What I Tell My Patients:
Faculty Physicians and Nurses Discuss Patient Education About New Treatments and Clinical Trials

Fifteenth Annual RTP Symposium Series Held During the Annual ONS Congress

Cervical and Endometrial Cancer

Wednesday, April 26, 2023
11:15 AM – 12:45 PM

Faculty

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

Moderator

Neil Love, MD

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Faculty

Paula J Anastasia, MN, RN, AOCN
GYN Oncology Patient-Nurse Educator
Los Angeles, California

Michael J Birrer, MD, PhD
Vice Chancellor, UAMS
Director, Winthrop P Rockefeller Cancer Institute
Director, Cancer Service Line
Professor of Biochemistry and Molecular Biology
Director's Endowed Chair for the Winthrop
P Rockefeller Cancer Institute
University of Arkansas for Medical Sciences
Little Rock, Arkansas

Jennifer Filipi, MSN, NP
Department of Gynecologic Oncology
Massachusetts General Hospital Cancer Center
Boston, Massachusetts

Brian M Slomovitz, MD
Professor, OB-GYN, Florida International University
Director, Gynecologic Oncology
Co-Chair, Cancer Research Committee
Mount Sinai Medical Center
Miami, Florida

Moderator

Neil Love, MD
Research To Practice
Miami, Florida

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Ms Anastasia — Disclosures

Advisory Committee	Merck
Speakers Bureau	Seagen Inc

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Dr Birrer — Disclosures

Advisory Board	AstraZeneca Pharmaceuticals LP, GSK, Mersana Therapeutics Inc

Ms Filipi — Disclosures

No relevant conflicts of interest to disclose.

Dr Slomovitz — Disclosures

Consulting Agreements	AstraZeneca Pharmaceuticals LP, Clovis Oncology, EQRx, Genentech, a member of the Roche Group, Genmab US Inc, GSK, Incyte Corporation, Lilly, Merck, Novartis, Seagen Inc

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Commercial Support

This activity is supported by educational grants from GSK and Karyopharm Therapeutics.

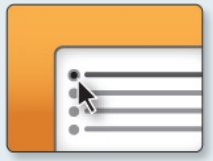
Research To Practice NCPD Planning Committee Members, Staff and Reviewers

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

Clinicians in the Meeting Room

Networked iPads are available.

Review Program Slides: Tap the Program Slides button to review speaker presentations and other program content.



Answer Survey Questions: Complete the pre- and postmeeting surveys. Survey questions will be discussed throughout the meeting.

Ask a Question: Tap Ask a Question to submit a challenging case or question for discussion. We will aim to address as many questions as possible during the program.

Complete Your Evaluation: Tap the NCPD Evaluation button to complete your evaluation electronically to receive credit for your participation.

For assistance, please raise your hand. Devices will be collected at the conclusion of the activity.

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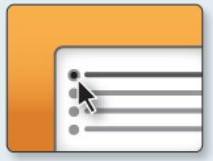
Clinicians Attending via Zoom

Review Program Slides: A link to the program slides will be posted in the chat room at the start of the program.



Answer Survey Questions: Complete the pre- and postmeeting surveys. Survey questions will be discussed throughout the meeting.

Ask a Question: Submit a challenging case or question for discussion using the Zoom chat room.

Get NCPD Credit: An NCPD credit link will be provided in the chat room at the conclusion of the program.

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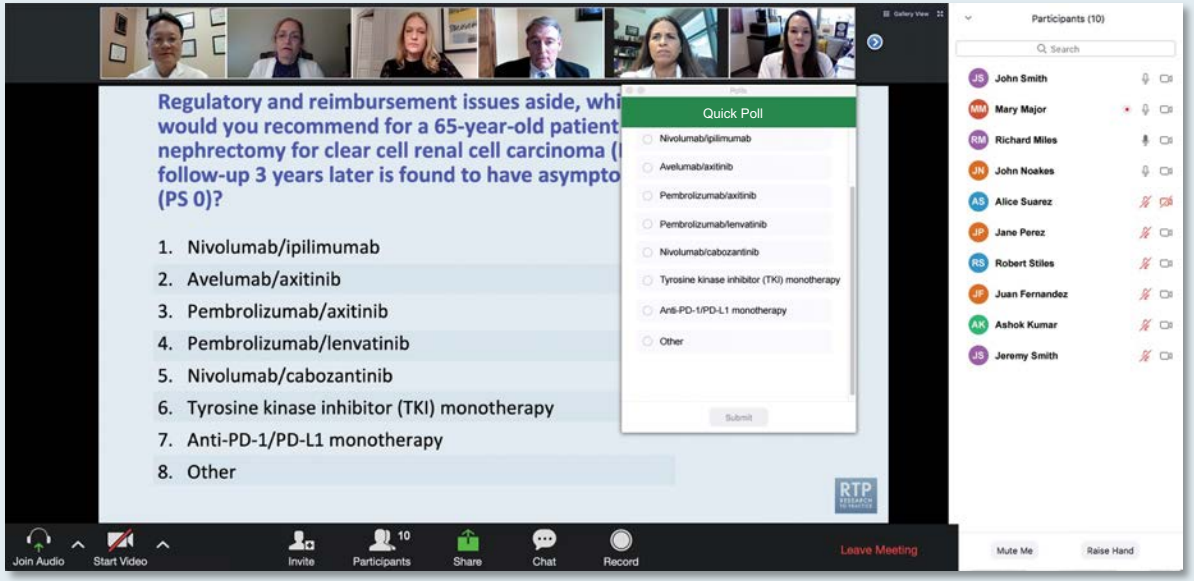
Clinicians, Please Complete the Pre- and Postmeeting Surveys



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About the Enduring Program

- The live meeting is being video and audio recorded.
- The proceedings from today will be edited and developed into an enduring web-based video/PowerPoint program.
  An email will be sent to all attendees when the activity is available.
- To learn more about our education programs, visit our website, **www.ResearchToPractice.com**

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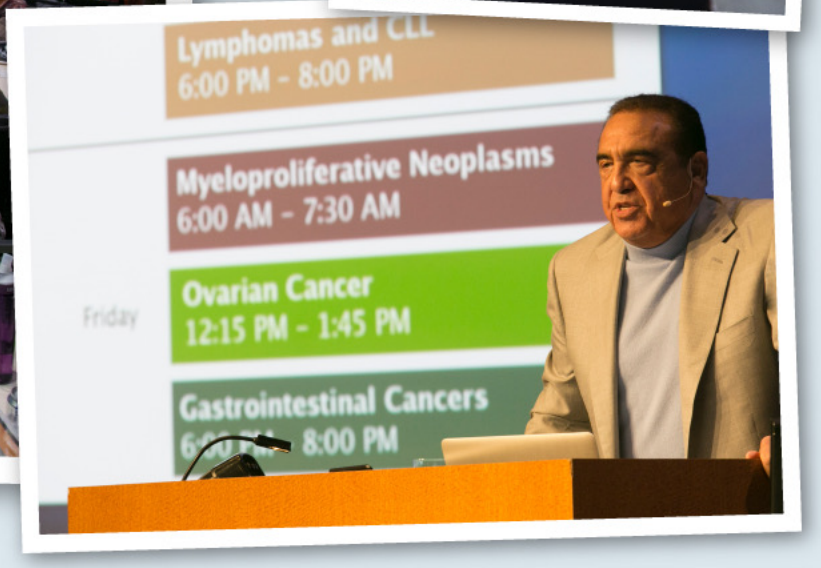
What I Tell My Patients

2009-2023

85 Symposia 355 Faculty



“What I Tell My Patients”
Fifteenth Annual RTP-ONS NCPD Symposium Series
ONS Congress, San Antonio, Texas — April 26 to 29, 2023

Wednesday April 26	**Cervical and Endometrial Cancer** 11:15 AM – 12:45 PM CT (12:15 PM – 1:45 PM ET)
	Breast Cancer 6:00 PM – 8:00 PM CT (7:00 PM – 9:00 PM ET)
Thursday April 27	**Diffuse Large B-Cell Lymphoma** 6:00 AM – 7:30 AM CT (7:00 AM – 8:30 AM ET)
	Chronic Lymphocytic Leukemia 12:15 PM – 1:45 PM CT (1:15 PM – 2:45 PM ET)
	HER2-Targeted Antibody-Drug Conjugates 6:00 PM – 7:30 PM CT (7:00 PM – 8:30 PM ET)
Friday April 28	**Hepatobiliary Cancers** 6:00 AM – 7:30 AM CT (7:00 AM – 8:30 AM ET)
	Ovarian Cancer 12:15 PM – 1:45 PM CT (1:15 PM – 2:45 PM ET)
	Lung Cancer 6:00 PM – 8:00 PM CT (7:00 PM – 9:00 PM ET)
Saturday April 29	**Acute Myeloid Leukemia, Myelodysplastic Syndromes and Myelofibrosis** 6:00 AM – 7:30 AM CT (7:00 AM – 8:30 AM ET)
	Prostate Cancer 12:15 PM – 1:45 PM CT (1:15 PM – 2:45 PM ET)

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Cervical and Endometrial Cancer Faculty

Paula J Anastasia, MN, RN, AOCN
GYN Oncology Patient-Nurse Educator
Los Angeles, California

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Professor, OB-GYN, Florida International University
Director, Gynecologic Oncology
Co-Chair, Cancer Research Committee
Mount Sinai Medical Center
Miami, Florida

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Breast Cancer Faculty

Jamie Carroll, APRN, MSN, CNP
Mayo Clinic
Rochester, Minnesota

Joyce O'Shaughnessy, MD
Celebrating Women Chair in Breast Cancer Research
Baylor University Medical Center
Director, Breast Cancer Research Program
Texas Oncology
US Oncology
Dallas, Texas

Virginia Kaklamani, MD, DSc
Professor of Medicine
Ruth McLean Bowman Bowers Chair in Breast Cancer Research and Treatment
AB Alexander Distinguished Chair in Oncology
Leader, Breast Oncology Program
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Diffuse Large B-Cell Lymphoma Faculty

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MD Anderson Cancer Center
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Assistant Professor of Medicine
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Assistant Vice Chair of Research, Department of Medicine
Assistant Vice Chancellor for Clinical Research
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Chronic Lymphocytic Leukemia Faculty

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HER2-Targeted Antibody-Drug Conjugates Faculty

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Hepatobiliary Cancers Faculty

Ahmed Omar Kaseb, MD, CMQ
John E and Dorothy J Harris Professor in
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Tenured Professor and Director, Hepatocellular
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Director, MD Anderson HCC SPORE
Editor-in-Chief, Journal of Hepatocellular Carcinoma
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Ovarian Cancer Faculty

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Stephenson Cancer Center
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Chief Academic Office
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MD Anderson Cancer Center
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Acute Myeloid Leukemia, Myelodysplastic Syndromes and Myelofibrosis Faculty

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MD Anderson Cancer Center
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University Presidential Chair
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Tampa, Florida

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Prostate Cancer Faculty

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Professor of Medicine
Senior Director for Clinical Research Innovation
Huntsman Cancer Institute Presidential Endowed Chair of Cancer Research
Director, Center of Investigational Therapeutics
Director, Genitourinary Oncology Program
Huntsman Cancer Institute, University of Utah (NCI-CCC)
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City of Hope Comprehensive Cancer Center
Duarte, California

Sandy Srinivas, MD
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Stanford, California

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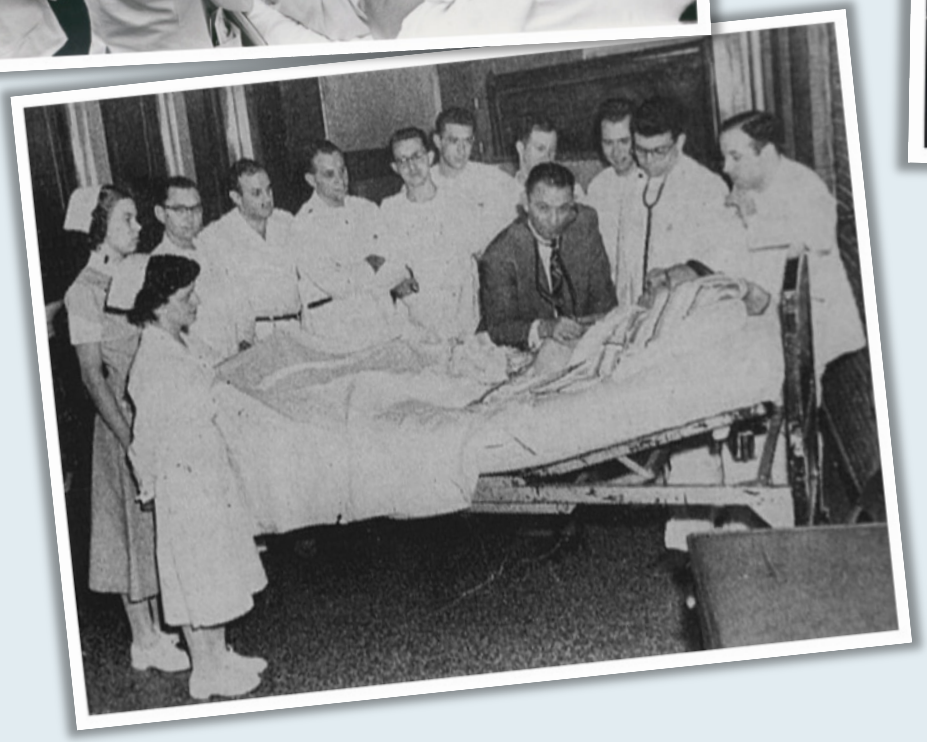

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The Core Oncology Triad
Developing an Individualized Oncology Strategy

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What I Tell My Patients

2023 ONS Congress

San Antonio, Texas

Symposia Themes

- New agents and therapies; ongoing trials related to specific clinical scenarios
- Patient education: Preparing to receive new therapies
- The bond that heals
- THANKS! (Great job)

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How was it different to take care of this patient versus another patient in the same oncologic setting?

What unique biopsychosocial factors (eg, attitude, comorbidities, social support) were considered in the overall management of this case?

