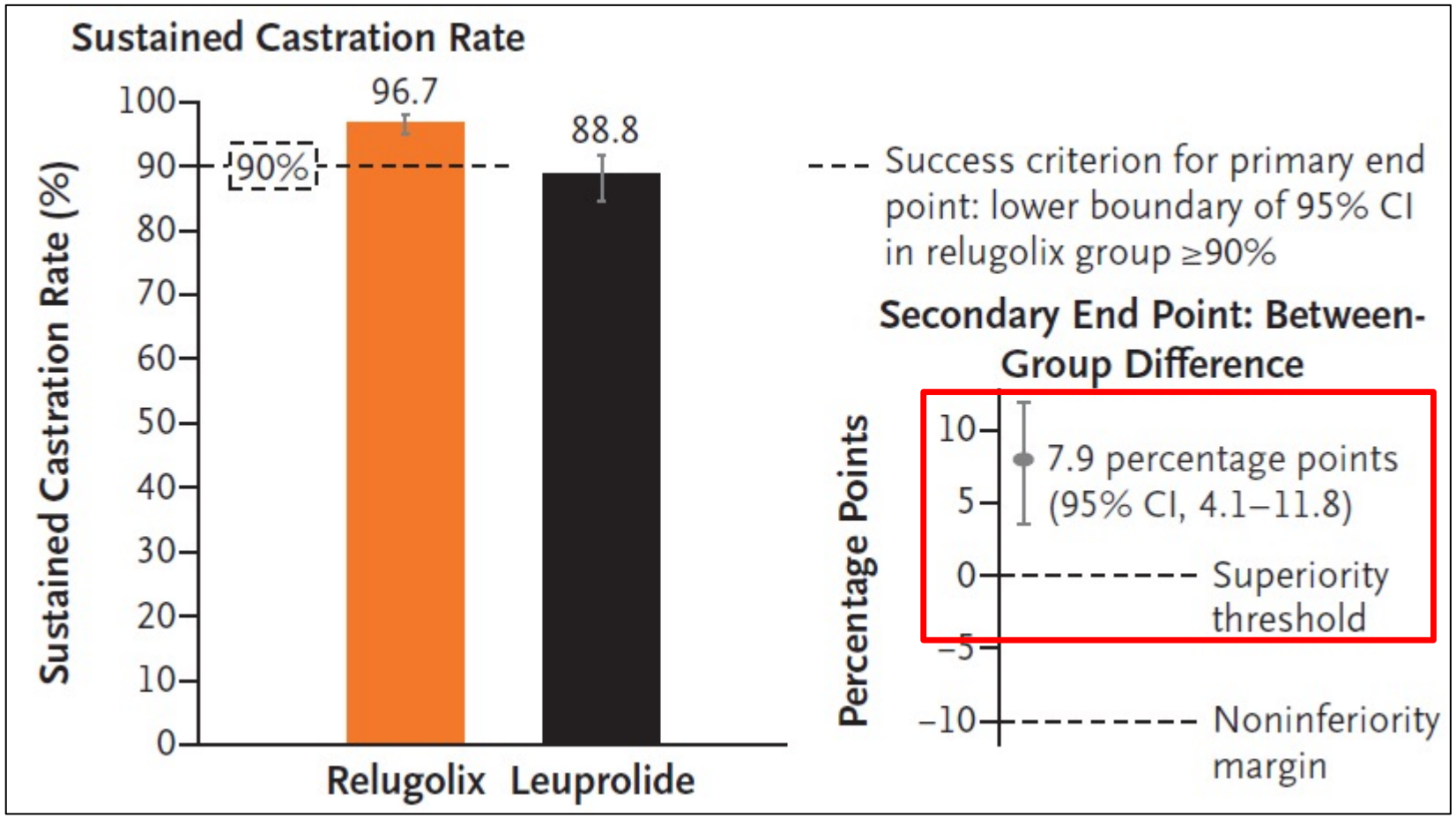


Shore ND et al, NEJM 2020

Courtesy of Alan H Bryce, MD

PHASE III HERO TRIAL

RESULTS: PRIMARY ENDPOINT



Shore ND et al, NEJM 2020

Courtesy of Alan H Bryce, MD

PHASE III HERO TRIAL

RESULTS: ADVERSE EVENTS

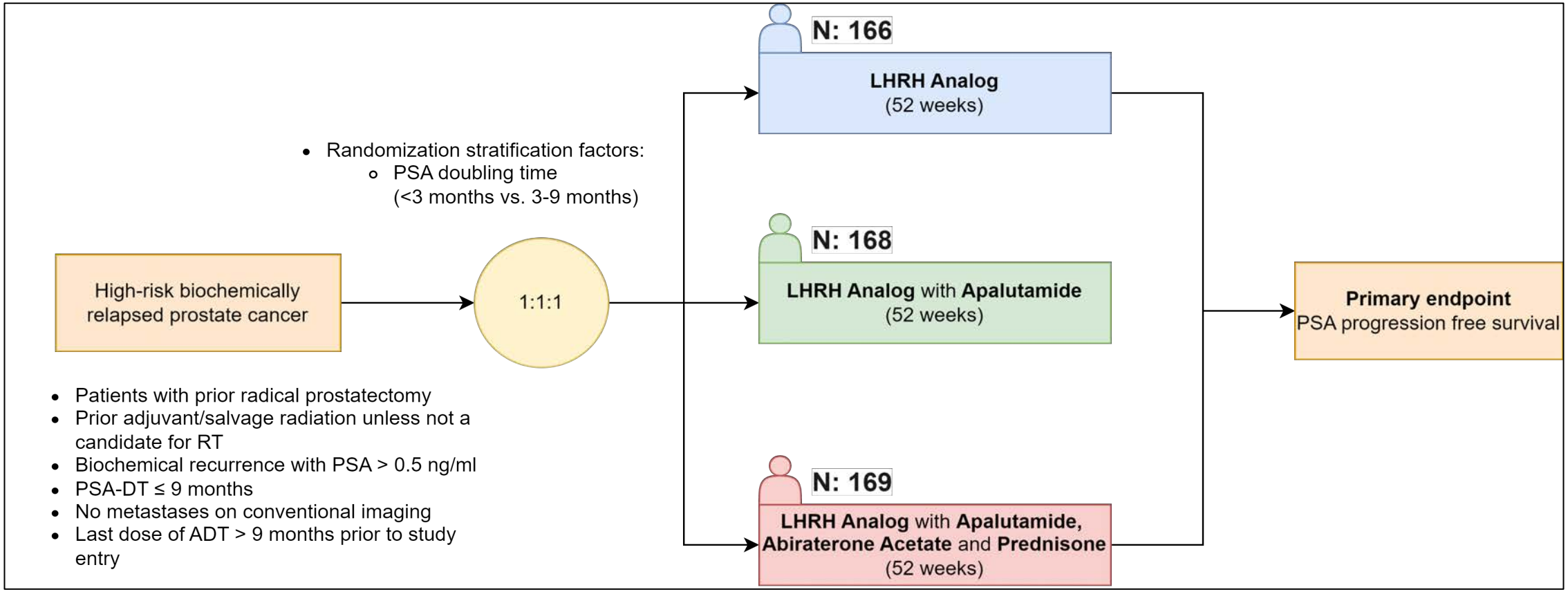
Adverse Events - N (%)	Relugolix (N=622)		Leuprolide (N=308)	
	Any Grade	Grade 3 or 4	Any Grade	Grade 3 or 4
Any adverse event	578 (92.9)	112 (18.0)	288 (93.5)	63 (20.5)
Serious adverse event	76 (12.2)	61 (9.8)	47 (15.3)	35 (11.4)
Fatal adverse event	7 (1.1)		9 (2.9)	
MACE	18 (2.9)	8 (1.3)	19 (6.2)	4 (1.3)
Without prior history of MACE	15/538 (2.8)		11/263 (4.2)	
With prior history of MACE	3/84 (3.6)		8/45 (17.8)	

Shore ND et al, NEJM 2020

Courtesy of Alan H Bryce, MD

PHASE III PRESTO TRIAL

STUDY DESIGN



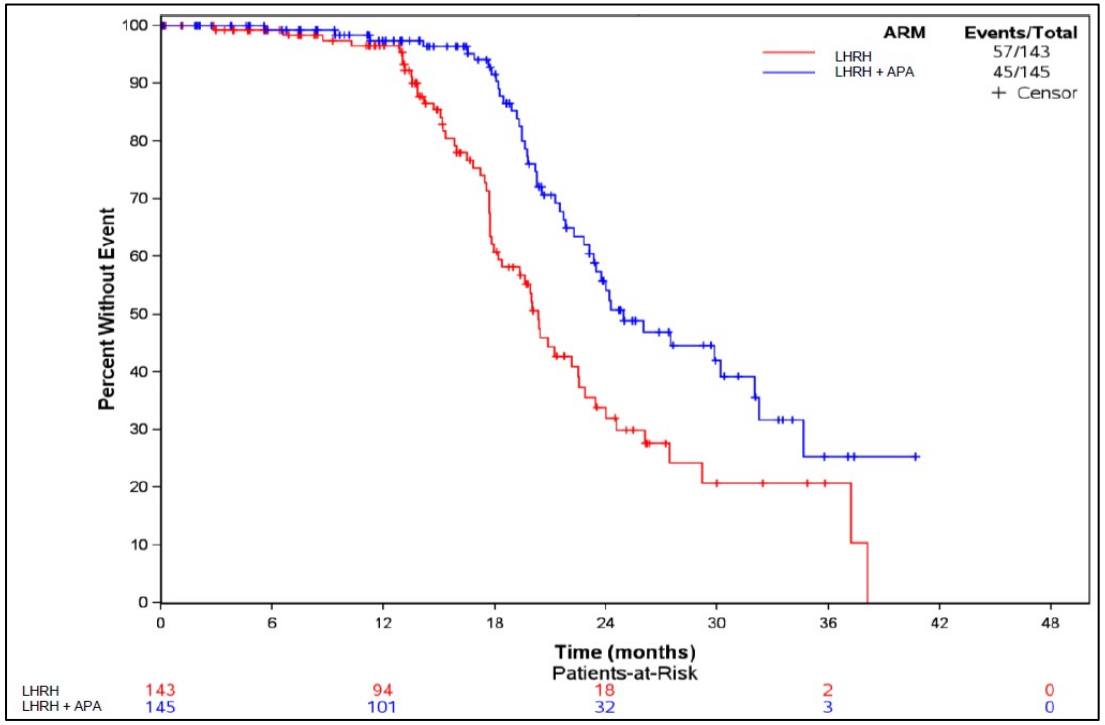
Aggarwal et al, ESMO 2022

Courtesy of Alan H Bryce, MD

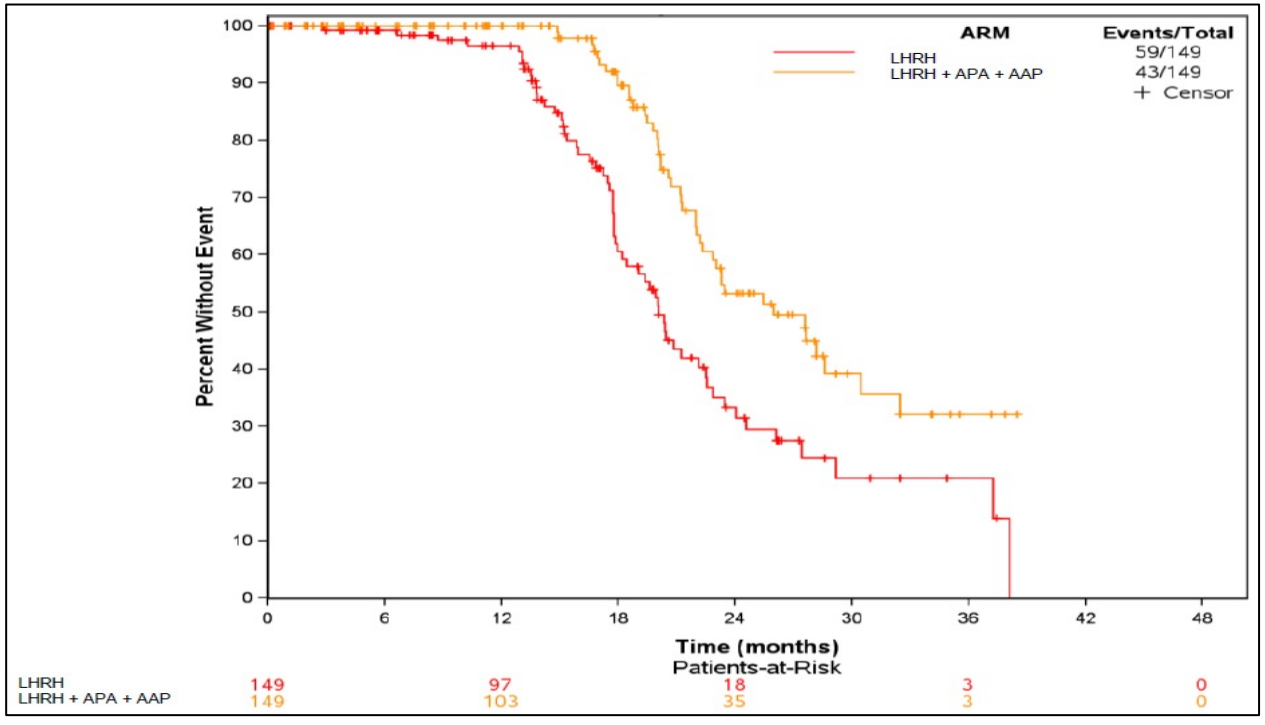
PHASE III PRESTO TRIAL

RESULTS: PSA PROGRESSION FREE SURVIVAL

	PSA Progression-Free Survival	
	Apalutamide + ADT	ADT alone
Events/Total	45/145	57/143
Median PSA PFS (months)	24.9 (95% CI: 23.3 – 32.3)	20.3 (95% CI: 18.2 – 22.9)
Hazard Ratio (95% CI) | p-value	0.52 (95% CI: 0.35 – 0.77) | 0.00047*	
*One sided p-value		



	PSA Progression-Free Survival	
	Apalutamide + Abiraterone + ADT	ADT alone
Events/Total	43/149	59/149
Median PSA PFS (months)	26.0 (95% CI: 22.9 – 32.5)	20.0 (95% CI: 18.2 – 22.5)
Hazard Ratio (95% CI) | p-value	0.48 (95% CI: 0.32 – 0.71) | 0.00008*	
*One-sided p-value		



Courtesy of Alan H Bryce, MD

PHASE III PRESTO TRIAL

RESULTS: ANALYSIS BY PSA DOUBLING TIME

PSA Progression-Free Survival		
Subgroup Analysis by PSA Doubling Time	**Total Participants**	**HR (95% CI)**
Apalutamide + ADT vs ADT		
< 3 months	Apalutamide + ADT: 39 ADT: 38	0.57 (0.28-1.18)
3-9 months	Apalutamide + ADT: 106 ADT: 105	0.50 (0.31-0.80)
Apalutamide + Abiraterone + ADT vs ADT		
< 3 months	Apalutamide + Abiraterone ADT: 41 ADT: 40	0.46 (0.22-0.95)
3-9 months	Apalutamide + Abiraterone ADT: 108 ADT: 109	0.48 (0.30-0.77)

Aggarwal et al, ESMO 2022

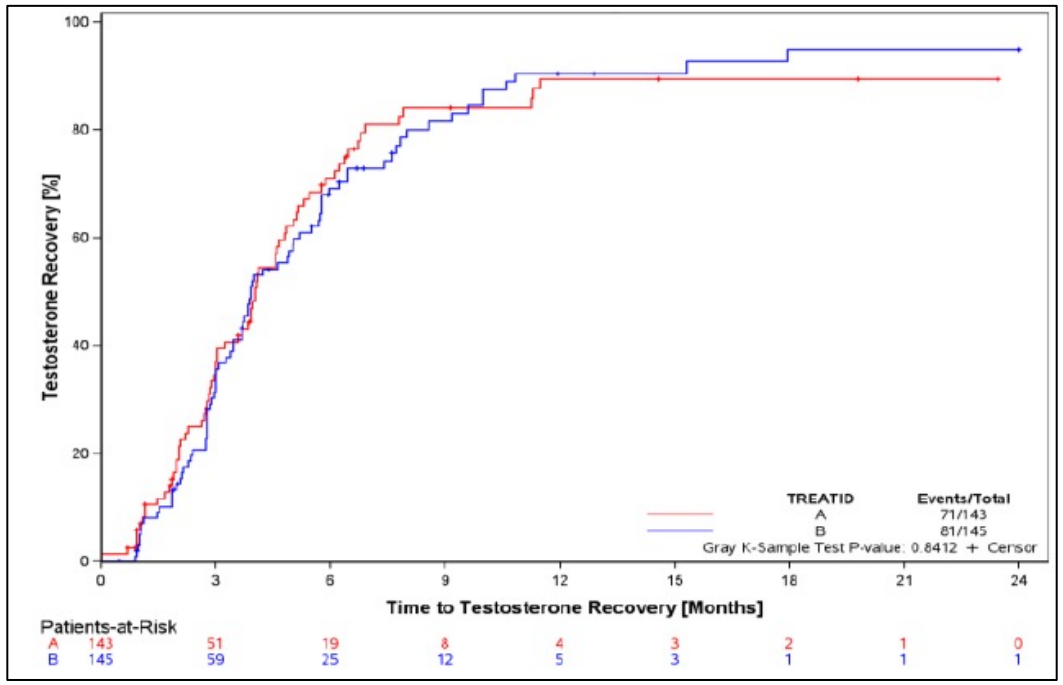
Courtesy of Alan H Bryce, MD

PHASE III PRESTO TRIAL

RESULTS: TIME TO TESTOSTERONE RECOVERY

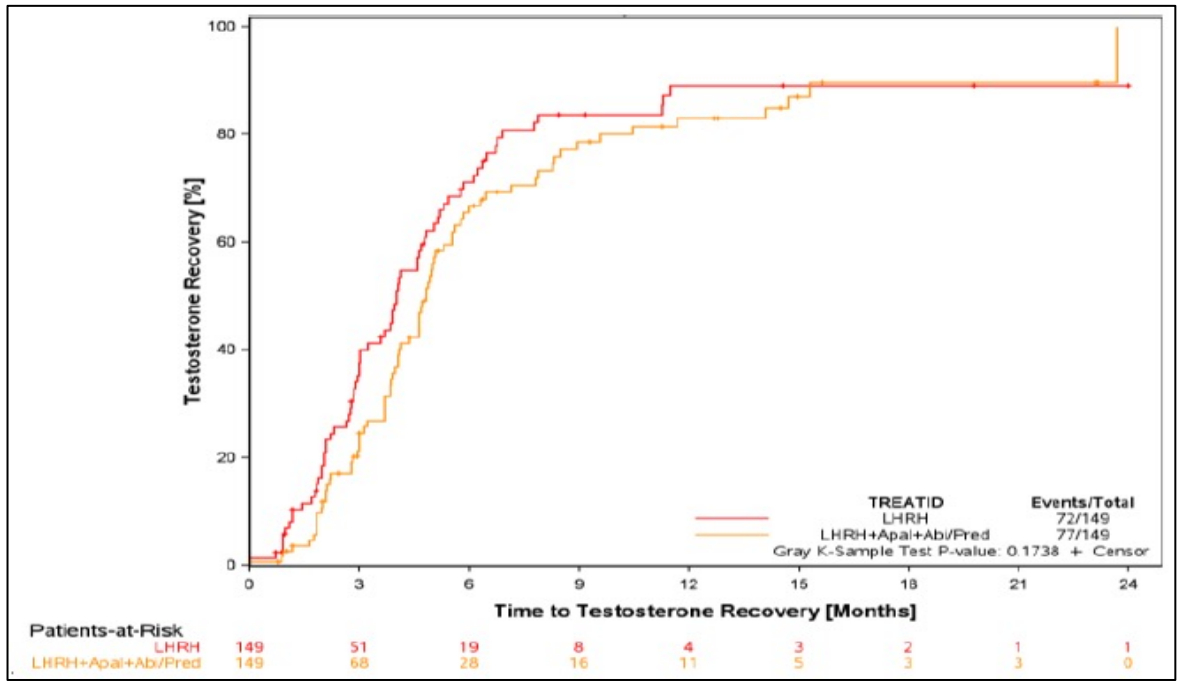
	Time to Testosterone Recovery (>50 ng/dL)	
	ADT alone	Apalutamide + ADT
Events/Total	71/143	81/145
Median TTR (months)	4	3.9
Hazard Ratio (95% CI) | p-value	0.96 (95% CI: 0.70-1.32) | 0.8412*	

*Gray's test



	Time to Testosterone Recovery (>50 ng/dL)	
	ADT alone	Apalutamide + Abiraterone + ADT
Events/Total	72/149	77/149
Median TTR (months)	4	4.8
Hazard Ratio (95% CI) | p-value	0.80 (95% CI: 0.58-1.10) | 0.1738*	

