Cancer Conference Update: What Happened at the 2020 San Antonio Breast Cancer Symposium®

Management of Triple-Negative Breast Cancer

Monday, February 22, 2021
5:00 PM – 6:00 PM ET

Faculty

Joyce O'Shaughnessy, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Faculty

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

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Commercial Support

This activity is supported by educational grants from AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Eisai Inc, Genentech, a member of the Roche Group, and Merck.

Dr Love — Disclosures

Dr Love is president and CEO of Research To Practice. Research To Practice receives funds in the form of educational grants to develop CME activities from the following commercial interests: AbbVie Inc, Acerta Pharma — A member of the AstraZeneca Group, Adaptive Biotechnologies Corporation, Agendia Inc, Agios Pharmaceuticals Inc, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, Biodesix Inc, bioTheranostics Inc, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Daiichi Sankyo Inc, Dendreon Pharmaceuticals Inc, Eisai Inc, EMD Serono Inc, Epizyme Inc, Exact Sciences Inc, Exelixis Inc, Five Prime Therapeutics Inc, Foundation Medicine, Genentech, a member of the Roche Group, Genmab, Gilead Sciences Inc, GlaxoSmithKline, Grail Inc, Guardant Health, Halozyme Inc, Helsinn Healthcare SA, ImmunoGen Inc, Incyte Corporation, Infinity Pharmaceuticals Inc, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Karyopharm Therapeutics, Kite, A Gilead Company, Lexicon Pharmaceuticals Inc, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, Merck, Merrimack Pharmaceuticals Inc, Myriad Genetic Laboratories Inc, Natera Inc, Novartis, Novocure Inc, Oncopeptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Prometheus Laboratories Inc, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sandoz Inc, a Novartis Division, Sanofi Genzyme, Seagen Inc, Sirtex Medical Ltd, Spectrum Pharmaceuticals Inc, Sumitomo Dainippon Pharma Oncology Inc, Taiho Oncology Inc, Takeda Oncology, Tesaro, A GSK Company, Teva Oncology, Tokai Pharmaceuticals Inc and Verastem Inc.

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

Dr O'Shaughnessy — Disclosures

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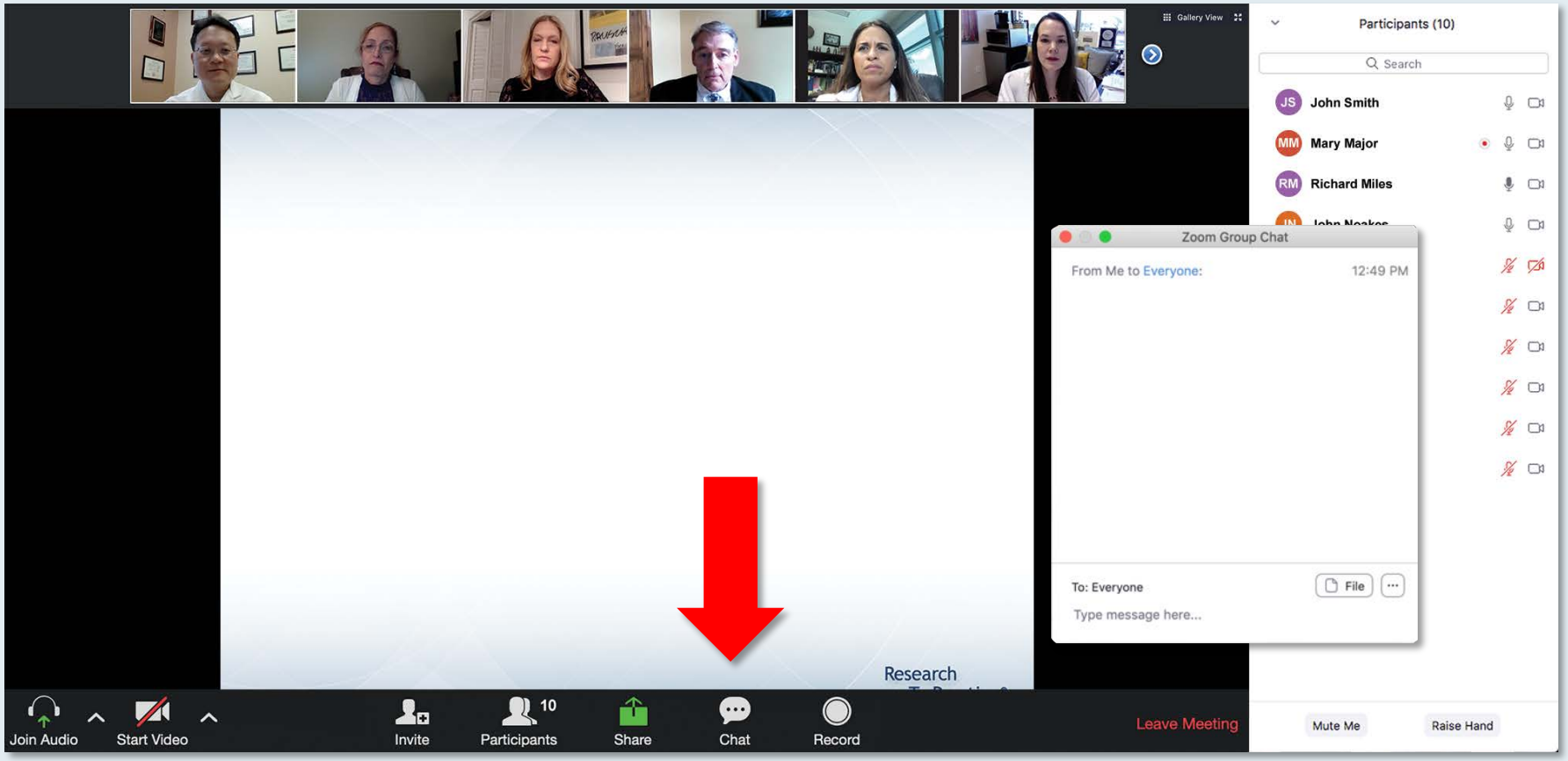
Speakers Bureau	AstraZeneca Pharmaceuticals LP, Lilly, Novartis, Seagen Inc

We Encourage Clinicians in Practice to Submit Questions



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Familiarizing Yourself with the Zoom Interface

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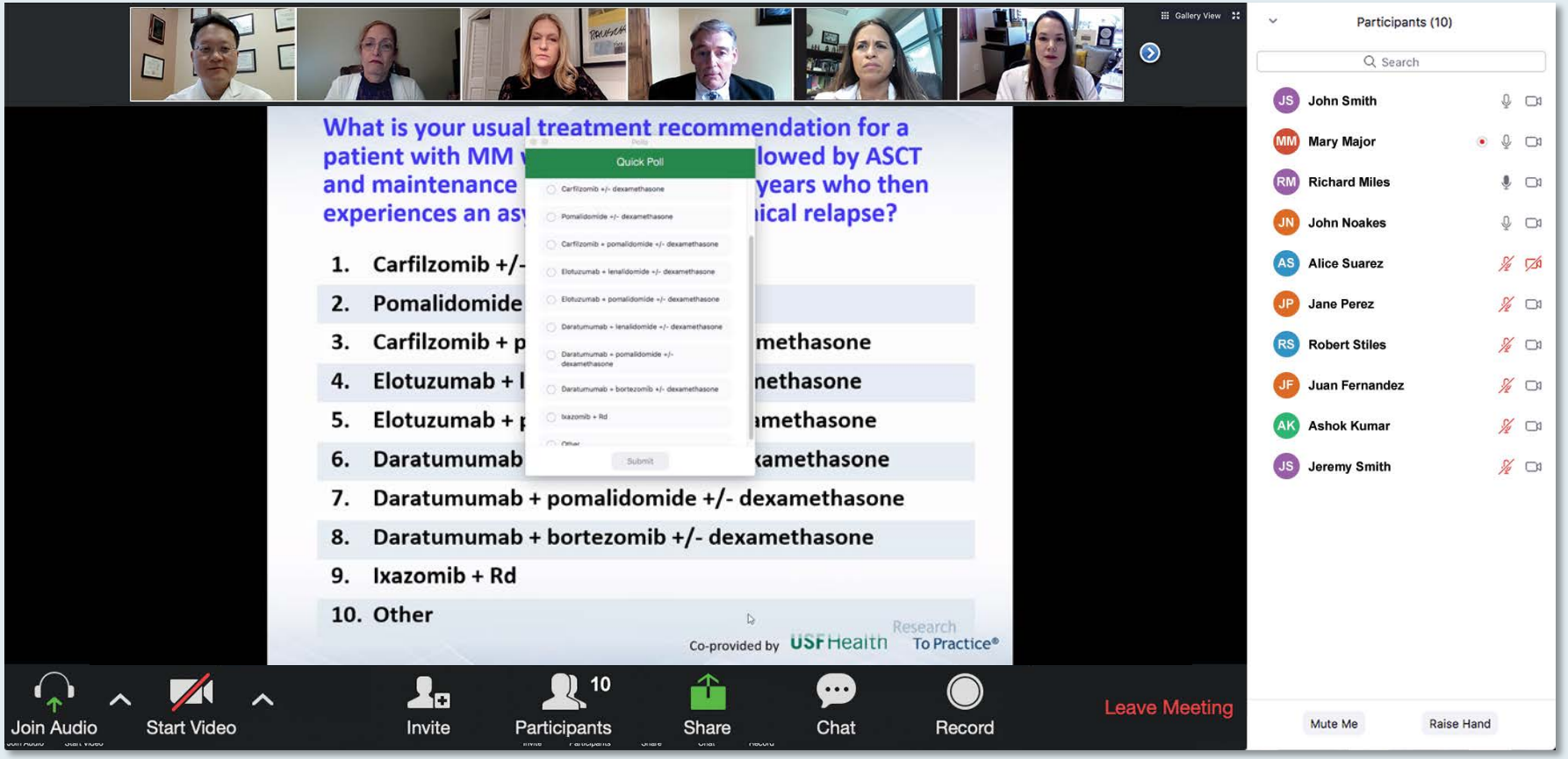

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ONCOLOGY TODAY

WITH DR NEIL LOVE

The Role of PARP Inhibition in the Management of Breast Cancer

HOPE S RUGO, MD
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Cases from the Community: Investigators Discuss Emerging Research and Actual Patients with Prostate Cancer (Part 1 of a 3-Part Series)

Thursday, February 25, 2021
5:00 PM – 6:30 PM ET

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Tanya B Dorff, MD
Fred Saad, MD
A Oliver Sartor, MD
Matthew R Smith, MD, PhD

Moderator

Neil Love, MD

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Cases from the Community: Investigators Discuss Emerging Research and Actual Patients with Renal Cell Carcinoma (Part 2 of a 3-Part Series)

Monday, March 1, 2021
5:00 PM – 6:00 PM ET

Faculty

Thomas E Hutson, DO, PharmD
Thomas Powles, MBBS, MRCP, MD

Moderator

Neil Love, MD

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Meet The Professor
Management of Ovarian Cancer

Tuesday, March 2, 2021
5:00 PM – 6:00 PM ET

Faculty

Thomas J Herzog, MD

Moderator

Neil Love, MD

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Meet The Professor
Management of Multiple Myeloma

Wednesday, March 3, 2021
5:00 PM – 6:00 PM ET

Faculty

Morie A Gertz, MD, MACP

Moderator

Neil Love, MD

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TO PRACTICE

Cases from the Community: Investigators Discuss Emerging Research and Actual Patients with Urothelial Bladder Carcinoma (Part 3 of a 3-Part Series)

Thursday, March 4, 2021
5:00 PM – 6:15 PM ET

Faculty

Arjun Balar, MD
Elisabeth I Heath, MD
Jonathan E Rosenberg, MD

Moderator

Neil Love, MD

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Cancer Conference Update: What Happened at the 2020 San Antonio Breast Cancer Symposium®

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Monday, March 8, 2021
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Mark D Pegram, MD

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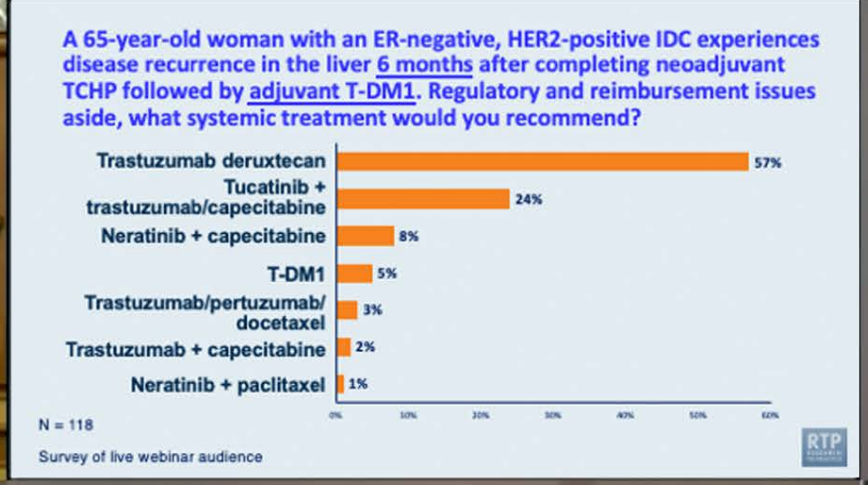
Thank you for joining us!

CME credit information will be emailed to each participant within 3 business days.