ONS 2023 Playlist

ONS Cervical and Endometrial Cancer
Almost Cut My Hair — **Crosby, Stills, Nash & Young**
Still the Same — **Bob Seger & The Silver Bullet Band**
Beautiful Day — **U2**
Victim of Love — **Eagles**
ONS Breast Cancer
Jane — **Jefferson Starship**
Gimme Shelter — **The Rolling Stones**
Rock and Roll Music — **The Beatles**
Everybody I Love You — **Crosby, Stills, Nash & Young**
ONS Diffuse Large B-Cell Lymphoma
Suite: Judy Blue Eyes — **Crosby, Stills, Nash & Young**
Straight On — **Heart**
Clocks — **Coldplay**
Boom, Like That — **Mark Knopfler**

https://www.researchtopractice.com/ONS2023/Playlist

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ONS 2023 Playlist

ONS Chronic Lymphocytic Leukemia
A Message — **Coldplay**
Sit Yourself Down — **Stephen Stills**
Jammin' Me — **Tom Petty and The Heartbreakers**
Carry On — **Crosby, Stills, Nash & Young**
ONS HER2-Targeted Antibody-Drug Conjugates
Good Vibrations — **The Beach Boys**
Simple Man — **Bad Company**
Yellow — **Coldplay**
The Walker — **Fitz and The Tantrums**
ONS Hepatobiliary Cancers
One — **Creed**
Like Water — **Bad Company**
Bitter Sweet Symphony — **The Verve**
Live for the Music — **Bad Company**

https://www.researchtopractice.com/ONS2023/Playlist

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ONS 2023 Playlist

ONS Ovarian Cancer
Blue on Black — **Kenny Wayne Shepherd Band**
Come as You Are — **Nirvana**
Feel Like a Number — **Bob Seger & The Silver Bullet Band**
To Live and Die in L.A. — **Wang Chung**
ONS Lung Cancer
Girl on the Moon — **Foreigner**
Small Town Trap — **Eve 6**
City of Blinding Lights — **U2**
Brass in Pocket — **The Pretenders**
ONS Acute Myeloid Leukemia, Myelodysplastic Syndromes and Myelofibrosis
Little Queen — **Heart**
She's Long Gone — **The Black Keys**
I Won’t Back Down — **Tom Petty**
Magic — **The Cars**

https://www.researchtopractice.com/ONS2023/Playlist

RTP RESEARCH TO PRACTICE

ONS 2023 Playlist

ONS Prostate Cancer
Burnin’ Sky — **Bad Company**
Heartbroken, in Disrepair — **Dan Auerbach**
In My Place — **Coldplay**
Learn to Fly — **Foo Fighters**

https://www.researchtopractice.com/ONS2023/Playlist

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Miami, Florida

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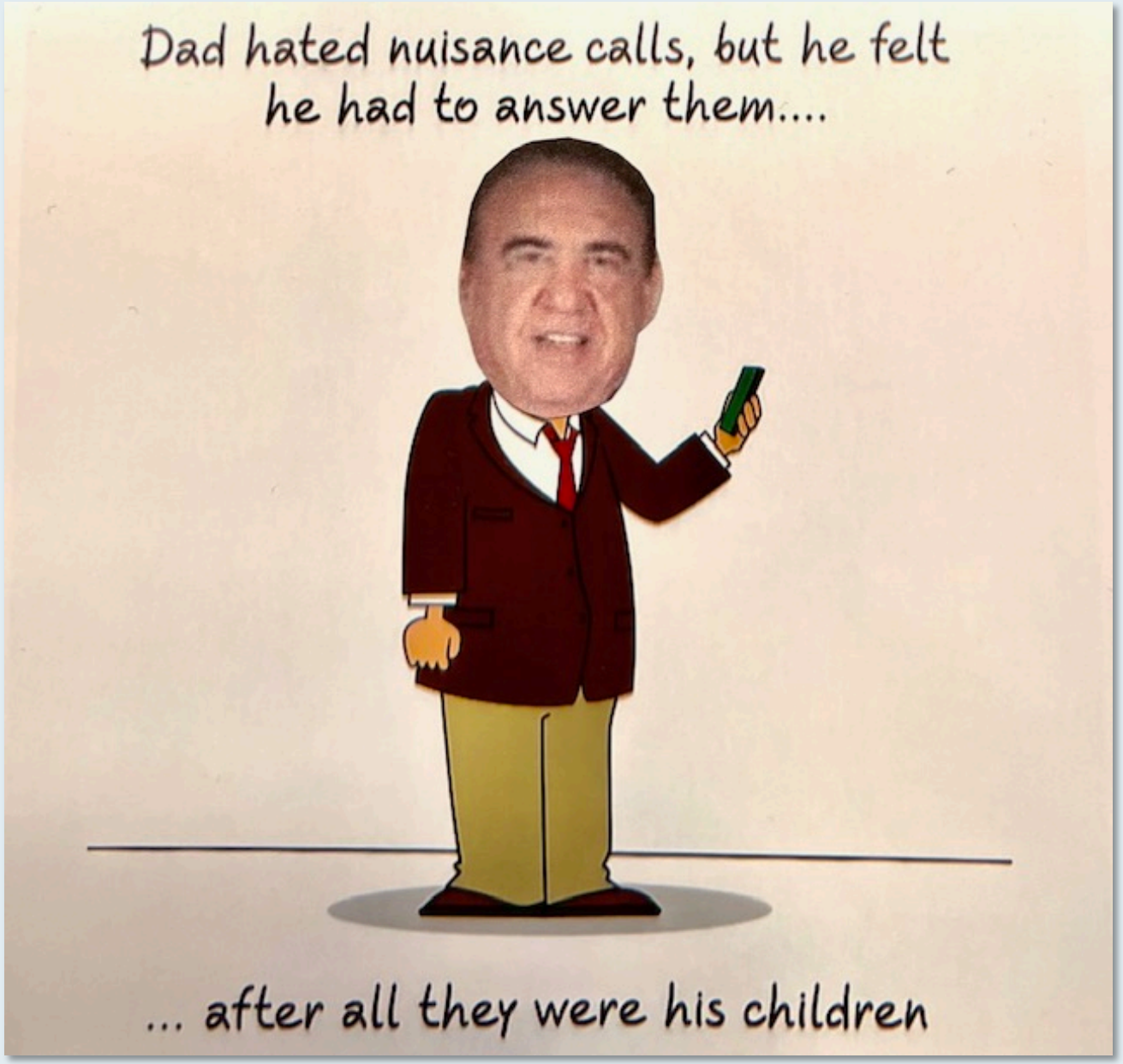


Fabulous never goes out of style


"You're not retaining water.
You're retaining cookies and
ice cream and pizza and . . ."

Agenda

Module 1: Overview of Endometrial Cancer

Module 2: Management of MSI-High Endometrial Cancer

Module 3: Management of MSS Endometrial Cancer

Module 4: Clinical Trials in Endometrial Cancer

Module 5: Systemic Therapy for Cervical Cancer: Immunotherapy

Module 6: Antibody-Drug Conjugates for Cervical Cancer: Tisotumab vedotin

Agenda

Module 1: Overview of Endometrial Cancer

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Module 4: Clinical Trials in Endometrial Cancer

Module 5: Systemic Therapy for Cervical Cancer: Immunotherapy

Module 6: Antibody-Drug Conjugates for Cervical Cancer: Tisotumab vedotin

Paula J Anastasia, MN, RN, AOCN

70-year-old woman with MSI-H endometrial cancer who received carboplatin/paclitaxel/pembrolizumab followed by maintenance pembrolizumab

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Dr Birrer
Little Rock, Arkansas

Clinical Research Background

Dr Slomovitz
Miami, Florida

- **Overview of endometrial cancer: Incidence, mortality**
- **Management of localized disease**

Agenda

Module 1: Overview of Endometrial Cancer

Module 2: Management of MSI-High Endometrial Cancer

Module 3: Management of MSS Endometrial Cancer

Module 4: Clinical Trials in Endometrial Cancer

Module 5: Systemic Therapy for Cervical Cancer: Immunotherapy

Module 6: Antibody-Drug Conjugates for Cervical Cancer: Tisotumab vedotin

Jennifer Filipi, MSN, NP

45-year-old woman with MSI-H endometrial cancer who received pembrolizumab

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Dr Birrer
Little Rock, Arkansas

Clinical Research Background

Dr Slomovitz
Miami, Florida

- **Systemic treatment of endometrial cancer**
- **Management of MSI-high disease: Pembrolizumab and dostarlimab**

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Agenda

Module 1: Overview of Endometrial Cancer

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Module 5: Systemic Therapy for Cervical Cancer: Immunotherapy

Module 6: Antibody-Drug Conjugates for Cervical Cancer: Tisotumab vedotin

Paula J Anastasia, MN, RN, AOCN

68-year-old woman with MSS, HER2-low endometrial cancer who received pembrolizumab/lenvatinib and T-DXd

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Dr Birrer
Little Rock, Arkansas

Clinical Research Background

Dr Slomovitz
Miami, Florida

- **Treatment of MSS disease: Lenvatinib/pembrolizumab**
- **HER2-targeted agents in endometrial cancer**

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Jennifer Filipi, MSN, NP

62-year-old woman with recurrent MSS endometrial cancer who received pembrolizumab/lenvatinib

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Agenda

Module 1: Overview of Endometrial Cancer

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Module 4: Clinical Trials in Endometrial Cancer

Module 5: Systemic Therapy for Cervical Cancer: Immunotherapy

Module 6: Antibody-Drug Conjugates for Cervical Cancer: Tisotumab vedotin

Dr Birrer
Little Rock, Arkansas

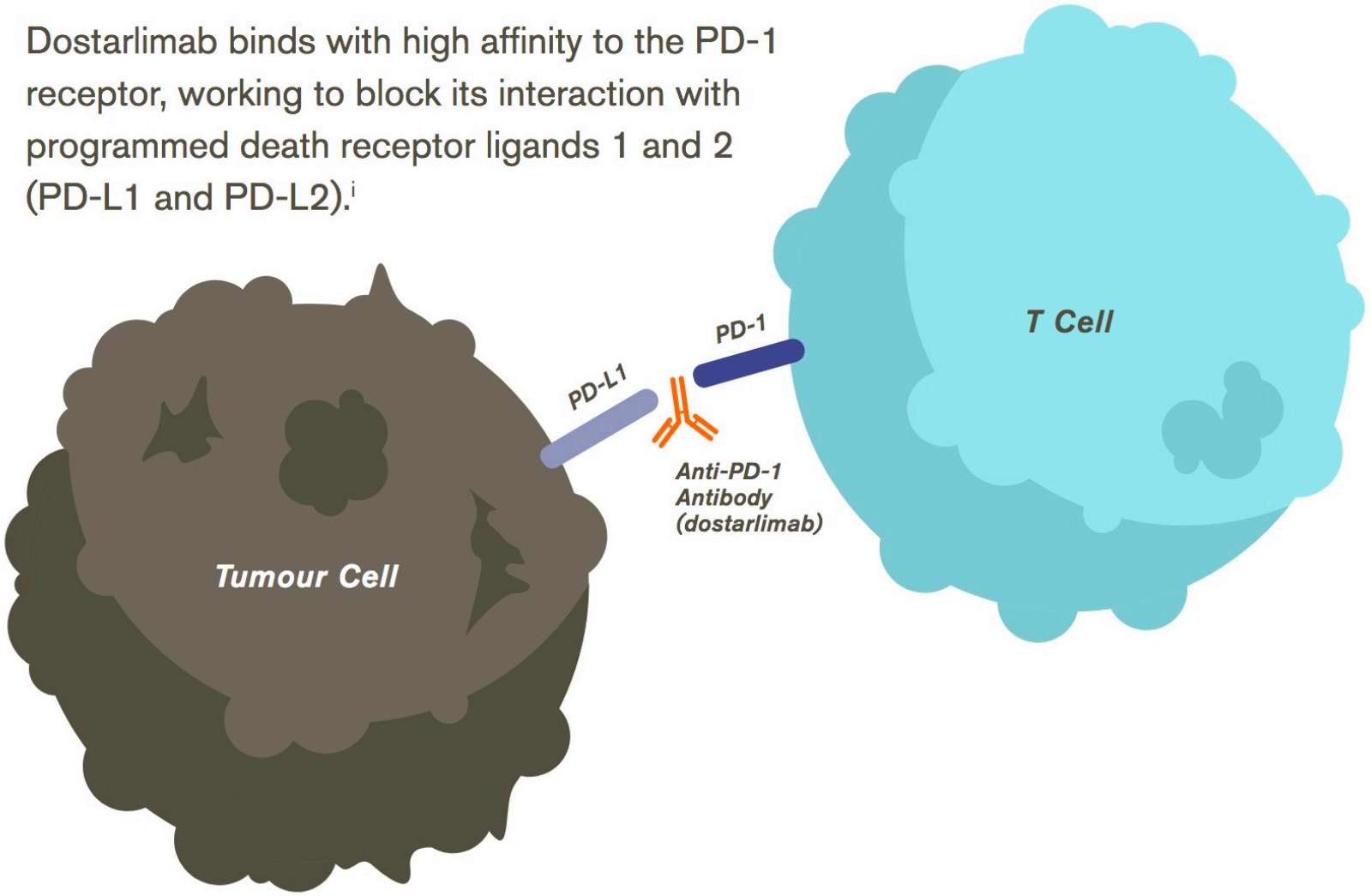
Clinical Research Background

Dr Slomovitz
Miami, Florida

- **Clinical Trials in Oncology**
  - **RUBY trial: Dostarlimab with chemotherapy**
  - **NRG-GY018: Pembrolizumab with chemotherapy**
  - **SIENDO: Selinexor as maintenance after first-line chemotherapy**

Dostarlimab Mechanism of Action

Dostarlimab binds with high affinity to the PD-1 receptor, working to block its interaction with programmed death receptor ligands 1 and 2 (PD-L1 and PD-L2).[i]



https://us.gsk.com/media/5875/dostarlimab-infographic_approved-0422.pdf

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Dostarlimab

Mechanism of action

- **Anti-PD-1 monoclonal antibody**

Indication

- **Patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer that has progressed on or following a prior platinum-containing regimen in any setting and are not candidates for curative surgery or radiation**

Recommended dose

- **500 mg IV q3wk doses 1-4, then 1,000 mg IV q6wk beginning 3 weeks after dose 4 and onwards**

Dostarlimab package insert, 2/2023.

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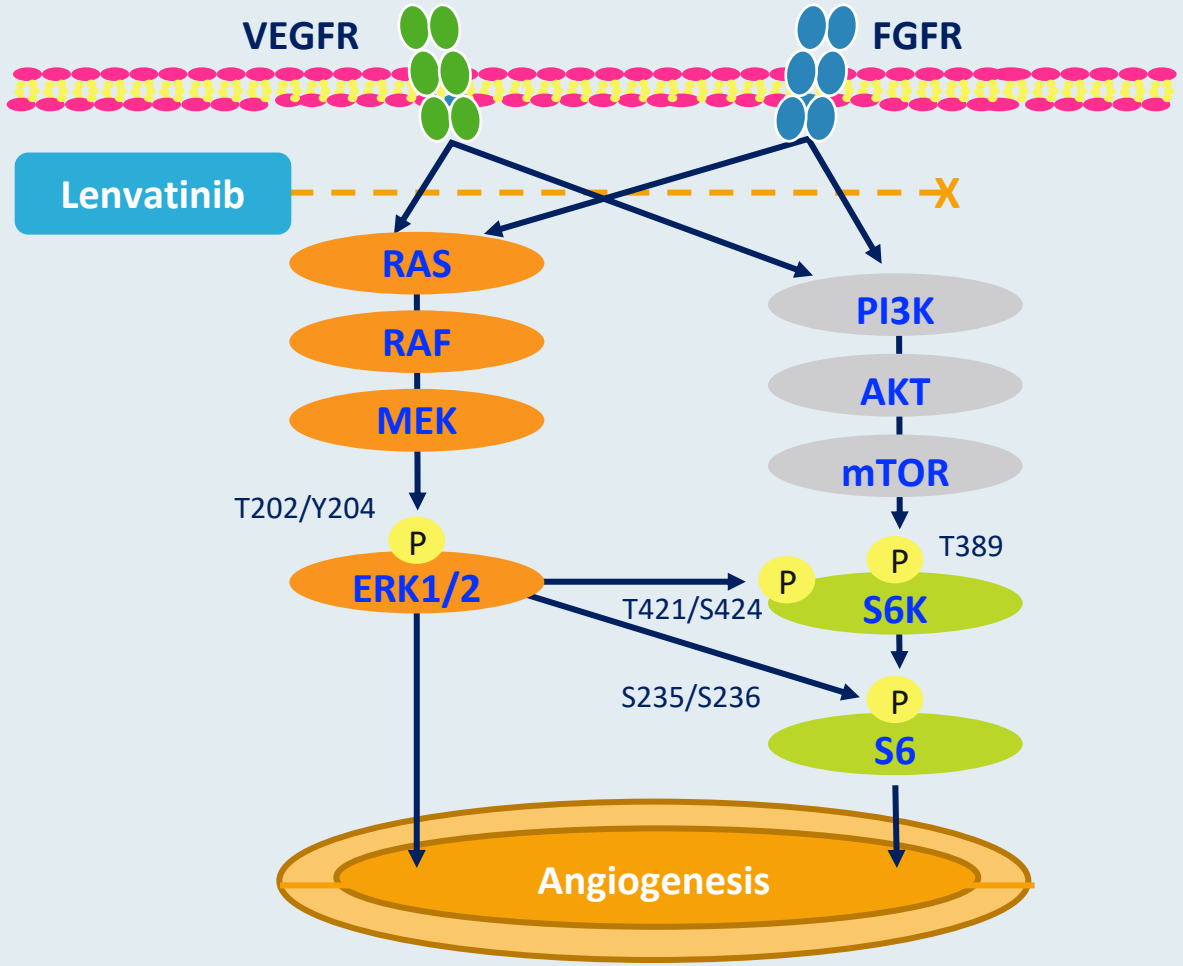
Mechanism of Action of Lenvatinib



- Orally available inhibitor of multiple tyrosine kinases including VEGF receptors, FGFR, RET, PDGFR and KIT
- Demonstrated promising radiographic response rates and survival results in Phase II and III trials in HCC

Finn RS et al. *Proc ASCO* 2014;Abstract TPS4153; Stjepanovic N et al. *Biologics* 2014;8:129-39; Cheng AL et al. *Proc ASCO* 2017;Abstract 4001; Ikeda K et al. *J Gastroenterol* 2017;52(4):512-9.