*Gray's test



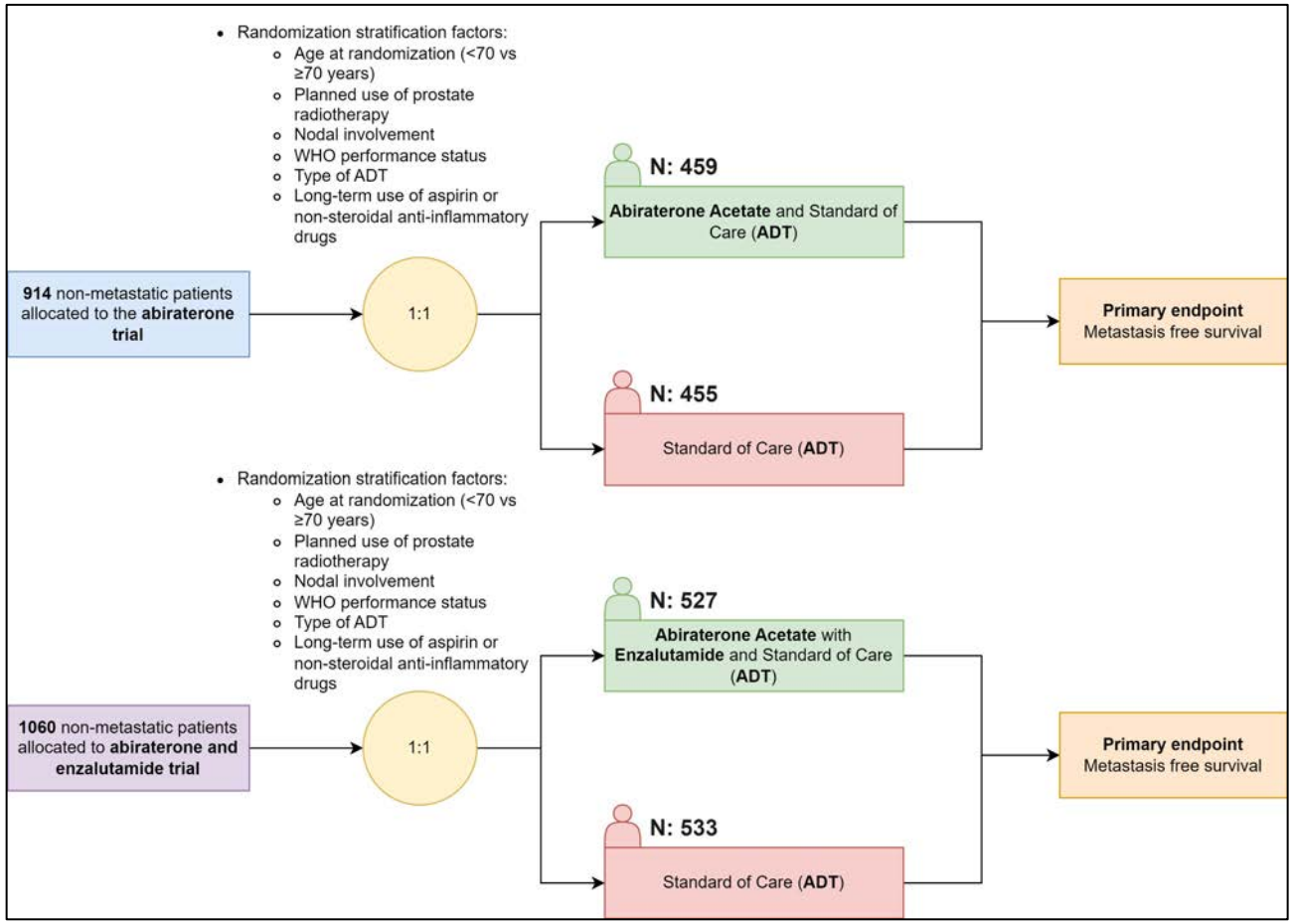
Courtesy of Alan H Bryce, MD

Aggarwal et al, ESMO 2022

PHASE III STAMPEDE TRIAL

STUDY DESIGN

Inclusion criteria	Type of definitive therapy	High risk definition
High risk local, or locally advanced - histologically confirmed prostatic adenocarcinoma	Planned for radiation therapy	Either: a) at least two of the following: - T3 or T4 - GS 8-10 - PSA ≥40 ng/mL b) Relapsing with high-risk features (≤12 months of total ADT with an interval of ≥12 months without treatment and a PSA ≥ 4ng/ml with a doubling time of <6 months or a PSA ≥20ng/ml)



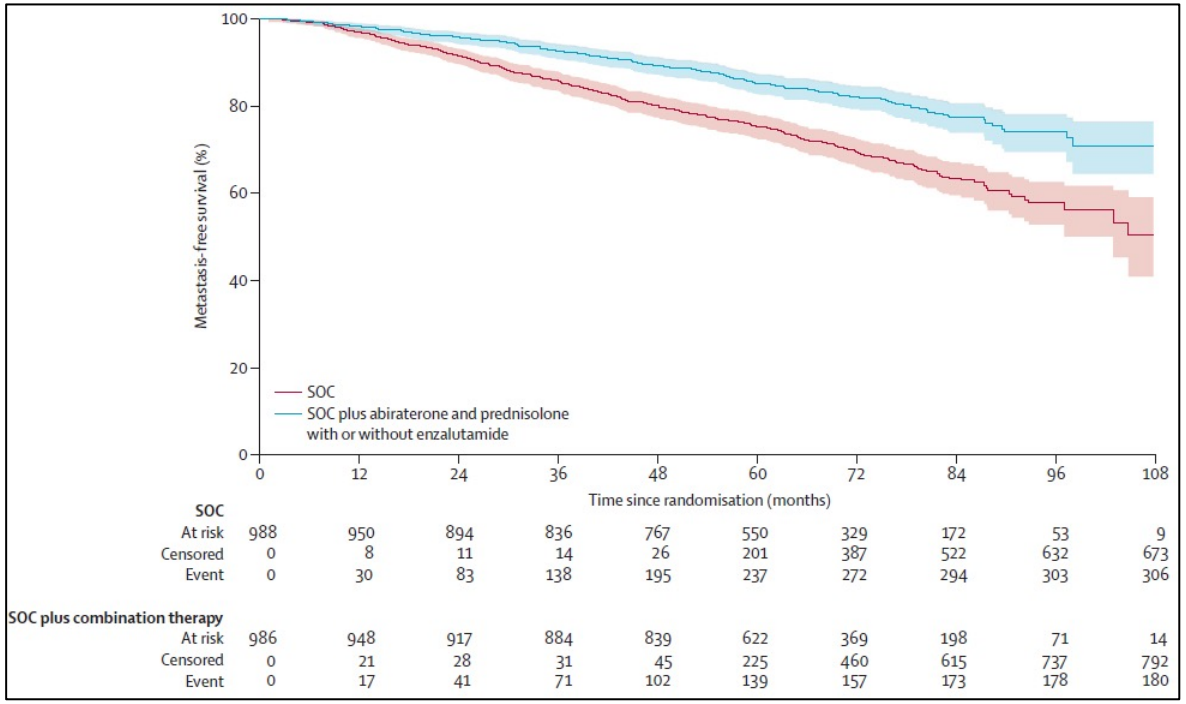
Attard G et al, Lancet 2022

Courtesy of Alan H Bryce, MD

PHASE III STAMPEDE TRIAL

RESULTS: METASTASIS FREE SURVIVAL

Arms	Metastasis free survival		
	Events in treatment arm	Events in control arm	HR (95% CI)
Treatment: Abiraterone Control: SOC (ADT)	111/459 Metastasis: 51 Death: 60	183/455 Metastasis: 110 Death: 73	0.54 (0.43-0.68)
Treatment: Abiraterone-Enzalutamide Control: SOC (ADT)	69/257 Metastasis: 36 Death: 33	123/533 Metastasis: 79 Death: 44	0.53 (0.39-0.71)



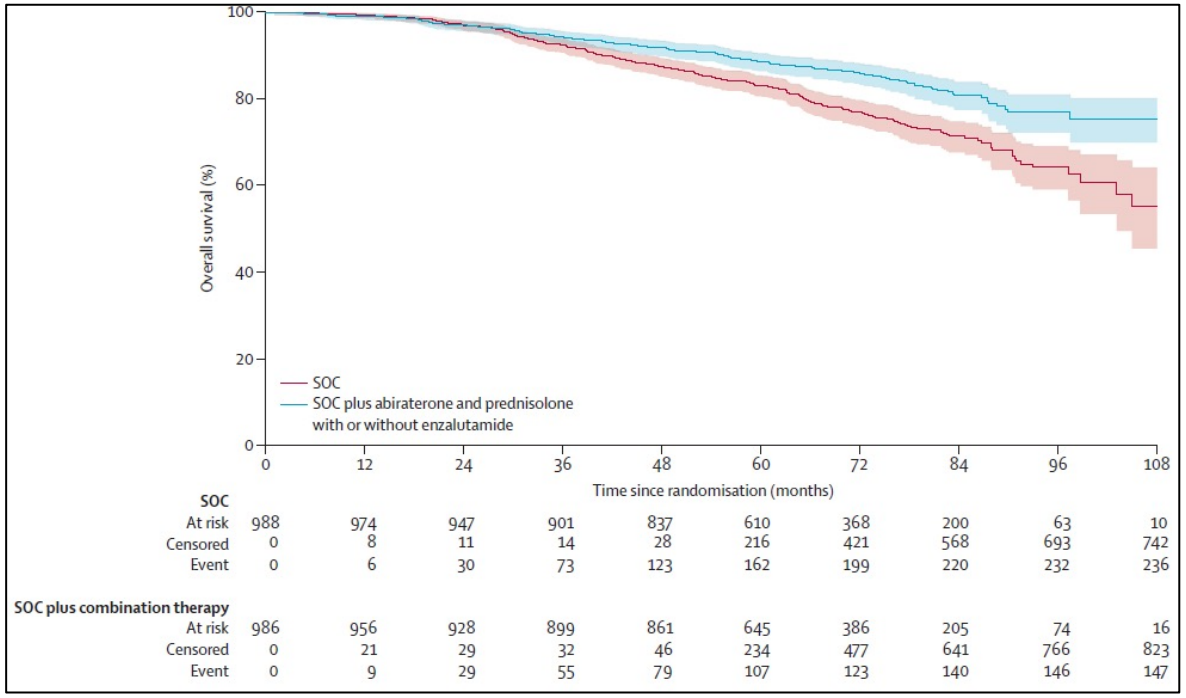
Attard G et al, Lancet 2022

Courtesy of Alan H Bryce, MD

PHASE III STAMPEDE TRIAL

RESULTS: OVERALL SURVIVAL

Arms	Overall survival		
	Events in treatment arm	Events in control arm	HR (95% CI)
Treatment: Abiraterone Control: SOC (ADT)	95/459	142/455	0.63 (0.48-0.82)
Treatment: Abiraterone-Enzalutamide Control: SOC (ADT)	52/527	94/533	0.54 (0.39-0.76)



Attard G et al, Lancet 2022

Courtesy of Alan H Bryce, MD

TRIALS IN M0 CRPC

OVERVIEW

Trial Name	Total Participants	Interventions	Primary Endpoint
PROSPER (NCT02003924)	1560	Enzalutamide 160mg once daily	Metastasis-free survival
SPARTAN (NCT01946204)	1200	Apalutamide 240mg once daily	Metastasis-free survival
ARAMIS (NCT02200614)	1500	Darolutamide 600mg twice daily	Metastasis-free survival

Courtesy of Alan H Bryce, MD

TRIALS IN M0 CRPC
ENDPOINTS

PROSPER

PRIMARY ENDPOINTS

- **Metastasis-free survival:** defined as the time from randomization to radiographic progression, as determined by central review at any time, or as the time to death from any cause during the period from randomization to 112 days after the discontinuation of the trial regimen without evidence of radiographic progression, whichever occurred first

SECONDARY ENDPOINTS

- Overall survival
- Time to PSA progression
- The PSA response rate
- The time to the first use of a subsequent antineoplastic therapy
- Quality of life
- Safety

SPARTAN

PRIMARY ENDPOINTS

- **Metastasis-free survival:** defined as the time from randomization to the first detection of distant metastasis on imaging (as assessed by means of blinded independent central review) or death from any cause, whichever occurred first

SECONDARY ENDPOINTS

- Overall survival
- Time to metastasis
- Progression-free survival
- Time to symptomatic progression
- Time to the initiation of cytotoxic chemotherapy

EXPLORATORY ENDPOINTS

- Time to PSA progression
- PSA response rate
- Second progression-free survival
- Patient reported outcomes

ARAMIS

PRIMARY ENDPOINTS

- **Metastasis-free survival:** defined as the time from randomization to confirmed evidence of distant metastasis on imaging or death from any cause, whichever occurred first

SECONDARY ENDPOINTS

- Overall survival
- Time to pain progression
- Time to first symptomatic skeletal event
- Time to the first cytotoxic chemotherapy

EXPLORATORY ENDPOINTS

- Progression-free survival
- Time to first prostate cancer related invasive procedure
- Time to initiation of subsequent antineoplastic therapy
- PSA progression and response
- Deterioration in ECOG performance status
- Quality of life

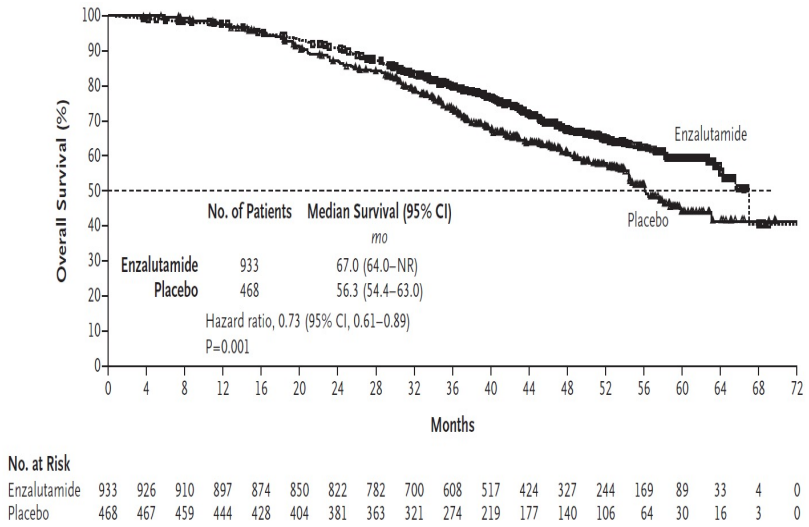
Courtesy of Alan H Bryce, MD

Hussain M et al, NEJM, 2018; Smith MR et al, NEJM 2018; Fizazi K et al, NEJM 2019

LONG-TERM RESULTS

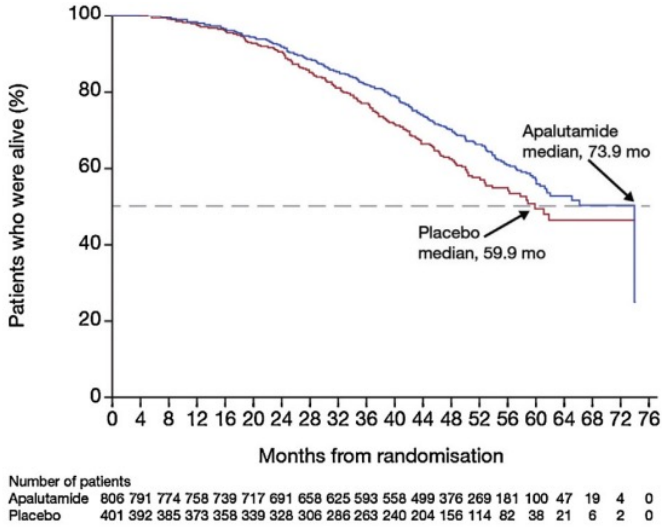
OVERALL SURVIVAL

PROSPER



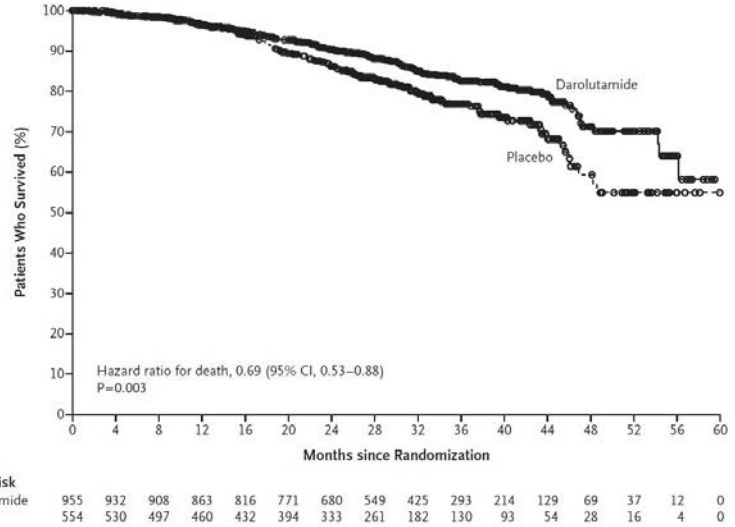
Arms	Overall survival	
	Median OS	HR (95% CI)
Treatment: Enzalutamide Control: ADT	67.0 vs. 56.3 (months)	0.73 (0.61-0.89)
Median Follow up: **48.0 months**		

SPARTAN



Arms	Overall survival	
	Median OS	HR (95% CI)
Treatment: Apalutamide Control: ADT	73.9 vs. 59.9 (months)	0.78 (0.64–0.96)
Median Follow up: **52.0 months**		

ARAMIS



Arms	Overall survival	
	Median OS	HR (95% CI)
Treatment: Darolutamide Control: ADT	NR vs. NR (months)	0.69 (0.53-0.88)
Median Follow up: **29.0 months**		

Sternberg CJ et al, NEJM 2020; Smith MR et al, Eur Urol 2021; Fizazi K et al, NEJM 2020

Courtesy of Alan H Bryce, MD

Pathways/Targets & Agents

Pathway	Target	Agents
Angiogenesis	PDGF receptor	Olaratumab
	VEGF	Aflibercept
	VEGF receptor	Ramucirumab
Androgen signaling *	Androgen receptor, CYP17	Abi, Enza, Orteronel, Apalutamide, EPI-506, *Darolutamide*, Galeterone, *High dose testosterone*
Apoptosis	BCL-2	AT-101
	Clusterin, MDM2	Custirsen, MI-773
Cell Cycle *	Microtubules, CDK4/6	Docetaxel, Cabazitaxel, Palbociclib
DNA repair	PARP	Veliparib, Olaparib, Rucaparib, Niraparib, Talazoparib
Bone *	Osteoclast, RANKL, Integrins	Radium 223, Zoledronic acid, Denosumab, EMD 525797
Immune modulation *	Vaccine, CTLA-4	Sipuleucel-T, Ipilimumab
	PDL, Multiple	Pembrolizumab, PROSTVAC, Atezolizumab, Tasquinimod
Other Pathways	HSP27, Src MET +/-VEGFR2, I3K Bromodomain, *EZH2, TGF-B*	OGX-427, LY2875358, PAM4983g, OTX015, GSK525762, Tazemetostat, Galunisertib, Lu-PSMA, Ipatasertib

* FDA approved based on Phase III trials or other registrational mechanism

Courtesy of Maha Hussain, MD, FACP, FASCO

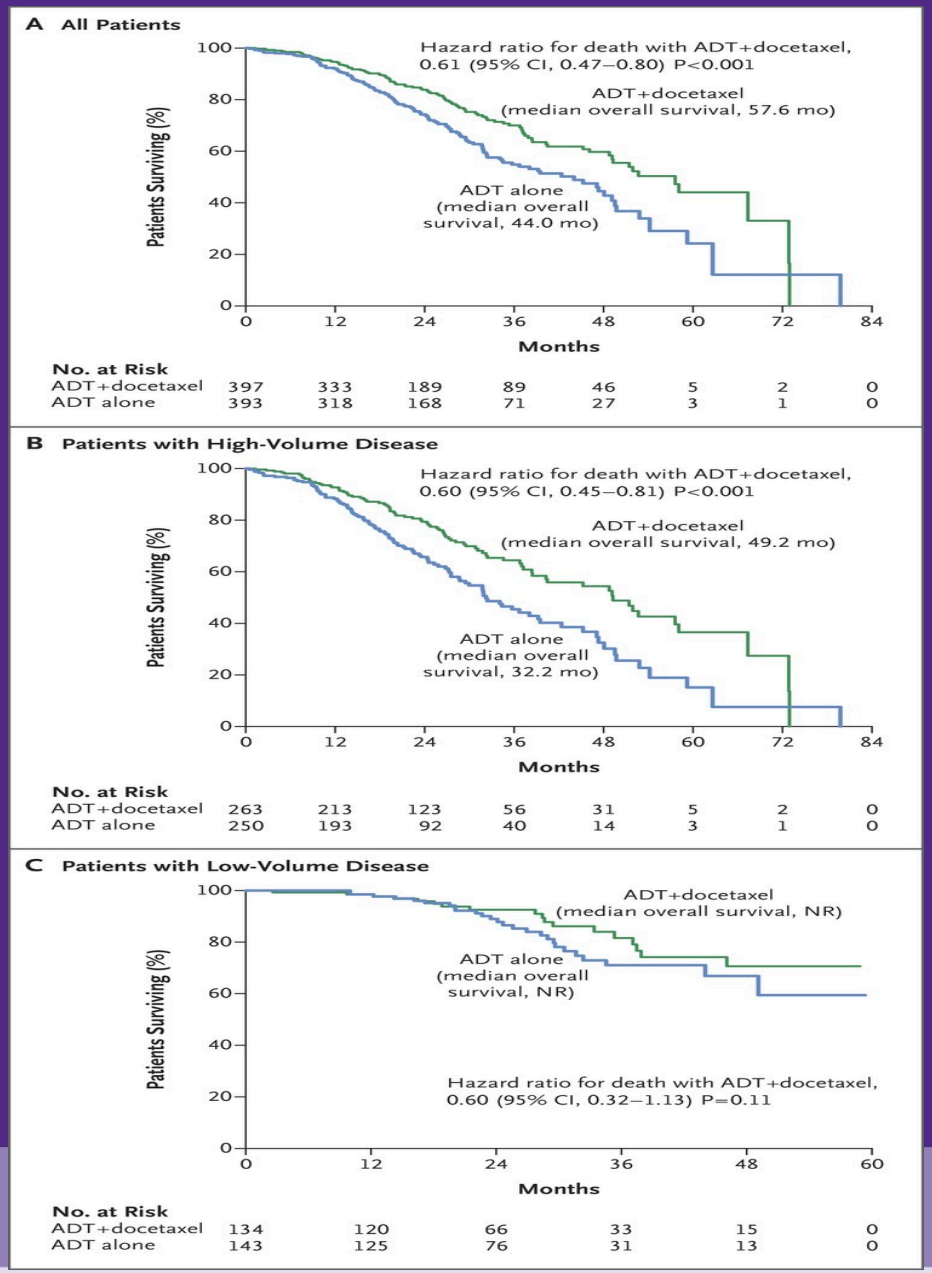
Life Prolonging Doublet and Triplet Therapies for Metastatic Hormone Sensitive Prostate Cancer

Trial	Experimental Arm	Comparison
CHAARTED	ADT + Docetaxel	ADT
STAMPEDE	ADT + Abiraterone/Pred	ADT
LATITUDE	ADT + Abiraterone/Pred	ADT
TITAN	ADT + Apalutamide	ADT (+/- Docetaxel 11%)
ENZAMET (+/- Docetaxel 45%)	ADT + Enzalutamide	ADT +NSAA
PEACE-1	ADT + Docetaxel + Abiraterone/Pred	ADT + Docetaxel
ARASENS	ADT + Docetaxel + Darolutamide	ADT + Docetaxel