A 65-year-old woman with an ER-negative, HER2-positive IDC experiences disease recurrence in the liver 6 months after completing neoadjuvant TCHP followed by adjuvant T-DM1. Regulatory and reimbursement issues aside, what systemic treatment would you recommend?
Trastuzumab deruxtecan
57%
Tucatinib + trastuzumab/capecitabine
24%
Neratinib + capecitabine
8%
T-DM1
5%
Trastuzumab/pertuzumab/ docetaxel
3%
Trastuzumab + capecitabine
2%
Neratinib + paclitaxel
1%
0%
10%
20%
30%
40%
50%
60%
N = 118
Survey of live webinar audience
RTP


THE
Fairm


THE Fairmont
MIRAMAR HOTEL
SANTA MONICA


Prevalence of BRCA mutations
BRCA1 1 in 300
BRCA2 1 in 800
Certain ethnic groups have higher prevalence:
Ashkenazi Jews 1 in 40
SARAH CANNON
Development of breast cancer in women
12%
General Population
72%
BRCA1 Mutation
69%
BRCA2 Mutation
20 years after the
breast cancer diagnosis
40%
Women with BRCA1 mutation that will have contralateral BC
26%
Women with BRCA2 mutation that will have contralateral BC


KEYNOTE 522: NEOADJUVANT CHEMO + PEMBROLIZUMAB IN TNBC
Addition of pembrolizumab to neoadjuvant chemo led to statistically significant improvement in pCR of 13.6%
Benefit with pembrolizumab was independent of PD-L1 status
SARAH CANNON
KEYNOTE 522: NEOADJUVANT CHEMO + PEMBROLIZUMAB IN TNBC
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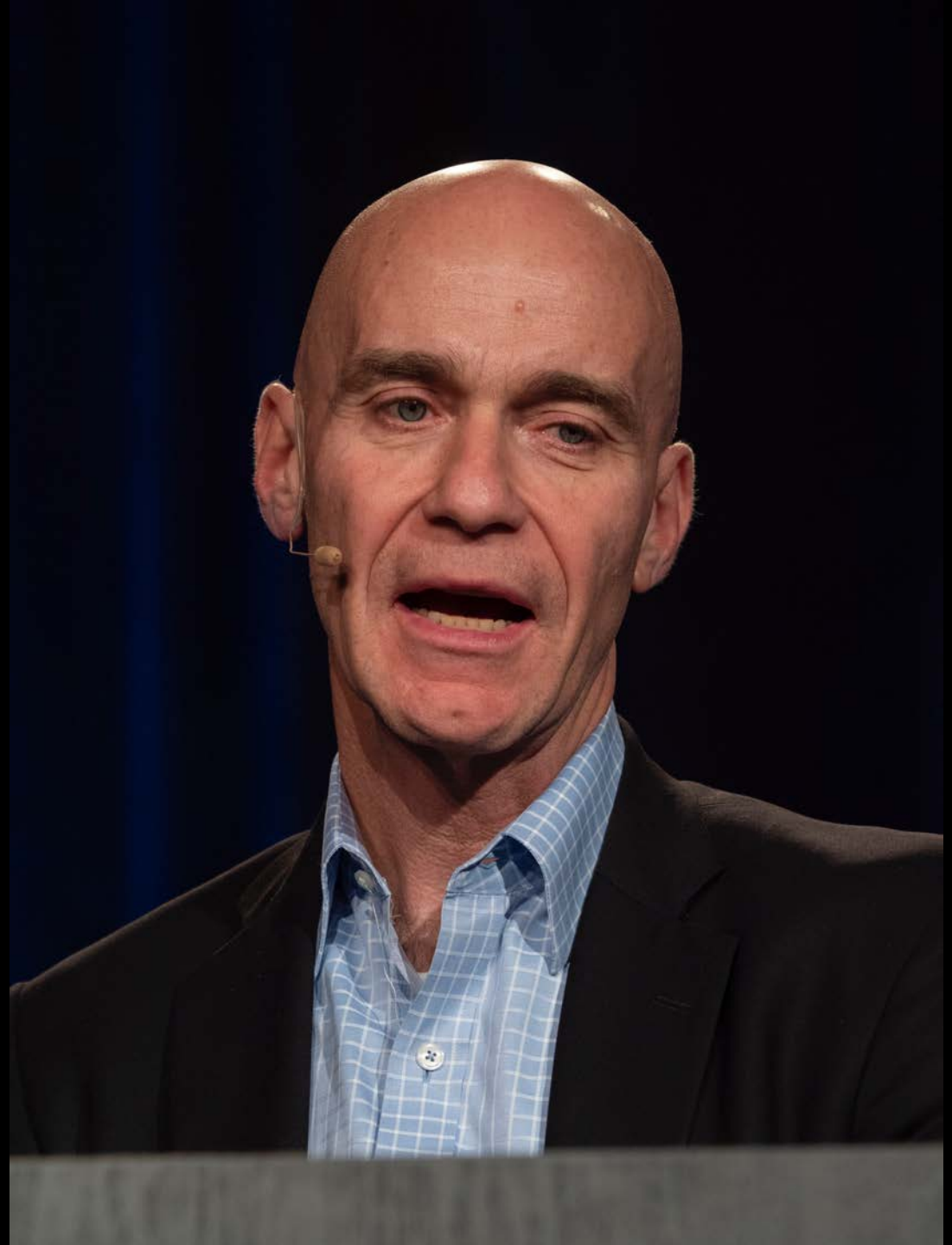


Gemcitabine
Capecitabine
Vinorelbine
Eribulin
Other


HIGHER IMMUNOGENICITY IN PRIMARY TUMORS COMPARED TO METASTATIC
Potential Biomarkers of Immune Response
SARAH CANNON
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CASE PRESENTATION: DR HAMILTON

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Beyond the Guidelines: Clinical Investigator Perspectives on the Management of Triple-Negative Breast Cancer

Friday, December 11, 2020
8:30 PM – 10:00 PM ET

Faculty

P Kelly Marcom, MD
Joyce O'Shaughnessy, MD
Hope S Rugo, MD
Professor Peter Schmid, MD, PhD

Moderator

Neil Love, MD

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Faculty

P Kelly Marcom, MD
Director, Breast Oncology Program
Professor of Medicine
Duke Cancer Institute
Durham, North Carolina

Hope S Rugo, MD
Professor of Medicine
Director, Breast Oncology and Clinical Trials Education
University of California, San Francisco
Helen Diller Family Comprehensive Cancer Center
San Francisco, California

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

Professor Peter Schmid, MD, PhD
Centre Lead
Centre for Experimental Cancer Medicine
Barts Cancer Institute
London, United Kingdom

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Presentation Library

Triple-Negative Breast Cancer, Friday, December 11, 2020

Optimal Integration of Immune Checkpoint Inhibitors into the Management of Metastatic Triple-Negative Breast Cancer (mTNBC)
Professor Peter Schmid, MD, PhD

Download Slides

Novel Applications of Immune Checkpoint Inhibitors for Patients with Early TNBC
Hope S Rugo, MD

Download Slides

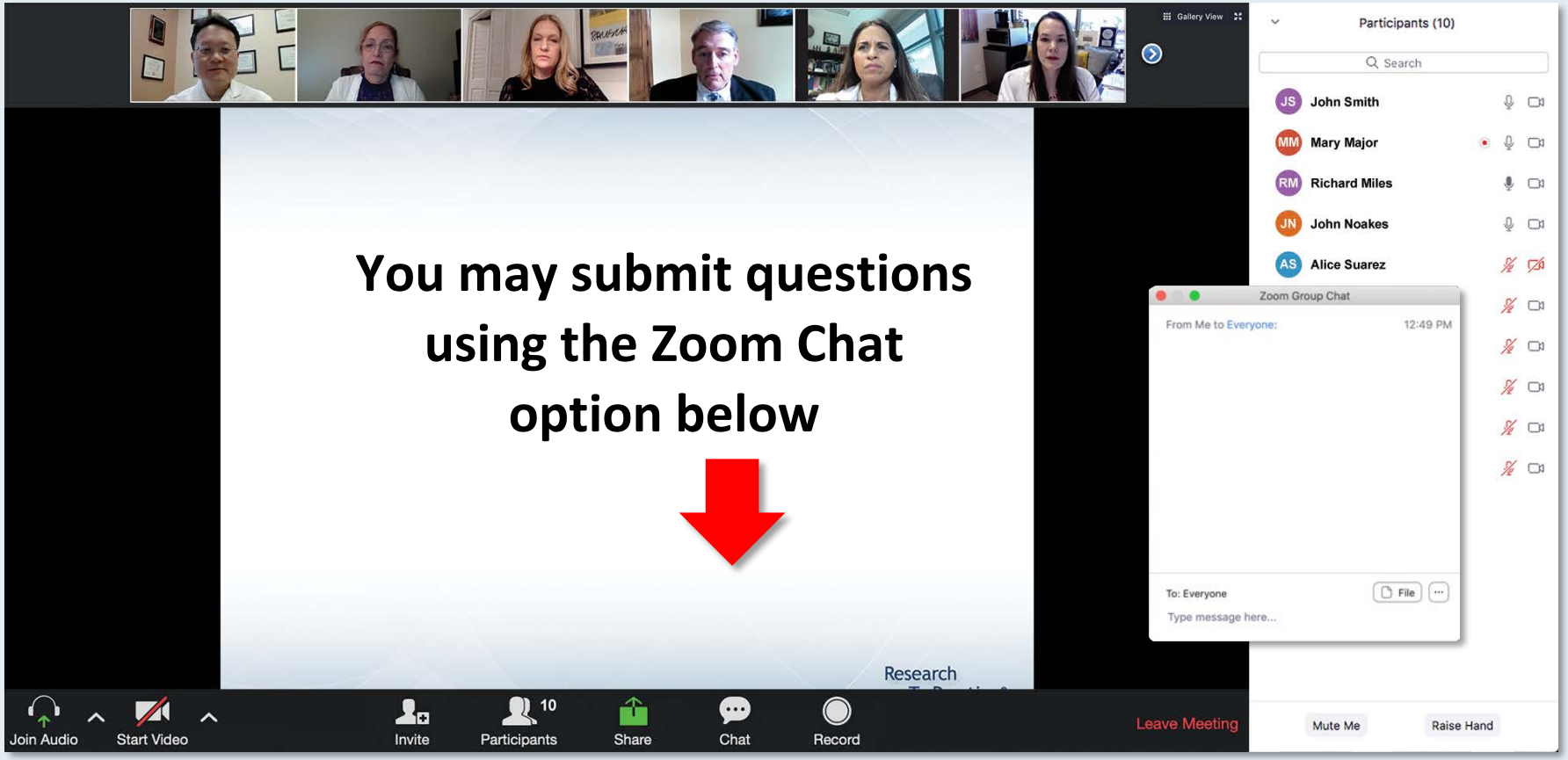
Current and Future Role of PARP Inhibitors for Patients with TNBC and a BRCA Mutation
P Kelly Marcom, MD

Download Slides

Current and Future Management of PD-L1-Negative mTNBC
Joyce O'Shaughnessy, MD

Download Slides

We Encourage Clinicians in Practice to Submit Questions



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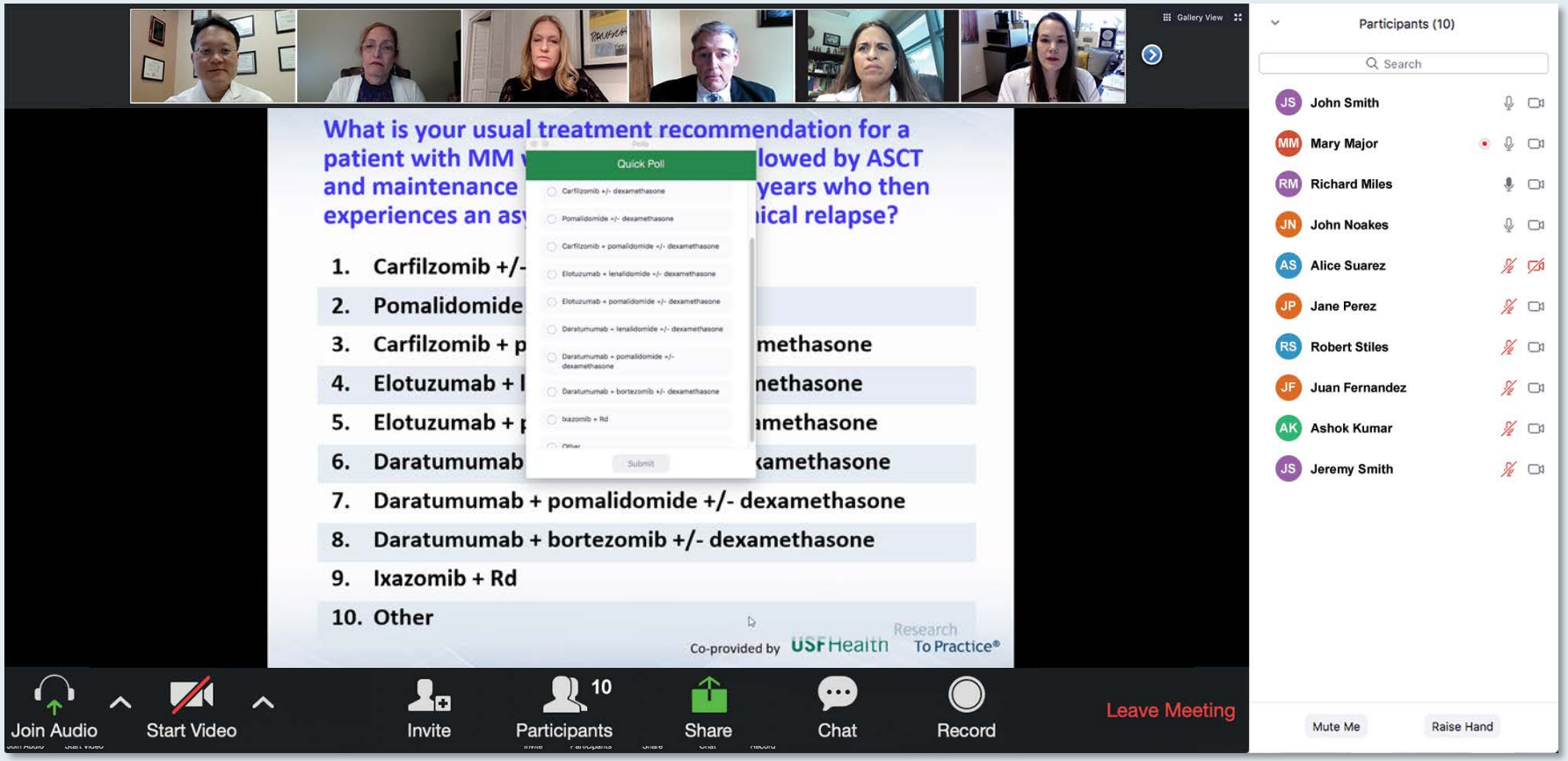

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Triple-Negative Breast Cancer Survey Participants

1. Sylvia Adams, MD
2. Carey K Anders, MD
3. Aditya Bardia, MD, MPH
4. Joanne L Blum, MD, PhD
5. Adam M Brufsky, MD, PhD
6. Howard A Burris III, MD
7. Harold J Burstein, MD, PhD
8. Lisa A Carey, MD
9. Matthew Goetz, MD
10. Erika Hamilton, MD
11. Sara Hurvitz, MD
12. Virginia Kaklamani, MD, DSc
13. Hannah M Linden, MD
14. P Kelly Marcom, MD
15. Jennifer M Matro, MD
16. Kathy D Miller, MD
17. Rita Nanda, MD
18. Ruth O'Regan, MD
19. Joyce O'Shaughnessy, MD
20. Mark D Pegram, MD
21. Lajos Pusztai, MD, DPhil
22. Hope S Rugo, MD
23. Professor Peter Schmid, MD, PhD
24. Joseph A Sparano, MD
25. Sara M Tolaney, MD, MPH