Lenvatinib

Mechanism of action

- **Oral multikinase inhibitor**

Indication

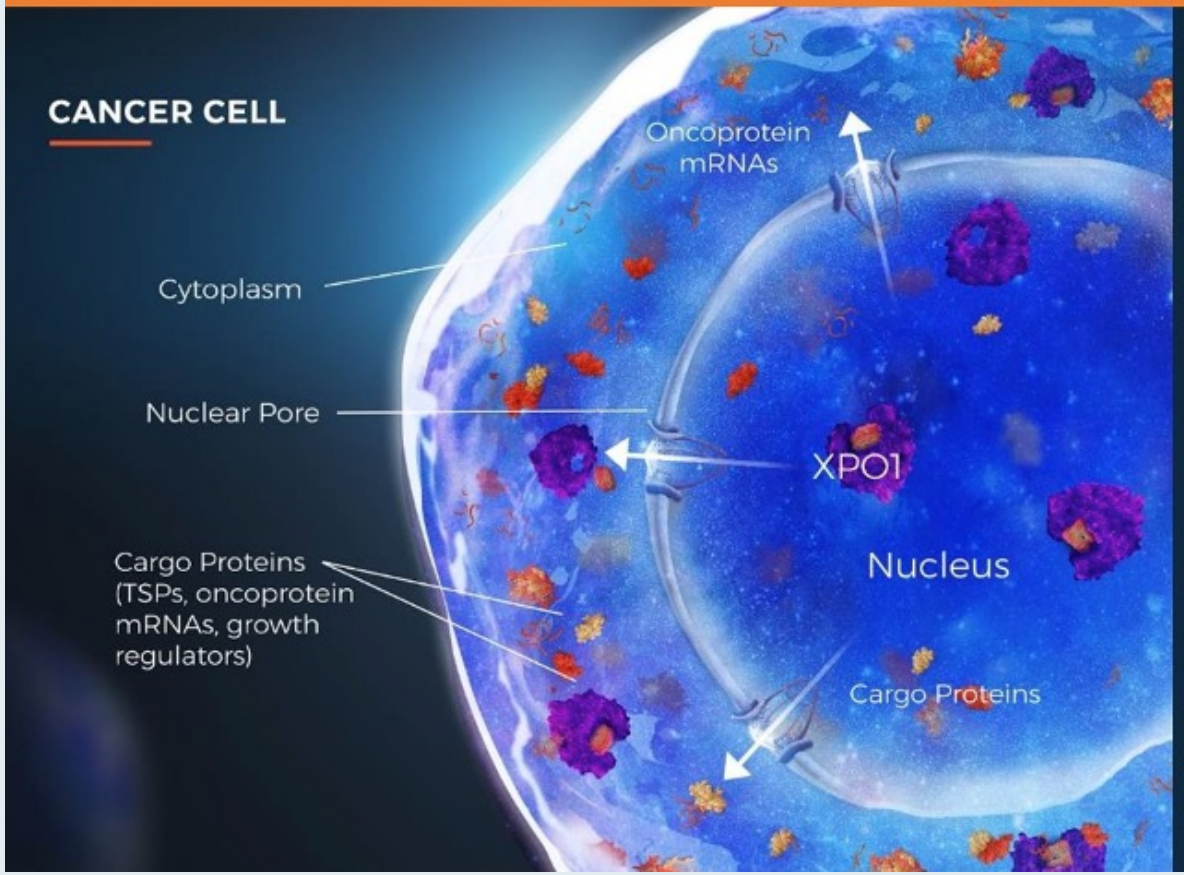
- **In combination with pembrolizumab for patients with advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation**

Recommended dose

- **20 mg orally once daily in combination with pembrolizumab 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks**

Lenvatinib package insert, 12/2021.

Mechanism of Action of Selinexor



Selinexor is an oral selective inhibitor of XPO1-mediated nuclear export (SINE) compound

- XPO1 exports the major tumor suppressor proteins (TSPs) including p53 away from the nucleus, where TSPs carry out their function
- Tumor cells overexpress XPO1
- Tumor cells inactivate cytoplasmic *p53* through protein degradation
- Selinexor inhibits XPO1 nuclear export, leads to retention / reactivation of TSPs in the nucleus and stabilization of p53
- Retention of wild-type *p53* (p53wt) and other TSPs in the cell nucleus leads to selective killing of cancer cells, while largely sparing normal cells

Makker V et al. ASCO 2022;Abstract 5511.

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Selinexor

Mechanism of action

- Inhibitor of the nuclear exporter XPO1

Indication

- Investigational

Pivotal clinical trial

- Phase III SIENDO trial evaluating selinexor as front-line maintenance therapy in advanced or recurrent endometrial cancer

Key Issue

- Gastrointestinal toxicity

Vergote I et al. SGO 2022;Abstract 249.

Agenda

Module 1: Overview of Endometrial Cancer

Module 2: Management of MSI-High Endometrial Cancer

Module 3: Management of MSS Endometrial Cancer

Module 4: Clinical Trials in Endometrial

Module 5: Systemic Therapy for Cervical Cancer – Immunotherapy

Module 6: Antibody-Drug Conjugates for Cervical Cancer – Tisotumab vedotin

Jennifer Filipi, MSN, NP

36-year-old woman with Stage IV cervical cancer who received pembrolizumab

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Dr Birrer
Little Rock, Arkansas

Clinical Research Background

Dr Slomovitz
Miami, Florida

- **Overview of cervical cancer: Incidence, mortality**
- **Management of localized disease**
- **Systemic therapy for cervical cancer: Immunotherapy**

Agenda

Module 1: Overview of Endometrial Cancer

Module 2: Management of MSI-High Endometrial Cancer

Module 3: Management of MSS Endometrial Cancer

Module 4: Clinical Trials in Endometrial

Module 5: Systemic Therapy for Cervical Cancer – Immunotherapy

Module 6: Antibody-Drug Conjugates for Cervical Cancer – Tisotumab vedotin

Paula J Anastasia, MN, RN, AOCN

32-year-old woman with HPV-positive metastatic cervical cancer who received tisotumab vedotin

RTP
RESEARCH
TO PRACTICE

Dr Birrer
Little Rock, Arkansas

Clinical Research Background

Dr Slomovitz
Miami, Florida

- **Antibody-drug conjugates (ADCs) for cervical cancer: Tisotumab vedotin**
- **Unique side-effect profiles of ADCs: Ocular toxicity**
- **Minor children (and grandchildren) of patients with cancer**

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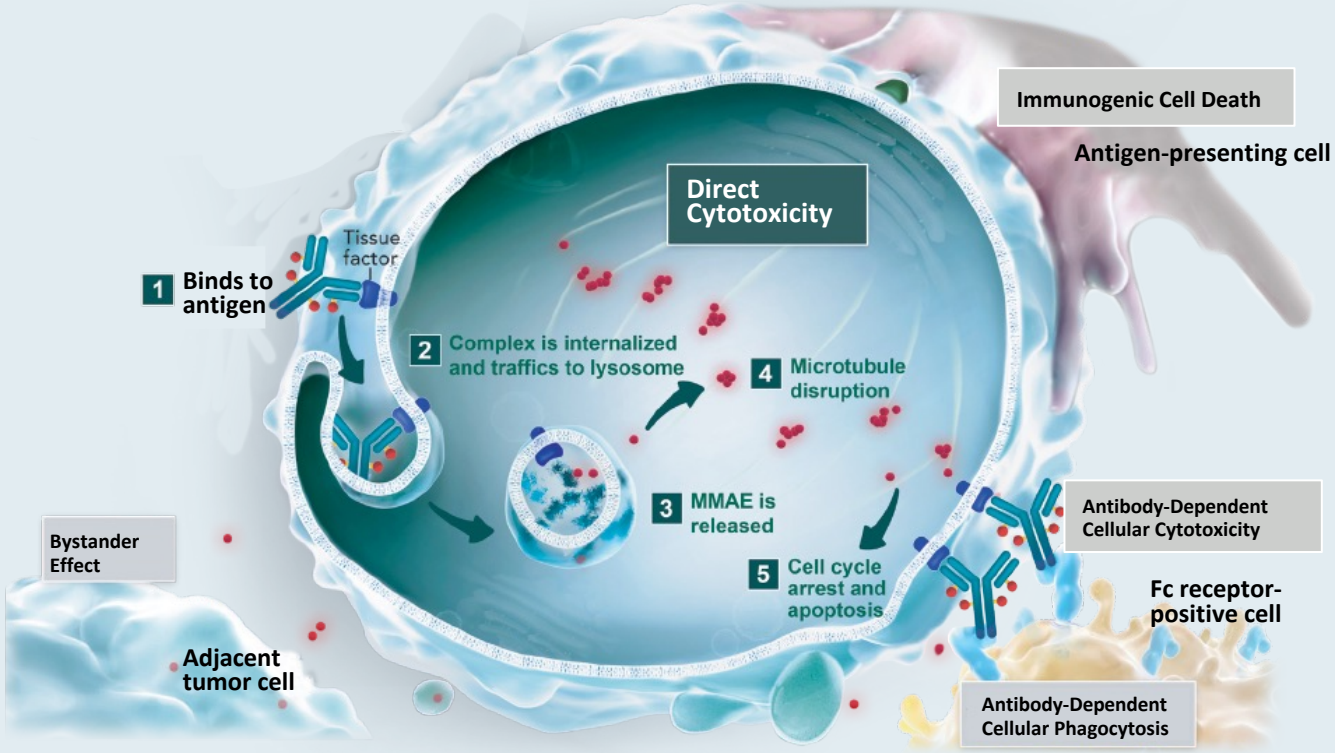
Mechanism of Action of Tisotumab Vedotin

- Tissue factor (TF) is aberrantly expressed in a broad range of solid tumours, including cervical cancer,[1,2] and TF expression has been associated with higher tumour stage and grade, higher metastatic burden and poor prognosis[2]
- TF expression in cervical cancer makes TF a novel target for patients with cervical cancer
- ADC targets TF
  - Monoclonal Antibody targets TF
  - Payload: Microtubule disrupting MMAE
- Allowing for direct cytotoxicity and bystander killing, as well as antibody-dependent cellular cytotoxicity[3,4]



1. Förster Y, et al. *Clin Chim Acta,* 2006. 2. Cocco E, et al. *BMC Cancer,* 2011.
3. Breij EC, et al. *Cancer Res,* 2014. 4. De Goeij BE, et al. *Mol Cancer Ther,* 2015.

Courtesy of David M O'Malley, MD

RTP RESEARCH TO PRACTICE

Tisotumab Vedotin

Mechanism of action

- **Antibody-drug conjugate directed against tissue factor (TF)**

Indication

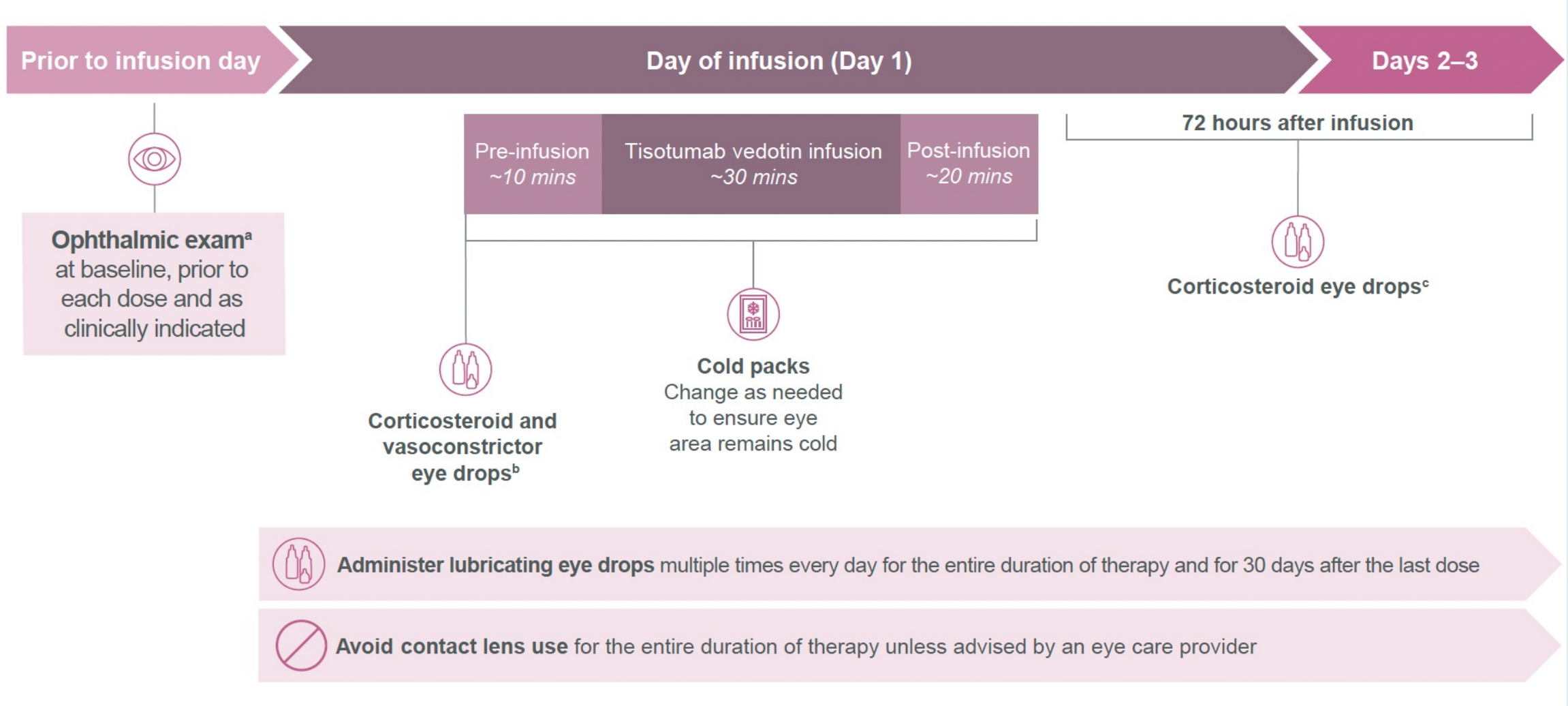
- **For patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy**

Recommended dose

- **2 mg/kg (up to a maximum of 200 mg) administered as an IV infusion over 30 minutes q3wk until disease progression or unacceptable toxicity**

Tisotumab vedotin package insert, 1/2022.

Required Eye Care to Mitigate Risk of Ocular AEs

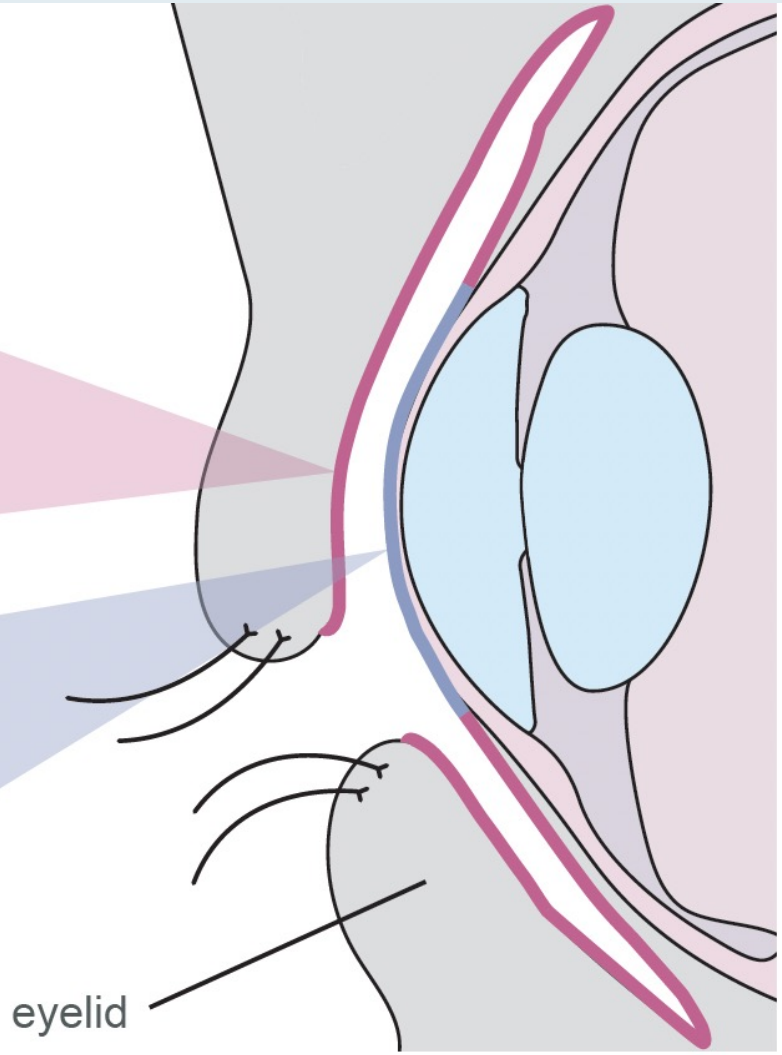


Arn CJ et al. *J Adv Pract Oncol* 2023 March;14(2):139-52.