Courtesy of Maha Hussain, MD, FACP, FASCO

ADT: Androgen deprivation

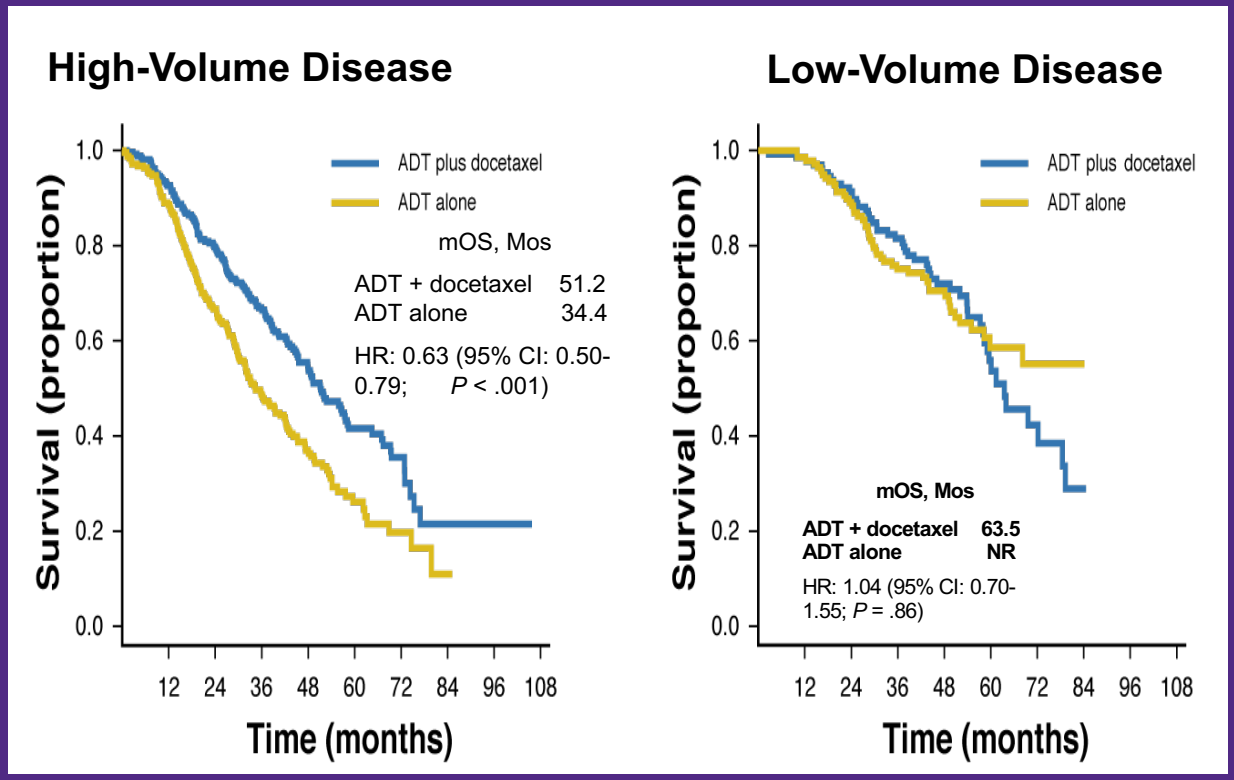
CHAARTED: ADT +/- Docetaxel in mHSPC



Sweeney CJ et al. NEJM 2015

(N = 790, Median follow-up 53.7m)

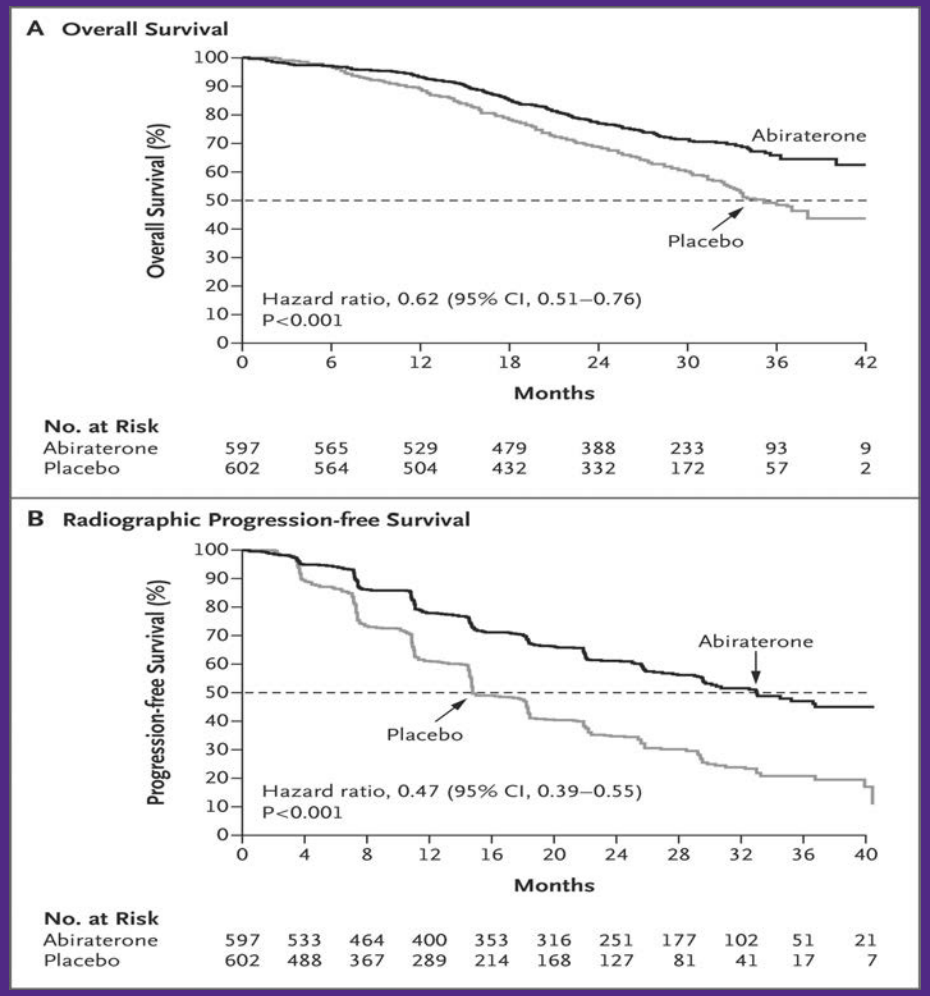
Long-Term Follow-up: High-Volume vs Low-Volume Disease

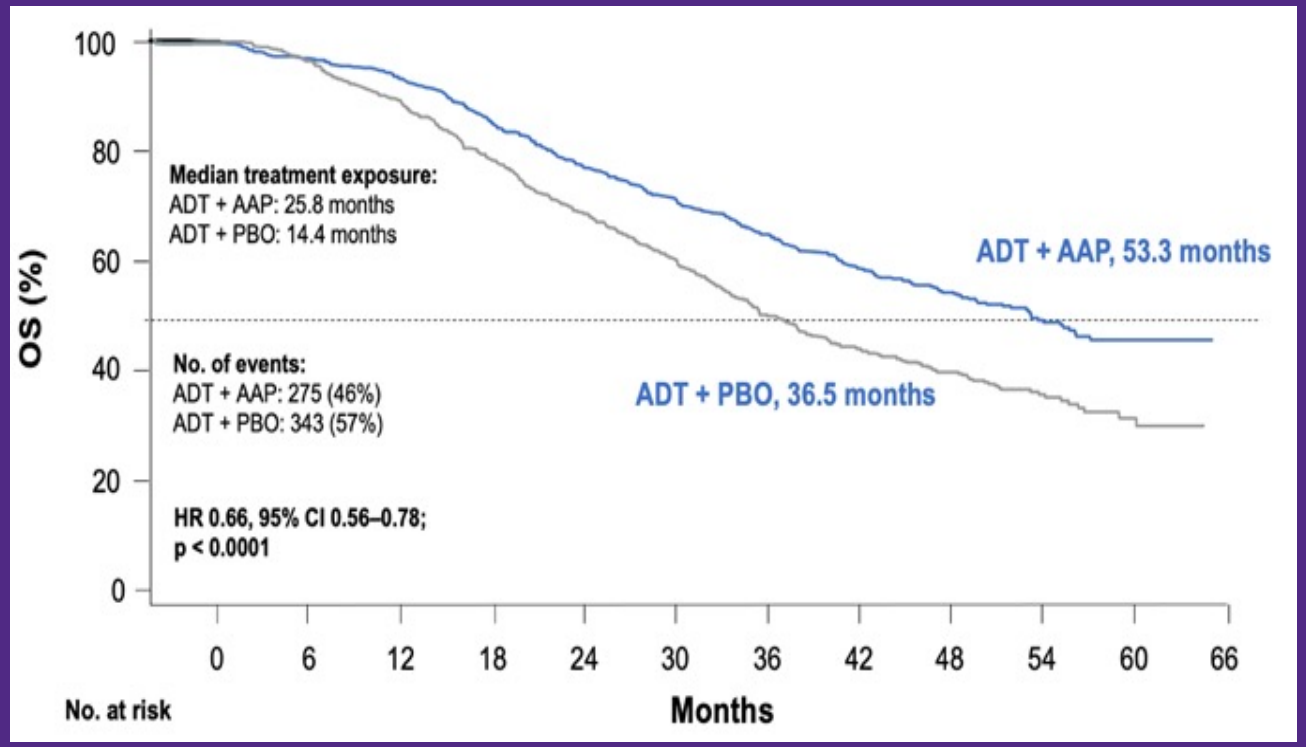


Kyriakopoulos CE, et al. J Clin Oncol. 2018

Courtesy of Maha Hussain, MD, FACP, FASCO

LATITUDE: ADT + Abiraterone/Prednisone or Placebo in Newly Diagnosed High-Risk mHSPC





- Median follow-up of 51.8 months
- 34% reduction in risk of death
- Median OS was significantly longer for abiraterone + ADT vs placebo + ADT
  - 53.3 months vs 36.5 months
  - **HR = 0.66; *p* < 0.0001**

OS rate at 3 years:
ADT + AA + P: 66%
ADT + placebos: 49%

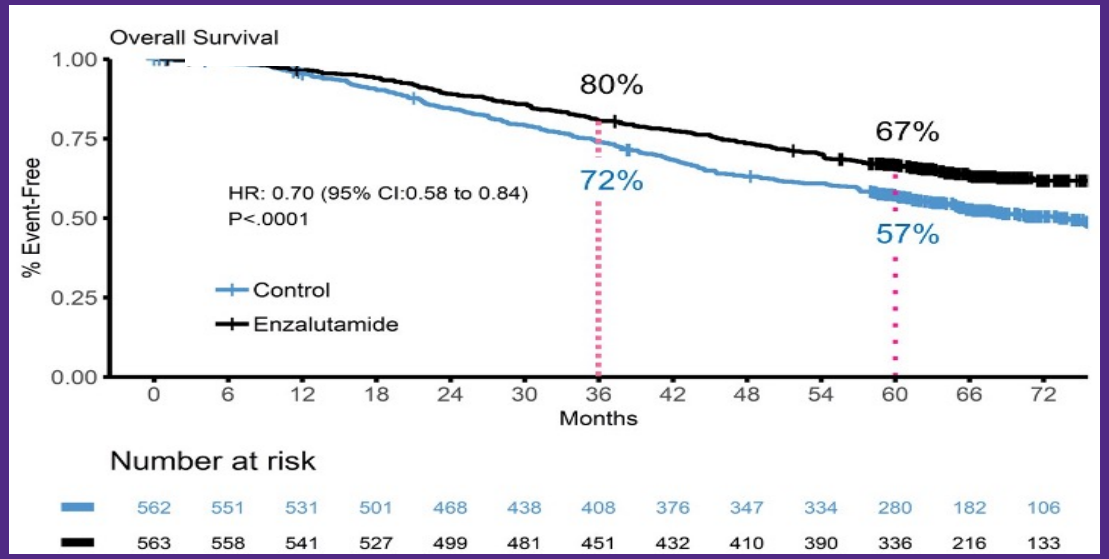
Courtesy of Maha Hussain, MD, FACP, FASCO

Fizazi et al. NEJM 2017

Fizazi K et al. Lancet Oncol 2019;20(5):686-700

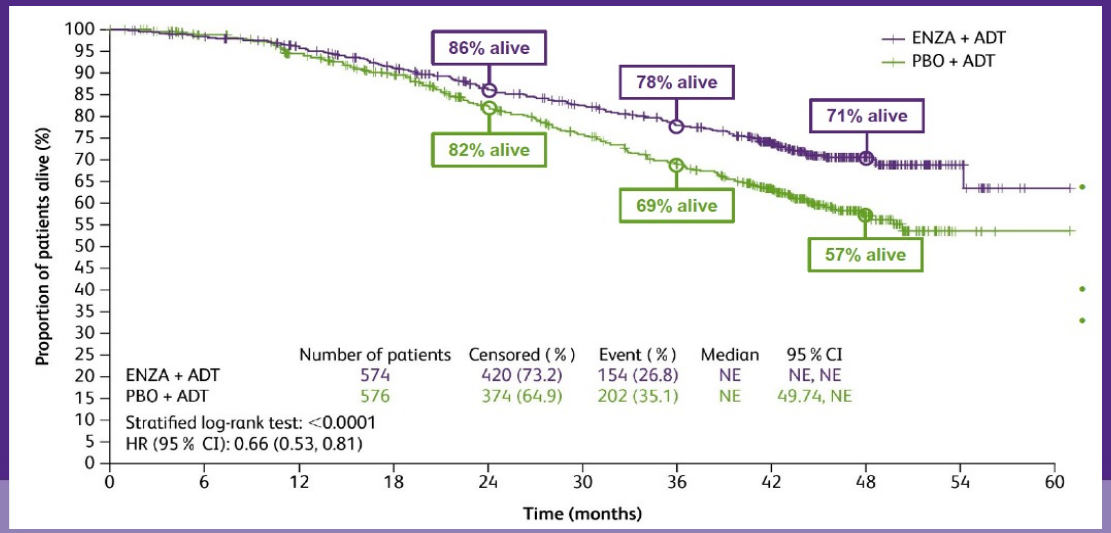
Final Overall Survival (OS) Analyses: Enzalutamide for Metastatic Hormone-Sensitive Prostate Cancer

ENZAMET[1]
Enzalutamide + testosterone suppression (TS)



- Median follow-up of 68.0 months
- 30% reduction in risk of death
- Median OS was significantly longer for enzalutamide + TS versus standard NSAA + TS
  - **Not reached vs 73.2 months**
  - **HR = 0.70; p < 0.0001**

ARCHES[2]
Enzalutamide + ADT

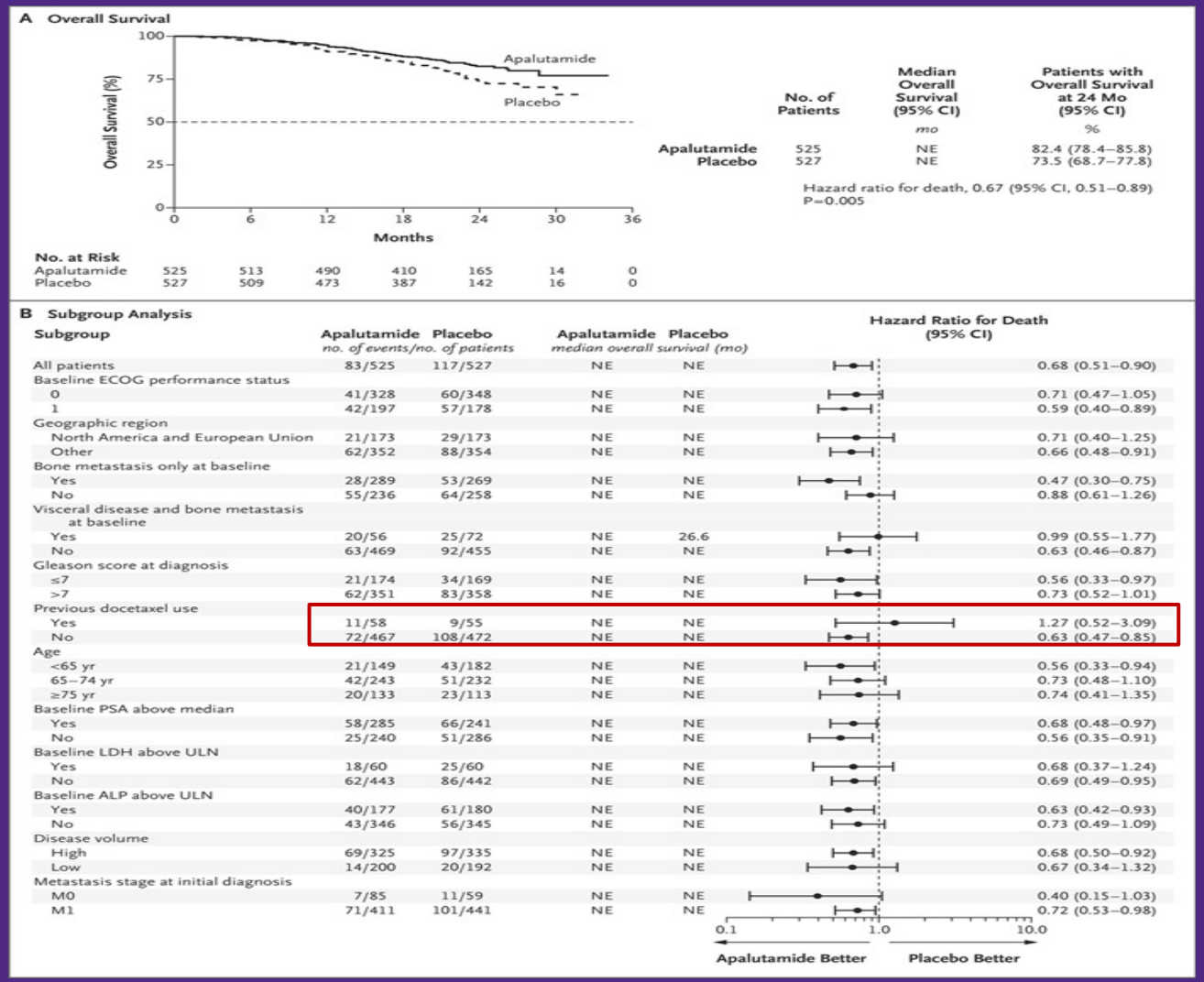


- Median follow-up of 44.6 months
- 34% reduction in risk of death
- Median OS was not reached for enzalutamide plus ADT, but was 47.7 months (95% CI, 43.3 to not evaluable) for placebo plus ADT.
  - **- HR = 0.66; p< 0.001**

Courtesy of Maha Hussain, MD, FACP, FASCO

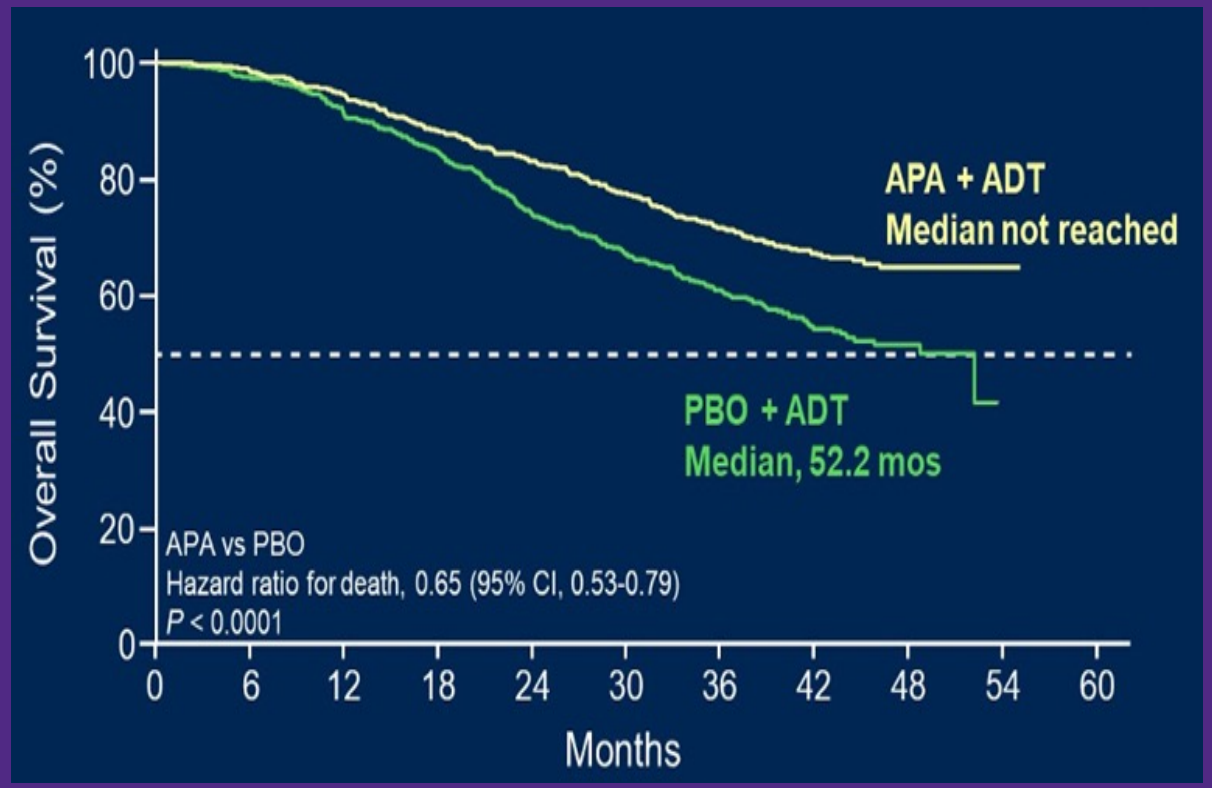
1. Davis ID et al. ASCO 2022;Abstract LBA5004; 2. Armstrong AJ et al. J Clin Oncol 2022;40(15):1616-22.