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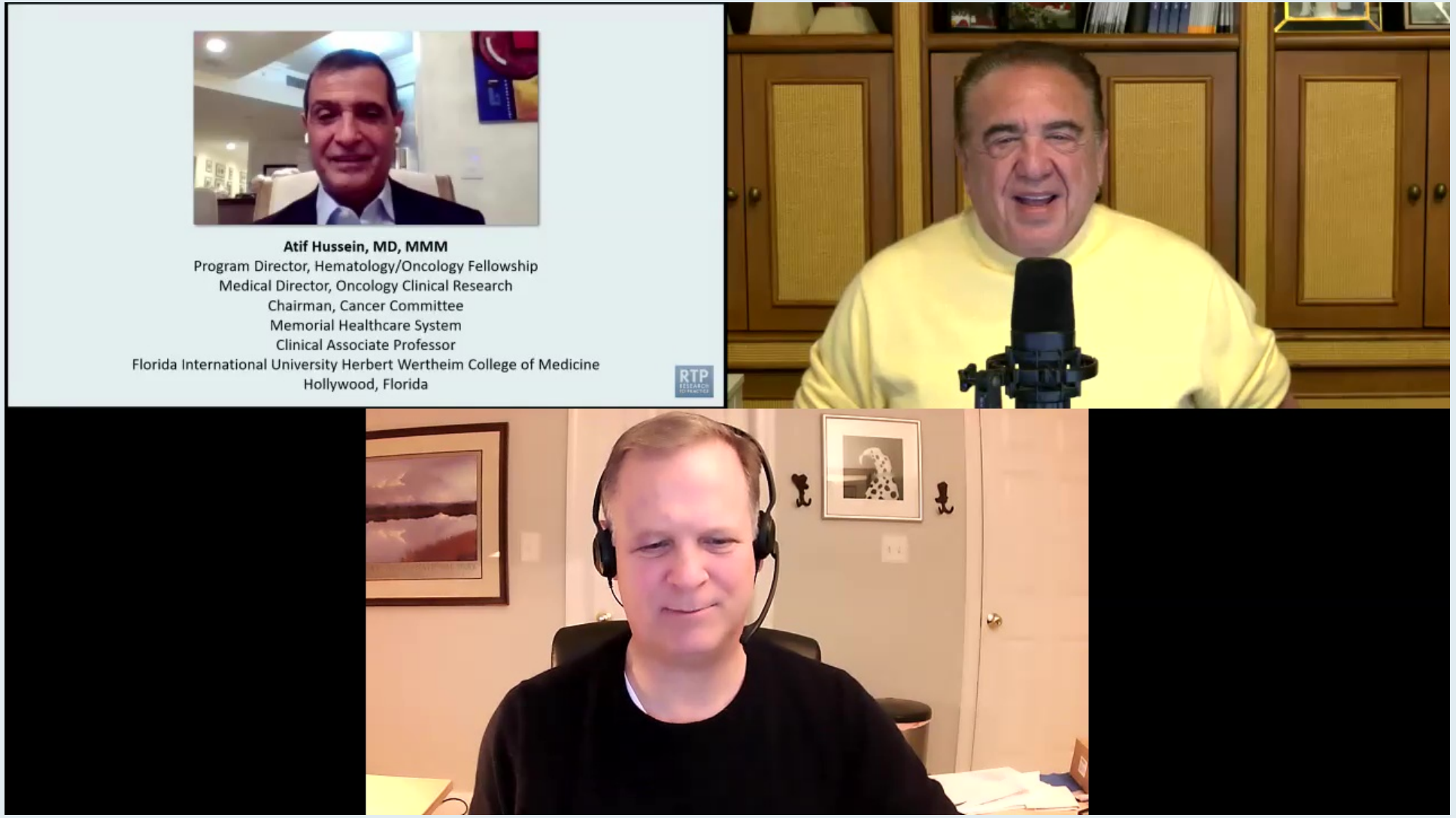
What Happened at the 2020 San Antonio Breast Cancer Symposium: Session 1 - January 11, 2021



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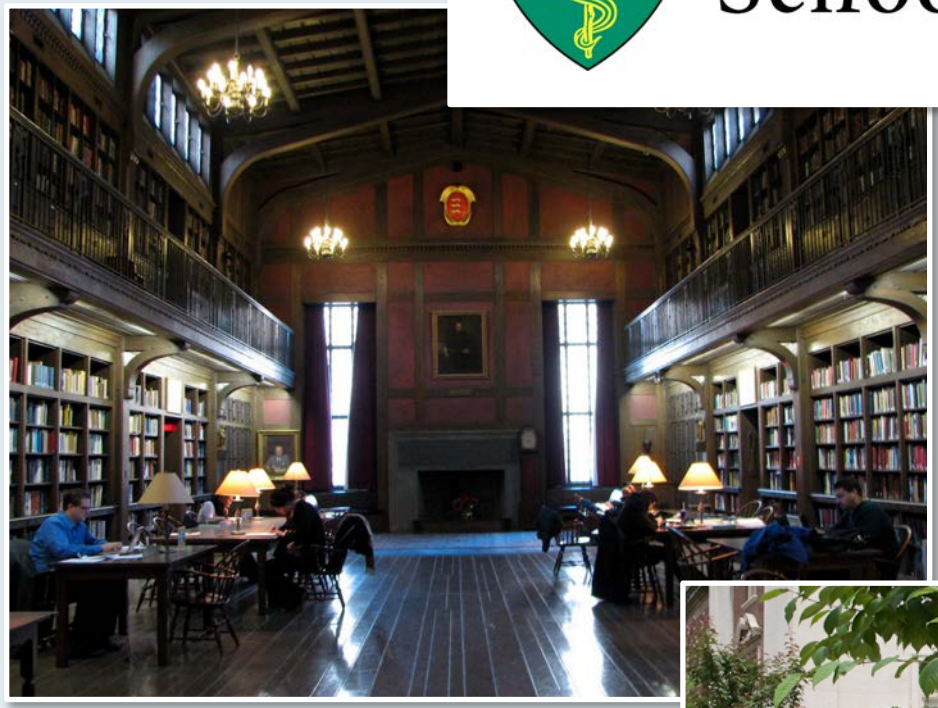
Yale University School of Medicine



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Alan B Astrow, MD
Chief, Hematology/Medical Oncology
NewYork-Presbyterian Brooklyn Methodist Hospital
Professor of Clinical Medicine
Weill Cornell Medical College
Brooklyn, New York

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Agenda

Module 1: Case Presentations

- An 88-year-old woman with triple-negative lobular carcinoma
- A 66-year-old woman with triple-negative, node-positive breast cancer
- A 31-year-old woman with triple-negative, node-negative IDC

Module 2: San Antonio Breast Cancer Symposium Review – Part 1

Module 3: Case Presentations

- A 40-year-old woman with metastatic triple-negative breast cancer (TNBC)
- A 61-year-old woman with a germline BRCA1 mutation and locally advanced breast cancer

Module 4: San Antonio Breast Cancer Symposium Review – Part 2

Module 5: Case Presentations

- A 46-year-old woman with triple-negative small cell carcinoma of the breast
- A 37-year-old woman with triple-negative IDC
- A 68-year-old woman with triple-negative, node-negative IDC

Module 6: San Antonio Breast Cancer Symposium Review – Part 3

Agenda

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Module 6: San Antonio Breast Cancer Symposium Review – Part 3

Case Presentation – Dr Astrow: An 88-year-old woman with a multifocal invasive triple-negative lobular carcinoma with clinically negative nodes

Dr Alan Astrow

- Excellent performance status
- 2.6-cm multifocal invasive lobular carcinoma
- Grade 3, triple-negative, Ki67 ~50%
- No sentinel lymph node performed but no palpable nodes in the axilla
- Predict UK: 2% benefit from adding chemotherapy at 10 years

Question

- Should I recommend adjuvant chemotherapy or not?

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Case Presentation – Dr Astrow: An 88-year-old woman with a multifocal invasive triple-negative lobular carcinoma with clinically negative nodes

Dr Alan Astrow

Predict Breast – Survival After Surgery*

	Surgery only	With adjuvant chemotherapy	Additional benefit
5-year survival			
60-year-old woman	78%	84%	6.4%
85-year-old woman	51%	57%	5.3%
10-year survival			
60-year-old woman	67%	75%	7.9%
85-year-old woman	22%	25%	3.3%

* Chemotherapy is a taxane-based regimen; 85 years is the upper age limit of the tool.

- For an 85-year-old woman, if death from breast cancer were excluded:
  - 67% would survive at least 5 years, and 33% would die of other causes
  - 32% would survive at least 10 years, and 68% would die of other causes

https://breast.predict.nhs.uk

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Case Presentation – Dr Astrow: A 66-year-old woman with 4-cm TNBC (axilla positive) with residual disease after neoadjuvant chemotherapy

Dr Alan Astrow

- Right, 4-cm, Grade 3, triple-negative IDC, with biopsy-proven positive axillary node
- Neoadjuvant dose-dense AC-paclitaxel
- Lumpectomy/ALND → 1.7-cm residual Grade 3 IDC, 1/10 positive axillary nodes
- Patient declines strongly recommended adjuvant capecitabine
- Nine months later, after discovery of a breast seroma, patient strongly wants to receive capecitabine
  - No distant metastases

Questions

- Should I give her the capecitabine, even though the data don't support it?
- If I give her capecitabine, should it be for 6 months as in the CREATE-X trial, or one-year of metronomic capecitabine per the report from China in *JAMA Oncology*? Do you have a preference if not giving it neoadjuvantly?

Case Presentation – Dr Astrow: A 31-year-old woman with triple-negative, node-negative IDC – 3 separate sites

Dr Alan Astrow

- Three separate right breast masses: 1.8-cm, 1.6-cm, 1.3-cm
- Core biopsy: Grade 2 IDC, triple-negative
- Neoadjuvant dose-dense AC-paclitaxel
- Mastectomy: 2 foci of residual Grade 2 IDC – 1.2-cm and 0.2-cm; SLNB: Negative
- Adjuvant capecitabine

Questions

- Would you have given carboplatin in addition to the neoadjuvant AC-paclitaxel?
- Should I give her additional treatment beyond the adjuvant capecitabine?
- What schedule of capecitabine should I give her?
- In a non-protocol setting, for a young woman with aggressive breast cancer, have you given adjuvant pembrolizumab?

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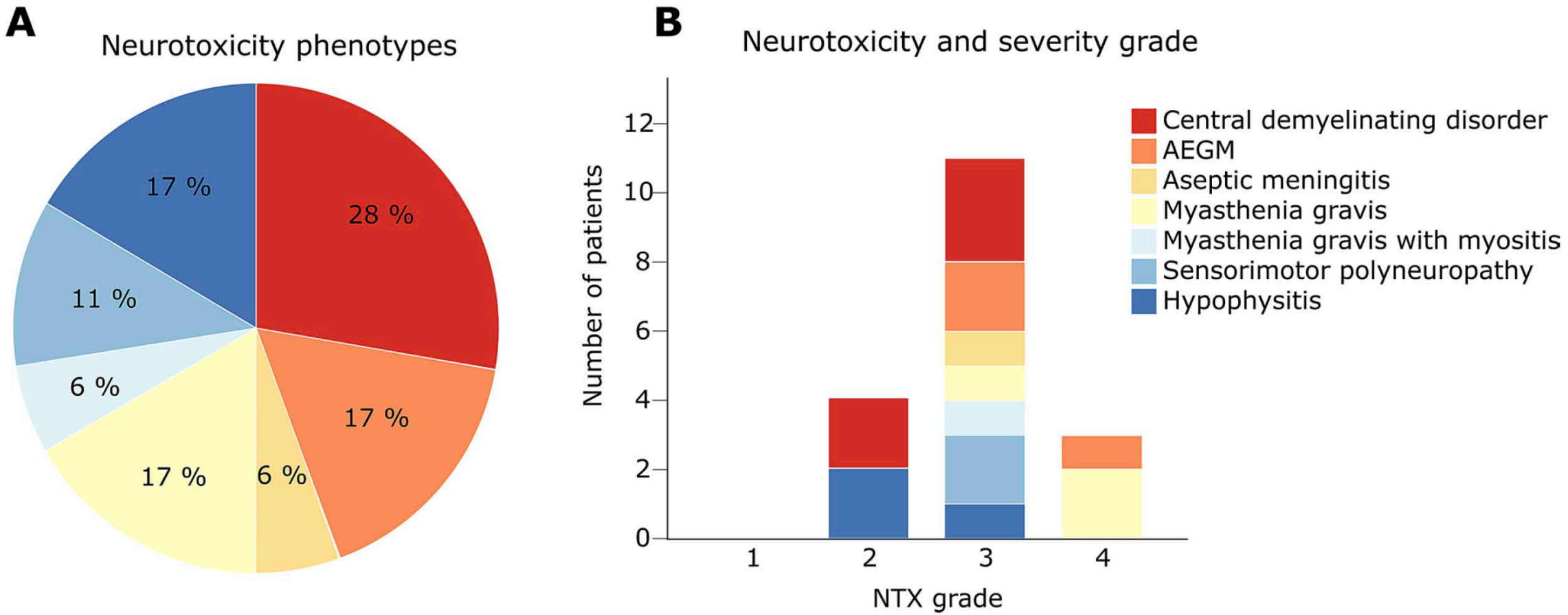
CLINICAL STUDY

Neurotoxicities associated with immune checkpoint inhibitor therapy

Sophie L. Duong[1,2] · Frank J. Barbiero[1] · Richard J. Nowak[1] · Joachim M. Baehring[3,4]

Duong SL et al. J Neuro-oncology;2021

Characteristics of Neurotoxicity



Duong SL et al. J Neuro-oncology;2021

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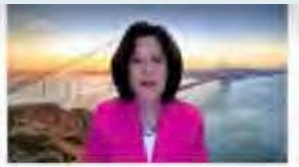
Module 6: San Antonio Breast Cancer Symposium Review – Part 3



Additional Efficacy Endpoints from the Phase 3 KEYNOTE-355 Study of Pembrolizumab + Chemotherapy versus Placebo + Chemotherapy as First-Line Therapy for Locally Recurrent Inoperable or Metastatic Triple-Negative Breast Cancer (mTNBC)

Hope S. Rugo[1], Peter Schmid[2], David W. Cescon[3], Zbigniew Nowecki[4], Seock-Ah Im[5], Mastura Md Yusof[6], Carlos Gallardo[7], Oleg Lipatov[8], Carlos Henrique Barrios[9], Jose Perez-Garcia[10], Hiroji Iwata[11], Norikazu Masuda[12], Marco Torregroza Otero[13], Erhan Gokmen[14], Sherene Loi[15], Zifang Guo[16], Jing Zhao[16], Vassiliki Karantza[16], Gursel Aktan[16], Javier Cortes[17]

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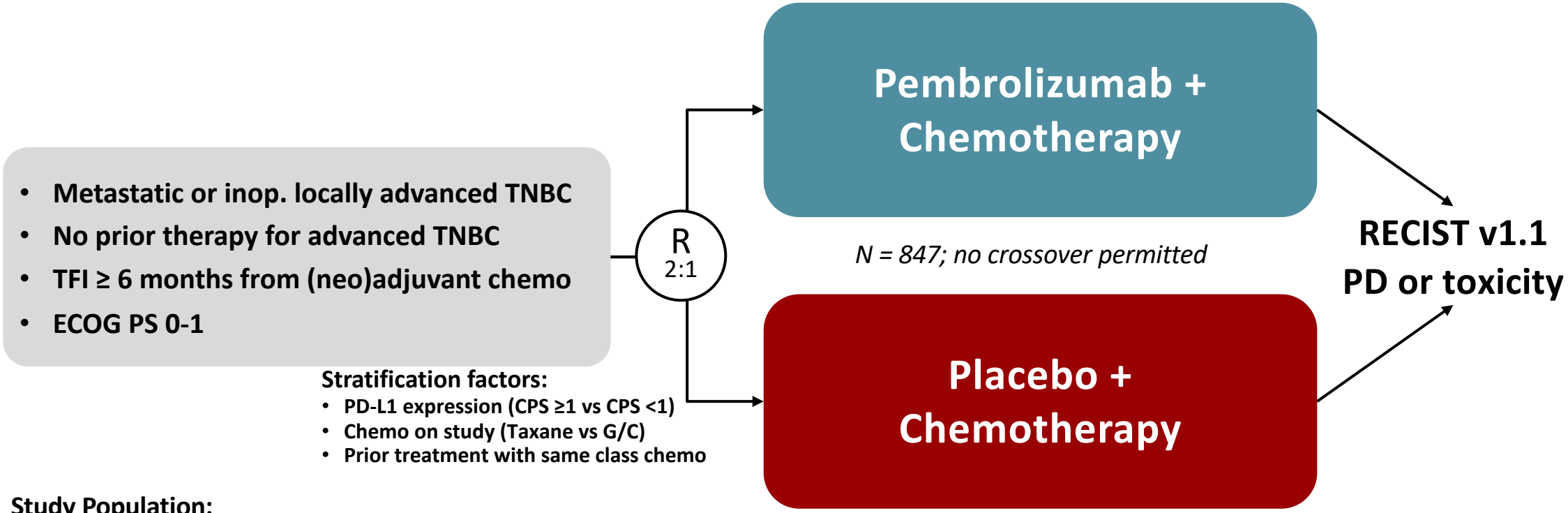
Pembrolizumab (anti-PD-1) plus chemotherapy in TNBC