Selected Eye Anatomy of Interest

Selected eye anatomy of interest

conjunctiva	Thin layer of tissue that lines the inner surface of the eyelid and covers the white part of the eye
cornea	Outermost layer of the eye that covers the iris and functions in focusing



Arn CJ et al. *J Adv Pract Oncol* 2023 March;14(2):139-52.

Ocular AE Definitions and CTCAE v5.0 Grading Scales

Conjunctivitis: a disorder characterized by inflammation, swelling, and redness to the conjunctiva of the eye

Dry eye: a disorder characterized by dryness of the cornea and conjunctiva

Keratitis: a disorder characterized by inflammation to the cornea of the eye

Blepharitis: an inflammatory condition of the eyelids

Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Conjunctivitis	Asymptomatic or mild symptoms; intervention not indicated	Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline)	Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); limiting self care ADL	Best corrected visual acuity of 20/200 or worse in the affected eye	N/A
Dry eye	Asymptomatic; clinical or diagnostic observations only; symptoms relieved by lubricants	Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline)	Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); limiting self care ADL	N/A	N/A
Keratitis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline)	Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); corneal ulcer; limiting self care ADL	Perforation; best corrected visual acuity of 20/200 or worse in the affected eye	N/A
Eye disorders - other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated; no change in vision	Moderate; minimal, local or noninvasive intervention indicated; limiting instrumental ADL; best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline	Severe or medically significant but not immediately sight-threatening; limiting self care ADL; decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200)	Sight-threatening consequences; urgent intervention indicated; best corrected visual acuity of 20/200 or worse in the affected eye	N/A

CTCAE = Common Terminology Criteria for Adverse Events

Arn CJ et al. *J Adv Pract Oncol* 2023 March;14(2):139-52.

Tisotumab Vedotin Dose Modification Guidelines for Ocular AEs

Adverse reaction	Severity	Occurrence	Tisotumab vedotin dose modification
Keratitis[a]	SPK	Any	Monitor.
	Confluent superficial keratitis	First occurrence	Withhold dose until SPK or normal, then resume treatment at the next lower dose level.
		Second occurrence	Permanently discontinue.
	Ulcerative keratitis or perforation	Any	Permanently discontinue.
Conjunctival ulceration[a]	Any ulceration	First occurrence	Withhold dose until complete conjunctival re-epithelialization, then resume treatment at the next lower dose level.
		Second occurrence	Permanently discontinue.
Conjunctival or corneal scarring or symblepharon[a]	Any scarring or symblepharon	Any	Permanently discontinue.
Conjunctivitis and other ocular adverse reactions[a]	Grade 1	Any	Monitor.
	Grade 2	First occurrence	Withhold dose until grade ≤ 1, then resume treatment at the same dose.
		Second occurrence	Withhold dose until grade ≤ 1, then resume treatment at the next lower dose level. If no resolution to grade ≤ 1, permanently discontinue.
		Third occurrence	Permanently discontinue.
	Grade 3 or 4	Any	Permanently discontinue.

Arn CJ et al. *J Adv Pract Oncol* 2023 March;14(2):139-52.

RTP RESEARCH TO PRACTICE

Tisotumab Vedotin Dose Modification Guidelines for Peripheral Neuropathy, Hemorrhage and Pneumonitis

Adverse reaction	Severity	Occurrence	Tisotumab vedotin dose modification
Peripheral neuropathy	Grade 2	Any (initial or worsening of pre-existing condition)	Withhold dose until grade ≤ 1, then resume treatment at the next lower dose level.
	Grade 3 or 4	Any	Permanently discontinue.
Hemorrhage	Any-grade pulmonary or CNS	Any	Permanently discontinue.
	Grade 2 in any other location	Any	Withhold until resolved, then resume treatment at the same dose.
	Grade 3 in any other location	First occurrence	Withhold dose until resolved, then resume treatment at the same dose.
		Second occurrence	Permanently discontinue.
	Grade 4 in any other location	Any	Permanently discontinue.
Pneumonitis	Grade 2	Any	Withhold dose until grade ≤ 1 for persistent or recurrent pneumonitis, consider resuming treatment at next lower dose level.
	Grade 3 or 4	Any	Permanently discontinue.

Arn CJ et al. *J Adv Pract Oncol* 2023 March;14(2):139-52.

Symptoms of Immunotherapy Toxicity

Hypophysitis
(fatigue)

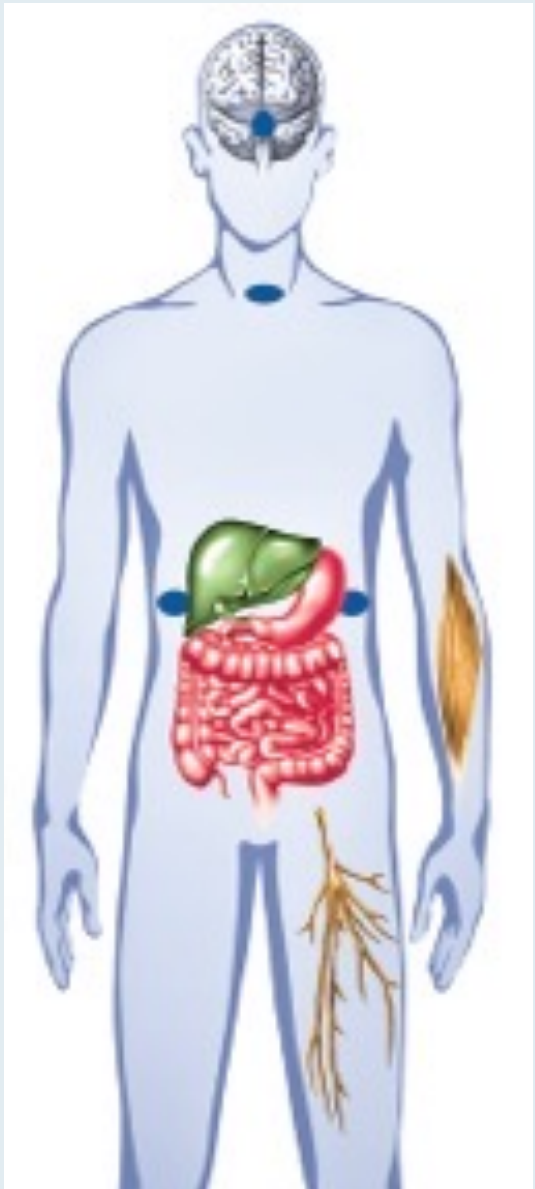
Thyroiditis
(over/underactive thyroid)

Adrenal Insufficiency
(fatigue)

Diabetes Mellitus
(type I, II, fatigue, DKA)

Colitis
(diarrhea, abd pain)

Dermatitis
(rash, itch, blistering)



Pneumonitis
(dyspnea, cough)

Myocarditis
(chest pain, dyspnea)

Hepatitis
(abn LFTs, jaundice)

Pancreatitis
(abd pain)

Neurotoxicities
(MG, encephalitis)

Arthritis
(joint pain)

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APPENDIX

Endometrial Cancer

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N Engl J Med 2023 March;[Online ahead of print].

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Dostarlimab for Primary Advanced or Recurrent Endometrial Cancer

M.R. Mirza, D.M. Chase, B.M. Slomovitz, R. dePont Christensen, Z. Novák, D. Black, L. Gilbert, S. Sharma, G. Valabrega, L.M. Landrum, L.C. Hanker, A. Stuckey, I. Boere, M.A. Gold, A. Auranen, B. Pothuri, D. Cibula, C. McCourt, F. Raspagliesi, M.S. Shahin, S.E. Gill, B.J. Monk, J. Buscema, T.J. Herzog, L.J. Copeland, M. Tian, Z. He, S. Stevens, E. Zografos, R.L. Coleman, and M.A. Powell, for the RUBY Investigators*

ENGOT European Network of Gynaecological Oncological Trial groups | NSGO-CTU Nordic Society of Gynaecological Oncology - Clinical Trial Unit | GOG FOUNDATION

SGO 2023;Abstract 265.

Dostarlimab in Combination with Chemotherapy for the Treatment of Primary Advanced or Recurrent Endometrial Cancer: a Placebo-Controlled Randomized Phase 3 Trial (ENGOT-EN6-NSGO/GOG-3031/RUBY)

Mansoor R. Mirza,[1] Dana Chase,[2] Brian Slomovitz,[3] René DePont Christensen,[4] Zoltán Novák,[5] Destin Black,[6] Lucy Gilbert,[7] Sudarshan Sharma,[8] Giorgio Valabrega,[9] Lisa M. Landrum,[10] Lars C. Hanker,[11] Ashley Stuckey,[12] Ingrid Boere,[13] Michael A. Gold,[14] Sarah E. Gill,[15] Bradley J. Monk,[16] Zangdong He,[17] Shadi Stevens,[18] Robert L. Coleman,[19] Matthew A. Powell[20]

[1]Department of Oncology, Rigshospitalet, Copenhagen University Hospital, Copenhagen, and Nordic Society of Gynaecologic Oncology-Clinical Trial Unit, Copenhagen Denmark; [2]*David Geffen School of Medicine at UCLA, Los Angeles, CA, USA; [3]Department of Gynecologic Oncology, Mount Sinai Medical Center, and Department of Obstetrics and Gynecology, Florida International University, Miami Beach, FL, USA; [4]Research Unit for General Practice, University of Southern Denmark, Institute of Public Health, Odense, Denmark; [5]Department of Gynecology, Hungarian National Institute of Oncology, Budapest, Hungary; [6]Department of Obstetrics and Gynecology, LSU Health Shreveport, and Willis-Knighton Physician Network, Shreveport, LA, USA; [7]Division of Gynecologic Oncology, McGill University Health Centre, Montreal, Quebec, Canada; [8]Department of Obstetrics/Gynecology, AMITA Adventist Hinsdale Hospital, Hinsdale, IL, USA; [9]University of Torino, AO Ordine Mauriziano, Torino, Italy; [10]Indiana University Health and Simon Cancer Center, Indianapolis, IN, USA; [11]Department of Gynecology and Obstetrics, University Hospital Schleswig-Holstein, Campus Lübeck, Lübeck, Germany; [12]Women and Infants Hospital, Providence, RI, USA; [13]Department of Medical Oncology, Erasmus MC Cancer Centre, Rotterdam, The Netherlands; [14]Oklahoma Cancer Specialists and Research Institute, Tulsa, OK, USA; [15]Division of Gynecologic Oncology, Nancy N. and J.C Lewis Cancer and Research Pavilion, Savannah, GA, USA; [16]HonorHealth Research Institute, University of Arizona College of Medicine, Phoenix, and Creighton University School of Medicine, Phoenix, AZ, USA; [17]GSK, Collegeville, PA, USA; [18]GSK, London, UK; [19]US Oncology Research, The Woodlands, TX, USA; [20]National Cancer Institute sponsored NRG Oncology, Washington University School of Medicine, St Louis, MO, USA;
*Current affiliation. Affiliation at time of study Arizona Center for Cancer Care, Creighton University School of Medicine Phoenix, AZ, USA

SGO ANNUAL MEETING ON WOMEN'S CANCER TAMPA, FL · 2023

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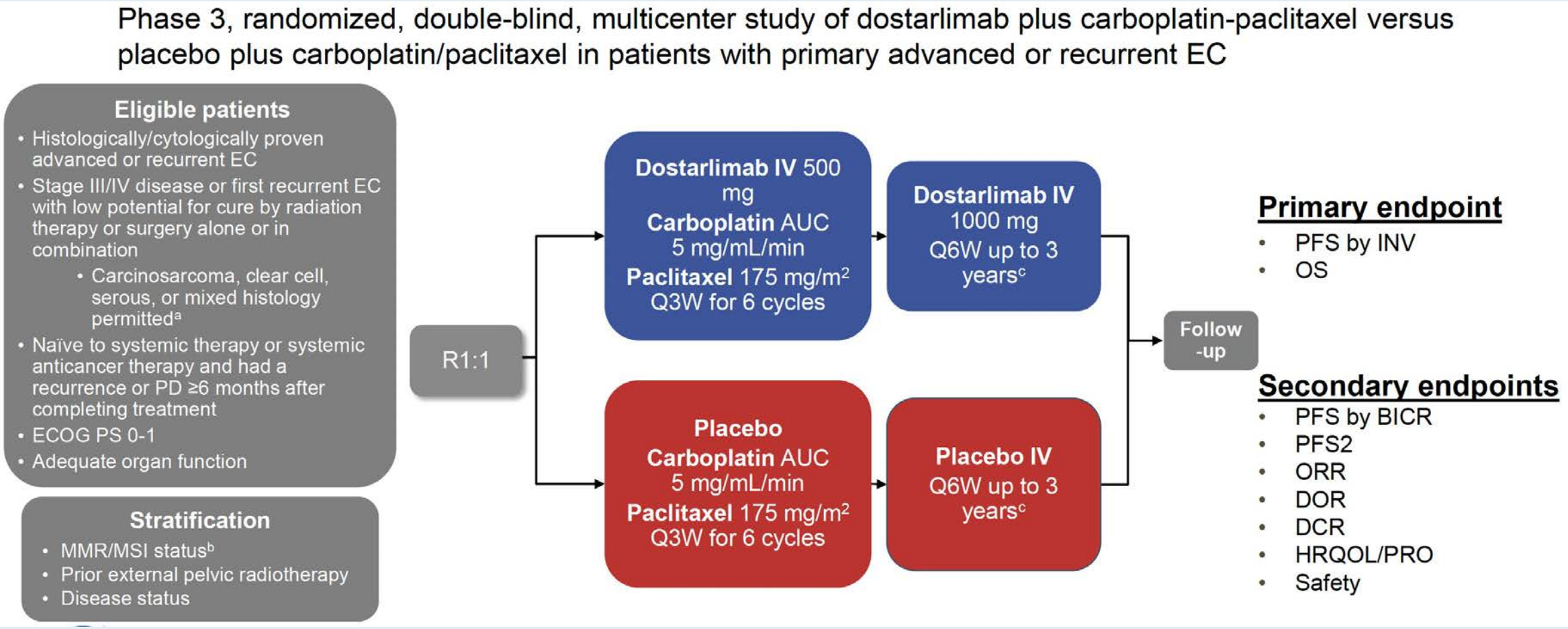
RTP RESEARCH TO PRACTICE

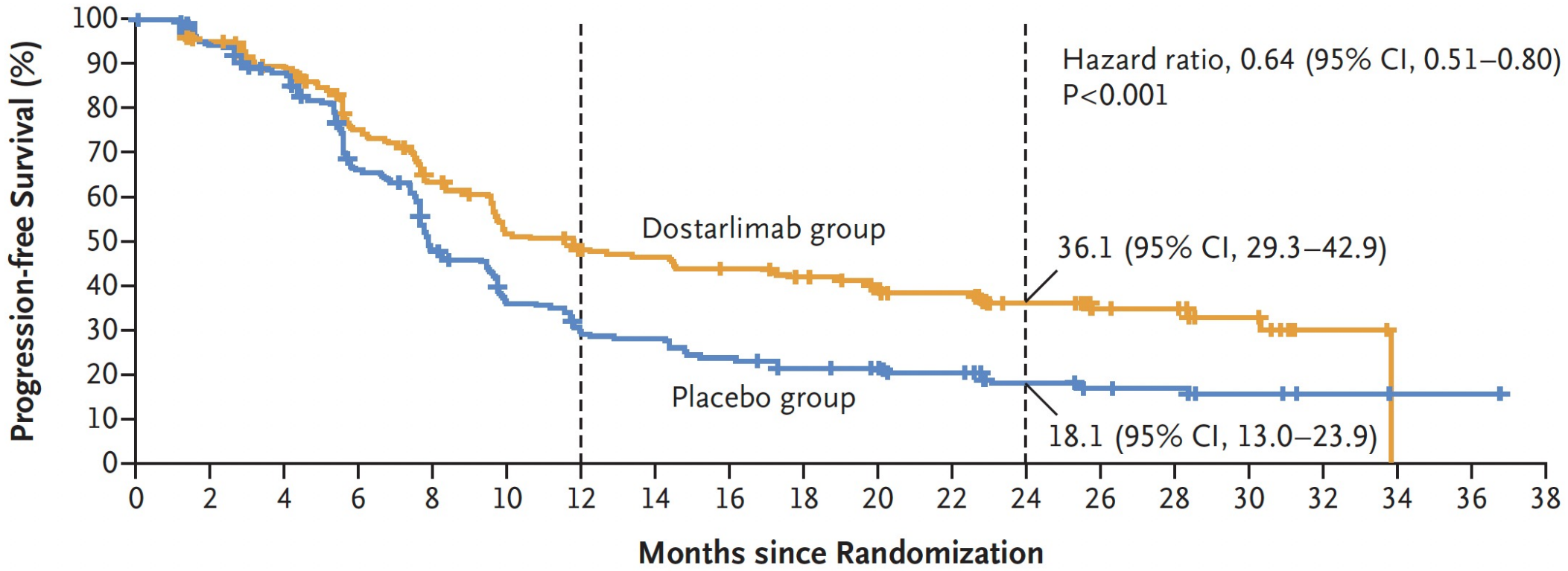
RUBY Phase III Study Design

Phase 3, randomized, double-blind, multicenter study of dostarlimab plus carboplatin-paclitaxel versus placebo plus carboplatin/paclitaxel in patients with primary advanced or recurrent EC



Mirza MR et al. SGO 2023;Abstract 265.