Apalutamide for Metastatic, Castration-Sensitive Prostate Cancer



- **8% difference in OS at 2 years**
- **Reduced risk of death by 33%**

Chi KN et al.NEJM 2019



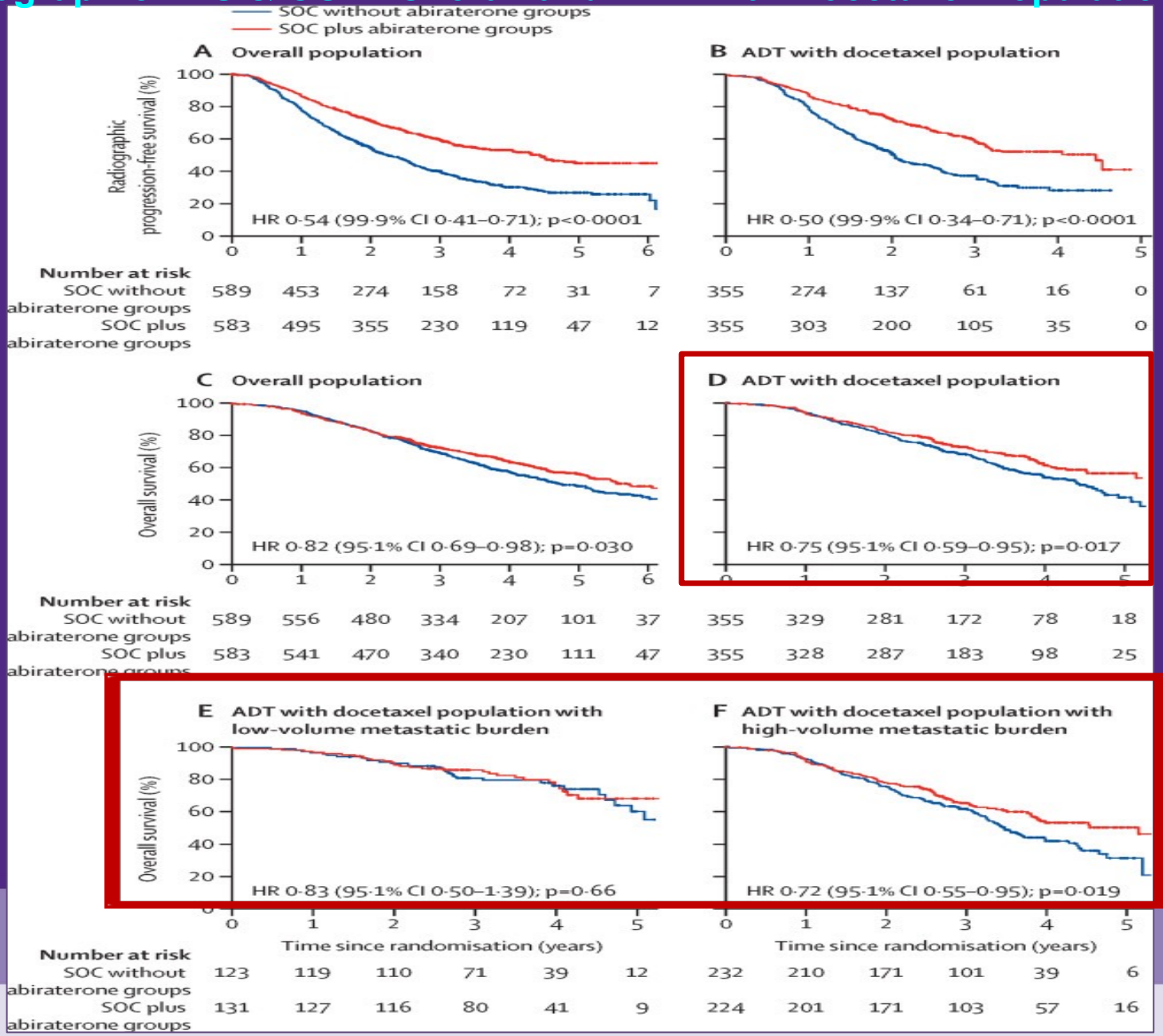
- Median follow-up of 44.0 months
  - 35% reduction in risk of death
- Median OS was significantly longer for apalutamide + ADT vs placebo + ADT:
  - Not reached vs 52.2 months
  - HR = 0.65; p < 0.0001

Courtesy of Maha Hussain, MD, FACP, FASCO

Chi KN et al. J Clin Oncol 2021

Triplet #1: PEACE-1: ADT + Abiraterone/Prednisone in De Novo mHSPC

Radiographic PFS & OS in Overall and ADT with Docetaxel Population

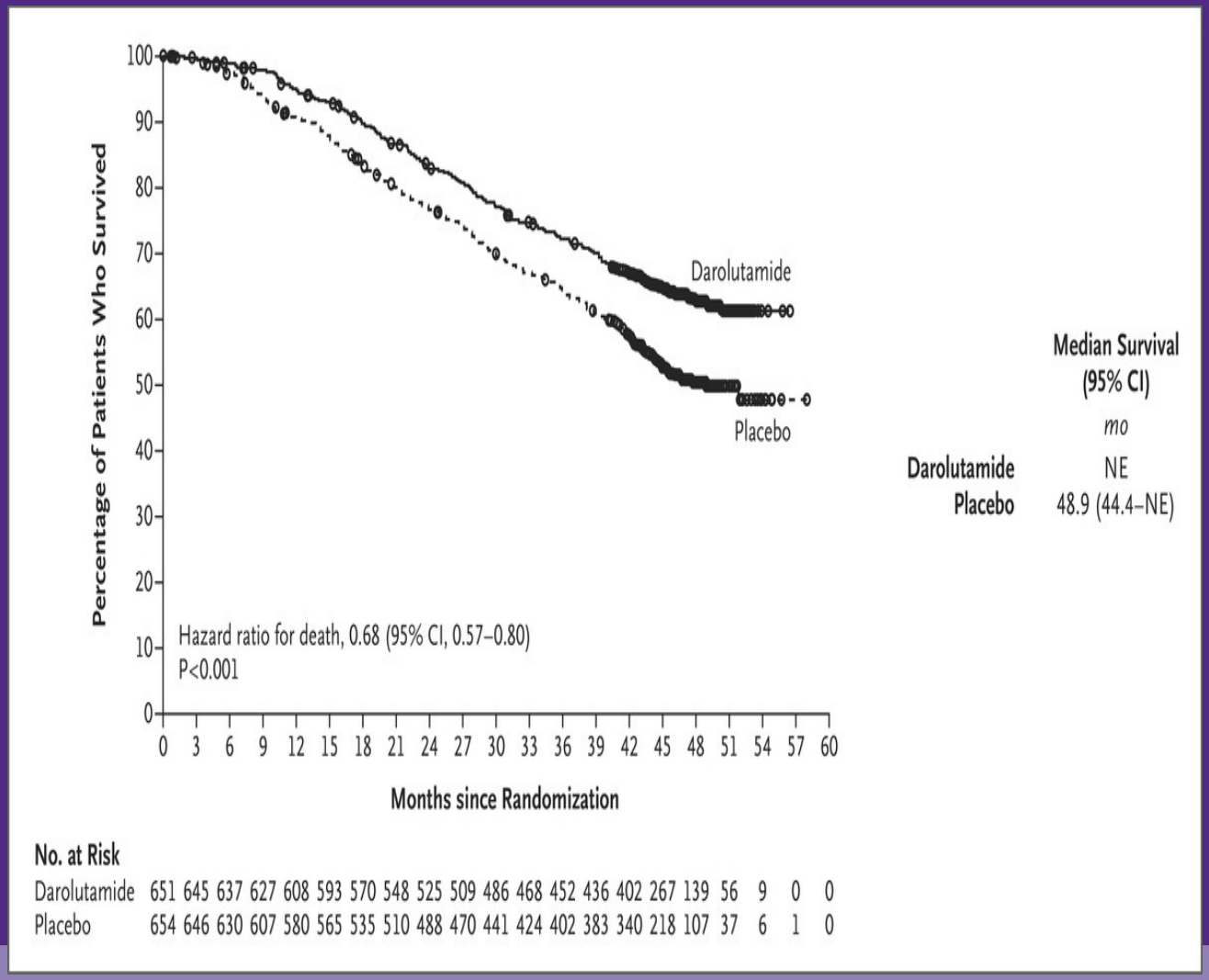


Fizazi et al: Lancet 2022

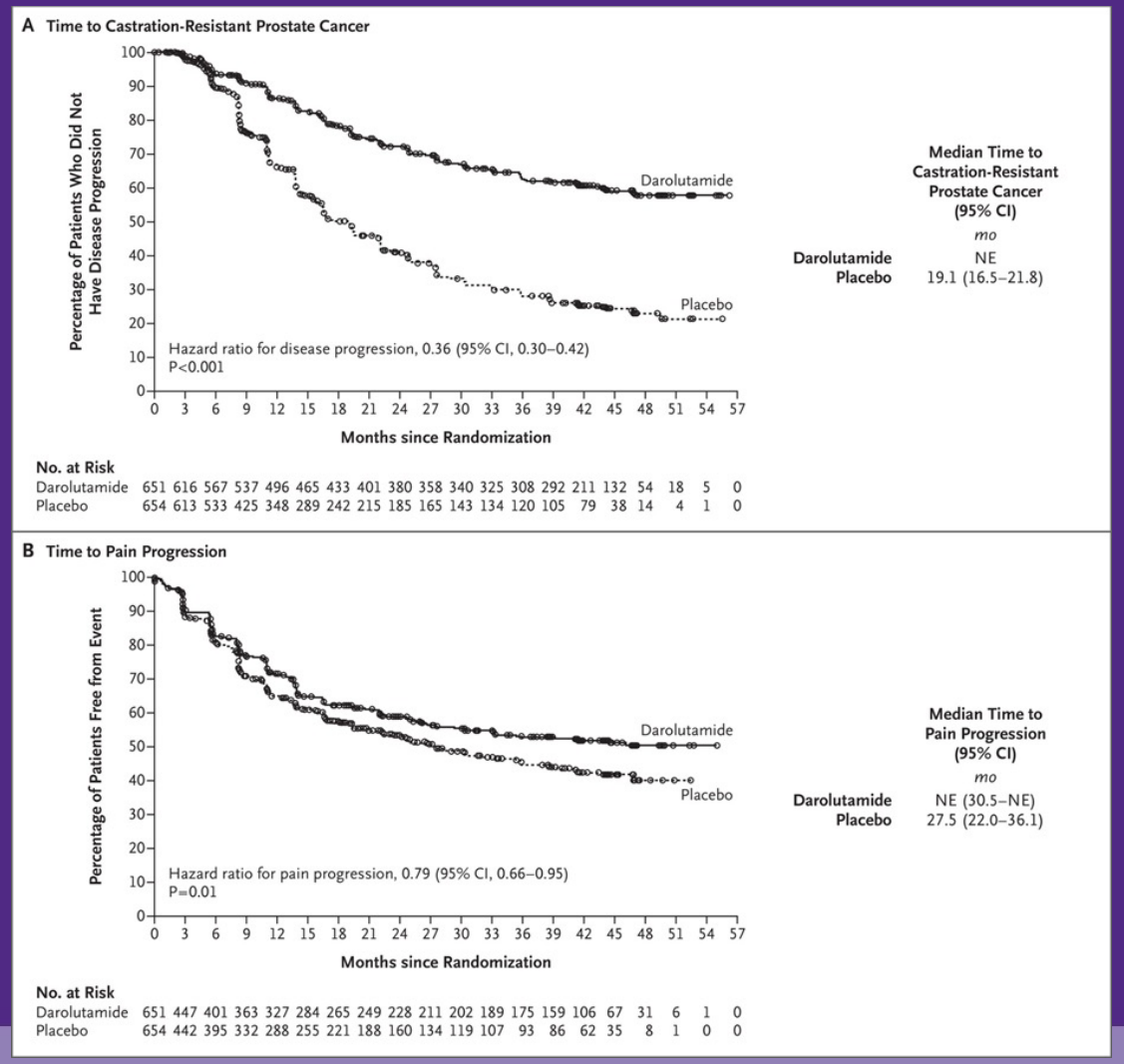
Courtesy of Maha Hussain, MD, FACP, FASCO

Triplet #2: ARASENS: ADT + Docetaxel + Darolutamide vs Placebo

Overall Survival



	Median Survival (95% CI)
	mo
Darolutamide	NE
Placebo	48.9 (44.4–NE)



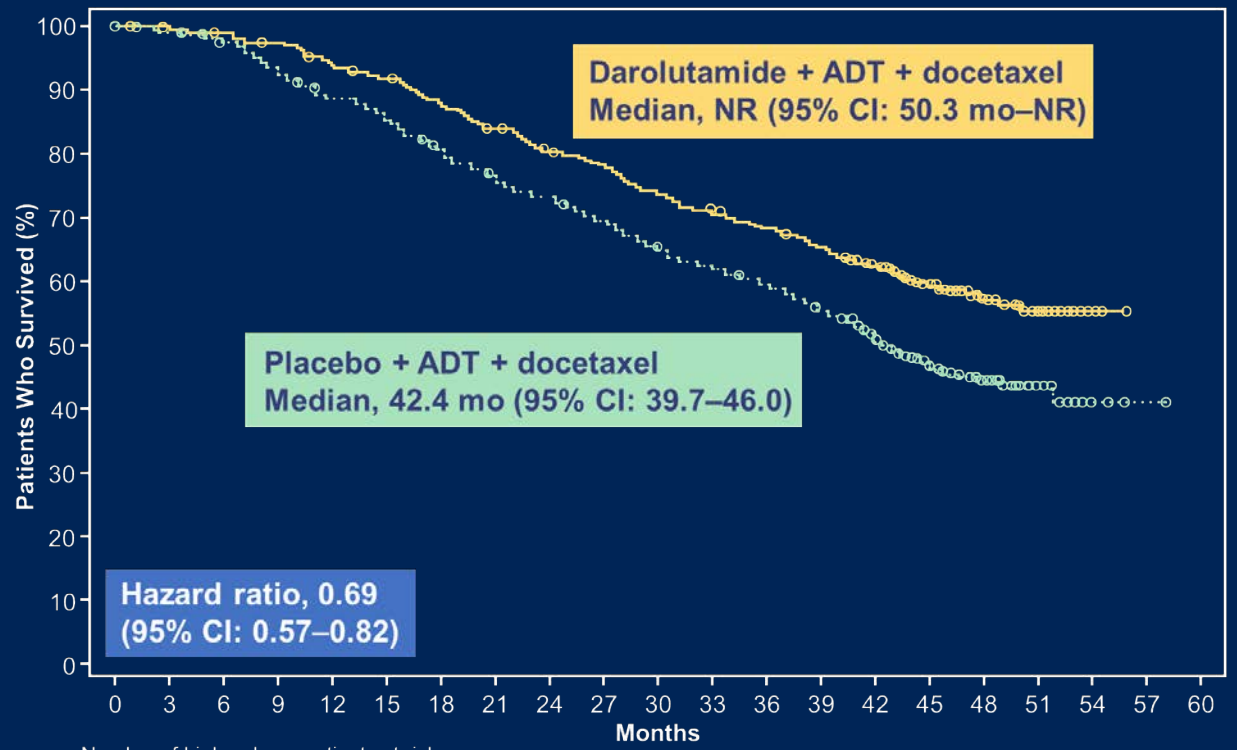
	Median Time to Castration-Resistant Prostate Cancer (95% CI)	Median Time to Pain Progression (95% CI)
	mo	*mo*
Darolutamide	NE	NE (30.5–NE)
Placebo	19.1 (16.5–21.8)	27.5 (22.0–36.1)

Courtesy of Maha Hussain, MD, FACP, FASCO

Smith et al. NEJM 2022

ARASENS VOLUME Subgroups: Overall Survival

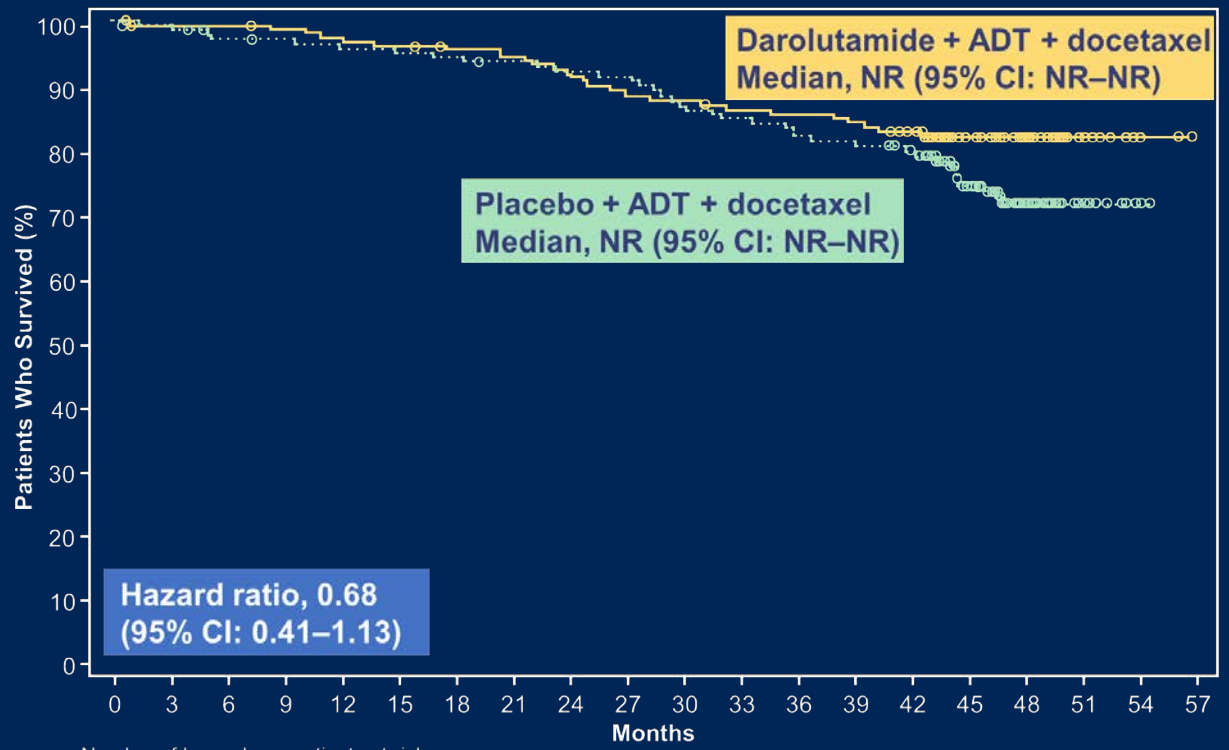
High-volume mHSPC



Number of high-volume patients at risk

Darolutamide	497	494	486	479	462	449	429	408	389	378	356	341	326	312	285	193	103	43	6	0	0
Placebo	508	502	491	469	444	430	401	378	358	341	319	304	286	269	233	153	72	23	4	1	0

Low-volume mHSPC



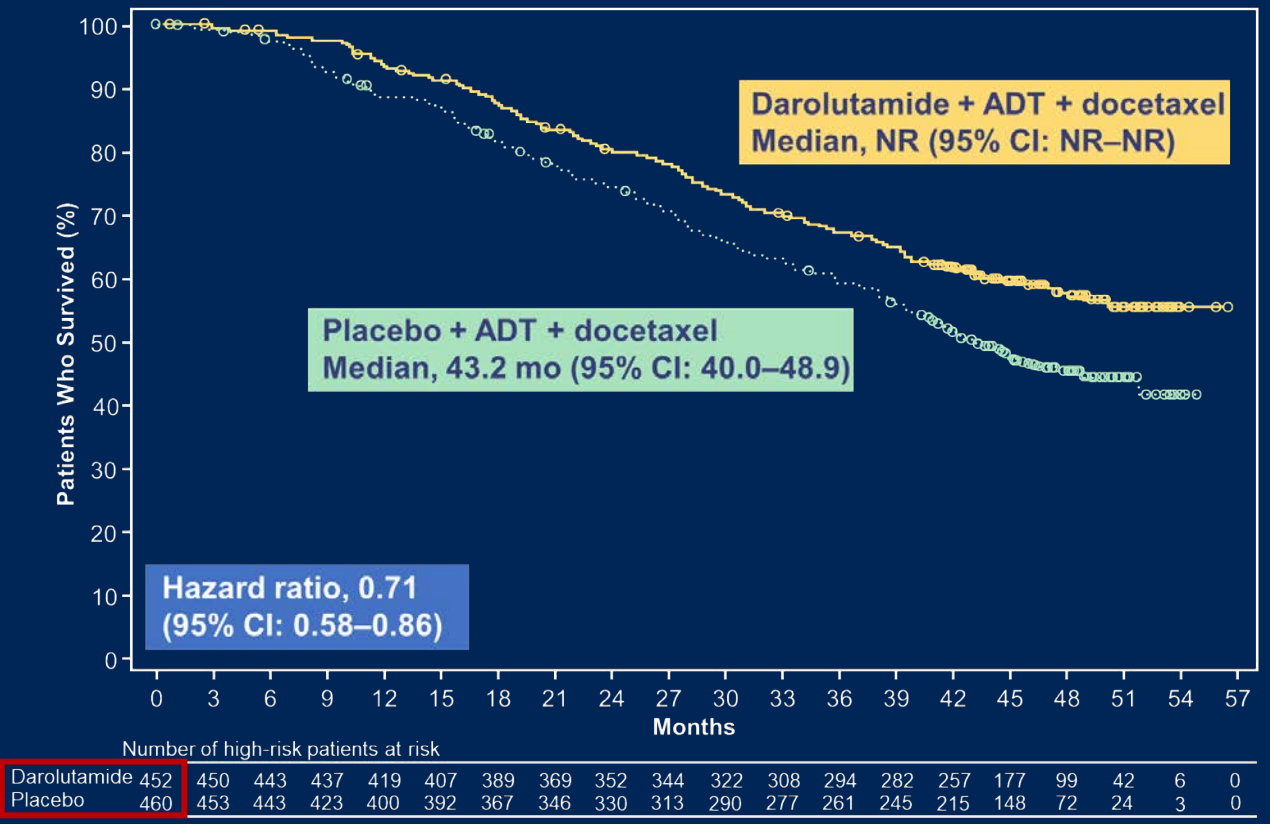
Number of low-volume patients at risk

Darolutamide	154	151	151	148	146	144	141	140	136	131	130	127	126	124	117	74	36	13	3	0
Placebo	146	144	139	138	136	135	134	132	130	129	122	120	116	114	107	65	35	14	2	0

Analysis by unstratified Cox regression model. CI, confidence interval; NR, not reached.