KEYNOTE-355 study design



- Metastatic or inop. locally advanced TNBC
- No prior therapy for advanced TNBC
- TFI ≥ 6 months from (neo)adjuvant chemo
- ECOG PS 0-1

Stratification factors:
- PD-L1 expression (CPS ≥1 vs CPS <1)
- Chemo on study (Taxane vs G/C)
- Prior treatment with same class chemo

Study Population:
- CPS≥10, 75%; CPS≥1, 38%; CPS <1, 25%
- Taxane, 45%; Gem/carboplatin, 55%
- Prior treatment with same class chemo, 22%
- De novo MBC, 30%; DFI 6-12, 21%; DFI >12, 49%

Nab-paclitaxel, 100 mg/m^2 IV on days 1, 8, and 15 every 28 days
Paclitaxel, 90 mg/m^2 IV on days 1, 8, and 15 every 28 days
Gemcitabine, 1000 mg/m^2/carboplatin AUC 2 on days 1 and 8 every 21 days

- **Co-primary endpoints were PFS and OS in the CPS ≥10, CPS ≥1, and ITT populations**

Statistical design: Overall alpha controlled at one-sided 0.025, split among PFS (0.005),OS (0.018), and ORR (0.002); hierarchical testing PFS (CSP10>CP1>ITT)

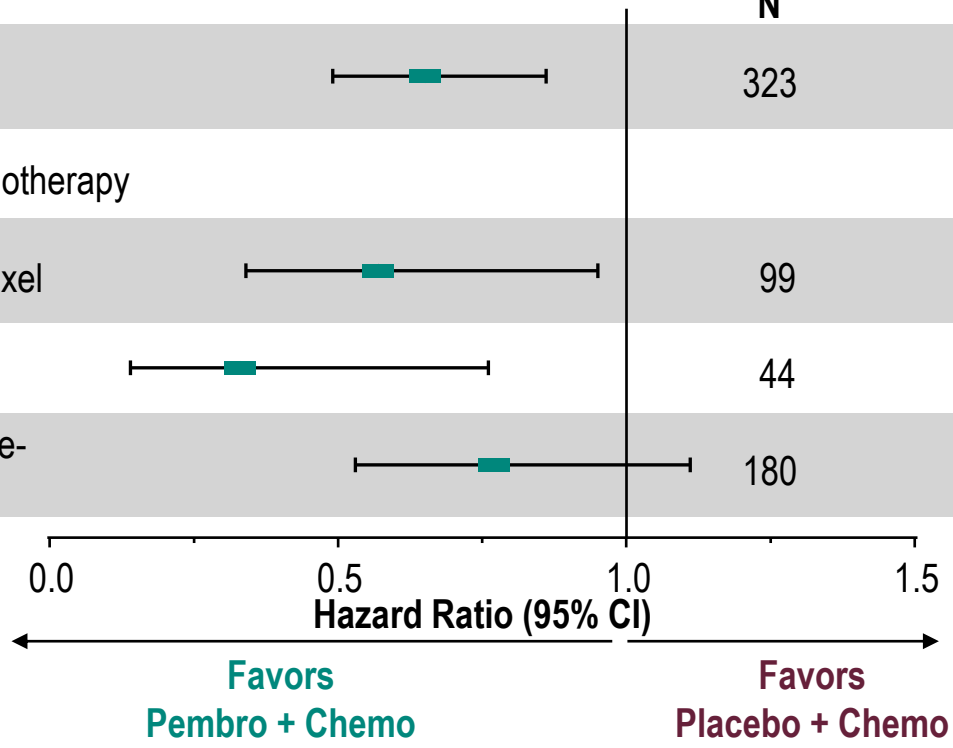
Courtesy of Professor Peter Schmid, MD, PhD

Cortes, et al. ASCO 2020

KEYNOTE-355: Progression-Free Survival in Subgroups by On-Study Chemotherapy

PD-L1 CPS ≥10

Subgroup	N	Median PFS (mo)		Hazard Ratio for Progression or Death (95% CI)
		Pembro + Chemo	Placebo + Chemo	
Overall	323	9.7	5.6	0.65 (0.49 to 0.86)
On-study chemotherapy				
Nab-Paclitaxel	99	9.9	5.5	0.57 (0.34 to 0.95)
Paclitaxel	44	9.6	3.6	0.33 (0.14 to 0.76)
Gemcitabine-Carboplatin	180	8.0	7.2	0.77 (0.53 to 1.11)

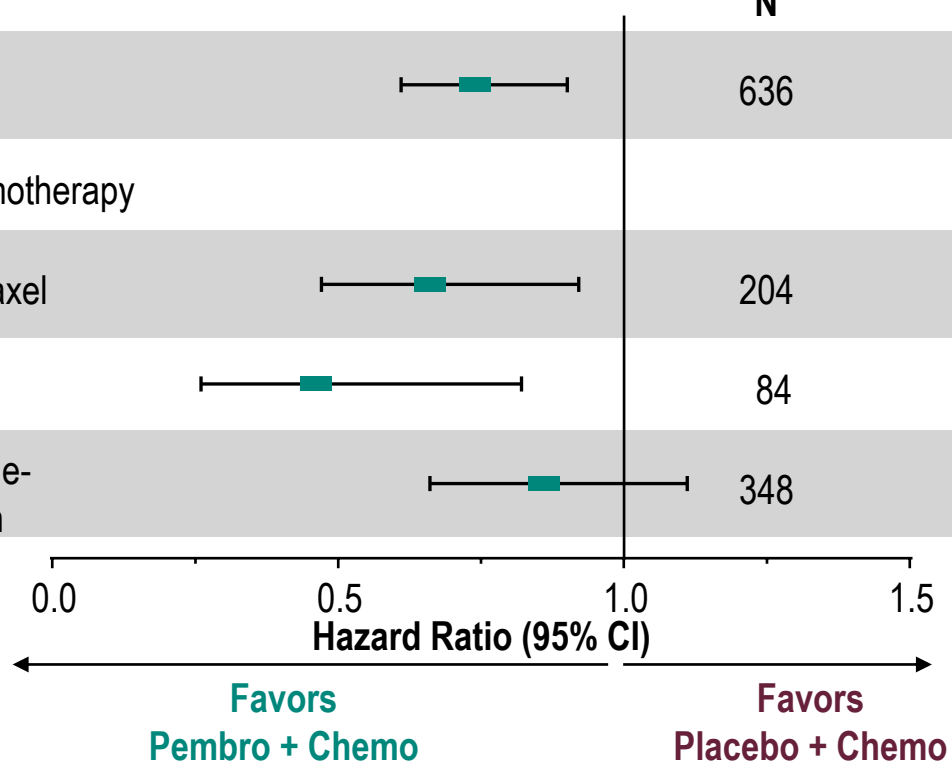


Rugo H et al. SABCS 2020;Abstract GS3-01.

KEYNOTE-355: Progression-Free Survival in Subgroups by On-Study Chemotherapy

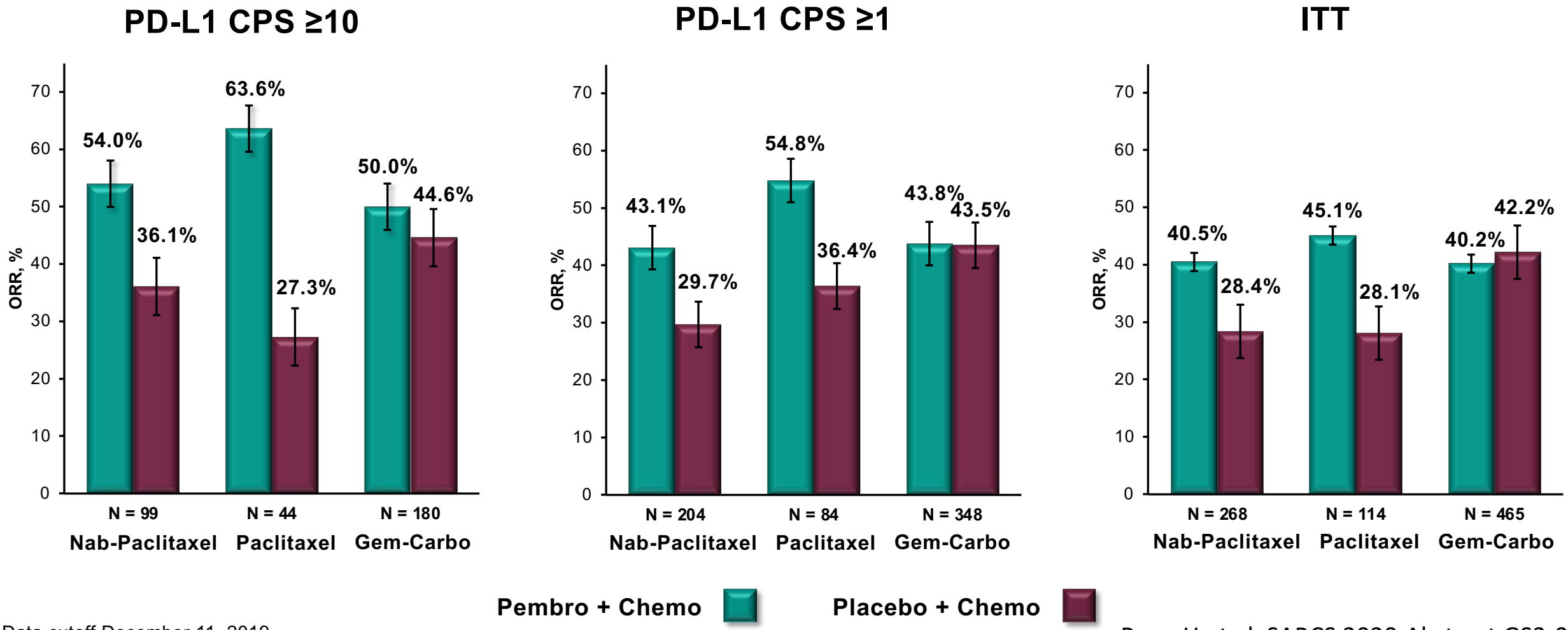
PD-L1 CPS ≥1

Subgroup	N	Median PFS (mo) Pembro + Chemo	Median PFS (mo) Placebo + Chemo	Hazard Ratio for Progression or Death (95% CI)
Overall	636	7.6	5.6	0.74 (0.61 to 0.90)
On-study chemotherapy				
Nab-Paclitaxel	204	6.3	5.3	0.66 (0.47 to 0.92)
Paclitaxel	84	9.4	3.8	0.46 (0.26 to 0.82)
Gemcitabine-Carboplatin	348	7.5	7.5	0.86 (0.66 to 1.11)



Rugo H et al. SABCS 2020;Abstract GS3-01.

KEYNOTE-355: Response Rate in Subgroups by On-Study Chemotherapy



Data cutoff December 11, 2019.

Rugo H et al. SABCS 2020;Abstract GS3-01.

Genomic Profiling and Clinical Outcomes with First-Line Atezolizumab and *Nab*-Paclitaxel in Triple-Negative Breast Cancer: An Exploratory Analysis from the Phase 3 IMpassion130 Trial

Emens L et al.

SABCS 2020;Abstract PD14-05.

Conclusions – Part 1

This exploratory retrospective subgroup analysis from the IMPassion130 study showed that:

- PD-L1 IC+ status was positively associated with *TP53* loss of function alterations and negatively associated with *VEGFA* and *CCND3* amplifications, however, [es]genes were not linked to clinical outcomes
- *BRCA1* alterations were more prevalent in primary tumors, while *PIK3R1* alterations were more prevalent in metastatic tumors
- *TP53 BRCA1* and *RB1* alterations were more prevalent in younger patients while older patients had more alterations in *PI3KCA* and *KM12C*
- *PIK3CA* mutations were more prevalent in Asian patients compared with other races
- *TP53* and *MYC* alterations were more prevalent in basal tumors while *PIK3CA* and *PTE* were more characteristic in LAR molecular subtype
- Few gene alterations had a prognostic effect. Loss of RB1 possibly boosting tumor cell proliferation, was most associated with prognosis

Emens L et al. SABCS 2020;Abstract PD14-05.

RTP RESEARCH TO PRACTICE

Conclusions – Part 2

This exploratory retrospective subgroup analysis from the IMPassion130 study showed that:

- CN alterations in CDKN2A and CDKN2B were linked to an improved clinical outcome with A + nP, while *MAP3K1* SVs were associated with a negative A + nP outcome
- MSI-H tumors were infrequent in Impassions 130, with the outcome associated with A + nP remaining unknown
- *PIK3CA, AKT1, PTEN*-altered status was not linked to PD-L1 IC status or A + nP clinical outcome

This analysis represents the largest data set evaluating the genomic profile of patients with locally advanced or mTNBC who were treated with immunotherapeutic agents

These data are hypothesis generating and require validation in an independent data set

Emens L et al. SABCS 2020;Abstract PD14-05.

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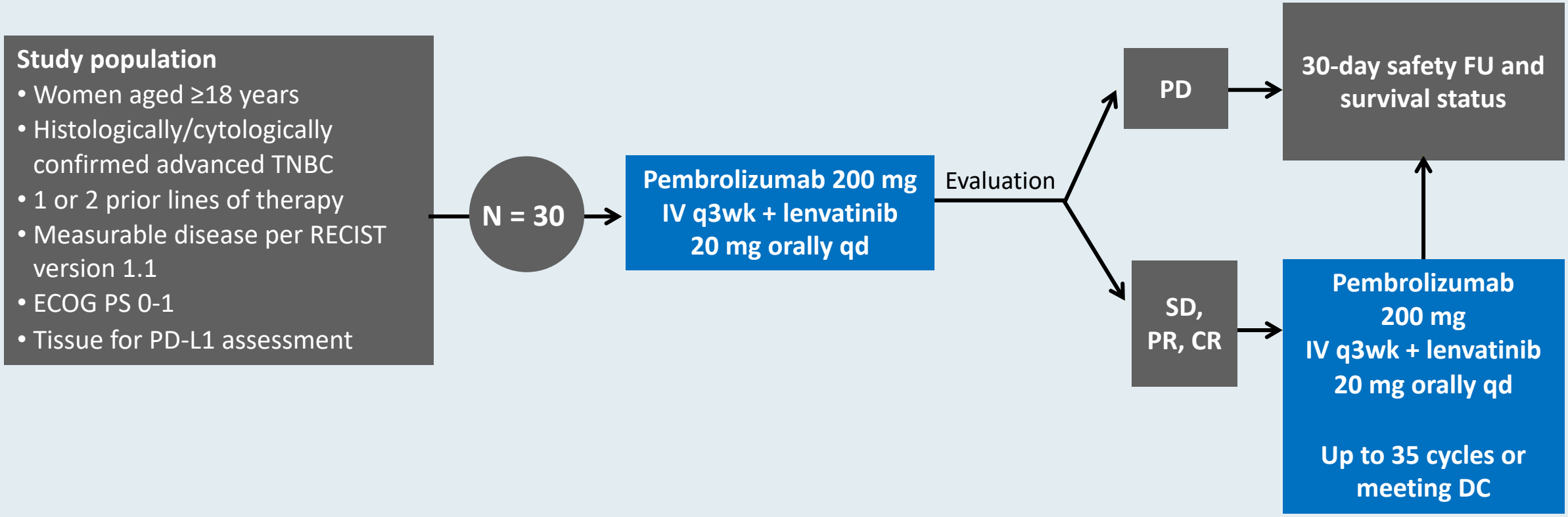
Lenvatinib plus Pembrolizumab for Previously Treated, Advanced Triple-Negative Breast Cancer: Early Results from the Multicohort Phase 2 LEAP-005 Study

Chung HC et al.