RUBY: Progression-Free Survival (Overall Population)

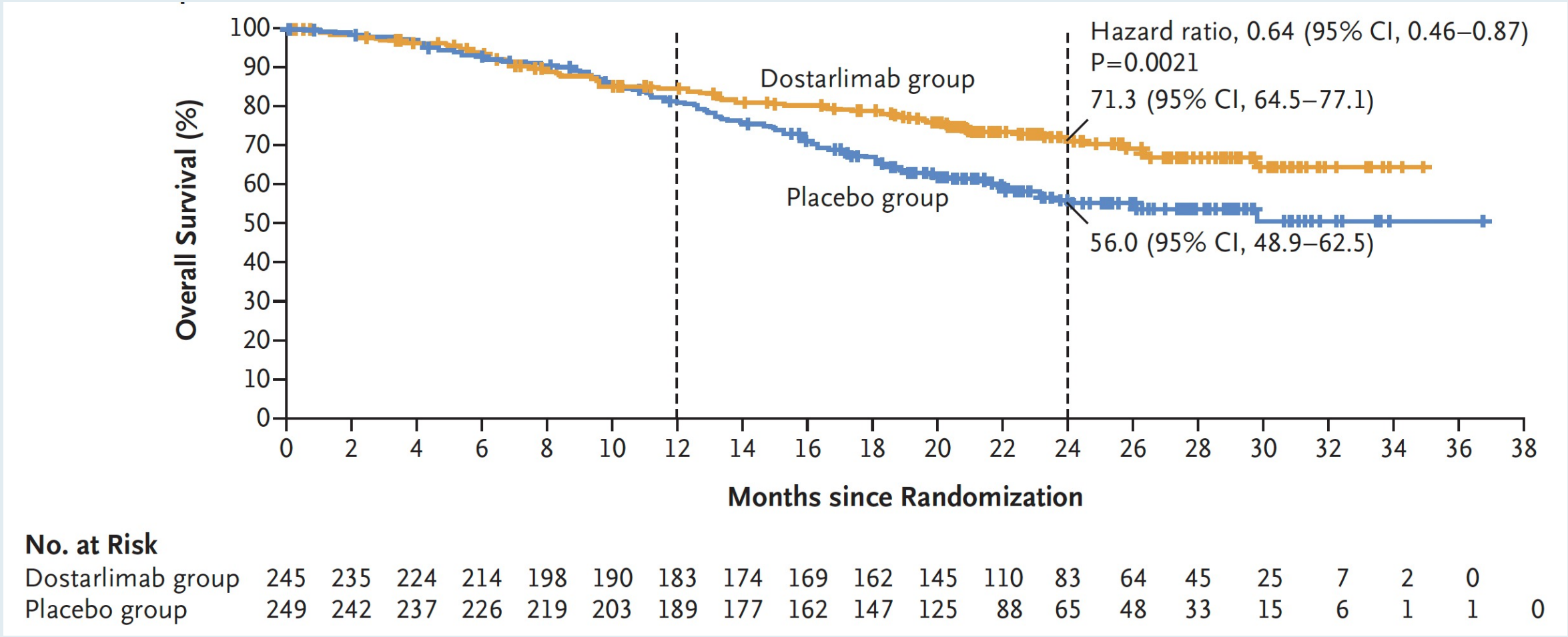


No. at Risk

Dostarlimab group	245	220	197	157	130	105	94	90	84	78	66	52	34	23	22	12	2	0		
Placebo group	249	219	200	144	103	74	59	57	48	42	39	32	20	14	13	5	2	1	1	0

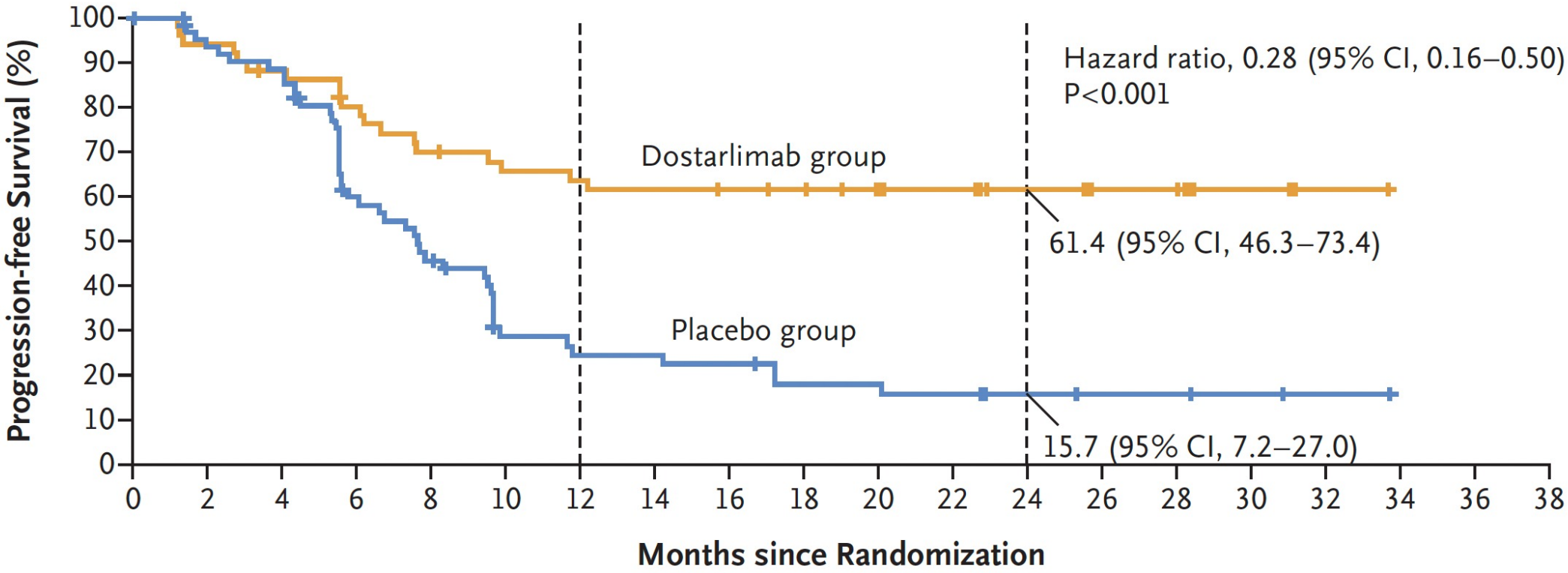
Mirza MR et al. *N Engl J Med* 2023 March;[Online ahead of print].

RUBY: Overall Survival (Overall Population)



Mirza MR et al. *N Engl J Med* 2023 March;[Online ahead of print].

RUBY: Progression-Free Survival (dMMR/MSI-H Population)

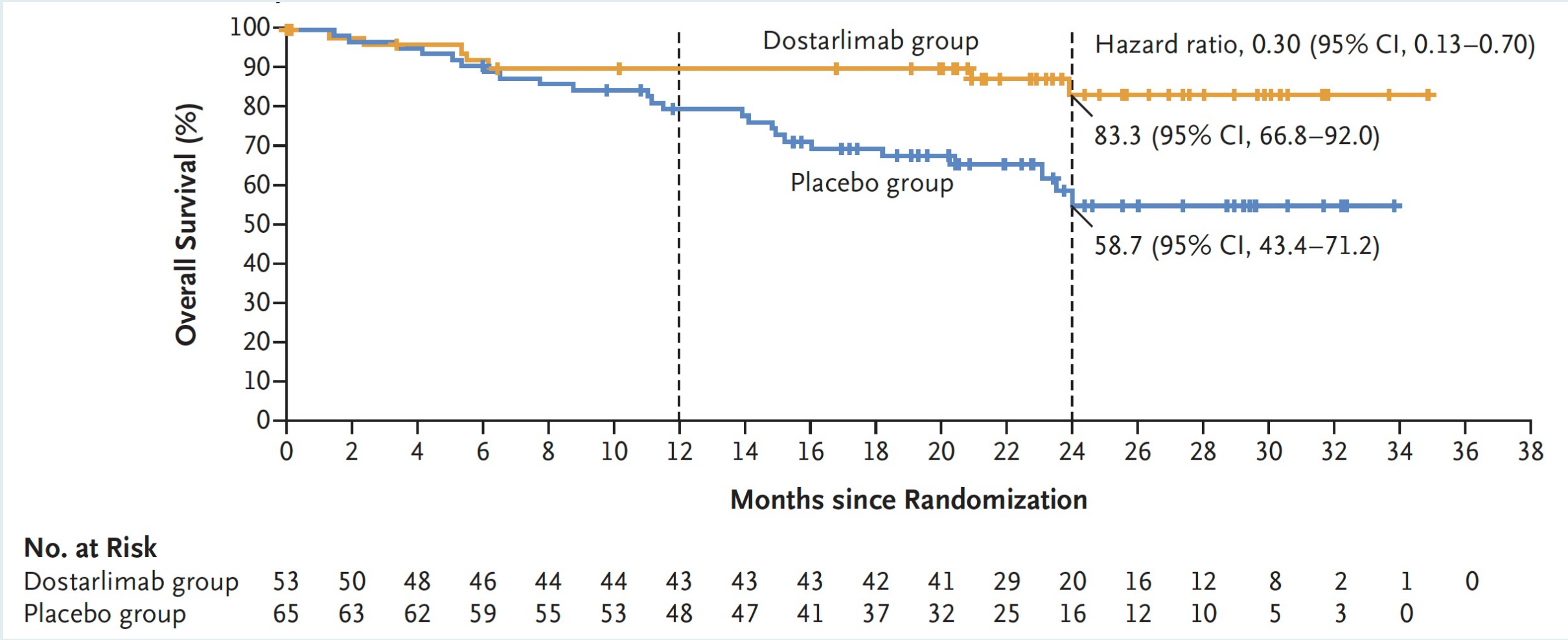


No. at Risk

Dostarlimab group	53	48	44	39	34	31	30	29	28	27	25	19	13	9	9	4	1	0
Placebo group	65	57	54	34	26	14	12	12	11	8	8	7	4	3	3	2	1	0

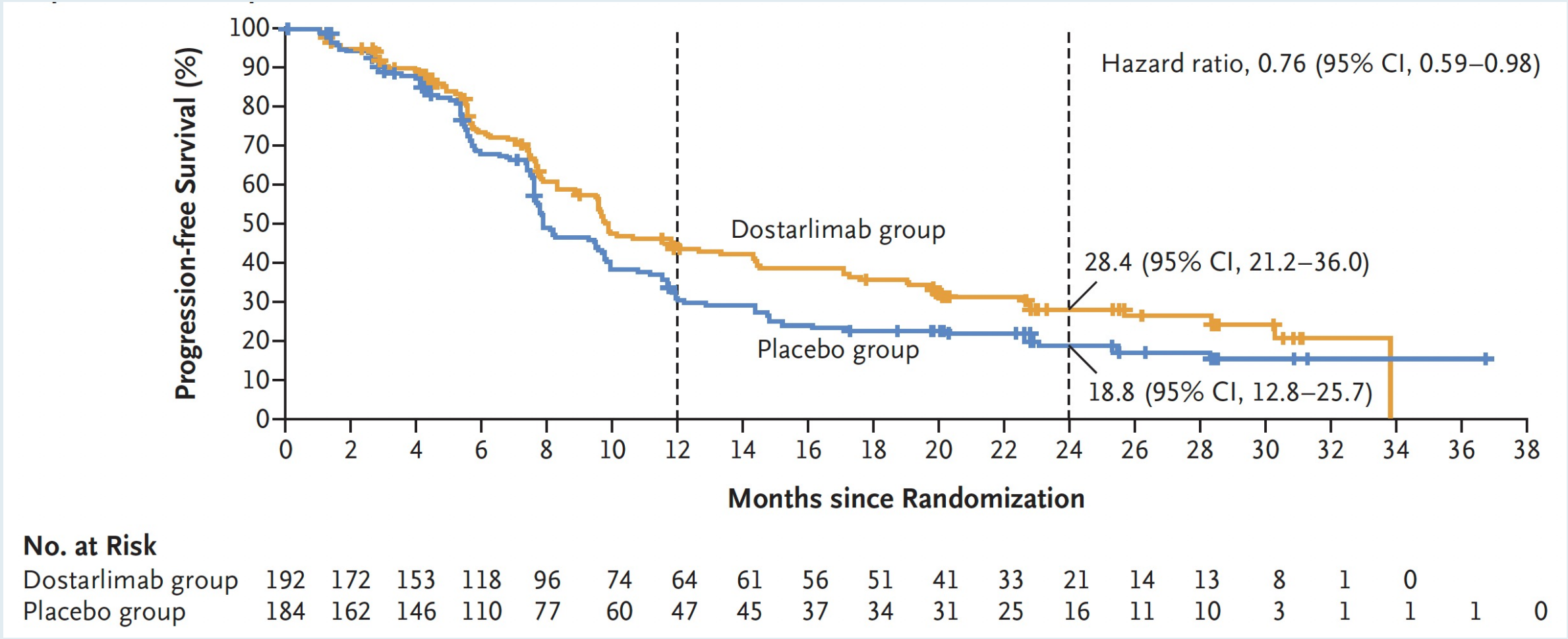
Mirza MR et al. *N Engl J Med* 2023 March;[Online ahead of print].

RUBY: Overall Survival (dMMR/MSI-H Population)



Mirza MR et al. *N Engl J Med* 2023 March;[Online ahead of print].

RUBY: Progression-Free Survival (pMMR/MSS Population)

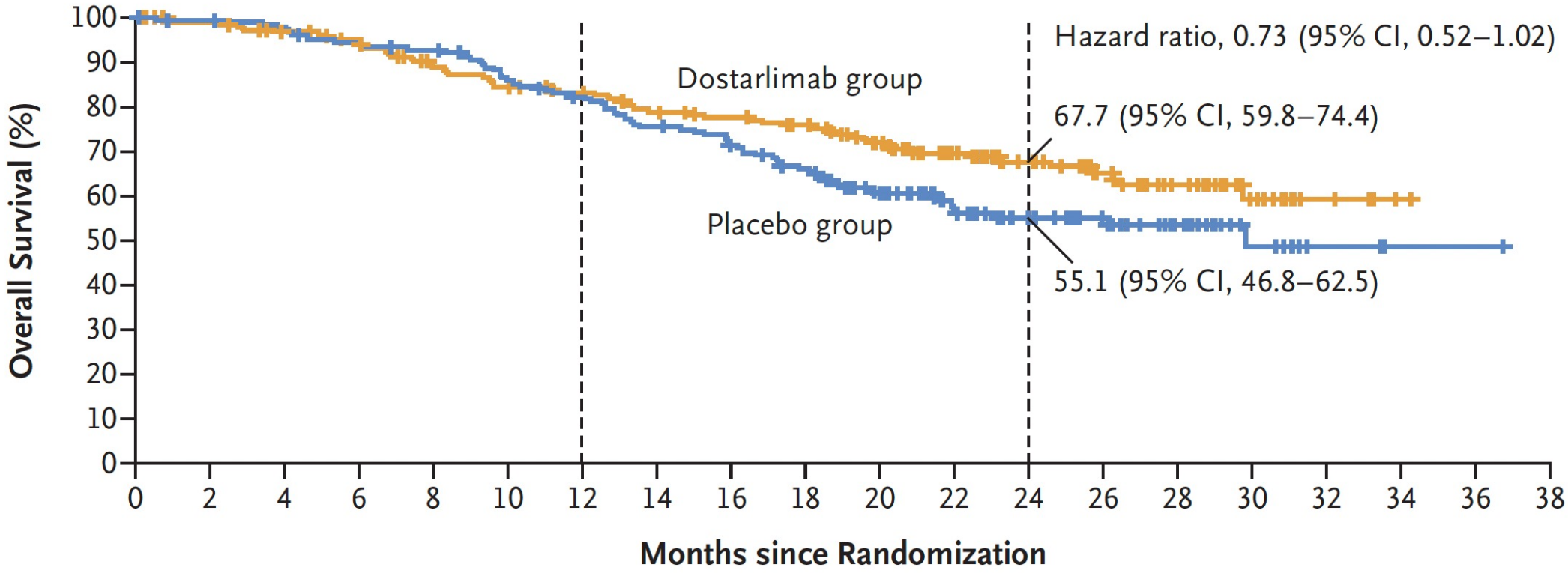


No. at Risk

Dostarlimab group	192	172	153	118	96	74	64	61	56	51	41	33	21	14	13	8	1	0	
Placebo group	184	162	146	110	77	60	47	45	37	34	31	25	16	11	10	3	1	1	1	0

Mirza MR et al. *N Engl J Med* 2023 March;[Online ahead of print].