ARASENS RISK Subgroups: Overall Survival

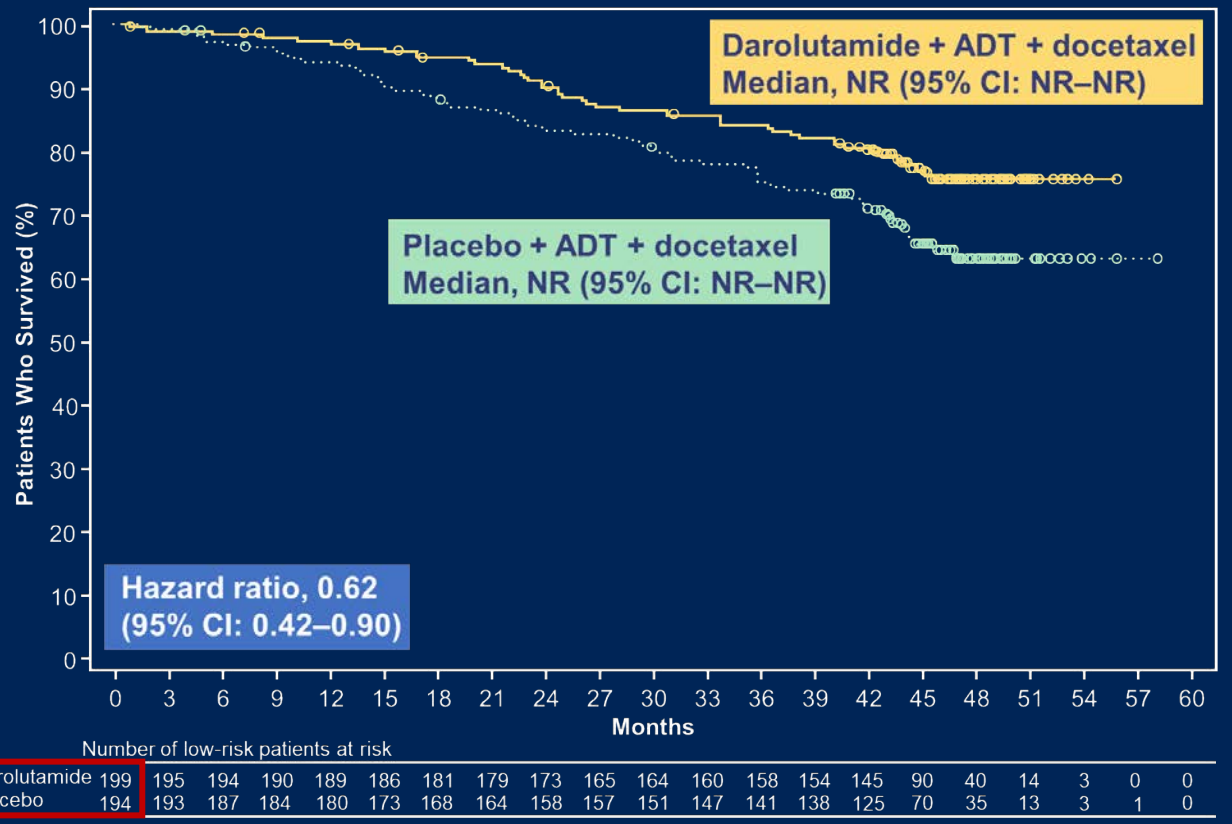
High-risk mHSPC



Number of high-risk patients at risk

Darolutamide	452	450	443	437	419	407	389	369	352	344	322	308	294	282	257	177	99	42	6	0
Placebo	460	453	443	423	400	392	367	346	330	313	290	277	261	245	215	148	72	24	3	0

Low-risk mHSPC



Number of low-risk patients at risk

Darolutamide	199	195	194	190	189	186	181	179	173	165	164	160	158	154	145	90	40	14	3	0	0
Placebo	194	193	187	184	180	173	168	164	158	157	151	147	141	138	125	70	35	13	3	1	0

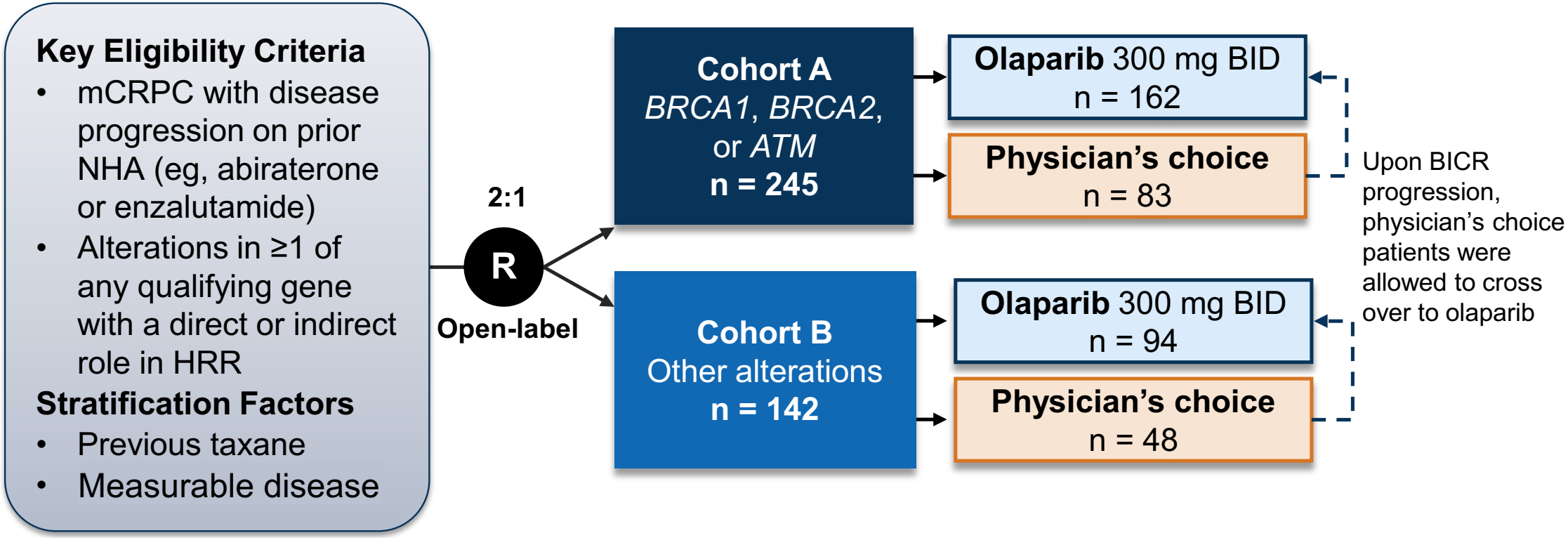
Summary of PARPi *monotherapy* trials in mCRPC

Study and treatment	Prior therapy	HRR status criteria; Sample type	Primary endpoint	Results
TOPARP-A[1] **Olaparib** 400 mg BID (N=50)	1–2 taxane CT regimens; 98% had prior NHT	Deficiency not required; tumor	Composite response rate	**33%** overall; 88% (14 of 16) with DDR gene alterations
TOPARP-B[2] **Olaparib** 300 mg or 400 mg BID, randomized 1:1 (N=98)	1–2 taxane CT regimens; 88%–92% had prior NHT	Deleterious germline or somatic DDR gene alterations; tumor	Composite response rate	**39.1%** 300-mg cohort; **54.3%** 400-mg cohort
TRITON2[3] **Rucaparib** 600 mg BID (N=115)	1 taxane and 1–2 NHT	Deleterious germline or somatic *BRCA1/2* alteration; tumor or plasma	ORR by blinded independent radiology review	**43.5%** (27 of 62)
GALAHAD[4] **Niraparib** 300 mg QD (N=289)	≥1 taxane and ≥1 NHT	Deleterious germline or somatic alteration in ≥1 of 8 prespecified DDR genes; tumor or plasma	ORR in patients with *BRCA* mutation and measurable disease	**34.2%** (26 of 76 measurable *BRCA* cohort) 10.6% (5 of 47 measurable non-*BRCA* cohort)
TALAPRO-1[5] **Talazoparib** 1 mg QD (N=128)	1–2 CT regimens (≥1 taxane) and ≥1 NHT	Deleterious germline or somatic alterations in ≥1 of 11 prespecified DDR-HRR genes; tumor or plasma	ORR by blinded independent review	**29.8%** (31 of 104)

1. Mateo J et al. *N Engl J Med.* 2015;373:1697-708; **2.** Mateo J et al. *Lancet Oncol.* 2020;21:162-174; **3.** Abida W et al. *J Clin Oncol.* 2020;38:3763-3772; **4.** Smith MR et al. *Lancet Oncol.* 2022;23:362-373; **5.** de Bono JS et al. *Lancet Oncol.* 2021;22:1250-1264.

Courtesy of Emmanuel S Antonarakis, MD

Olaparib: PROfound, Randomized Phase 3 Study

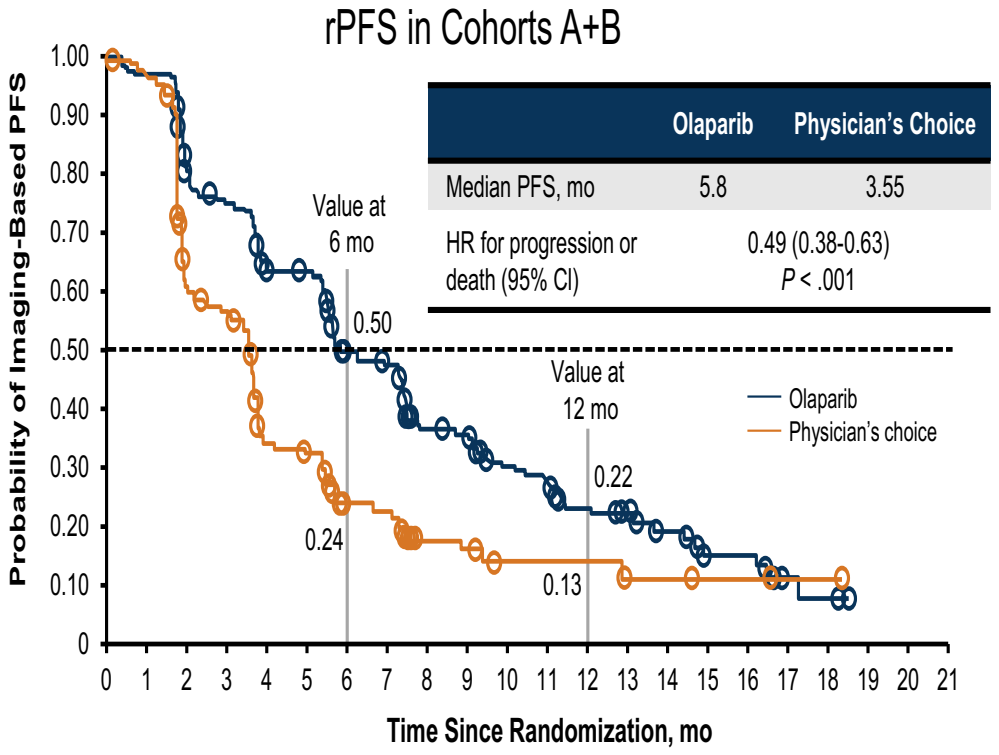


- Primary endpoint: rPFS in cohort A (RECIST 1.1 and PCWG3 by BICR)
- Key secondary endpoints: rPFS (cohorts A+B); confirmed radiographic ORR in cohort A; time to pain progression in cohort A; OS in cohort A

1. de Bono J et al. *N Engl J Med*. 2020;382:2091-2102.

Courtesy of Emmanuel S Antonarakis, MD

PROfound: rPFS and OS in whole population (A+B)

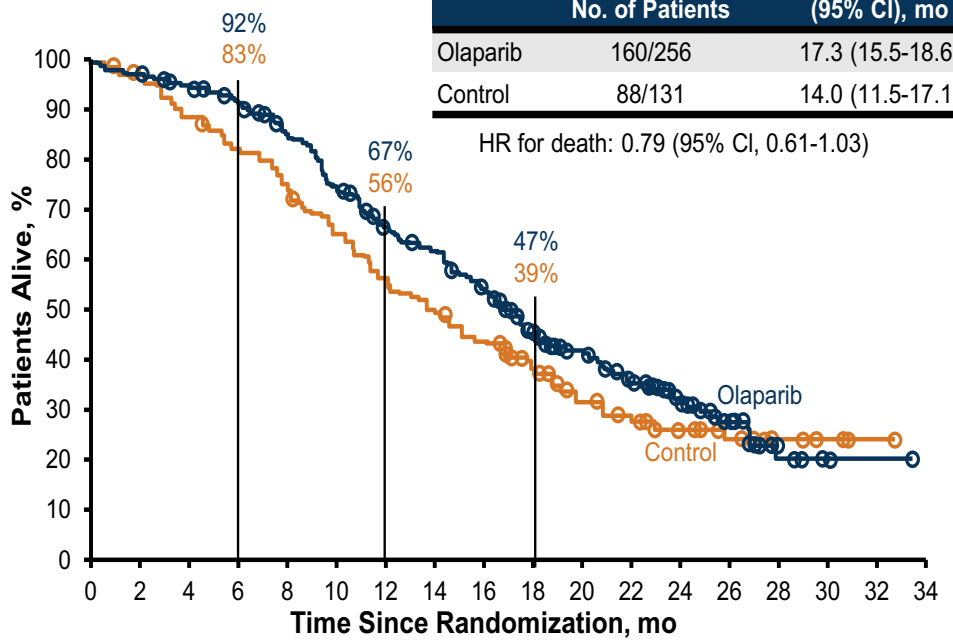


	Olaparib	Physician's Choice
Median PFS, mo	5.8	3.55
HR for progression or death (95% CI)	0.49 (0.38-0.63) $P < .001$	

No. at Risk

Olaparib	256	239	188	176	145	143	106	100	67	63	48	43	31	28	21	11	11	3	2	0	0	0
Control	131	123	73	67	38	35	20	19	9	8	5	5	5	3	3	2	2	1	1	0	0	0

OS in the Overall Population (Cohorts A + B)



	No. of Deaths/ No. of Patients	Median OS (95% CI), mo
Olaparib	160/256	17.3 (15.5-18.6)
Control	88/131	14.0 (11.5-17.1)

HR for death: 0.79 (95% CI, 0.61-1.03)

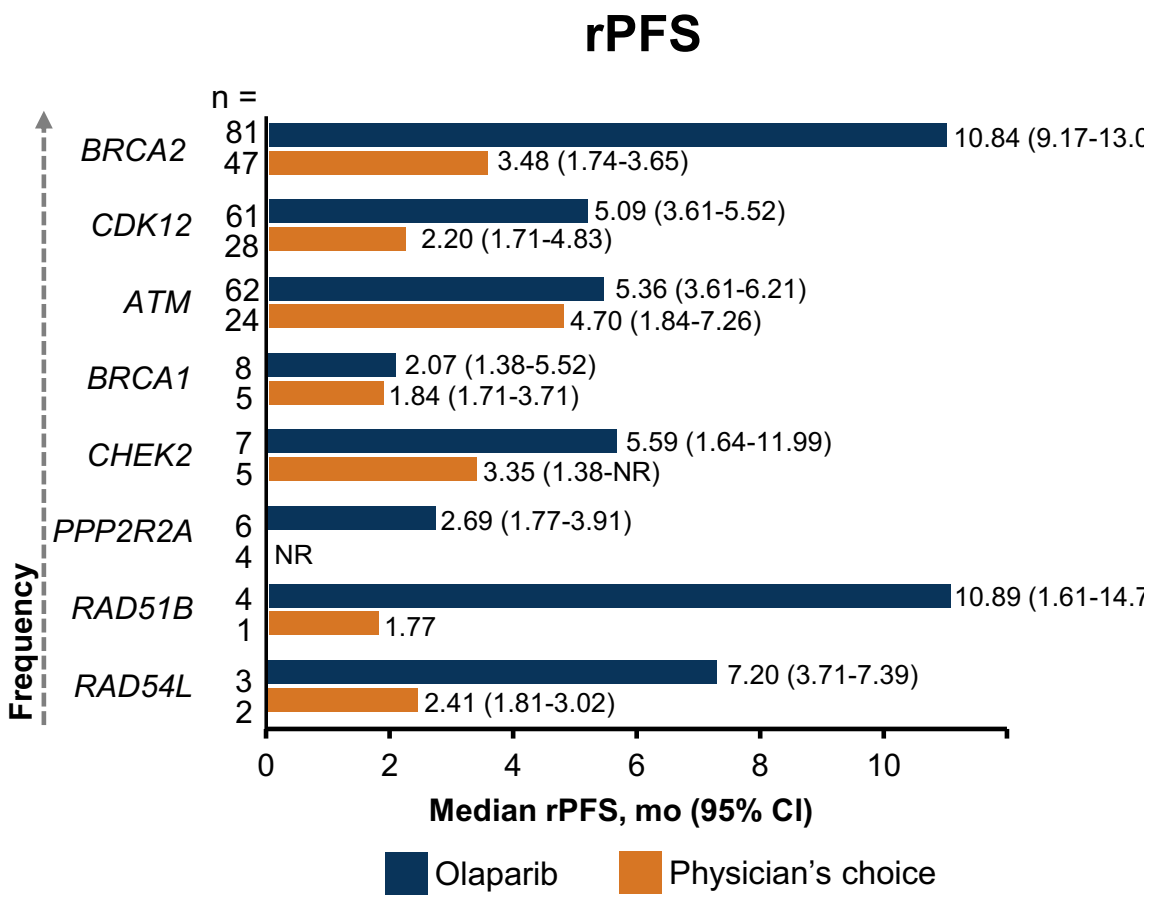
No. at Risk

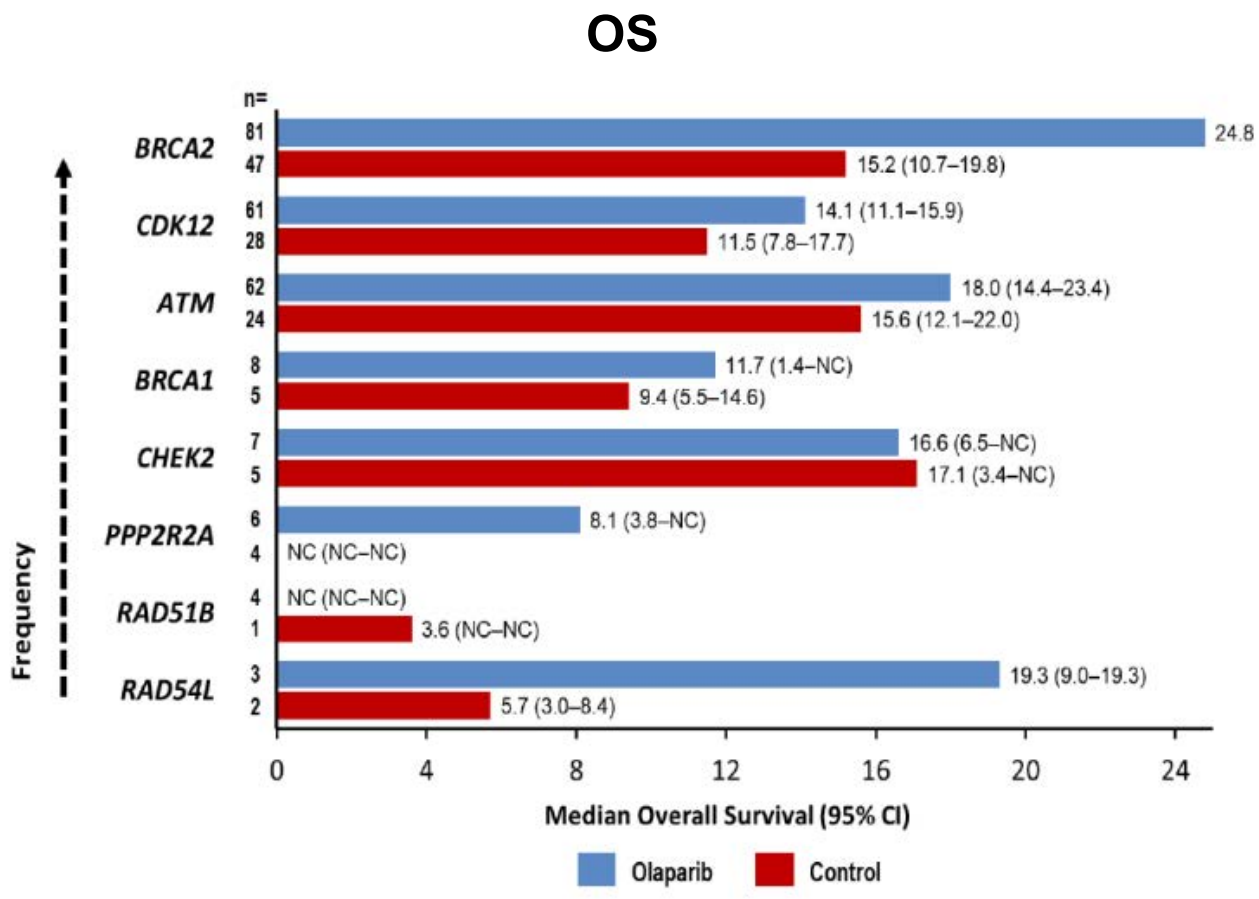
Olaparib	256	249	240	228	209	182	157	146	126	96	73	56	39	22	7	2	1	0		
Control	131	125	115	106	96	83	71	63	55	37	27	22	15	11	6	3	1	0		

1. de Bono J et al. *N Engl J Med*. 2020;382:2091-2102. 2. Hussain M et al. *N Engl J Med*. 2020.

Courtesy of Emmanuel S Antonarakis, MD

PROfound: Gene-by-gene, rPFS and OS analyses

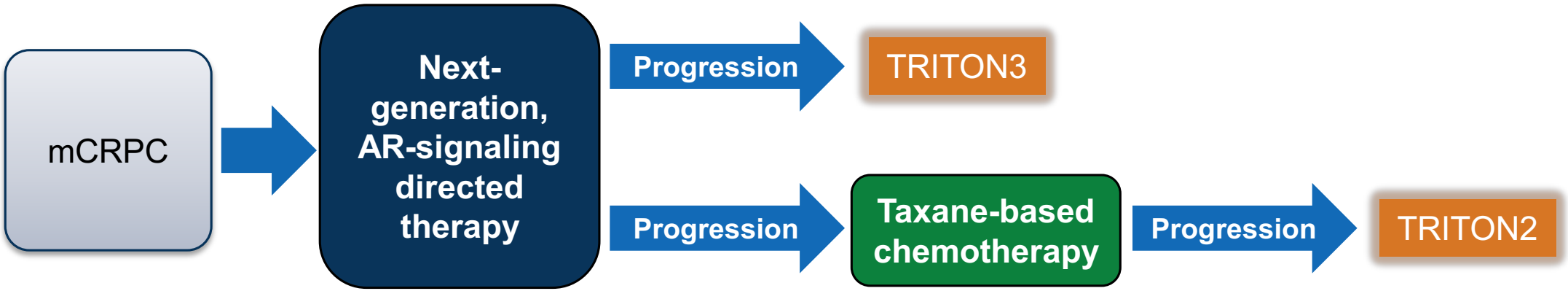




1. de Bono J et al. *N Engl J Med*. 2020;382:2091-2102. 2. Hussain M et al. *N Engl J Med*. 2020.