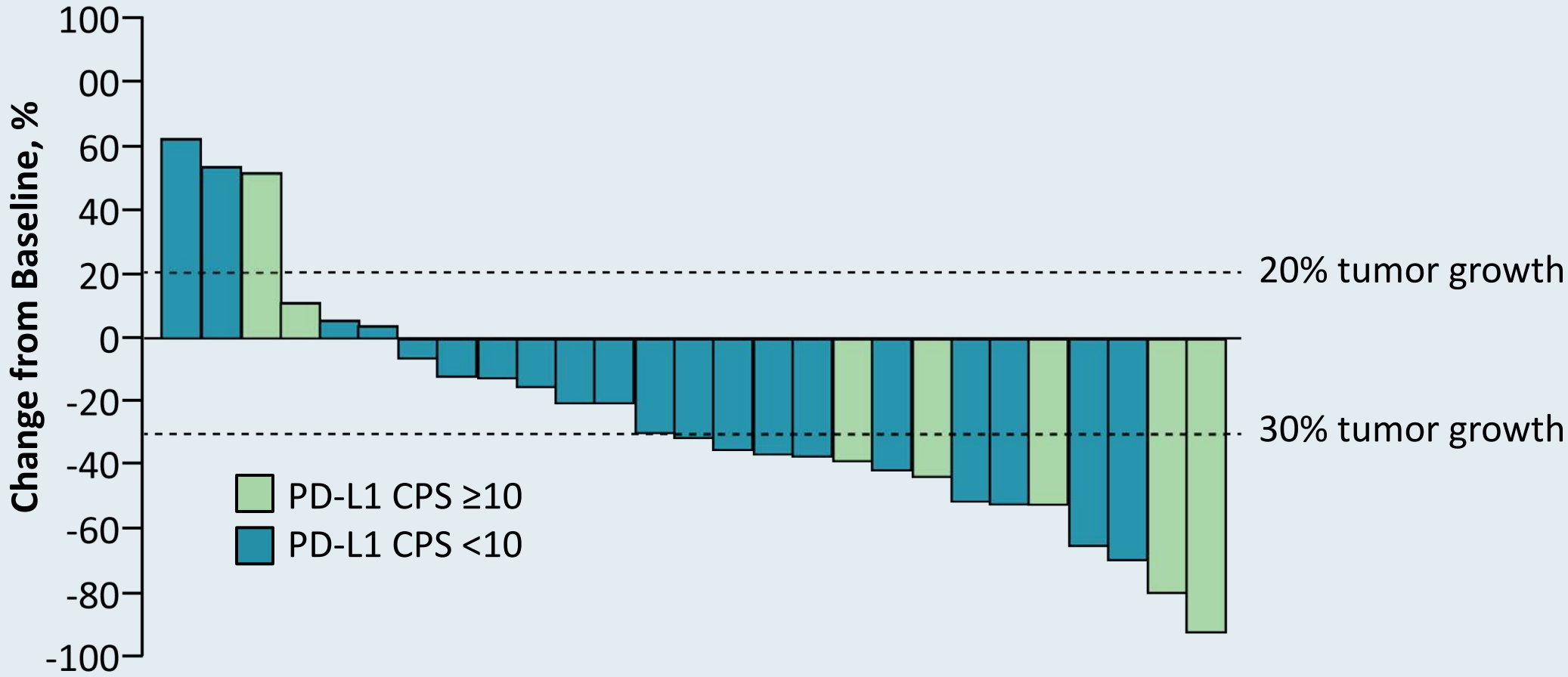
SABCS 2020;Abstract PS12-07.

LEAP-005 Study Design



Chung HC et al. SABCS 2020;Abstract PS12-07.

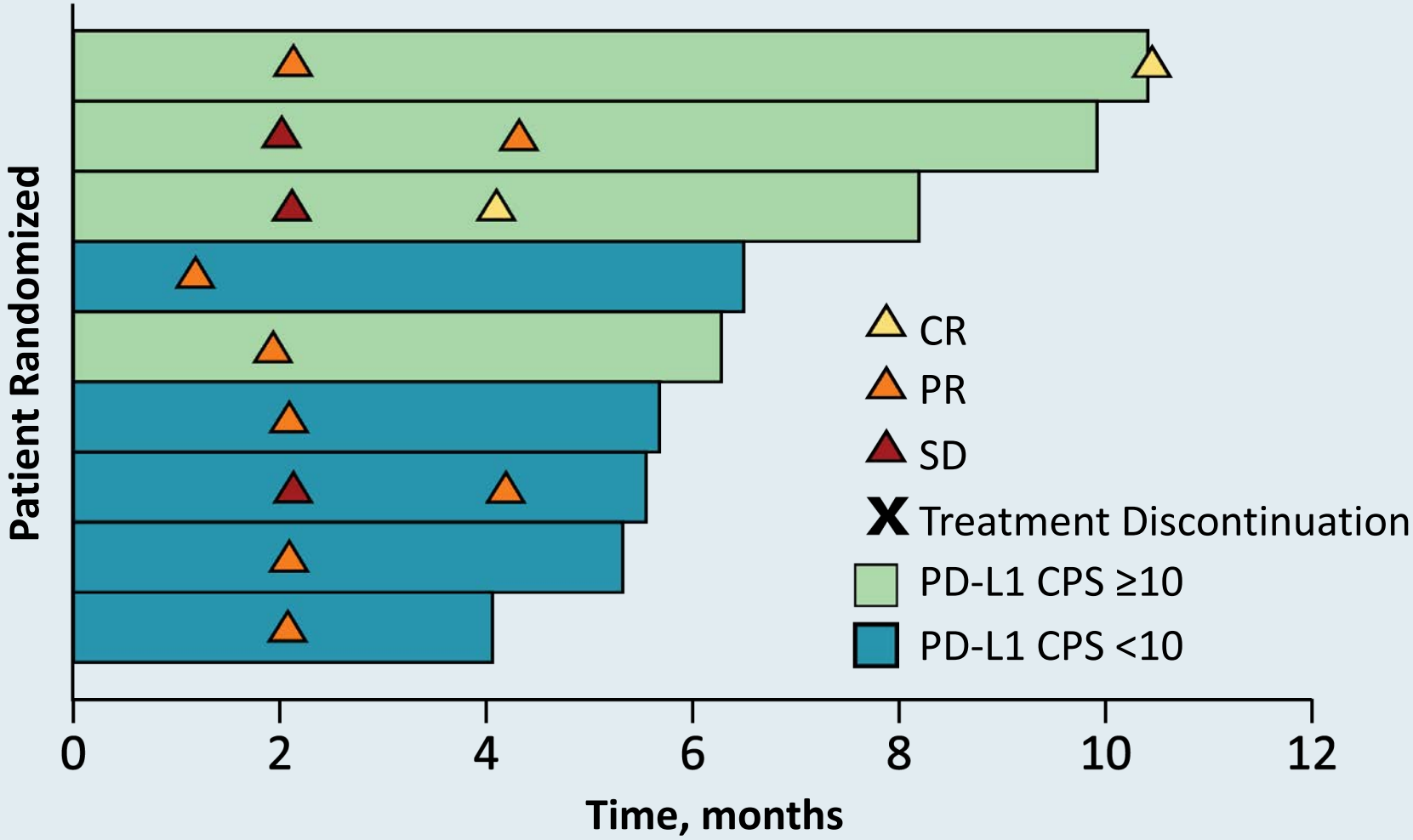
LEAP-005: Best Percentage Change from Baseline in Target Lesion Size



Includes patients with one or more evaluable post-baseline imaging assessment (n = 27).

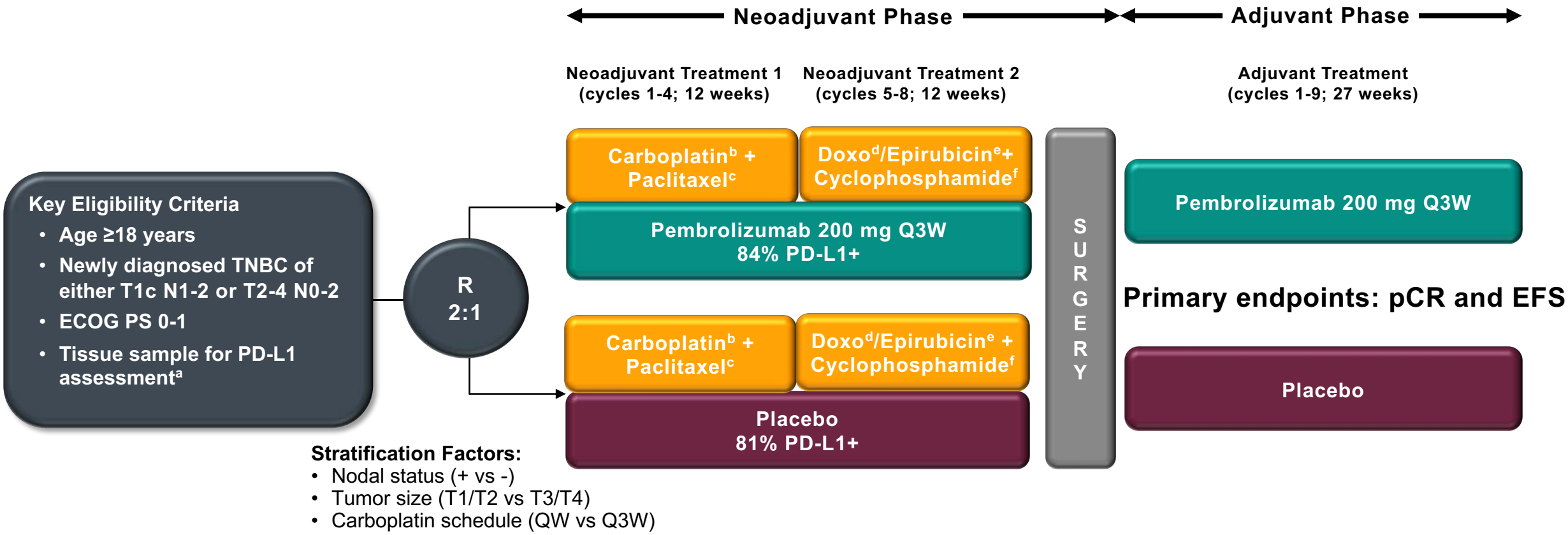
Chung HC et al. SABCS 2020;Abstract PS12-07.

LEAP-005: Treatment Duration and Response Evaluation



Chung HC et al. SABCS 2020;Abstract PS12-07.

KEYNOTE-522 Study Design (NCT03036488)



Neoadjuvant phase: starts from the first neoadjuvant treatment and ends after definitive surgery (post treatment included)

Adjuvant phase: starts from the first adjuvant treatment and includes radiation therapy as indicated (post treatment included)

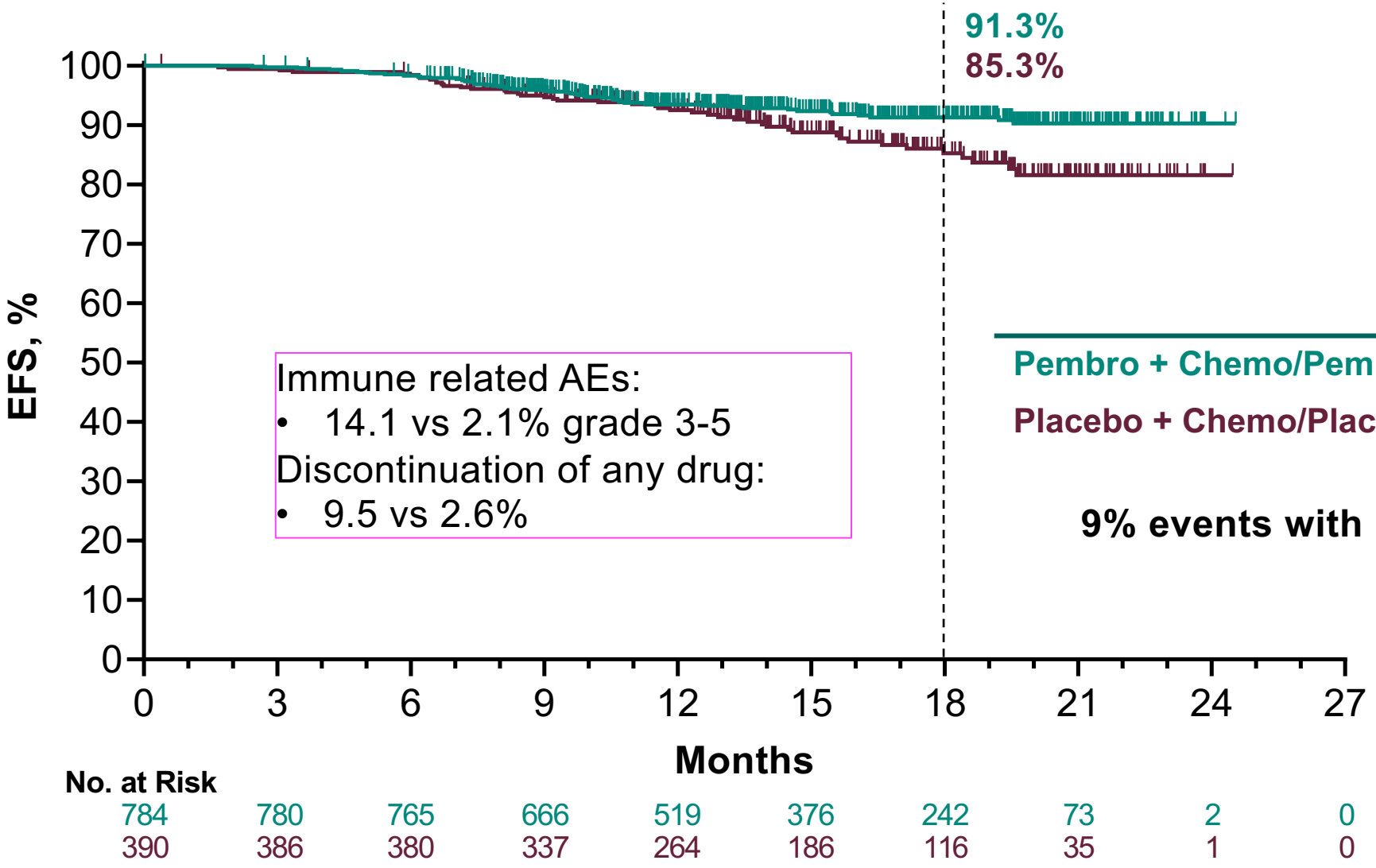
PD-L1 + defined by CPS ≥1

[a]Must consist of at least 2 separate tumor cores from the primary tumor.
[b]Carboplatin dose was AUC 5 Q3W or AUC 1.5 QW.
[c]Paclitaxel dose was 80 mg/m^2 QW.
[d]Doxorubicin dose was 60 mg/m^2 Q3W.
[e]Epirubicin dose was 90 mg/m^2 Q3W.
[f]Cyclophosphamide dose was 600 mg/m^2 Q3W.