RUBY: Overall Survival (pMMR/MSS Population)



No. at Risk

Dostarlimab group	192	185	176	168	154	146	140	131	126	120	104	81	63	48	33	17	5	1	0	
Placebo group	184	179	175	167	164	150	141	130	121	110	93	63	49	36	23	10	3	1	1	0

Mirza MR et al. *N Engl J Med* 2023 March;[Online ahead of print].

RUBY: Adverse Events

Event	Dostarlimab (N = 241)	Placebo (N = 246)
	no. of patients (%)	
Grade ≥3 events occurring in >5% of patients in either group		
Anemia	36 (14.9)	40 (16.3)
Neutropenia	23 (9.5)	23 (9.3)
Neutrophil count decreased	20 (8.3)	34 (13.8)
Lymphocyte count decreased	13 (5.4)	18 (7.3)
White-cell count decreased	16 (6.6)	13 (5.3)
Hypertension	17 (7.1)	8 (3.3)
Pulmonary embolism	12 (5.0)	12 (4.9)
Hypokalemia	12 (5.0)	9 (3.7)

Mirza MR et al. *N Engl J Med* 2023 March;[Online ahead of print].

N Engl J Med 2023 March;[Online ahead of print].

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Pembrolizumab plus Chemotherapy in Advanced Endometrial Cancer

Ramez N. Eskander, M.D., Michael W. Sill, Ph.D., Lindsey Beffa, M.D., Richard G. Moore, M.D., Joanie M. Hope, M.D., Fernanda B. Musa, M.D., Robert Mannel, M.D., Mark S. Shahin, M.D., Guilherme H. Cantuaria, M.D., Eugenia Girda, M.D., Cara Mathews, M.D., Juraj Kavecansky, M.D., Charles A. Leath III, M.D., M.S.P.H., Lilian T. Gien, M.D., Emily M. Hinchcliff, M.D., M.P.H., Shashikant B. Lele, M.D., Lisa M. Landrum, M.D., Floor Backes, M.D., Roisin E. O'Cearbhaill, M.D., Tareq Al Baghdadi, M.D., Emily K. Hill, M.D., Premal H. Thaker, M.D., Veena S. John, M.D., Stephen Welch, M.D., Amanda N. Fader, M.D., Matthew A. Powell, M.D., and Carol Aghajanian, M.D.

Pembrolizumab Versus Placebo in Addition to Carboplatin and Paclitaxel for Measurable Stage 3 or 4a, Stage 4b or Recurrent Endometrial Cancer: The Phase 3, NRG GY018 Study

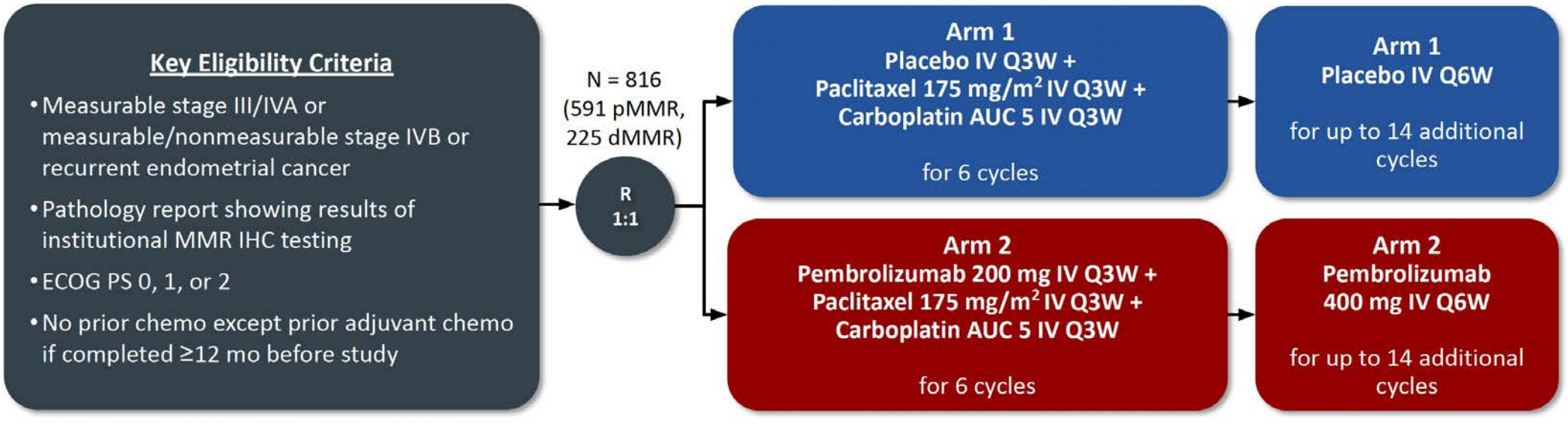
R.N. Eskander, M.W. Sill, L. Beffa, R.G. Moore, J. Mayer Hope, F.B. Musa, R. Mannel, M.S. Shahin, G.H. Cantuaria, E. Girda, C. Mathews, J. Kavecansky, C.A. Leath, III, L. Gien, E.M. Hinchcliff, S.B. Lele, L. Landrum, F. Backes, R.E. O'Cearbhaill, T. Al Baghdadi, E. Hill, P. Thaker, V.S. John, A. Nickles Fader, M.A. Powell, C. Aghajanian

SGO ANNUAL MEETING ON WOMEN'S CANCER TAMPA, FL • 2023

SGO 2023;Abstract 264.

RTP RESEARCH TO PRACTICE

NRG-GY018 Phase III Study Design



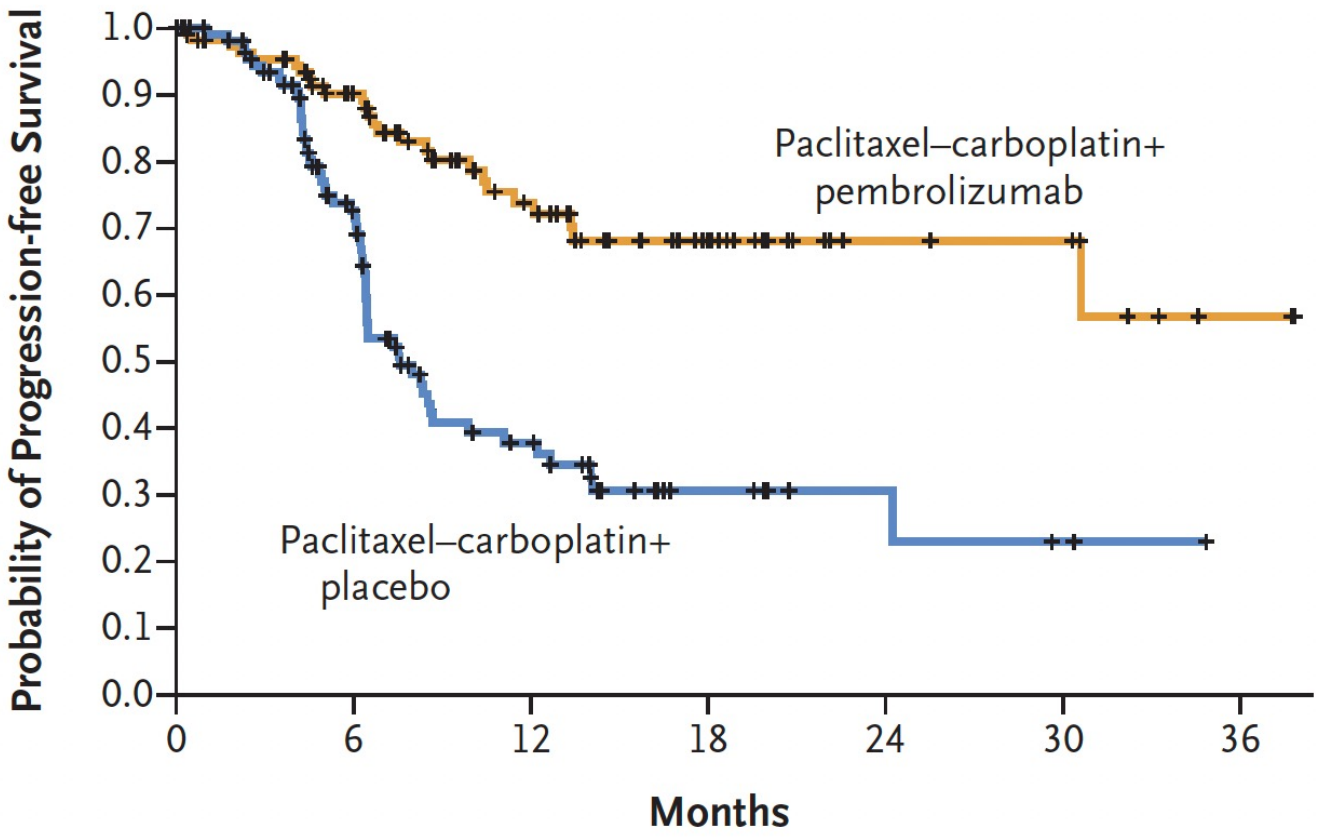
SGO ANNUAL MEETING ON WOMEN'S CANCER TAMPA, FL • 2023 PATIENTS • PURPOSE • PROGRESS

BICR, blinded independent central review; dMMR, mismatch repair deficient; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IHC, immunohistochemistry; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; pMMR, mismatch repair proficient; PRO, patient-reported outcomes; QoL, quality of life; RECIST, Response Evaluation Criteria in Solid Tumors.

Eskander RN et al. SGO 2023;Abstract 264.

RTP RESEARCH TO PRACTICE

NRG-GY018: Progression-Free Survival (dMMR Cohort)

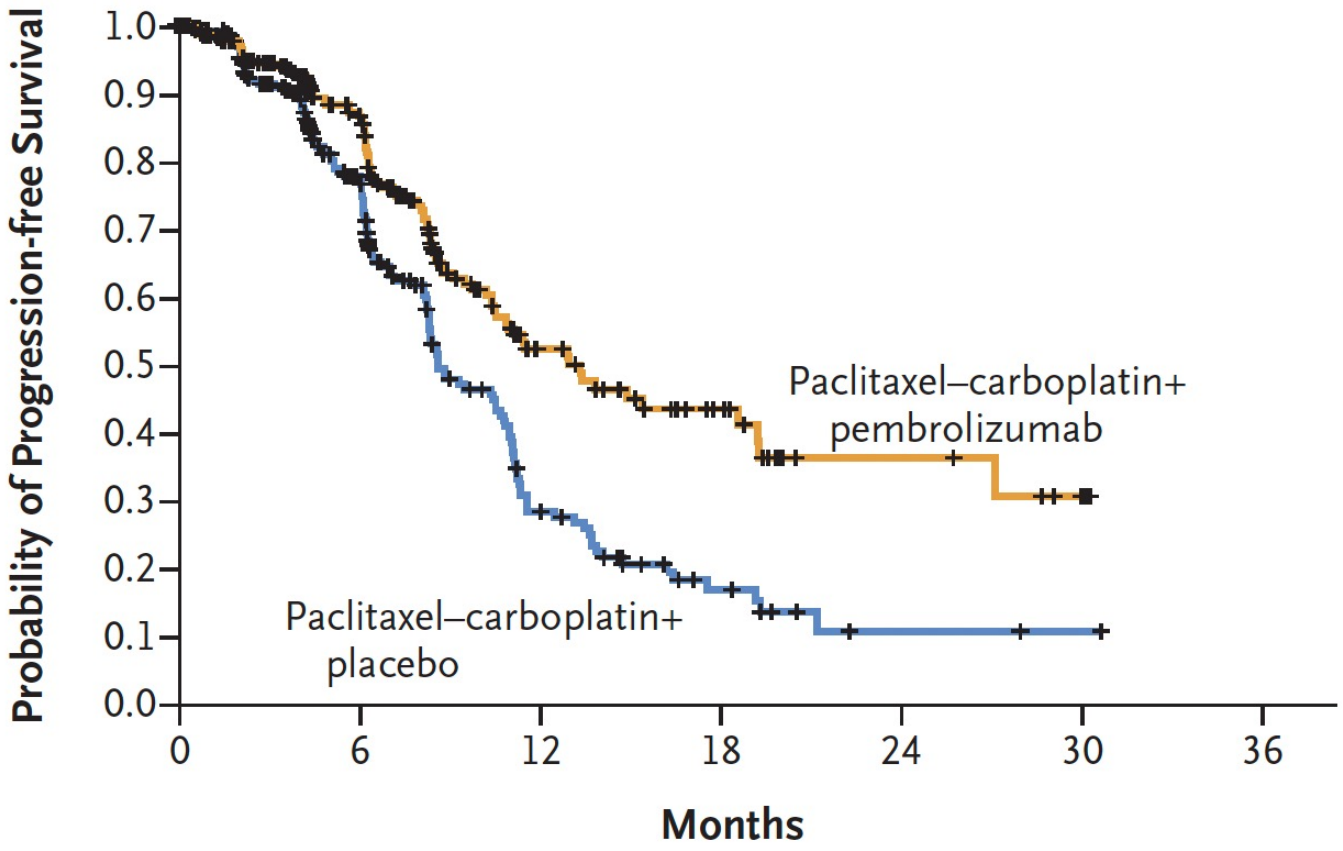


	No. of Events	No. of Patients	Median Progression-free Survival (95% CI)
			mo
Paclitaxel–Carboplatin+ Pembrolizumab	26	112	NR (30.6–NR)
Paclitaxel–Carboplatin+ Placebo	59	113	7.6 (6.4–9.9)

Hazard ratio for disease progression or death, 0.30 (95% CI, 0.19–0.48)

Eskander RN et al. *N Engl J Med* 2023 March;[Online ahead of print].

NRG-GY018: Progression-Free Survival (pMMR Cohort)



	No. of Events	No. of Patients	Median Progression-free Survival (95% CI)
			mo
Paclitaxel–Carboplatin+ Pembrolizumab	89	290	13.1 (10.5–18.8)
Paclitaxel–Carboplatin+ Placebo	133	292	8.7 (8.4–10.7)

Stratified hazard ratio for disease progression or death, 0.54 (95% CI, 0.41–0.71)

Eskander RN et al. *N Engl J Med* 2023 March;[Online ahead of print].