Courtesy of Emmanuel S Antonarakis, MD

Rucaparib: TRITON2 and TRITON3 studies



HRR-deficiency is defined by a deleterious alteration in *BRCA1*, *BRCA2*, *ATM*, or 12 other HRR genes (*BARD1, BRIP1, CDK12, CHEK2, FANCA, NBN, PALB2, RAD51, RAD51B, RAD51C, RAD51D, RAD54L)*

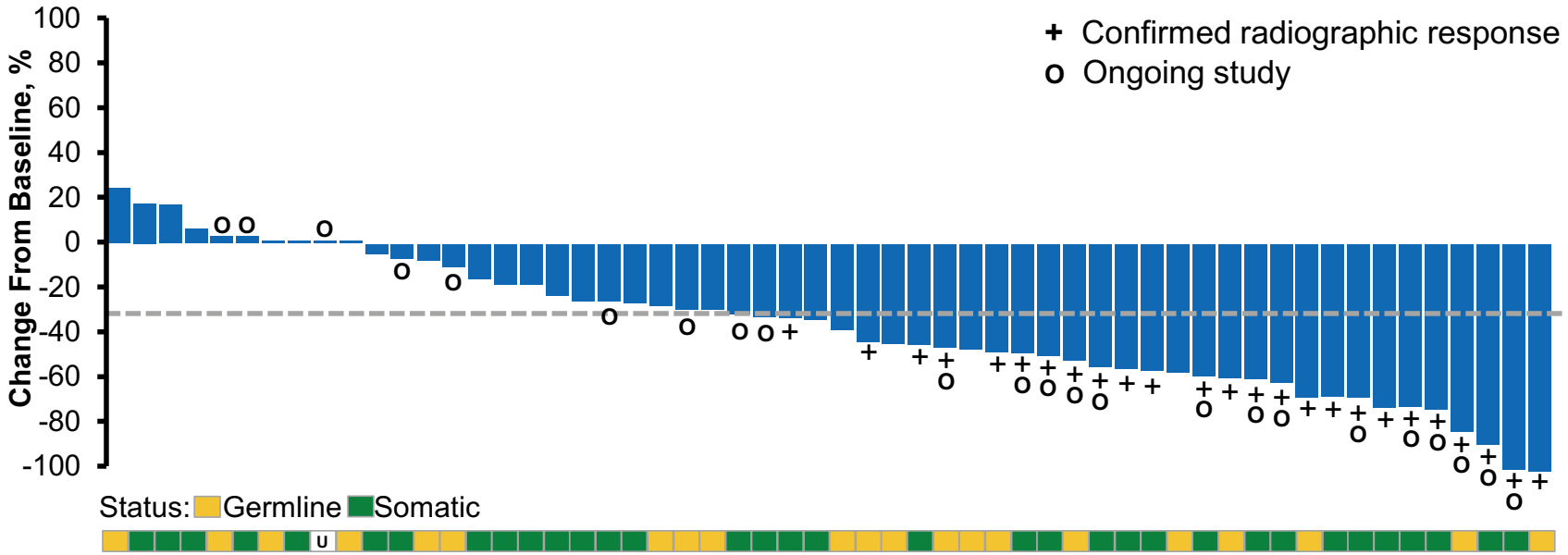
1. Abida W et al. *Annals Onc*. 2018:29(Suppl 8):viii271-viii302.

Courtesy of Emmanuel S Antonarakis, MD

TRITON2: Objective response rate (ORR)

	DDR Gene				
	***BRCA* 1/2 (n = 57)**	***ATM* (n = 21)**	***CDK12* (n = 9)**	***CHEK2* (n = 5)**	**Other (n = 13)**
ORR, n (%) [95% CI]	25 (43.9) [30.7-57.6]	2 (9.5) [1.2-30.4]	0 [0.0-33.6]	0 [0.0-52.2]	5 (38.5) [13.9-68.4]
CR, n (%)	3 (5.3)	0	0	0	1 (7.7)
PR, n (%)	22 (38.6)	2 (9.5)	0	0	4 (30.8)
SD, n (%)	26 (45.6)	10 (47.6)	5 (55.6)	3 (60.0)	6 (46.2)
PD, n (%)	5 (8.8)	8 (38.1)	3 (33.3)	2 (40.0)	1 (7.7)
N/E, n (%)	1 (1.8)	1 (4.8)	1 (11.1)	0	1 (7.7)

Best Change From Baseline in Sum of Target Lesions in Patients With *BRCA 1/2* Alteration (N = 56)



1. Abida W et al. ESMO 2019. Abstract 846PD. 2. Abida W et al. *Clin Cancer Res*. 2020 Feb 21

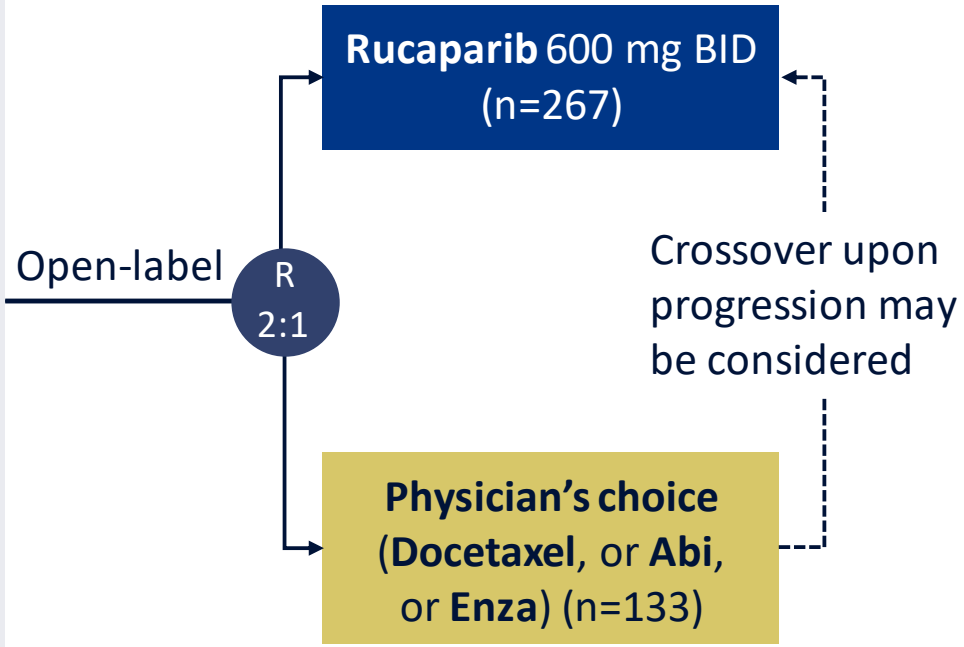
Courtesy of Emmanuel S Antonarakis, MD

TRITON3: Randomized phase III trial

Patient population

- mCRPC with progression after 1 prior AR signaling-directed therapy (abiraterone, enzalutamide, or investigational agent)
- Deleterious germline or somatic alteration in ***BRCA1, BRCA2,*** or ***ATM****
- No prior PARP inhibitor
- No prior chemotherapy for mCRPC

Planned enrollment: 400



Primary endpoint

rPFS
(RECIST 1.1 and PCWG3 by IRR)

Key secondary endpoints

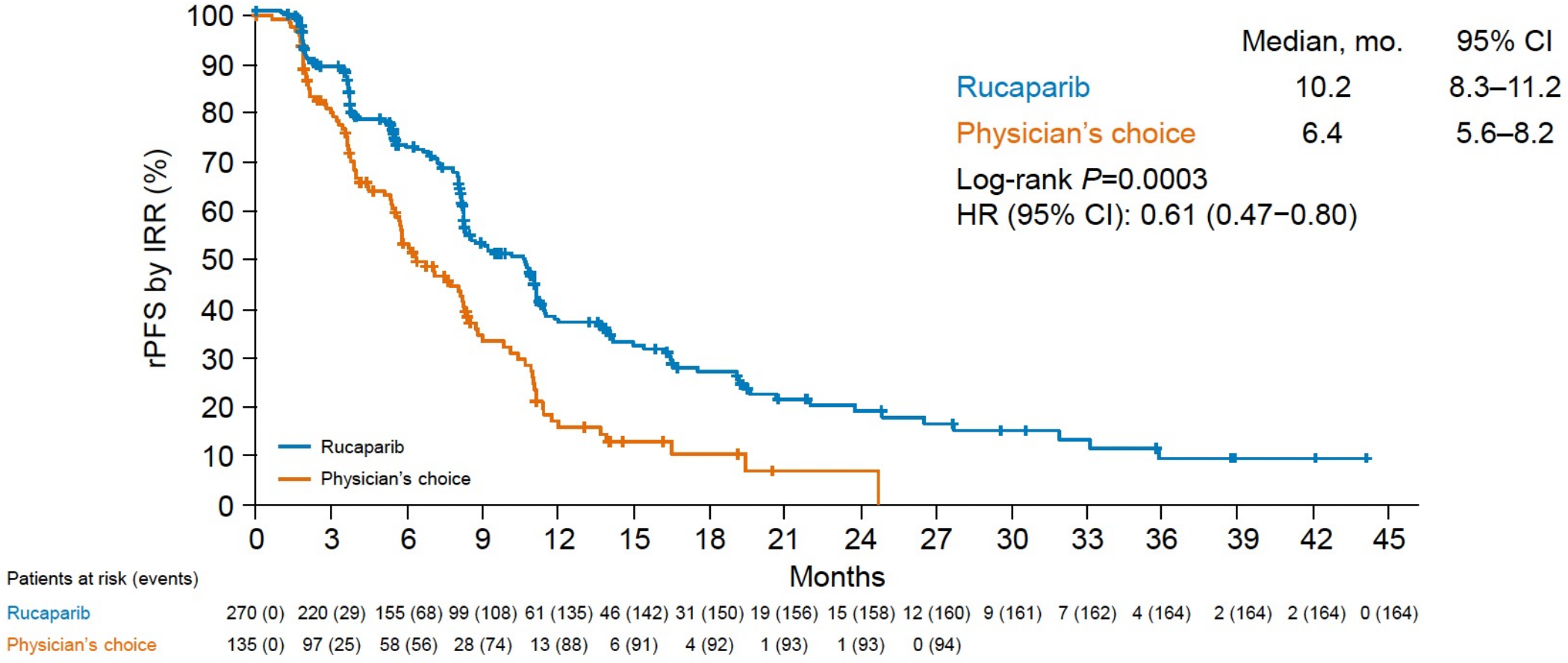
- ORR and DOR by modified RECIST criteria in patients with measurable nodal/visceral disease
- OS
- Clinical benefit rate
- PSA response of ≥50% and ≥90%
- Time to PSA progression
- Patient-reported outcomes
- Safety and tolerability

*Mutations identified in blood, archival tissue, or screening tumor tissue

Ryan CJ et al. ASCO GU 2018; abst TPS389; **NCT02975934**.

Courtesy of Emmanuel S Antonarakis, MD

TRITON3: rPFS in ITT population

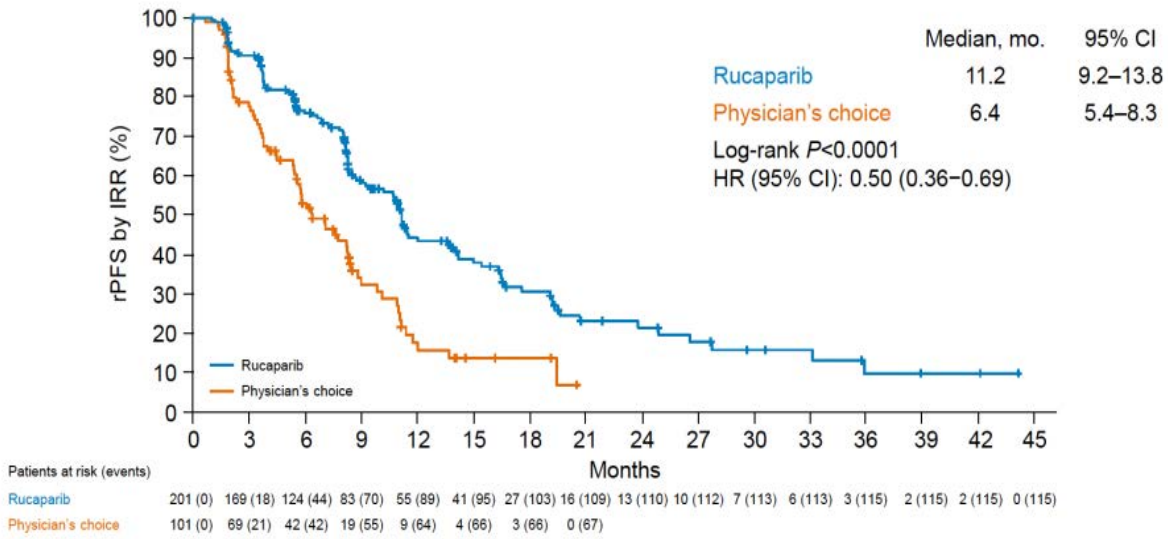


Bryce A, et al. Presented at PCF Retreat 2022.

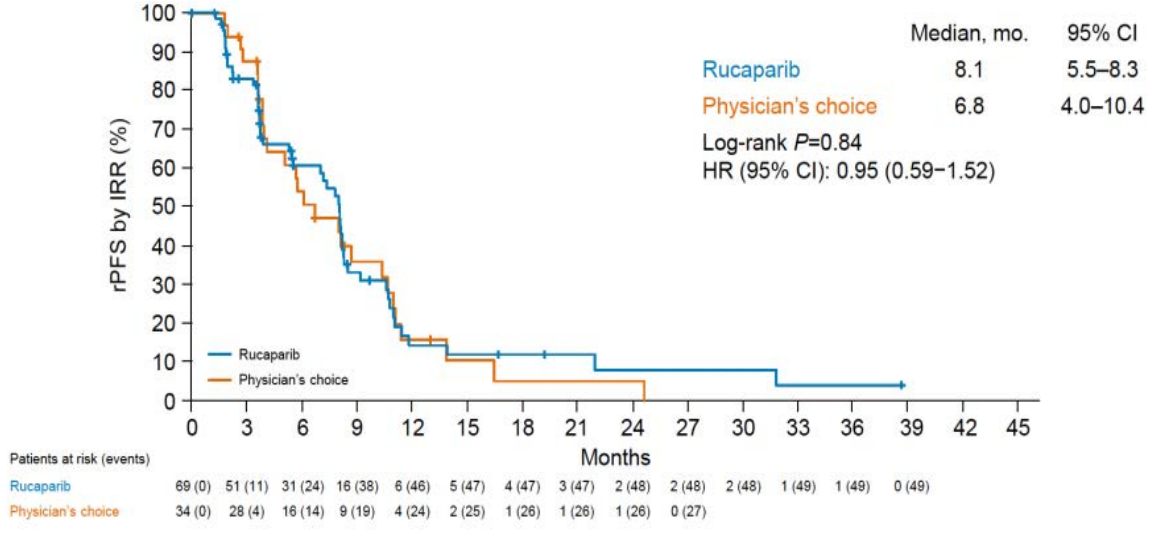
Courtesy of Emmanuel S Antonarakis, MD

TRITON3: rPFS in *BRCA1/2* and *ATM* subgroups

BRCA1/2 Subgroup



ATM Subgroup



Bryce A, et al. Presented at PCF Retreat 2022.

Courtesy of Emmanuel S Antonarakis, MD

MASSACHUSETTS GENERAL HOSPITAL
CANCER CENTER

PROpel: Abiraterone +/- Olaparib

Patient Population[a]

- 1L mCRPC
- Docetaxel allowed at mHSPC stage
- No prior abiraterone
- Other NHAs allowed if stopped ≥12 months prior to enrollment
- Ongoing ADT
- ECOG 0-1

Stratification Factors

- Site of distant metastases: bone only vs visceral vs other
- Prior taxane at mHSPC: yes vs no

R

1:1

Olaparib 300 mg BID + abiraterone 1,000 mg QD[b]
n = 399

Placebo + abiraterone 1,000 mg QD
n = 397

- **Primary endpoint:** rPFS
- **Secondary endpoint:** OS

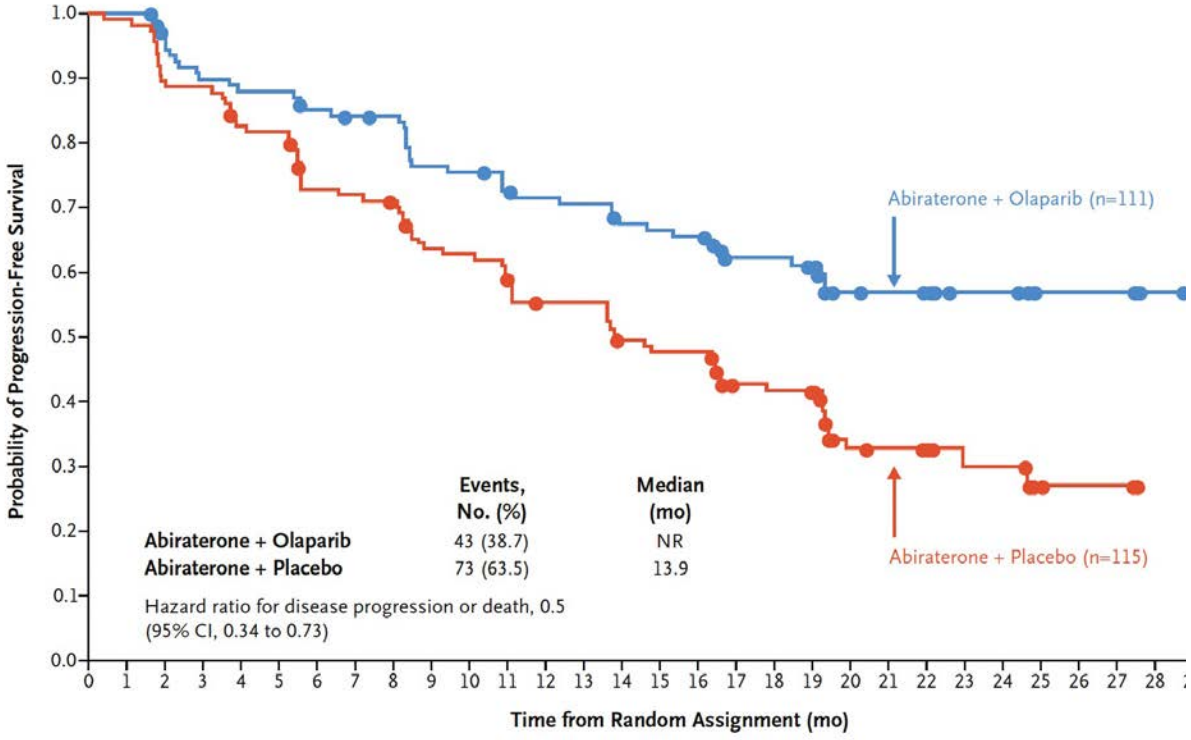
Clarke NW et al. NEJM Evid 2022; 1(9) DOI: 10.1056/EVIDoa2200043

Courtesy of Matthew R Smith, MD, PhD

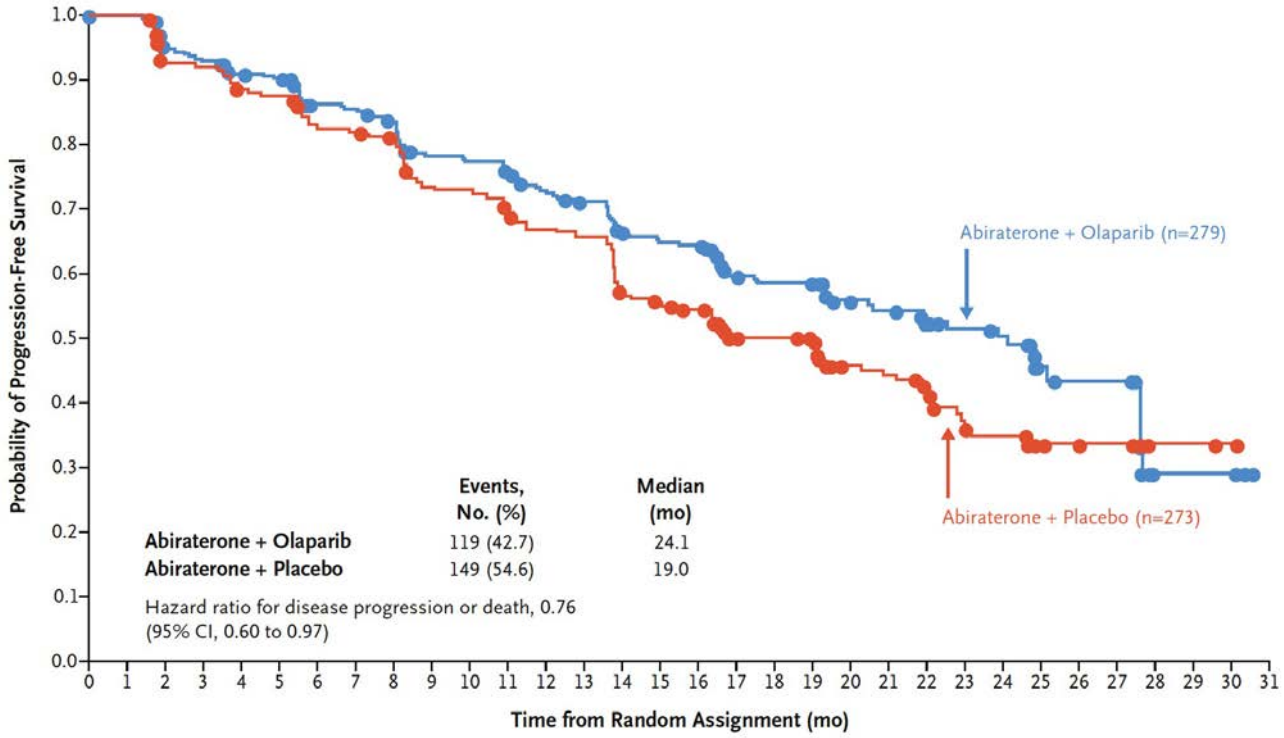
MASSACHUSETTS GENERAL HOSPITAL
CANCER CENTER

PROpel: Abiraterone +/- Olaparib
Image-Based Progression-Free Survival

HRRm Subgroup



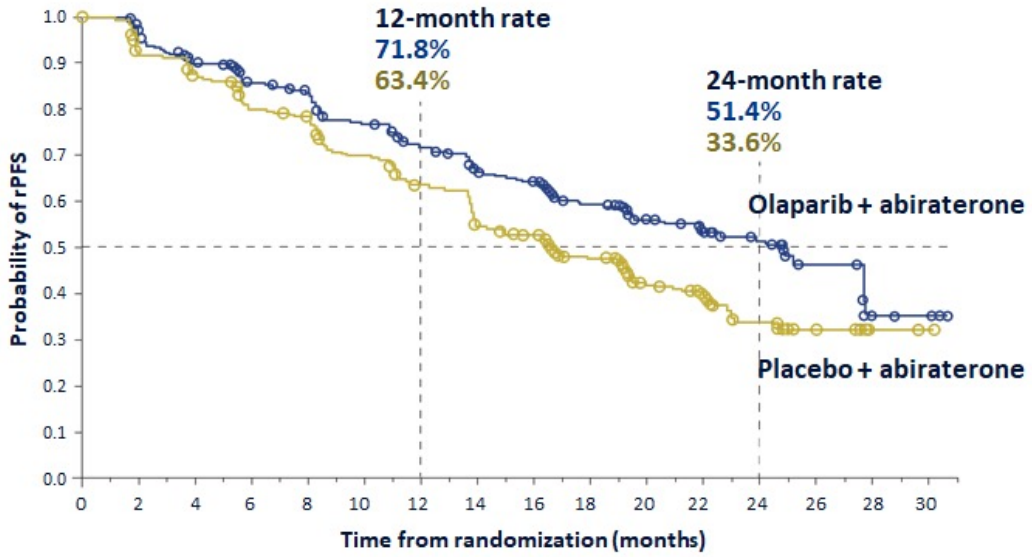
Non-HRRm Subgroup



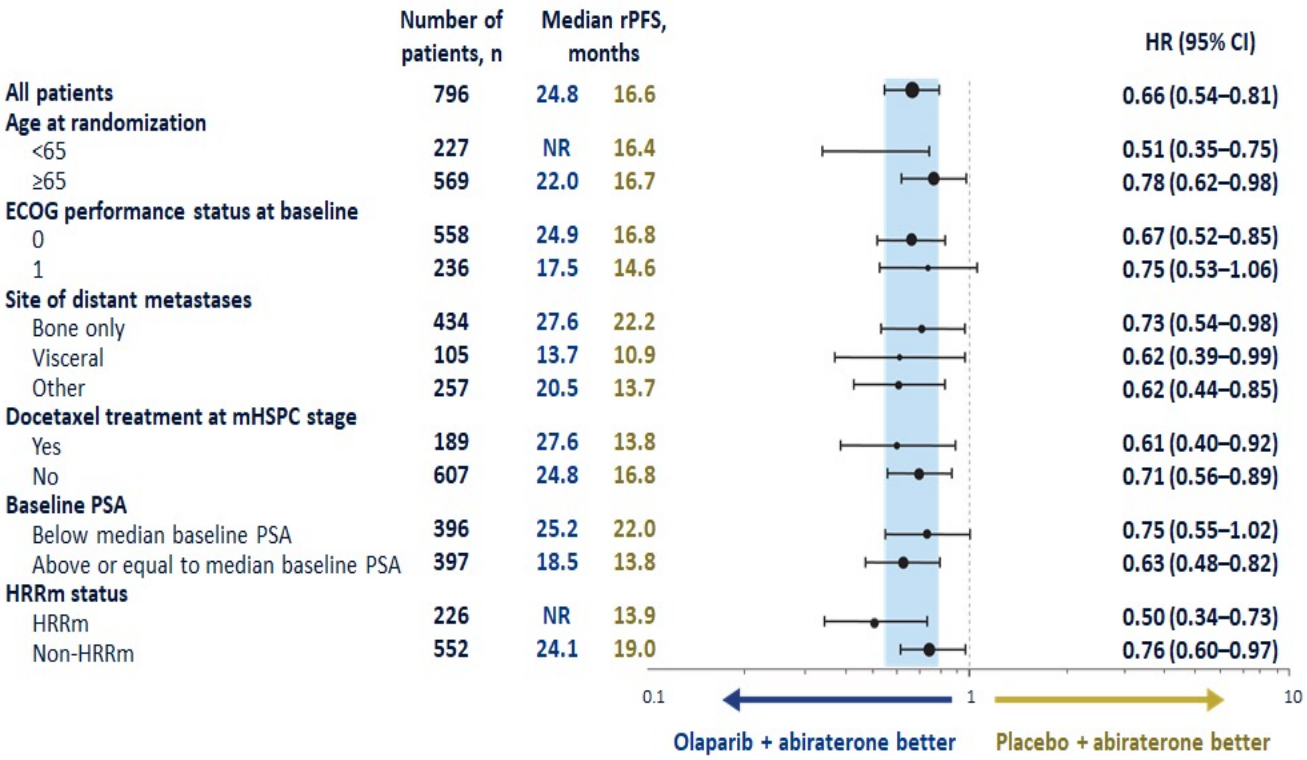
Clarke NW et al. NEJM Evid 2022; 1(9) DOI: 10.1056/EVIDoa2200043