Courtesy of Hope S Rugo, MD
Schmid et al, NEJM 2020

Event-Free Survival at IA2: 1st Interim Analysis

P value boundary for significance 0.000051 (HR<0.4)



Immune related AEs:
- 14.1 vs 2.1% grade 3-5

Discontinuation of any drug:
- 9.5 vs 2.6%

	Events	HR (95% CI)
Pembro + Chemo/Pembro	7.4%	0.63[a] (0.43-0.93)
Placebo + Chemo/Placebo	11.8%	

9% events with median FU 15.5 months

Courtesy of Hope S Rugo, MD

[a]Prespecified *P* value boundary of 0.000051 not reached at this analysis (the first interim analysis of EFS). IA2: If pCR hypothesis successful at IA1, pCR will not be formally tested at IA2

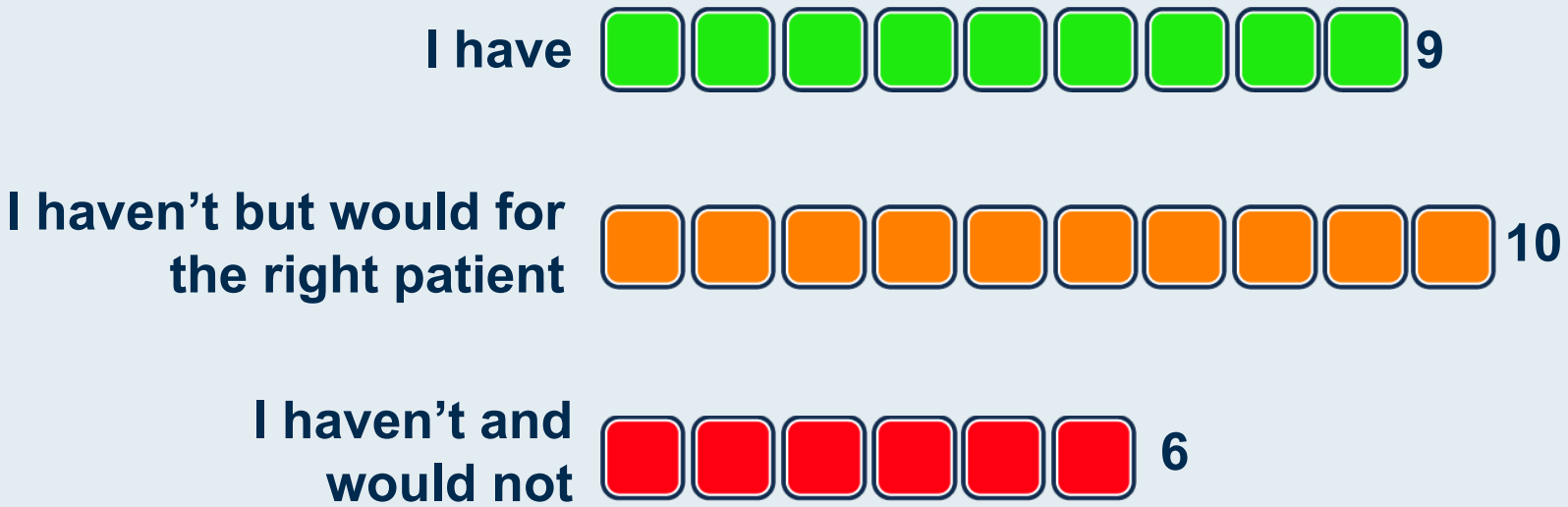
HR (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by randomization stratification factors. **Data cutoff April 24, 2019; 24 mo after last pt enrolled**

Regulatory and reimbursement issues aside, have you attempted or would you attempt to access an anti-PD-1/PD-L1 antibody as part of neoadjuvant therapy for a 60-year-old patient with a 6-cm TNBC with 3 positive axillary nodes on biopsy (PD-L1 60%)?

1. I have
2. I haven't but would for the right patient
3. I haven't and would not

Have you or would you attempt to access an anti-PD-1/PD-L1 antibody as part of neoadjuvant therapy off protocol for a 60-year-old patient with TNBC with the following characteristics?

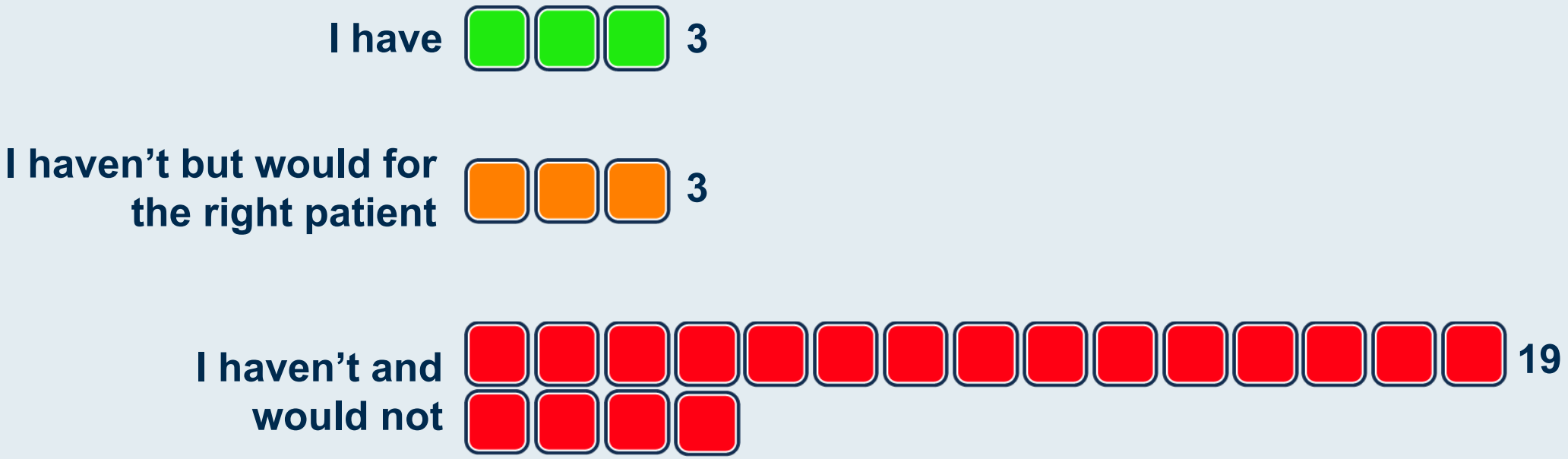
Tumor size: 6 cm, Nodal status: 3 positive nodes, PD-L1: 60%



Survey of 25 breast cancer clinical investigators

Regulatory and reimbursement issues aside, have you or would you attempt to access an anti-PD-1/PD-L1 antibody as part of neoadjuvant therapy off protocol for a 60-year-old patient with TNBC with the following characteristics?

Tumor size: 6 cm, Nodal status: node-negative, PD-L1: 10%

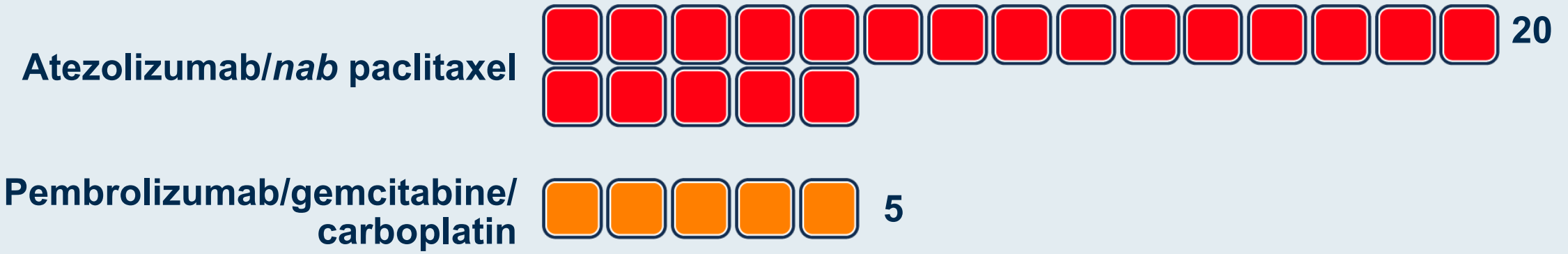


Survey of 25 breast cancer clinical investigators

A 32-year-old woman who completed neoadjuvant FEC/docetaxel and postoperative radiation therapy 21 months ago for localized TNBC now presents with small-volume liver and nodal metastases: BRCA wild type, PD-L1 positive. What therapy would you recommend?

1. Chemotherapy
2. Atezolizumab/*nab* paclitaxel
3. Atezolizumab/paclitaxel
4. Pembrolizumab/*nab* paclitaxel
5. Pembrolizumab/paclitaxel
6. Pembrolizumab/gemcitabine/carboplatin
7. Other

A 32-year-old woman who completed neoadjuvant FEC/T and radiation therapy 21 months ago for localized TNBC now presents with liver and nodal metastases. Biomarker assessment reveals BRCA WT, PD-L1-positive disease. What therapy would you recommend?



Survey of 25 breast cancer clinical investigators

Agenda

Module 1: Case Presentations

- An 88-year-old woman with triple-negative lobular carcinoma
- A 66-year-old woman with triple-negative, node-positive breast cancer
- A 31-year-old woman with triple-negative, node-negative IDC

Module 2: San Antonio Breast Cancer Symposium Review – Part 1

Module 3: Case Presentations

- A 40-year-old woman with metastatic TNBC
- A 61-year-old woman with a germline BRCA1 mutation and locally advanced breast cancer

Module 4: San Antonio Breast Cancer Symposium Review – Part 2

Module 5: Case Presentations

- A 46-year-old woman with triple-negative small cell carcinoma of the breast
- A 37-year-old woman with triple-negative IDC
- A 68-year-old woman with triple-negative, node-negative IDC

Module 6: San Antonio Breast Cancer Symposium Review – Part 3

Case Presentation – Dr Astrow: A 40-year-old woman with metastatic TNBC – PD-L1 CPS 15%

Dr Alan Astrow

- Left breast mass, Core biopsy: Grade 3 IDC, triple-negative
- Neoadjuvant dose-dense AC-paclitaxel → Residual 2.5-cm Grade 3 IDC, with 1/11 positive axillary nodes
- RT to left chest wall and regional nodes
- Patient did not tolerate adjuvant capecitabine well
- One year later: Multiple subcutaneous nodules in the mastectomy bed, biopsy-positive for TNBC
  - No other site of recurrence in CT chest/abdomen/pelvis and bone scan
  - PD-L1 CPS: 15%
- Gemcitabine/carboplatin/pembrolizumab

Questions

- What is the best treatment for metastatic triple-negative breast cancer, PD-L1-positive?
- Could I re-irradiate her? Is there any role for surgery? How long should I treat her for?
- If she is responding, should I stop the gem/carbo at some point and just continue her on pembrolizumab?

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Case Presentation – Dr Astrow: A 61-year-old woman with Grade II breast cancer – BRCA1 mutation

Dr Alan Astrow

- Presented 4 years ago with Grade 2 (T2N1M0) IDC, triple-negative
- Neoadjuvant dose-dense AC-paclitaxel → Complete clinical response
- Underwent mastectomy → Residual 3.0 mm IDC (ER/PR-positive, HER2-negative)
- Patient declined entering OlympiA (NSABP-B55) adjuvant PARP inhibitor trial
- Currently receiving adjuvant tamoxifen

Questions

- If the results of the OlympiA are positive, would you start this patient on delayed PARP inhibition?
- How would you approach treating a patient like this if she presented today?

A 61-year-old woman with a Grade II triple-negative IDC and a BRCA1 germline mutation has a complete clinical response to neoadjuvant dose-dense AC/paclitaxel but has 3.0-mm residual disease at surgery. What would you estimate to be her risk of recurrence?

1. Less than 5%
2. 5% - 10%
3. 11% - 20%
4. 21% - 30%
5. 31% - 40%
6. 41% - 50%
7. 51% - 60%
8. Greater than 60%

If the previous patient's risk of recurrence is currently 35%, regulatory and reimbursement issues aside, how much of an improvement in the risk of recurrence would you need to administer 1 year of adjuvant olaparib?

1. 1%
2. 5%
3. 10%
4. 15%
5. 20%
6. 25%
7. Greater than 25%

OlympiA Trial: Olaparib Crosses Superiority Boundary for Invasive Disease-Free Survival versus Placebo at Planned Interim Analysis

Press Release: February 17, 2021

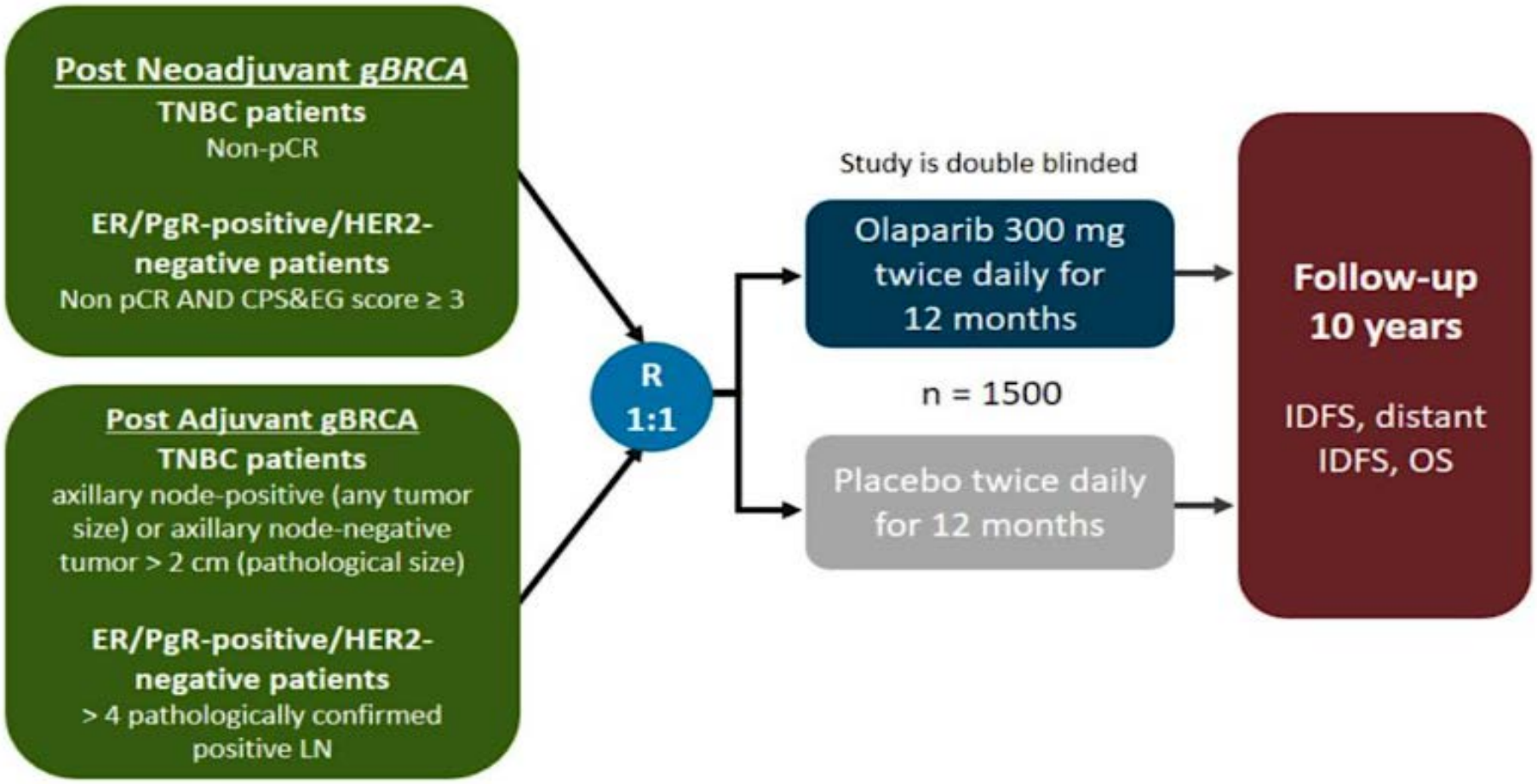
“The Phase 3 OlympiA trial for olaparib will move to early primary analysis and reporting following a recommendation from the Independent Data Monitoring Committee (IDMC).
Based on the planned interim analysis, the IDMC concluded that the trial crossed the superiority boundary for its primary endpoint of invasive disease-free survival (iDFS) versus placebo in the adjuvant treatment of germline *BRCA*-mutated (g*BRCA*m), high-risk human epidermal growth factor receptor 2 (HER2)-negative early-stage breast cancer following definitive local treatment and neoadjuvant or adjuvant chemotherapy.