NRG-GY018: Adverse Events of Interest

Adverse Event	dMMR Cohort (N=215)				pMMR Cohort (N=550)			
	Pembrolizumab (N=109)		Placebo (N=106)		Pembrolizumab (N=276)		Placebo (N=274)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3	Any Grade	Grade ≥3	Any Grade	Grade ≥3
	number of patients (percentage)							
Any event	42 (38.5)	9 (8.3)	28 (26.4)	6 (5.7)	92 (33.3)	10 (3.6)	54 (19.7)	7 (2.6)
Infusion reaction	16 (14.7)	4 (3.7)	16 (15.1)	3 (2.8)	41 (14.9)	4 (1.4)	35 (12.8)	5 (1.8)
Hypothyroidism	14 (12.8)	0	10 (9.4)	0	37 (13.4)	0	7 (2.6)	0
Hyperthyroidism	10 (9.2)	0	1 (0.9)	0	16 (5.8)	0	10 (3.6)	0
Colitis	7 (6.4)	0	0	0	4 (1.4)	0	4 (1.5)	1 (0.4)
Pneumonitis	3 (2.8)	2 (1.8)	2 (1.9)	1 (0.9)	2 (0.7)	0	1 (0.4)	0
Glucose intolerance	2 (1.8)	0	0	0	0	0	0	0
Acute kidney injury	2 (1.8)	2 (1.8)	2 (1.9)	2 (1.9)	5 (1.8)	5 (1.8)	1 (0.4)	1 (0.4)
Hepatic failure	1 (0.9)	1 (0.9)	0	0	0	0	0	0
Myositis	1 (0.9)	0	1 (0.9)	0	1 (0.4)	0	0	0
Hypophysitis	0	0	0	0	2 (0.7)	2 (0.7)	0	0
Pancreatitis	0	0	0	0	1 (0.4)	0	0	0
Adrenal insufficiency	0	0	0	0	4 (1.4)	0	1 (0.4)	0

Eskander RN et al. *N Engl J Med* 2023 March;[Online ahead of print].

RTP RESEARCH TO PRACTICE

Prospective double-blind, randomized phase III ENGOT-EN5/GOG-3055/SIENDO study of oral selinexor/placebo as maintenance therapy after first-line chemotherapy for advanced or recurrent endometrial cancer

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ANNUAL MEETING ON WOMENS' CANCER®
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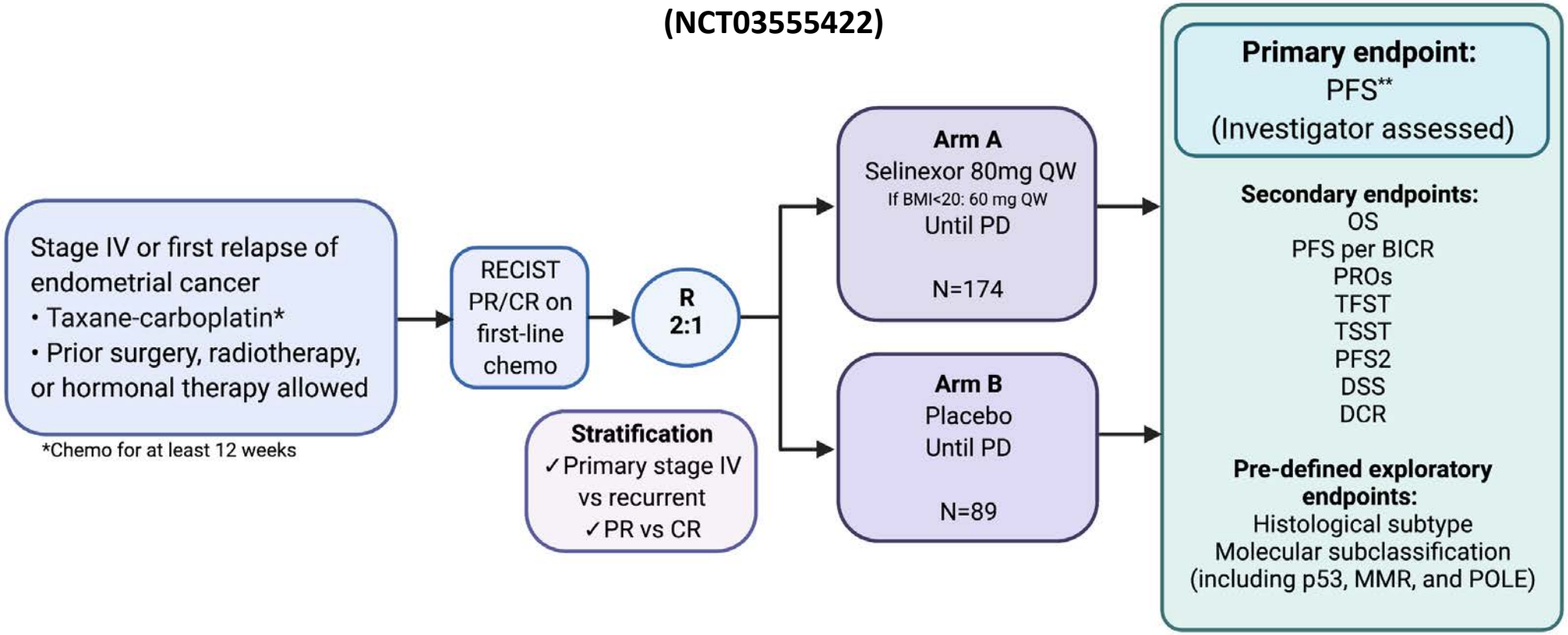
SGO // PHOENIX, ARIZONA // MARCH 18 – 21, 2022

Abstract 249

SIENDO Phase III Trial Design

Stage IV or first relapse of endometrial cancer endometrioid, serous, undifferentiated, or carcinosarcoma (NCT03555422)

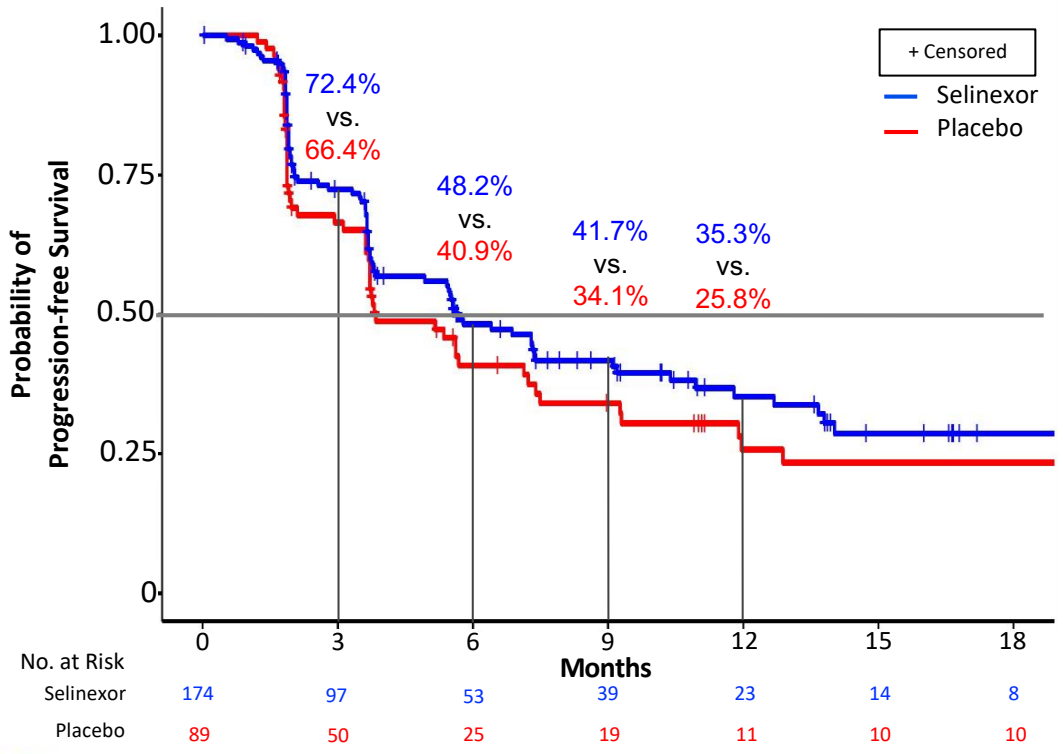


**140 PFS events needed to provide 80% power to detect a hazard ratio of 0.6 (median PFS 4.5 months for placebo and 7.5 months for selinexor) with a one-sided alpha of 0.025 and 2:1 randomization ratio favoring selinexor.

Vergote I et al. SGO 2022;Abstract 249.

SIENDO: Progression-Free Survival in ITT Population

(based on audited stratification factors)*



Median PFS (Investigator assessed)

Selinexor (n=174): 5.7 mo (95% CI 3.81-9.20)

Placebo (n=89): 3.8 mo (95% CI 3.68-7.39)

HR* = 0.705 (95% CI 0.499-0.996)

One-sided *p* value = 0.024

* In 7 patients (2.7% of 263), the stratification factor of CR/PR was incorrect and was corrected by the Investigators prior to database lock and unblinding.

The statistical analysis was validated by the independent ENGOT statistician and approved by the IDMC.

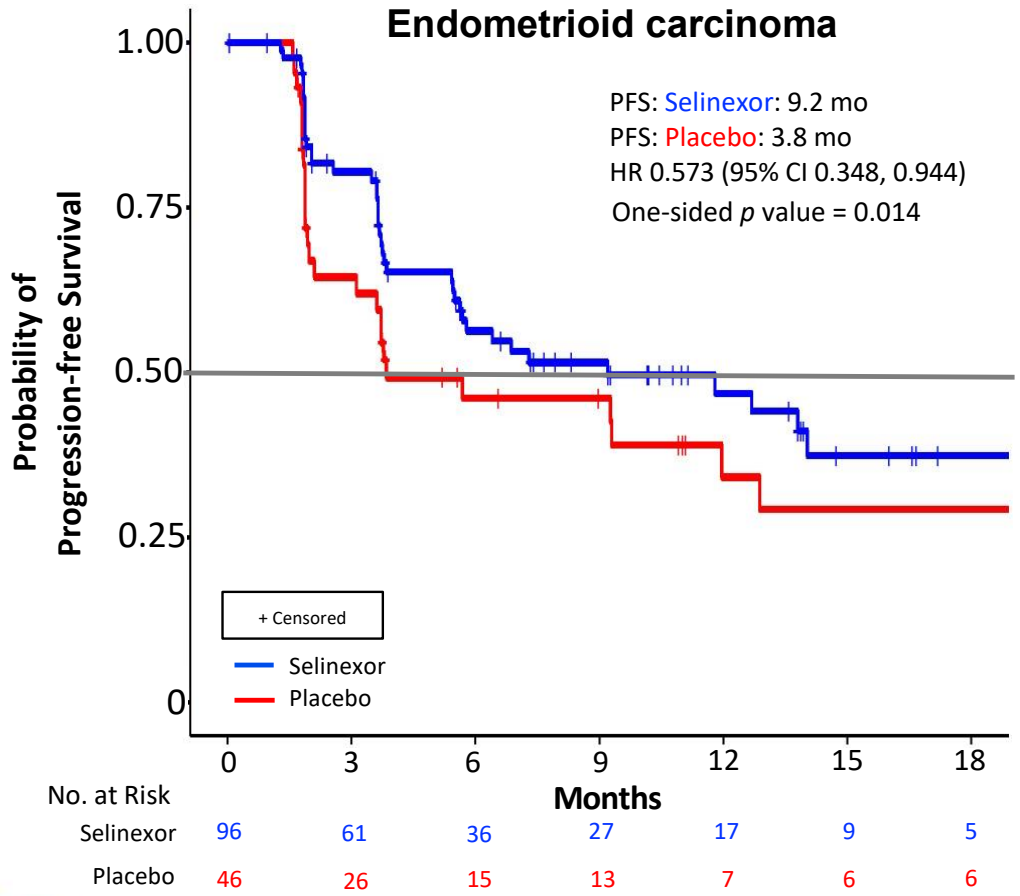
HR for ITT without correction of the stratification factors was 0.76 (95% CI: 0.543, 1.076).

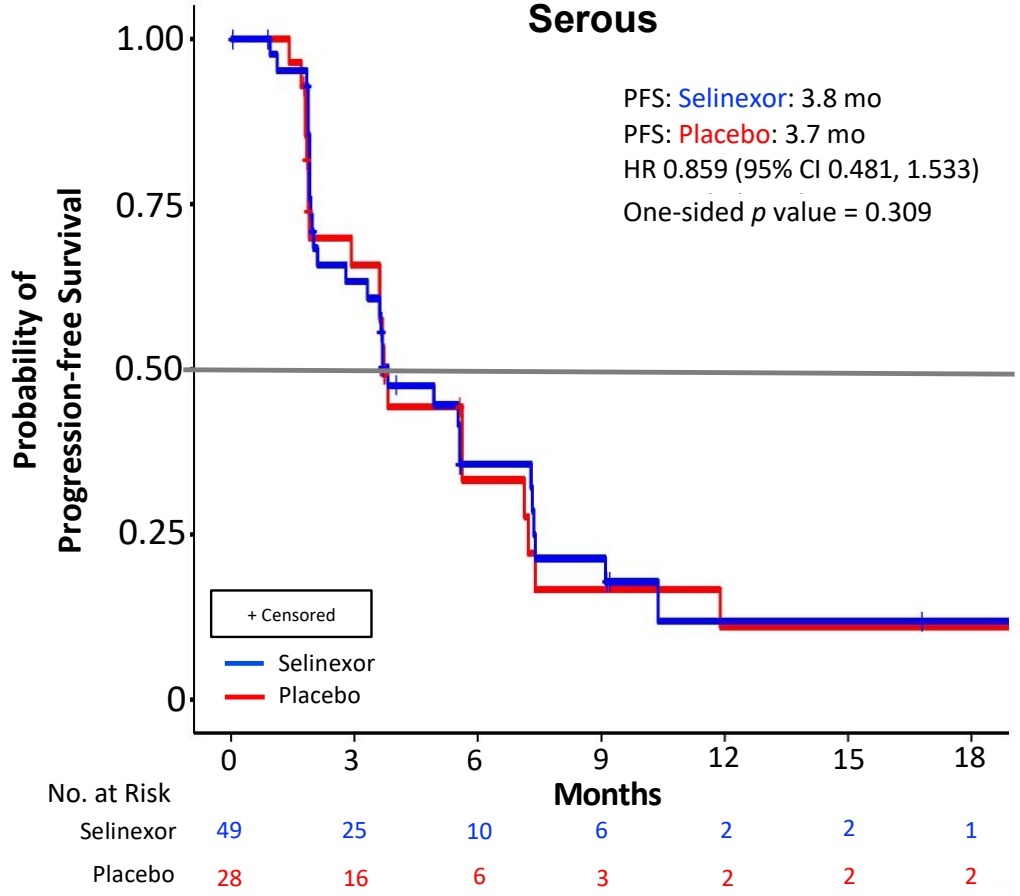
Median follow-up: 10.2 months (95% CI 8.97, 13.57)

Vergote I et al. SGO 2022;Abstract 249.

SIENDO: Progression-Free Survival by Histological Subtype

(based on audited stratification factors)



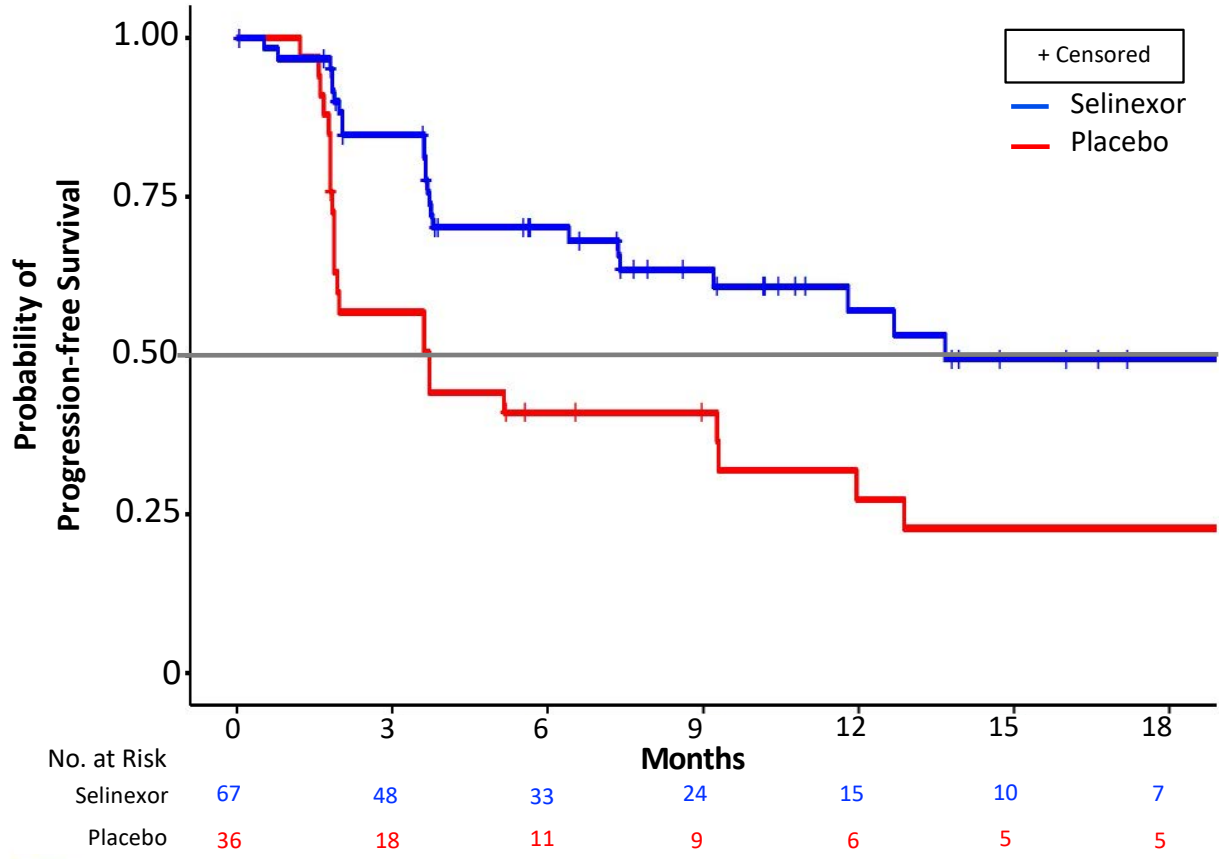


Vergote I et al. SGO 2022;Abstract 249.