Courtesy of Matthew R Smith, MD, PhD

PROpel: Radiographic progression-free survival



	Olaparib + abiraterone (n=399)	Placebo + abiraterone (n=397)
rPFS by investigator assessment		
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	
rPFS by blinded independent central review		
HR (95% CI)	0.61 (0.49–0.74); *P*<0.0001	



Clarke NW et al. *NEJM Evidence* 2022.

Courtesy of Matthew R Smith, MD, PhD

MASSACHUSETTS GENERAL HOSPITAL
CANCER CENTER

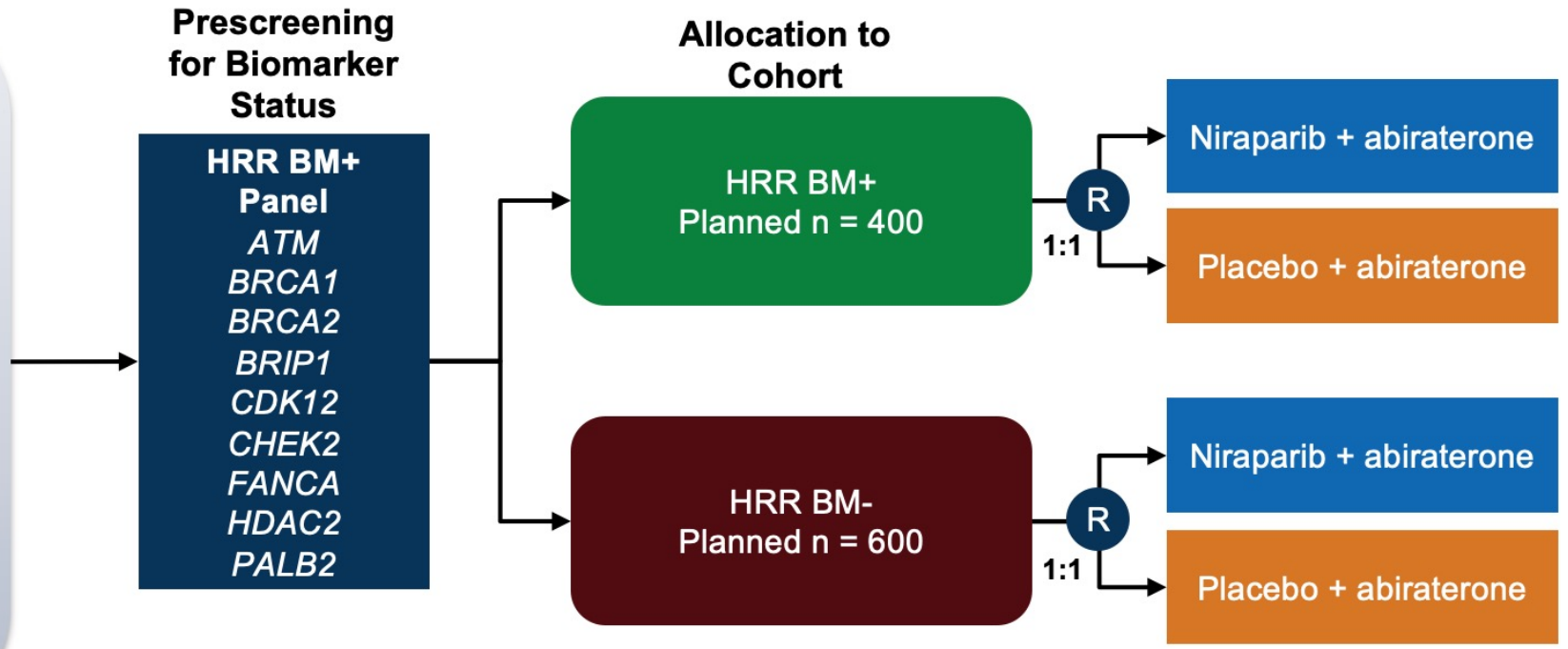
MAGNITUDE: Abiraterone +/- Niraparib

Key Eligibility Criteria

- L1 mCRPC
  - ≤4 months prior abiraterone allowed for mCRPC
- ECOG PS 0 or 1
- BPI-SF worst pain score ≤3

Stratification Factors

- Prior taxane-based chemo for mHSPC
- Prior ARi for nmCRPC
- Prior abiraterone for L1 mCRPC
- HRR BM+ cohort only
  - *BRCA*1/2 vs other HRR gene alterations



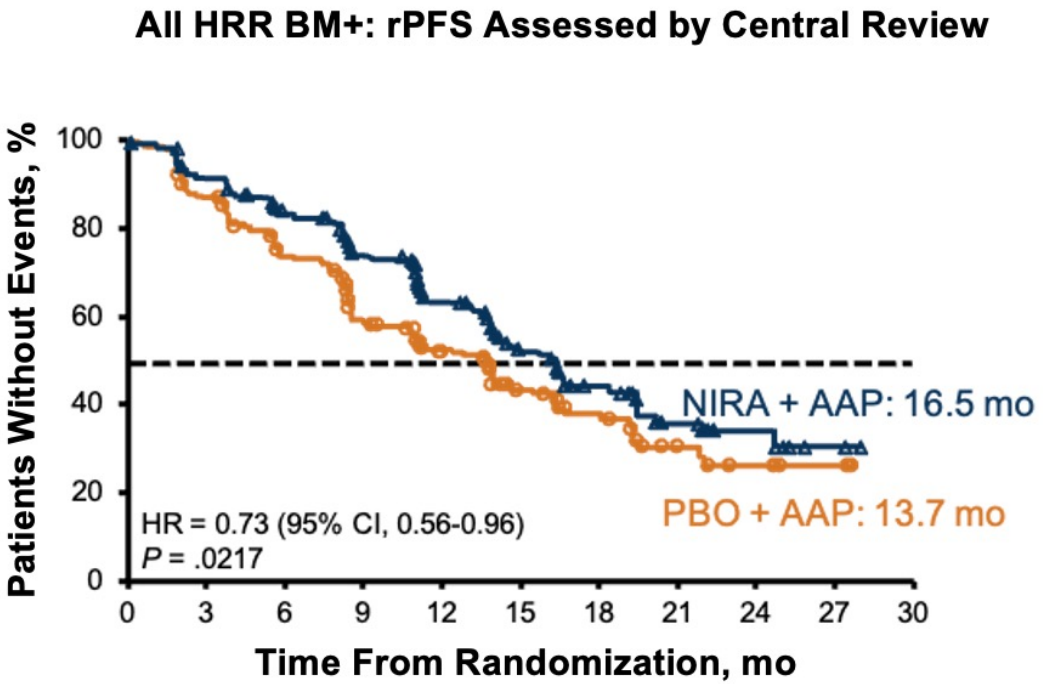
- Primary endpoint
  - rPFS by central review
- Secondary endpoints
  - Time to cytotoxicity chemotherapy
  - Time to symptomatic progression
  - OS

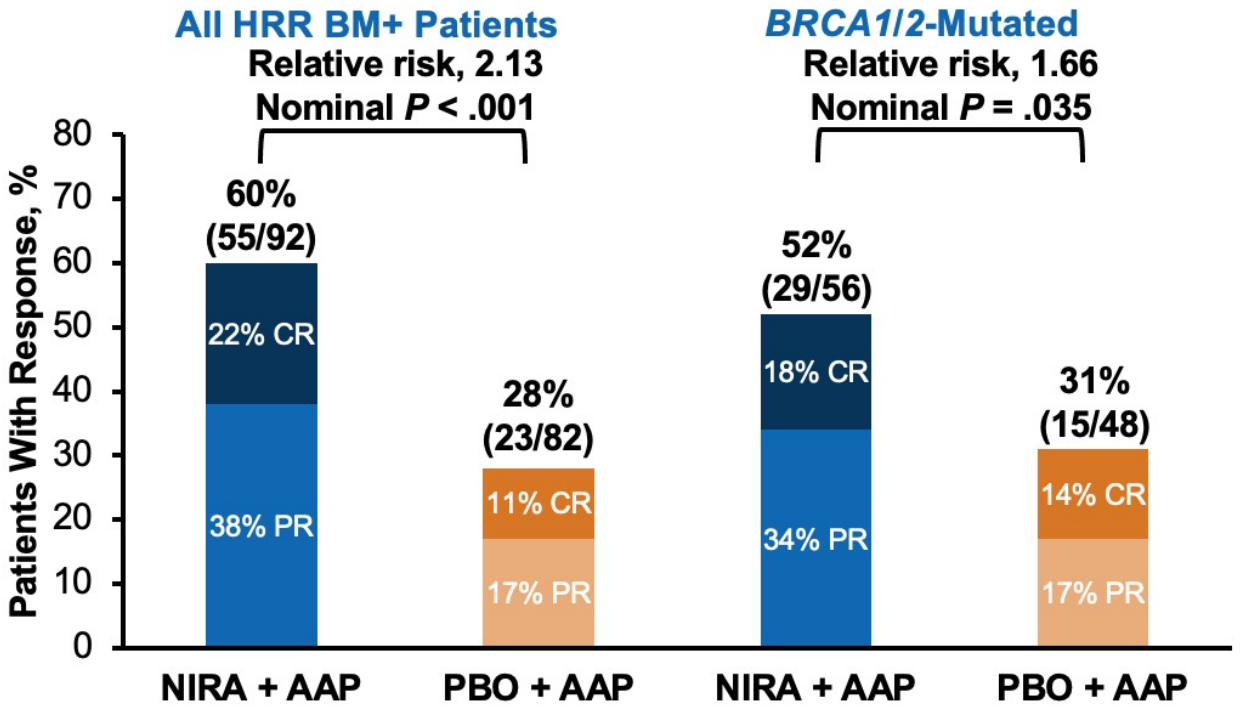
Chi K et al. ASCO GU 2022. Abstract 12

Courtesy of Matthew R Smith, MD, PhD

MASSACHUSETTS GENERAL HOSPITAL
CANCER CENTER

MAGNITUDE: Abiraterone +/- Niraparib





- Two distinct cohorts: with or without alterations in HRR genes
- Prior ARSI, docetaxel in mHSPC allowed
- No benefit in patients in the HRR BM- cohort
- Significantly improved rPFS in the HRR BM+ cohort
- Niraparib + AAP nearly doubles ORR and provides deeper response in patients with measurable disease

Chi K et al. ASCO GU 2022. Abstract 12; George DJ et al. SUO 2022. Abstract 74

Courtesy of Matthew R Smith, MD, PhD

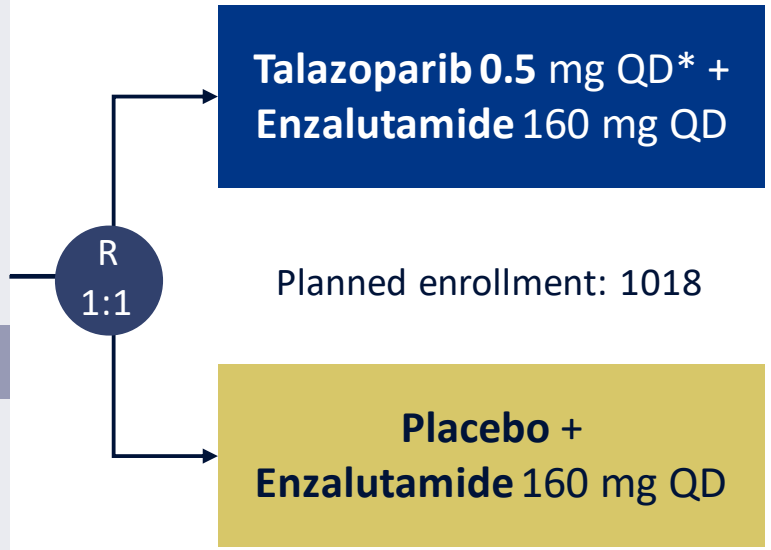
TALAPRO-2: Phase III Trial of Enza +/– Talazoparib

Patient population

- mCRPC with progression (PSA, bone, and/or soft tissue)
- Prior docetaxel and/or abiraterone in CSPC setting allowed
- Ongoing ADT or bilateral orchiectomy
- ECOG PS 0–1

Stratification factors

- Previous treatment with abiraterone or taxane-based chemotherapy for CSPC
- DDR# alteration status (deficient vs nondeficient/unknown)



Co-primary endpoints

- rPFS by BICR per RECIST 1.1 and PCWG3 in **All-comers (Cohort 1), n=804**
- rPFS by BICR in patients with **DDR# alterations (Cohort 2), n=214**

Key secondary endpoints (analyzed for both cohorts separately)

- OS
- OR per RESIST 1.1 (measurable disease)
- PSA response ≥50%
- Time to PSA progression
- Time to initiation of cytotoxic CT or antineoplastic therapy
- Time to first symptomatic skeletal event
- PFS2
- Safety
- Patient-reported outcomes

*0.35 mg QD if moderate renal impairment

DDR alterations (*BRCA1/2, PALB2, ATM, ATR, CHEK2, FANCA, RAD51C, NBN, MLH1, MRE11A, CDK12*).

Agarwal N et al. *Future Oncol.* 2022;18:425-436; **NCT03395197**.

Courtesy of Emmanuel S Antonarakis, MD

TALAPRO-2: Phase III Trial of Enza +/– Talazoparib

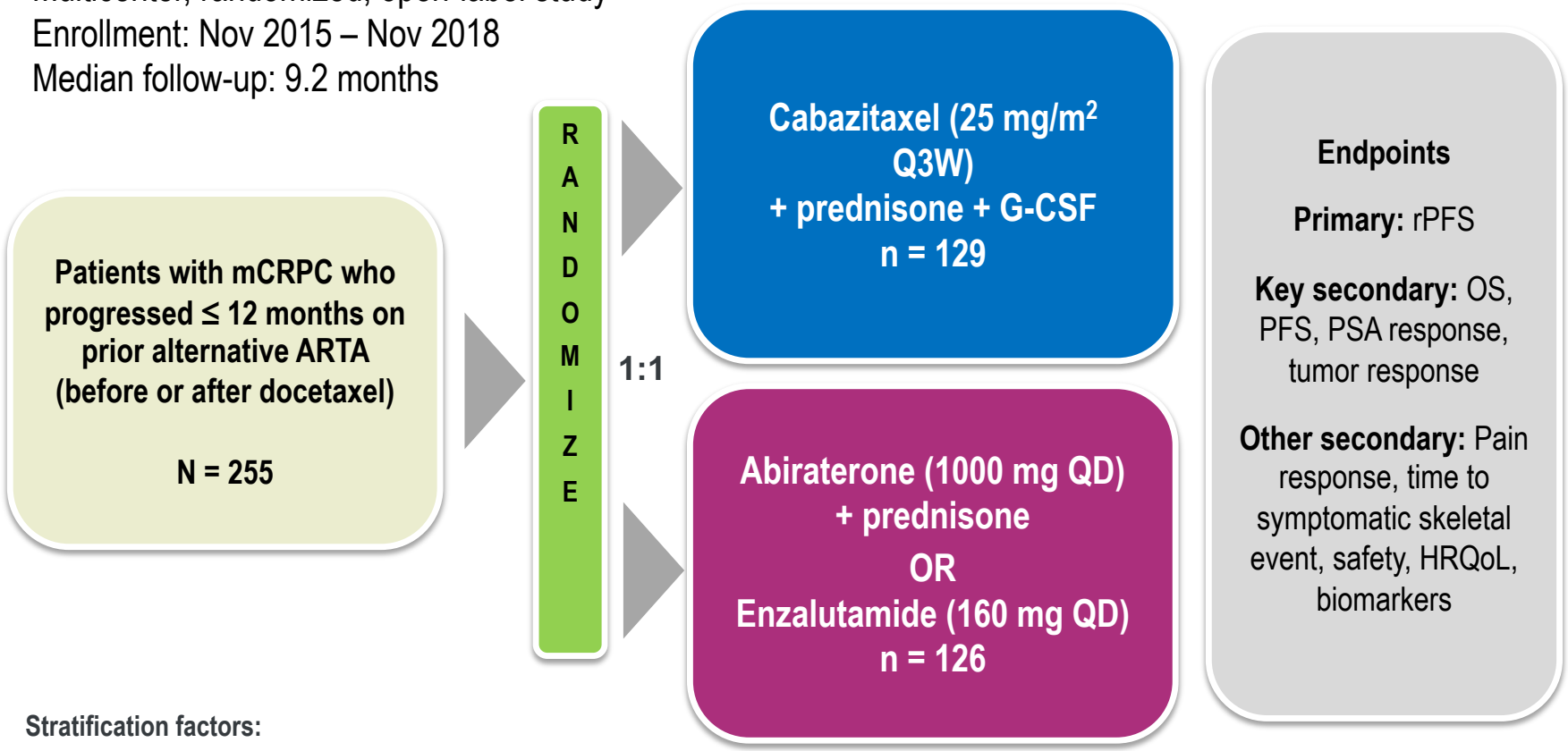
All-comers cohort	rPFS 21.9 mo → NR	HR 0.63 (0.51-0.78)	*P* <0.001
HRR *mutated*	rPFS 16.4 → 27.9 mo	HR 0.46 (0.30-0.70)	*P* <0.001
HRR *wild-type*	rPFS 16.6 → 25.8 mo	HR 0.66 (0.49-0.91)	*P* = 0.009

Agarwal N et al. ASCO GU 2023; abstr LBA17.

Courtesy of Emmanuel S Antonarakis, MD

CARD: STUDY DESIGN

- Multicenter, randomized, open-label study
- Enrollment: Nov 2015 – Nov 2018
- Median follow-up: 9.2 months



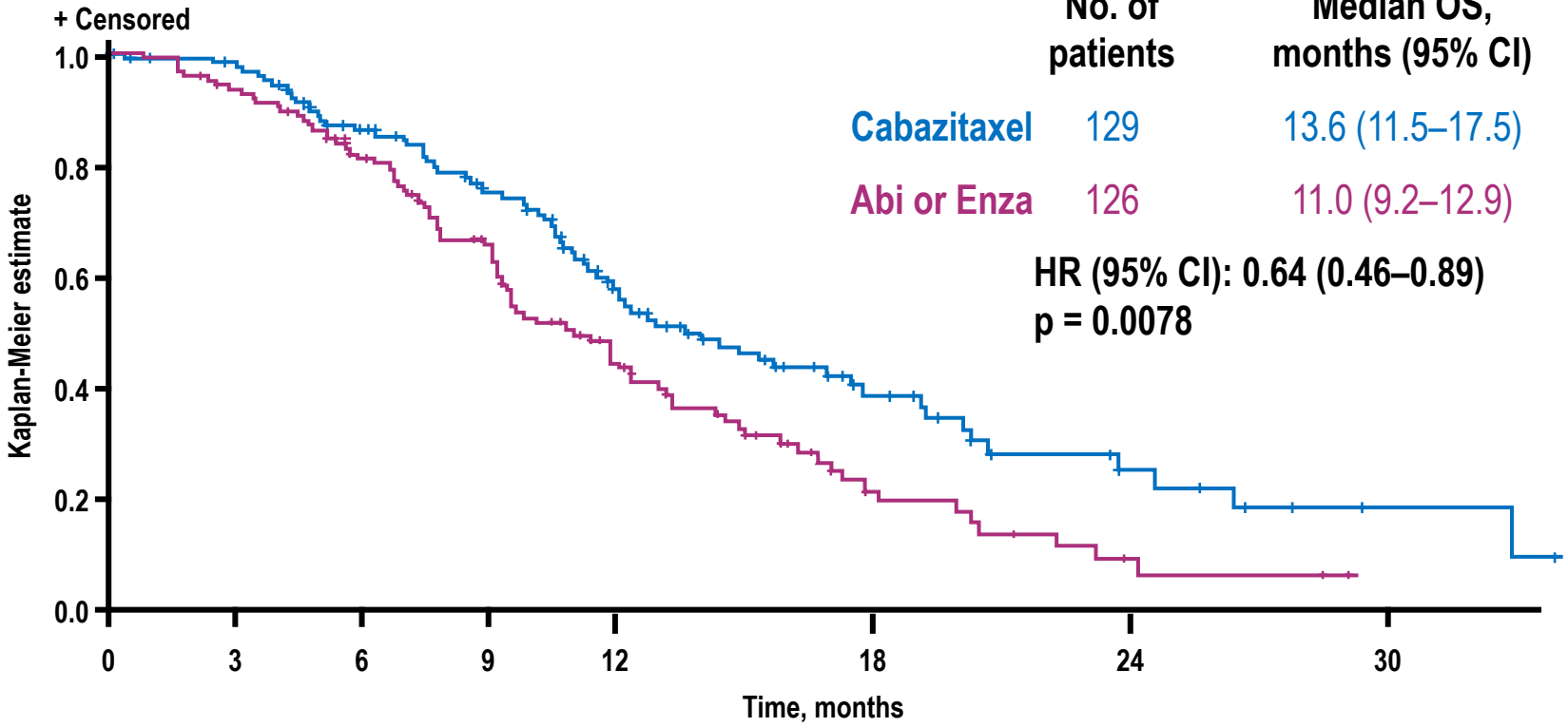
Stratification factors:

- ECOG PS (0/1 vs 2)
- Time to progression on prior alternative ARTA (0–6 vs > 6–12 months)
- Timing of ARTA (before vs after docetaxel)

ECOG PS, Eastern Cooperative Oncology Group performance status; G-CSF, granulocyte-colony stimulating factor; HRQoL, health-related quality of life; OS, overall survival; PFS, progression-free survival; PSA, prostate-specific antigen; QD, once daily; Q3W, every 3 weeks; rPFS, radiographic progression-free survival.