Andrew Tutt, global chair of the OlympiA Phase 3 trial and professor, Institute of Cancer Research and Kings College London, said, "We are delighted that our global academic and industry partnership has been able to help investigate a possible personalized treatment for women with hereditary breast cancer. The most common cause of hereditary breast cancer is an inherited mutation in the BRCA1 or BRCA2 genes, which also may cause the disease to develop at a significantly earlier age than is usual. The OlympiA trial has allowed us to go beyond using genetic testing to identify patients who are at risk of this disease and explore the potential of olaparib to prevent disease recurrence for these patients. We look forward to analyzing and presenting the full results of the trial at a forthcoming medical meeting."

https://finance.yahoo.com/news/independent-data-monitoring-committee-concludes-115500394.html

RTP RESEARCH TO PRACTICE

OlympiA (NSABP B55/BIG 6-13): Phase III Trial Design

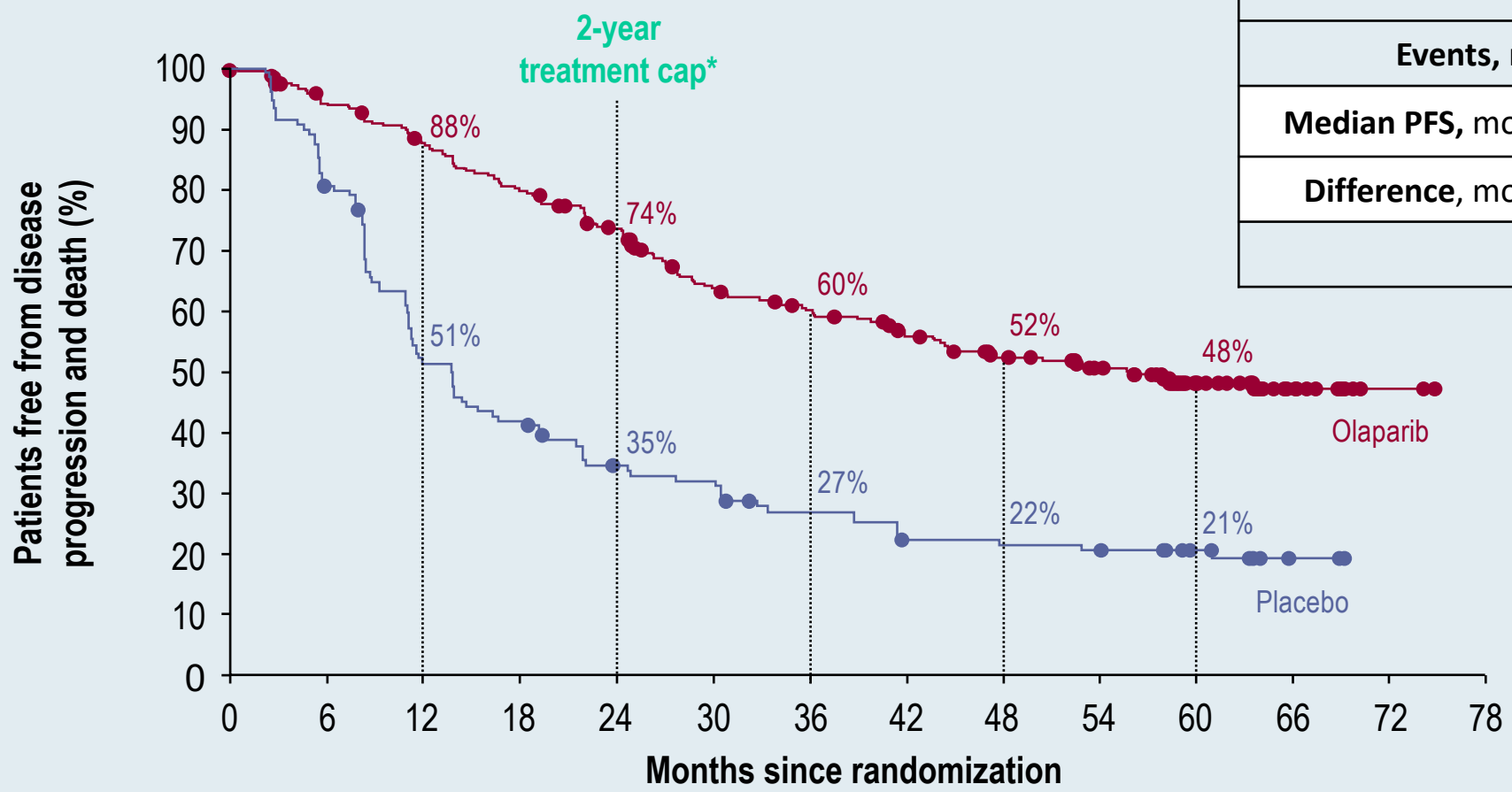


Estimated primary completion date: November 18, 2020

Courtesy of P Kelly Marcom, MD

SOLO-1: Updated PFS (60 Months Follow-Up)

	Olaparib (N=260)	Placebo (N=131)
Events, n (%)	118 (45)	100 (76)
Median PFS, months	**56.0**	**13.8**
Difference, months	42.2	
	HR 0.33 (95% CI 0.25–0.43)	



No. at risk

Olaparib	260	229	212	194	173	140	129	115	101	91	58	30	2	0
Placebo	131	103	65	53	41	38	30	24	23	22	16	3	0	

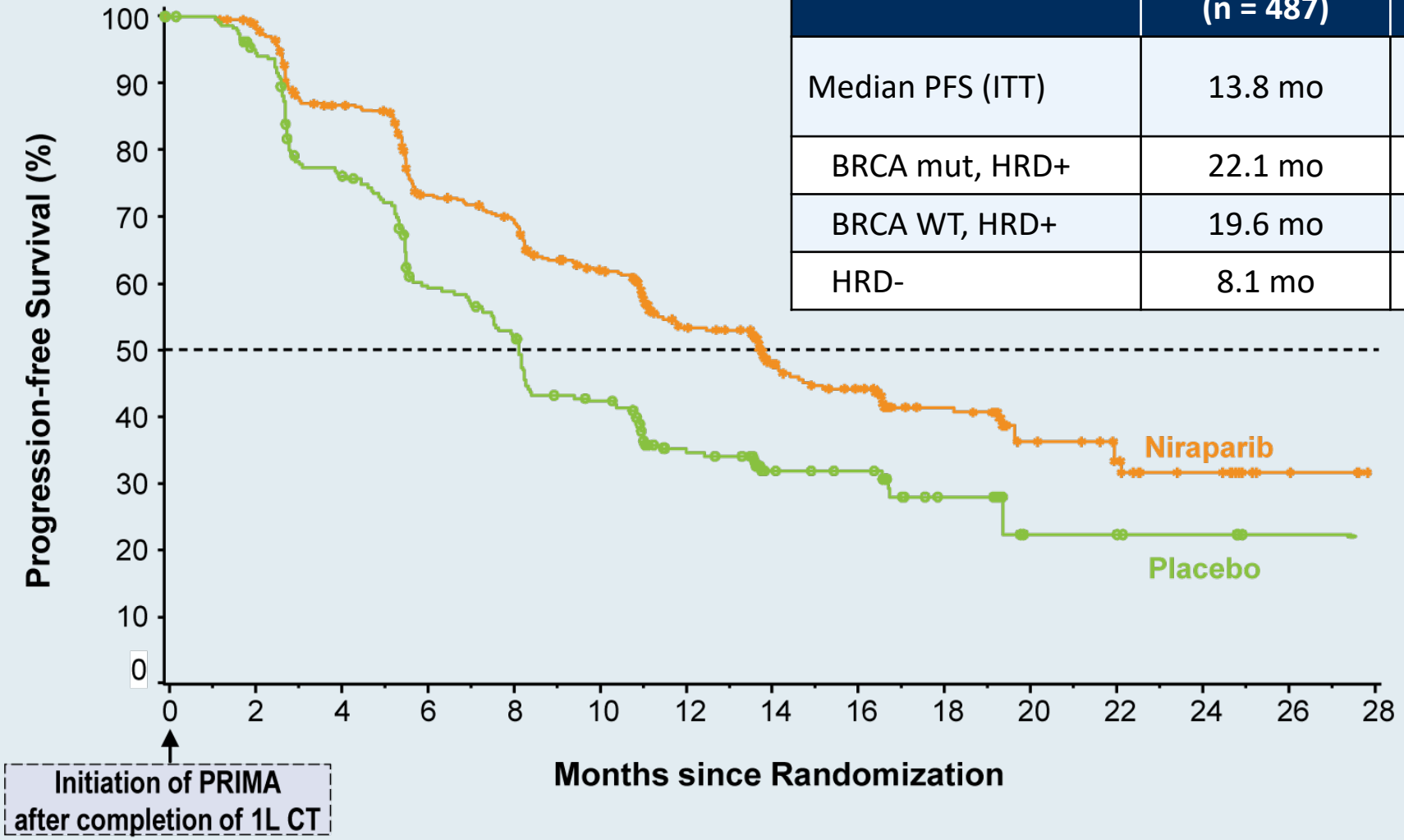
Median treatment duration:
Olaparib, 24.6 months
Placebo†, 13.9 months

Banerjee S et al. ESMO 2020;Abstract 811MO.

RTP RESEARCH TO PRACTICE

PRIMA Primary Endpoint: Progression-Free Survival

	Niraparib (n = 487)	Placebo (n = 246)	Hazard ratio
Median PFS (ITT)	13.8 mo	8.2 mo	HR: 0.62 ($p < 0.001$)
BRCA mut, HRD+	22.1 mo	10.9 mo	HR: 0.40
BRCA WT, HRD+	19.6 mo	8.2 mo	HR: 0.50
HRD-	8.1 mo	5.4 mo	HR: 0.68



Gonzalez-Martin A et al. *N Engl J Med* 2019;381:2391-402.

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Module 6: San Antonio Breast Cancer Symposium Review – Part 3

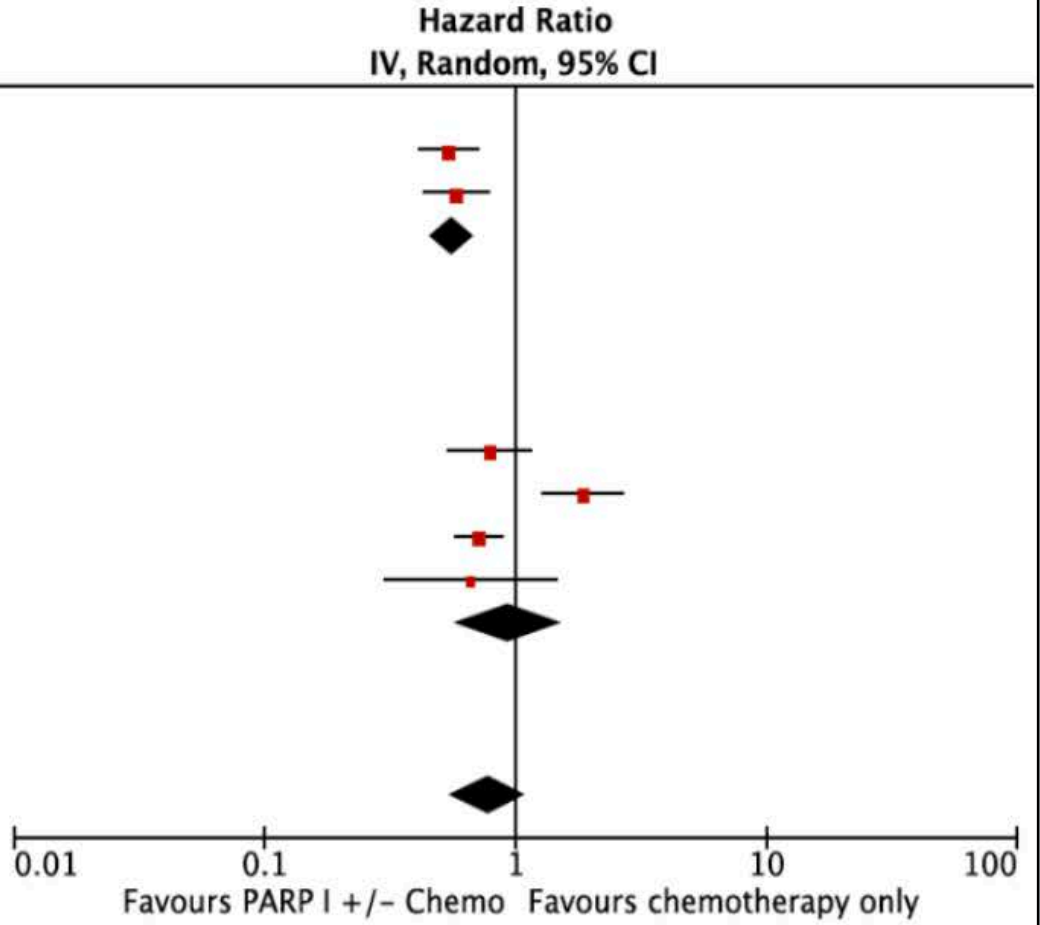
PARP Inhibitors for Treatment of BRCA Positive Metastatic Breast Cancer: A Systematic Review and Meta-Analysis

Kunwor R et al.

SABCS 2020;Abstract PS10-41.