RTP RESEARCH TO PRACTICE

SIENDO: Progression-Free Survival for Patients with Wild Type p53

(based on audited stratification factors)



Median PFS

Selinexor (n=67): 13.7 mo (95% CI 9.20-NR)

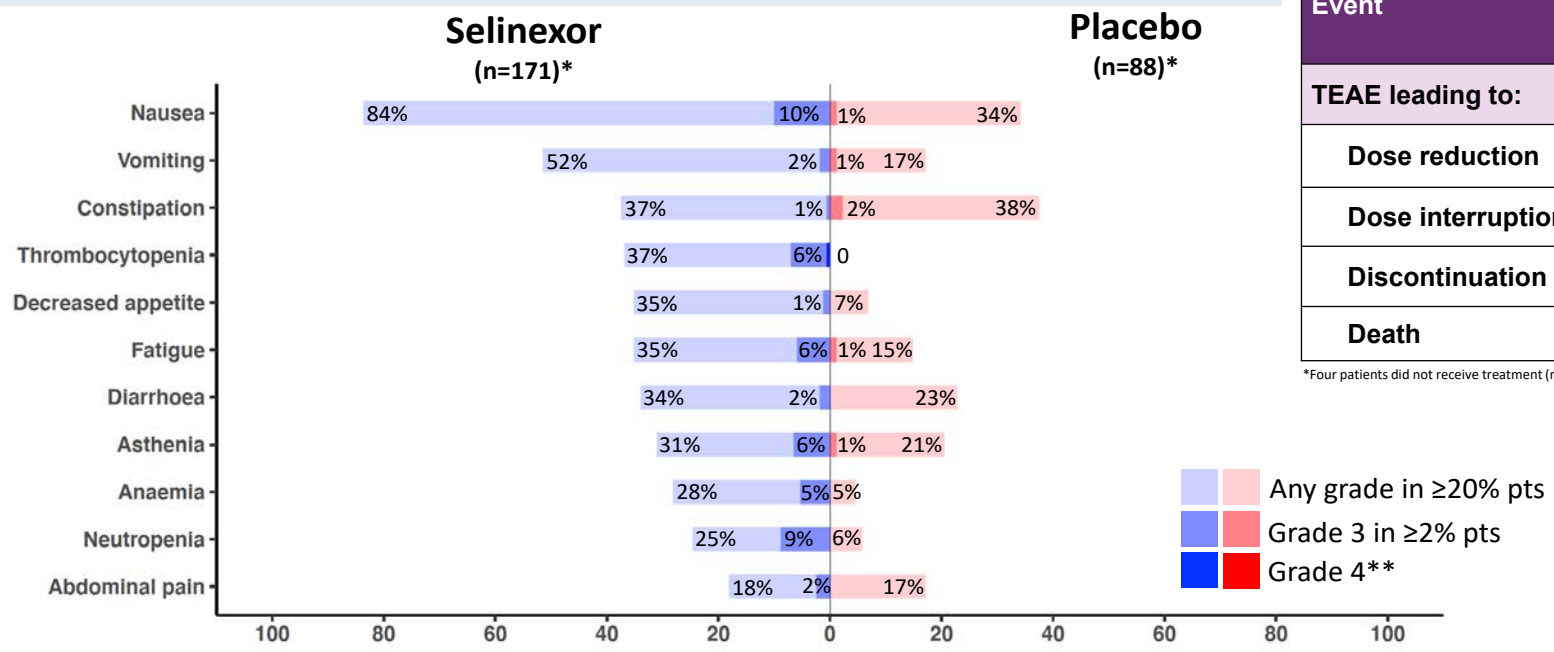
Placebo (n=36): 3.7 mo (95% CI 1.87-12.88)

HR = 0.375 (95% CI 0.210-0.670)

One-sided *p* value = 0.0003

Vergote I et al. SGO 2022;Abstract 249.

SIENDO: Treatment-Emergent Adverse Events (TEAEs)



*Four patients did not receive treatment (n=3 selinexor; n=1 placebo)
**n=1 Grade 4 thrombocytopenia; No cases of severe bleeding in patients with thrombocytopenia; No cases of febrile neutropenia

Event	Selinexor n=171* n (%) (per patient)	Placebo n=88* n (%) (per patient)
TEAE leading to:		
Dose reduction	85 (49.7)	3 (3.4)
Dose interruption	88 (51.5)	16 (18.2)
Discontinuation	18 (10.5)	1 (1.1)
Death	0	0

*Four patients did not receive treatment (n=3 selinexor; n=1 placebo)

Vergote I et al. SGO 2022;Abstract 249.

RTP RESEARCH TO PRACTICE

Cervical Cancer

FDA Grants Accelerated Approval to Tisotumab Vedotin-tftv for Previously Treated Recurrent or Metastatic Cervical Cancer

Press Release – September 20, 2021

"[The FDA] has granted accelerated approval to tisotumab vedotin-tftv, the first and only approved antibody-drug conjugate (ADC) for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Tisotumab vedotin-tftv is approved under the FDA's Accelerated Approval Program based on tumor response and the durability of the response. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials."

The accelerated approval was based on results from the innovaTV 204 trial. InnovaTV 301, a global, randomized, Phase III clinical trial intended to support global registrations, is underway. The prescribing information for tisotumab vedotin-tftv includes a boxed warning for ocular toxicity and warnings for peripheral neuropathy, hemorrhage, pneumonitis and embryo-fetal toxicity.

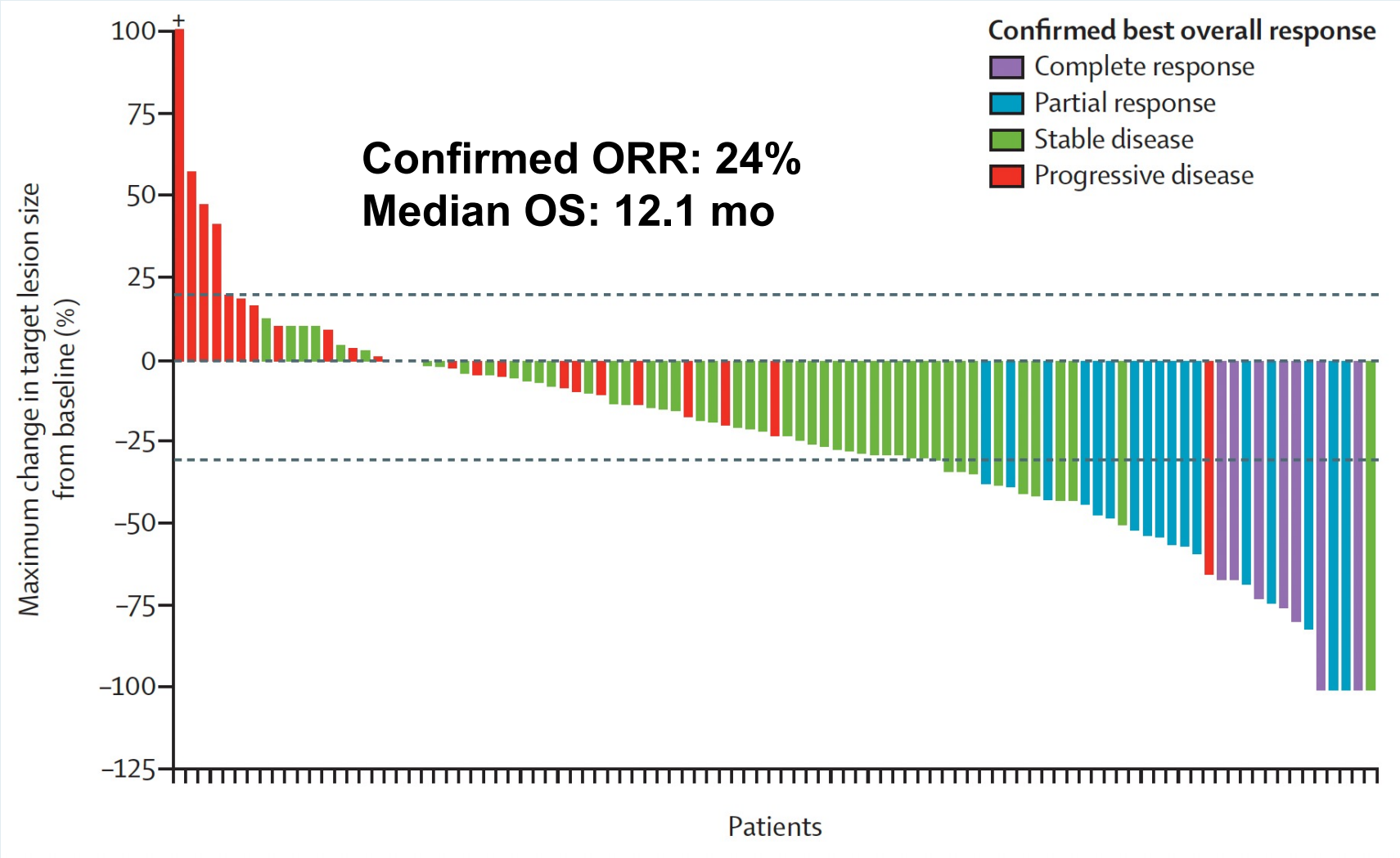
https://investor.seagen.com/press-releases/news-details/2021/Seagen-and-Genmab-Announce-FDA-Accelerated-Approval-for-TIVDAK-tisotumab-vedotin-tftv-in-Previously-Treated-Recurrent-or-Metastatic-Cervical-Cancer/default.aspx

Lancet Oncol 2021;22(5):609-19.

Efficacy and safety of tisotumab vedotin in previously treated recurrent or metastatic cervical cancer (innovaTV 204/GOG-3023/ENGOT-cx6): a multicentre, open-label, single-arm, phase 2 study

*Robert L Coleman, Domenica Lorusso, Christine Gennigens, Antonio González-Martín, Leslie Randall, David Cibula, Bente Lund, Linn Woelber, Sandro Pignata, Frederic Forget, Andrés Redondo, Signe Diness Vindeløv, Menghui Chen, Jeffrey R Harris, Margaret Smith, Leonardo Viana Nicacio, Melinda S L Teng, Annouschka Laenen, Reshma Rangwala, Luis Manso, Mansoor Mirza, Bradley J Monk, Ignace Vergote, on behalf of the innovaTV 204/GOG-3023/ENGOT-cx6 Collaborators**

innovaTV 204: Tisotumab Vedotin for Previously Treated Recurrent or Metastatic Cervical Cancer



Coleman RL et al. *Lancet Oncol* 2021;22(5):609-19.

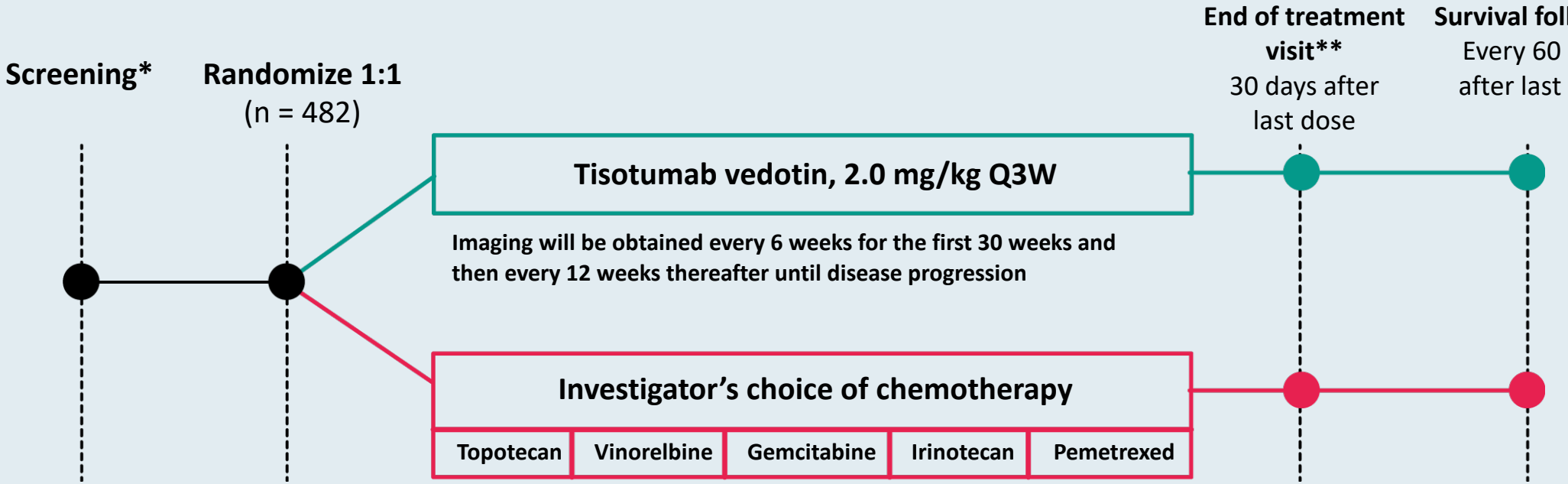
innovaTV 204: Treatment-Related Adverse Events with an Incidence of ≥15%

	Grade 1–2	Grade 3	Grade 4	Grade 5
Patients with at least one treatment-related adverse event	65 (65%)	25 (25%)	2 (2%)	1 (1%)
Treatment-related adverse events, by preferred terms, with an incidence of 15% or higher, or any grade 3 or worse event				
Alopecia	38 (38%)	0	0	0
Epistaxis	30 (30%)	0	0	0
Nausea	27 (27%)	0	0	0
Conjunctivitis	26 (26%)	0	0	0
Fatigue	24 (24%)	2 (2%)	0	0
Dry eye	23 (23%)	0	0	0
Myalgia	15 (15%)	0	0	0

Coleman RL et al. *Lancet Oncol* 2021;22(5):609-19.

RTP RESEARCH TO PRACTICE

Ongoing Phase III innovaTV 301 Confirmatory Trial of Tisotumab Vedotin in Second- or Third-Line Metastatic Cervical Cancer



* The proportion of patients who have not received prior bevacizumab in combination with chemotherapy as 1L treatment may be capped at 50%

** Some AESIs may be followed longer than 30 days until resolution, improvement, or stabilization

Abbreviations: 1L = first-line; AESI = adverse event of special interest; n = number of patients; Q3W = every 3 weeks

www.clinicaltrials.gov. NCT04697628. Accessed April 21, 2023.

What I Tell My Patients:
Faculty Physicians and Nurses Discuss Patient Education About New Treatments and Clinical Trials

Fifteenth Annual RTP Symposium Series Held During the Annual ONS Congress

Cervical and Endometrial Cancer

Wednesday, April 26, 2023
11:15 AM – 12:45 PM

Faculty

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

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

What I Tell My Patients:
Faculty Physicians and Nurses Discuss Patient Education About New Treatments and Clinical Trials

Fifteenth Annual RTP Symposium Series Held During the Annual ONS Congress

Breast Cancer

Wednesday, April 26, 2023
6:00 PM – 8:00 PM

Faculty

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

Moderator

Neil Love, MD

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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.

In-person attendees can use the networked iPads® to claim NCPD credit or use the QR code as instructed in the program syllabus.

Virtual attendees: The NCPD credit link is posted in the chat room.

NCPD/ONCC credit information will be emailed to each participant within 1 to 2 business days.

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