Courtesy of Prof Karim Fizazi, MD, PhD

CARD: IMPROVED OVERALL SURVIVAL WITH CABAZITAXEL



	No. of patients	Median OS, months (95% CI)
Cabazitaxel	129	13.6 (11.5–17.5)
Abi or Enza	126	11.0 (9.2–12.9)

HR (95% CI): 0.64 (0.46–0.89)
p = 0.0078

No. at risk								
Caba	129	122	96	77	51	21	8	2
Abi Enza	126	116	88	64	39	11	3	0

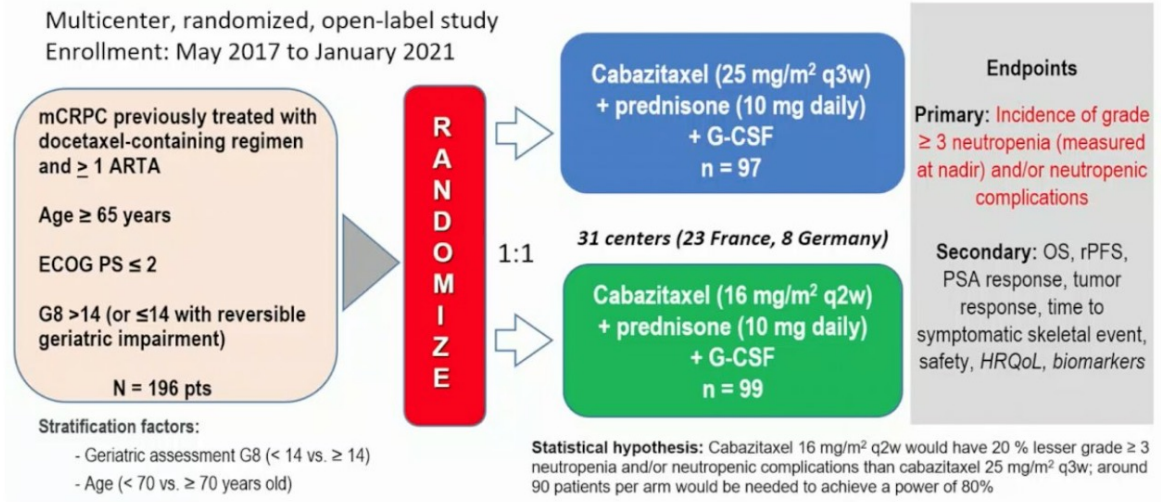
BARCELONA 2019 ESMO congress

De Wit R, NEJM 2019

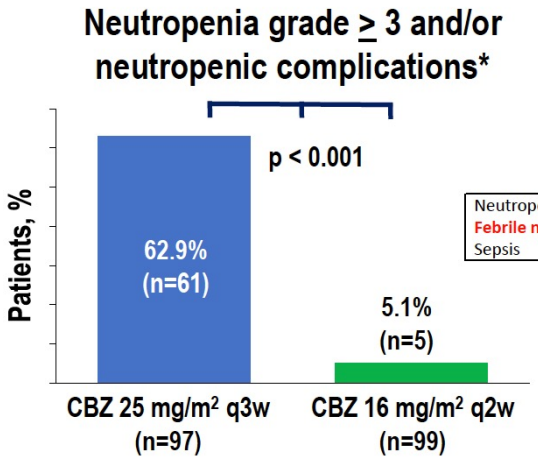
Courtesy of Prof Karim Fizazi, MD, PhD

Other Recently Reported Trials Investigating Cabazitaxel for mCRPC

CABASTY[1]

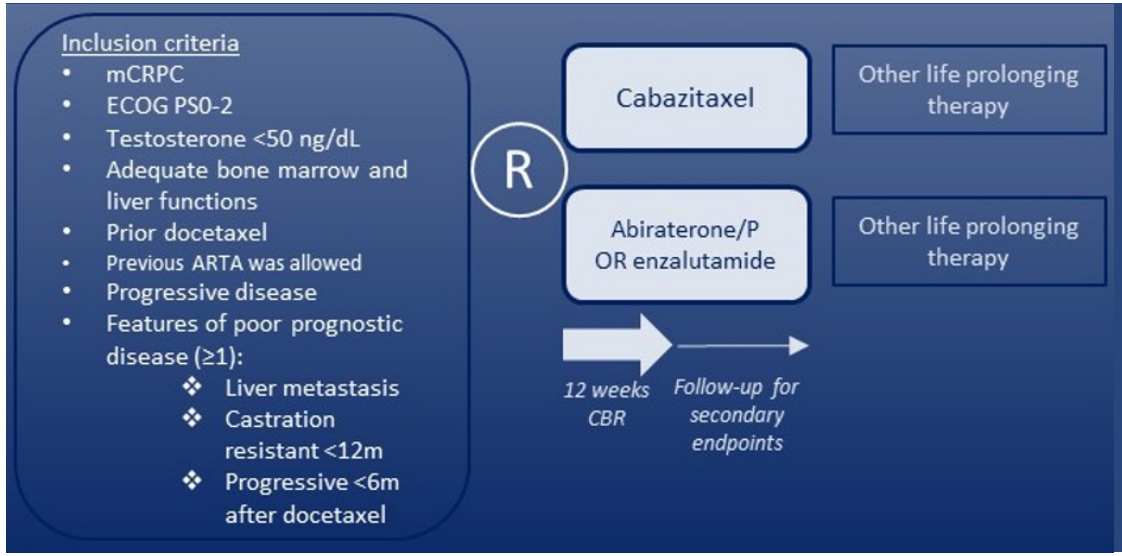


PRIMARY ENDPOINT



	CBZ 25 mg/m² q3w (N = 97)	CBZ 16 mg/m² q2w (N = 99)	P value
Neutropenia grade ≥ 3	61 (62.9)	2 (2.0)	
Febrile neutropenia	7 (7.3)	0	< 0.001
Sepsis	3 (3.1)	3 (3.0)	

OSTRICh[2]



Conclusions

- No significant difference in CBR between CBZ and ARTA treated patients at 12 weeks
- Visceral metastases were more frequent in CBZ patients
- Radiological response and stable disease at 12 weeks was significantly higher in patients treated with CBZ than with ARTA
- Time to clinical progression was significantly prolonged in patients treated with ARTA
- Overall survival and rPFS was similar in both groups

[1] Oudard S et al. ESMO 2022;Abstract 1363MO; [2] van der Zande K et al. ASCO 2021;Abstract 5059.

Courtesy of Prof Karim Fizazi, MD, PhD

Prostate specific membrane antigen (PSMA)

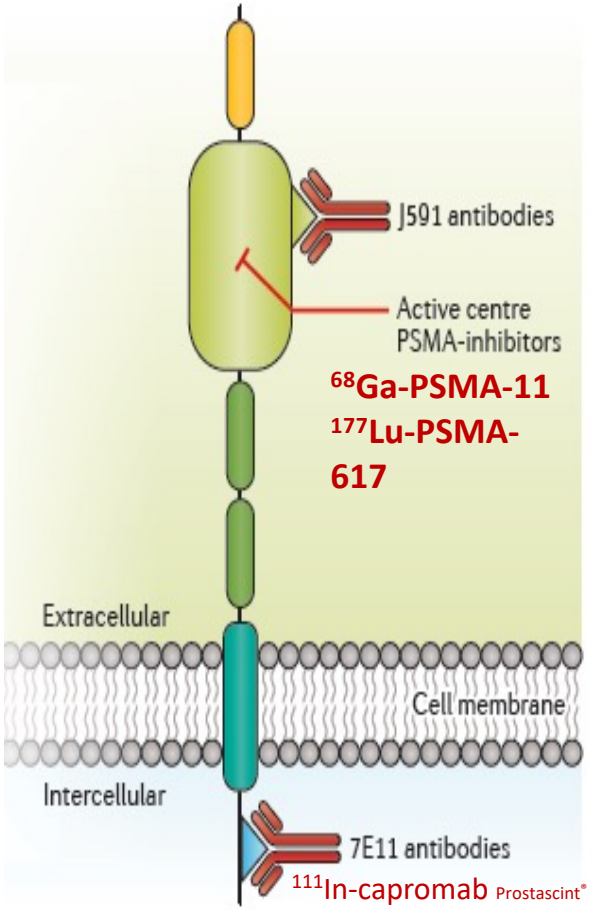
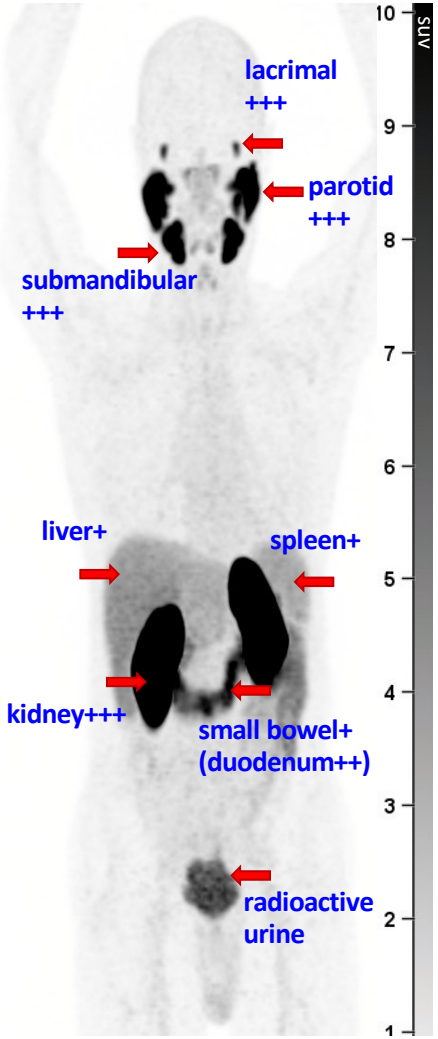


Image from Maurer T et al. Nat Rev Urol, 2016 Apr;13(4):226-35



- Type II transmembrane glycoprotein (FOLH1)
- Highly over-expressed in prostate cancer
- ↑↑ castrate-resistant metastatic disease

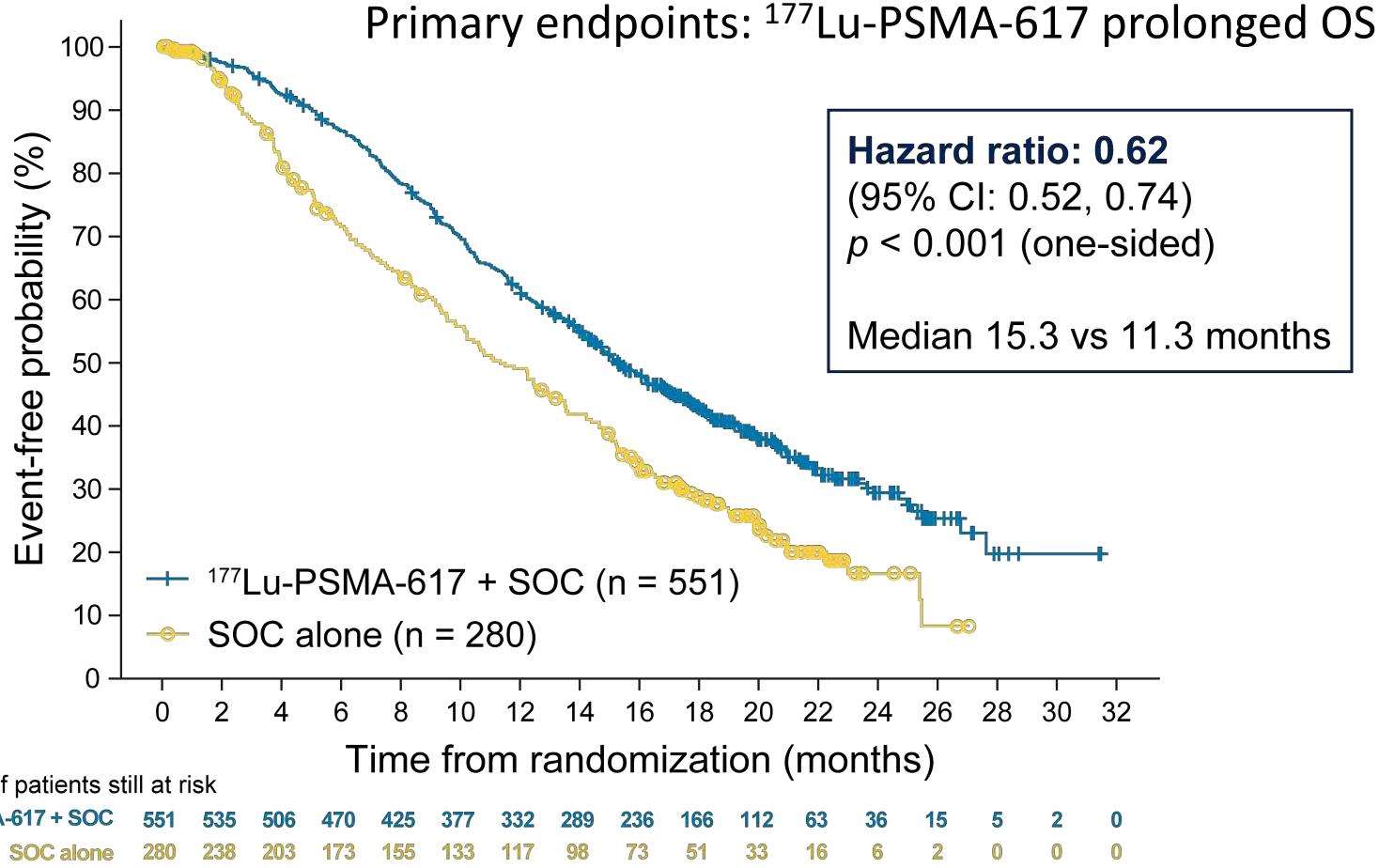
PSMA PET
normal biodistribution

Courtesy of Prof Karim Fizazi, MD, PhD

VISION: Open-label study of protocol-permitted standard of care ± ^{177}Lu-PSMA-617 in adults with PSMA-positive mCRPC

- Primary analysis
  - All randomized patients
  - (N = 831)

Primary endpoints: ^{177}Lu-PSMA-617 prolonged OS



Morris MJ et al. ASCO 2021;Abstract LBA4. Sartor O et al. *N Engl J Med* 2021;385(12):1091-103.

Courtesy of Prof Karim Fizazi, MD, PhD

Planned/ongoing phase 3 trials in earlier settings

	PSMAddition	PSMAfore	SPLASH	ProstAct
Experimental agent	177Lu-PSMA-617	177Lu-PSMA-617	177Lu-PNT2002	177Lu-TLX591
Setting	mCSPC	mCRPC prechemo	mCRPC prechemo	mCRPC post-docetaxel
Primary endpoint	rPFS OS	rPFS OS	rPFS	rPFS
Number of pts	1126	495	415	387

Courtesy of Prof Karim Fizazi, MD, PhD

Phase III PMSAfore Trial Meets Primary Endpoint with ^{177}Lu-PSMA-617 for PSMA-Positive mCRPC

Press Release: December 5, 2022

"Today, [it was announced that] the pivotal Phase III PSMAfore study with ^{177}Lu-PSMA-617, a prostate-specific membrane antigen (PSMA)-targeted radioligand therapy, met its primary endpoint. ^{177}Lu-PSMA-617 demonstrated a statistically significant and clinically meaningful improvement in radiographic progression-free survival (rPFS) in patients with PSMA-positive metastatic castration-resistant prostate cancer (mCRPC) after treatment with androgen-receptor pathway inhibitor (ARPI) therapy, compared to a change in ARPI. No unexpected safety findings were observed in PSMAfore; data are consistent with the already-well established safety profile of ^{177}Lu-PSMA-617.

This is the second positive read-out for ^{177}Lu-PSMA-617 in a Phase III trial following the VISION study, where patients with PSMA-positive mCRPC who received ^{177}Lu-PSMA-617 plus standard of care after being treated with ARPI and taxane-based chemotherapy had a statistically significant reduction in risk of death. The PSMAfore results continue to support the important role of ^{177}Lu-PSMA-617 in treating patients with prostate cancer. The Phase III data will be presented at an upcoming medical meeting and discussed with the US Food and Drug Administration (FDA) in 2023 for regulatory approval."

https://www.globenewswire.com/en/news-release/2022/12/05/2567028/0/en/Novartis-PluvictoTM-shows-statistically-significant-and-clinically-meaningful-radiographic-progression-free-survival-benefit-in-patients-with-PSMA-positive-metastatic-castration-re.html

COSMIC-021: Phase 1b Study Evaluating Cabozantinib + Atezolizumab for mHRPC – *HRPC Cohort 6 Expansion Design*

mCRPC
- **Radiographic progression in soft tissue after enzalutamide and/or abiraterone**
- **Measurable disease per RECIST v1.1**
- **ECOG PS 0 or 1**
- **Prior chemotherapy not permitted except docetaxel for mCSPC**

Confirmation of initial results

Cabozantinib 40 mg QD PO + Atezolizumab 1200 mg Q3W IV (N=30) → **First extended enrollment** (N=50) → **Second extended enrollment** (N=50)

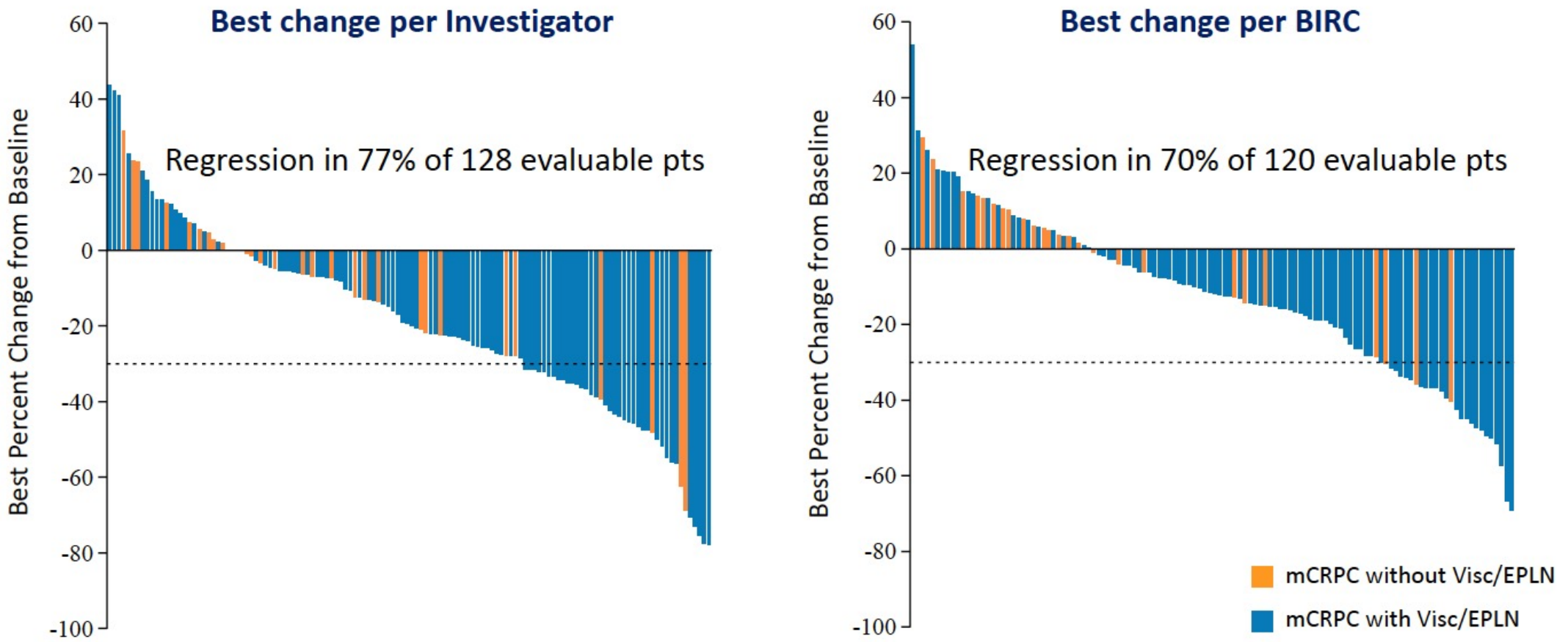
Tumor assessments per RECIST v1.1 by the investigator every 6 weeks for the first year and every 12 weeks thereafter; treatment until loss of clinical benefit or intolerable toxicity.

- Primary endpoint: investigator-assessed ORR per RECIST v1.1
- Secondary endpoint: safety including adverse events (AEs) and AEs of special interest (AESIs)
- Exploratory endpoints: PFS, OS, and biomarkers analyses
- Visceral metastases and/or extrapelvic lymphadenopathy (Visc/EPLN) was a key subgroup
- ORR and PFS were also analysed by blinded independent review committee (BIRC)
- Data as of Feb 19, 2021; 132 patients enrolled with a median follow-up of 15.2 mo (range, 5.7–33.9)

Agarwal N et al. ESMO 2021;Abstract LBA24.

Courtesy of Prof Karim Fizazi, MD, PhD

COSMIC-021 Cohort 6: 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.

Agarwal N et al. ESMO 2021;Abstract LBA24.

Courtesy of Prof Karim Fizazi, MD, PhD