PARP Inhibitors with or without Chemotherapy versus Chemotherapy Alone: Progression-Free Survival

Study or Subgroup	log[Hazard Ratio]	SE	Weight	Hazard Ratio IV, Random, 95% CI
1.1.1 PARP Inhibitor Vs Chemotherapy				
EMBRACA	-0.6162	0.1405	18.6%	0.54 [0.41, 0.71]
OlympiAD	-0.5447	0.1527	18.2%	0.58 [0.43, 0.78]
Subtotal (95% CI)			**36.9%**	**0.56 [0.46, 0.68]**
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.12$, df = 1 (P = 0.73); $I^2 = 0\%$				
Test for overall effect: Z = 5.64 (P < 0.00001)				
1.1.2 PARP Inhibitor + Chemotherapy Vs Chemotherapy alone				
BROCADE (VCP Vs PCP)	-0.237	0.1973	16.7%	0.79 [0.54, 1.16]
BROCADE (VT Vs PCP)	0.6195	0.1909	16.9%	1.86 [1.28, 2.70]
BROCADE 3	-0.3425	0.1121	19.5%	0.71 [0.57, 0.88]
SWOG S1416	-0.4155	0.4023	10.0%	0.66 [0.30, 1.45]
Subtotal (95% CI)			**63.1%**	**0.93 [0.57, 1.53]**
Heterogeneity: $Tau^2 = 0.20$; $Chi^2 = 19.80$, df = 3 (P = 0.0002); $I^2 = 85\%$				
Test for overall effect: Z = 0.28 (P = 0.78)				
Total (95% CI)			**100.0%**	**0.77 [0.55, 1.09]**
Heterogeneity: $Tau^2 = 0.15$; $Chi^2 = 31.10$, df = 5 (P < 0.00001); $I^2 = 84\%$				
Test for overall effect: Z = 1.47 (P = 0.14)				
Test for subgroup differences: $Chi^2 = 3.53$, df = 1 (P = 0.06), $I^2 = 71.6\%$				



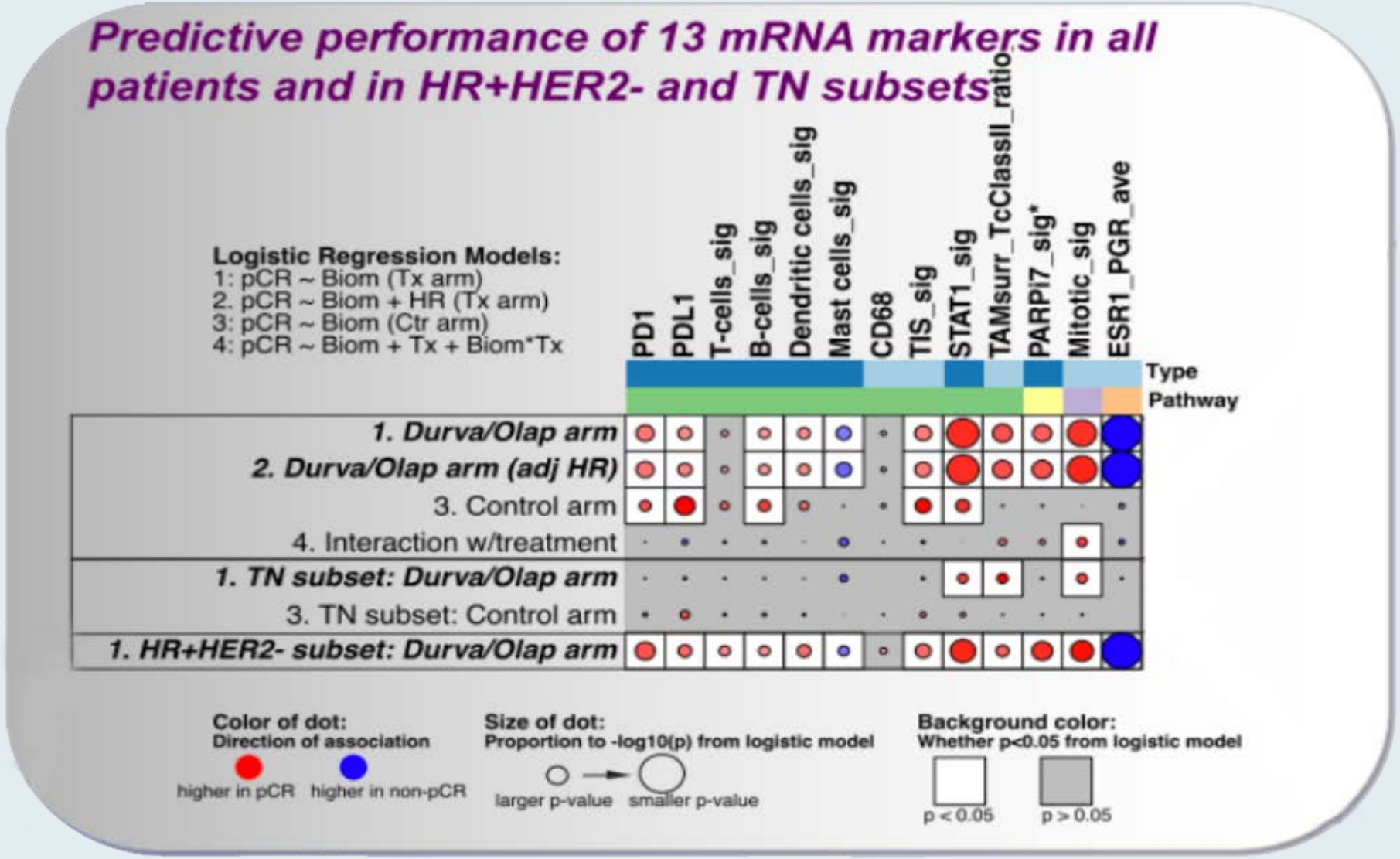
Kunwor R et al. SABCS 2020;Abstract PS10-41.

Biomarkers Predicting Response to Durvalumab Combined with Olaparib in the Neoadjuvant I-SPY 2 Trial for High-Risk Breast Cancer

Wolf DM et al.

SABCS 2020;Abstract PD14-02.

Biomarkers Predicting Response to Durvalumab/Olaparib Therapy



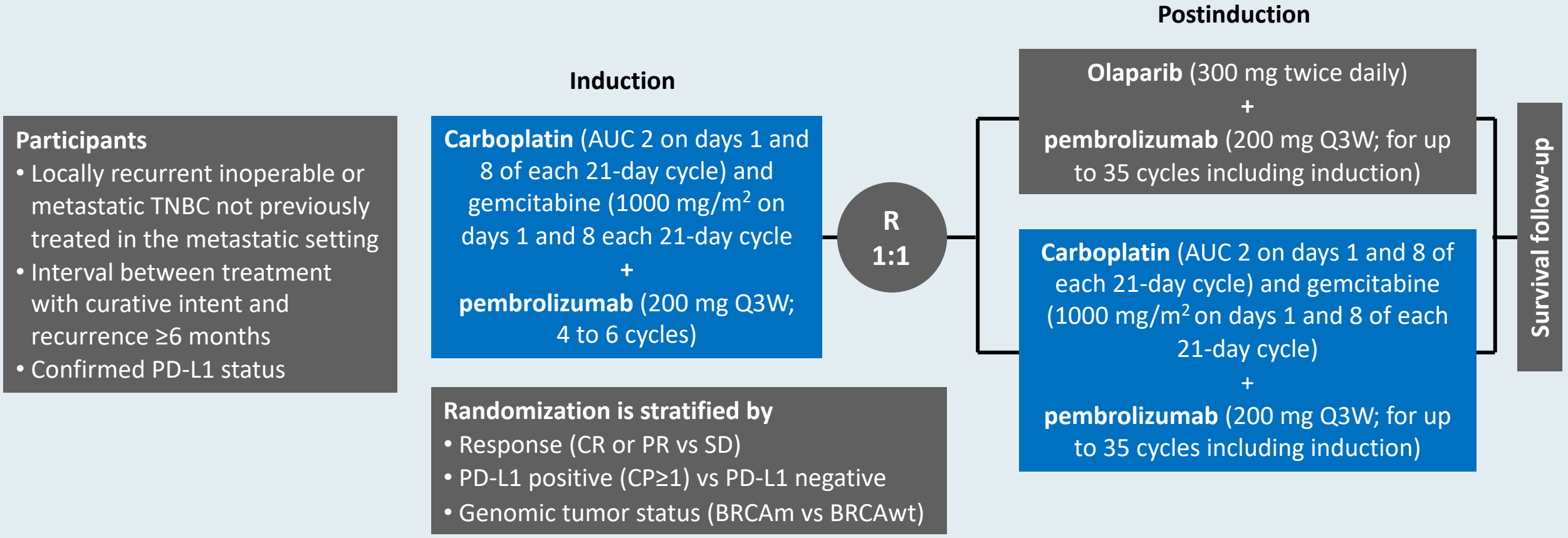
Wolf DM et al. SABCS 2020;Abstract PD14-02.

KEYLYNK-009: A Phase 2/3, Open-Label, Randomized Study of Pembrolizumab plus Olaparib vs Pembrolizumab plus Chemotherapy After Induction with First-Line Pembrolizumab plus Chemotherapy in Patients with Locally Recurrent Inoperable or Metastatic Triple-Negative Breast Cancer (TNBC)

Rugo H et al.

SABCS 2020;Abstract OT-30-01.

KEYLYNK-009 Study Design



Rugo H et al. SABCS 2020;Abstract OT-30-01.

Efficacy of Combined CDK4/6 Inhibitor and PARP Inhibitor in the Treatment of BRCA1 Mutant Triple Negative Breast Cancer

Zhu X et al.

SABCS 2020;Abstract PS4-39.

Results and Conclusions

Results

- We demonstrated for the first time that the combination of PARPi and CDK4/6i has synergistic effects against some TNBCs both in vitro and in vivo and was verified by CI < 0.9.
- Further experiments confirmed that PARPi combined with CDK4/6i inhibited cell proliferation and migration, and increased apoptosis and DNA damage.
- In the PARPi sensitive BRCA-/TNBC cell (MDA-MB-436), the inhibitory effect of monotherapy PARPi was obvious. In the PARPi resistant BRCA-/TNBC cells (HCC1937 and SUM149), CDK4/6i was added to achieve significant growth inhibition.
- In the timing of medication, PARPi followed by CDK4/6i had better inhibitory effect.

Conclusions

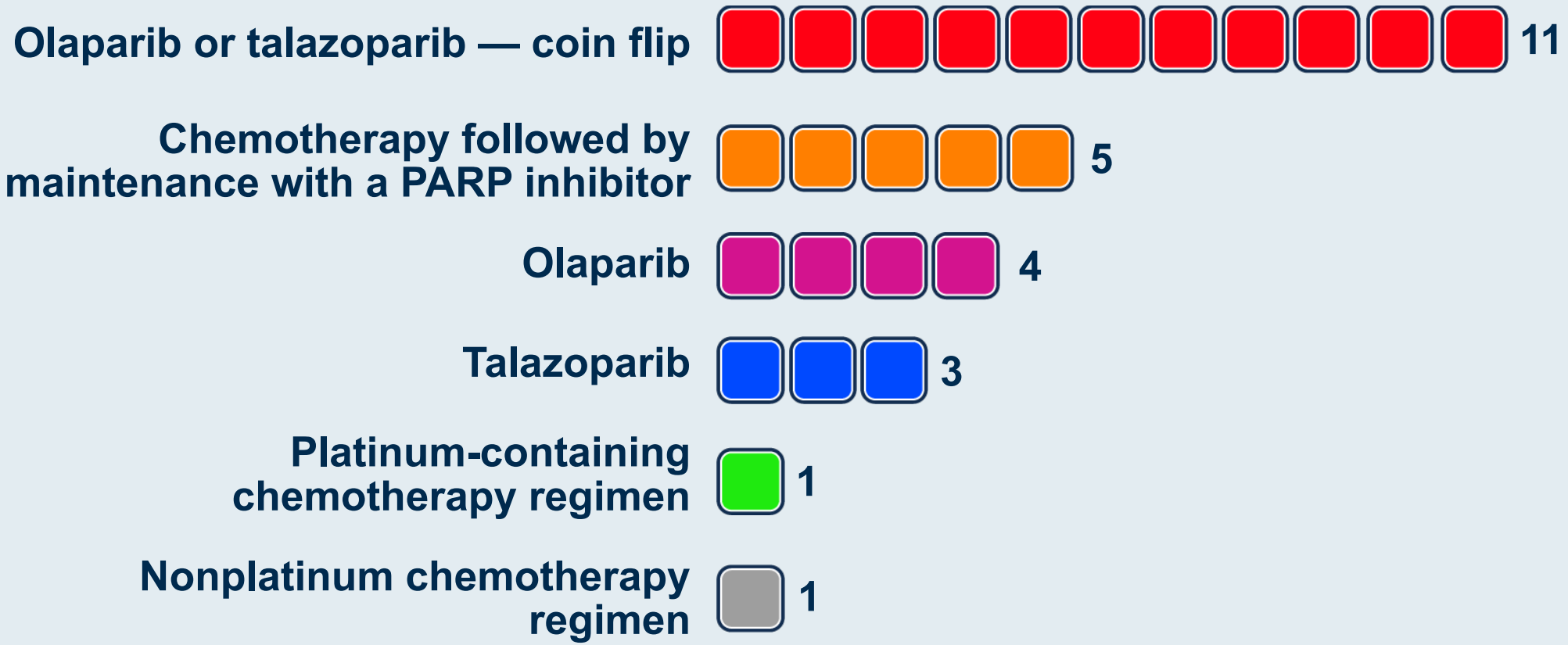
- In some BRCA-/ TNBCs, PARPi combined with CDK4/6i had a synergistic effect. Even in PARPi-resistant cells, combined treatment could enhance the efficacy and might reverse the drug resistance to some extent.

Zhu X et al. SABCS 2020;Abstract PS4-39.

What would be your preferred treatment approach for a 60-year-old patient with a BRCA germline mutation and de novo metastatic TNBC that is PD-L1-negative?

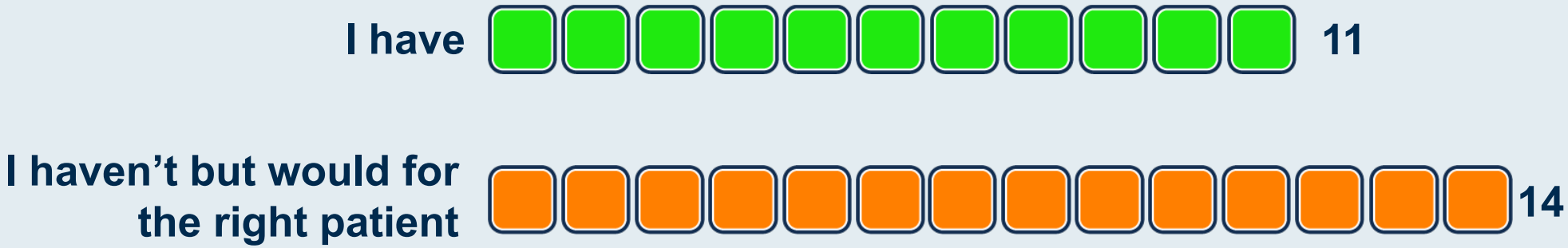
1. Olaparib
2. Talazoparib
3. Olaparib or talazoparib — coin flip
4. Nonplatinum chemotherapy
5. Platinum-containing chemotherapy
6. Chemotherapy followed by maintenance PARP inhibitor
7. Chemotherapy combined with a PARP inhibitor
8. Other

What would be your preferred treatment approach for a 60-year-old patient with a BRCA germline mutation and de novo metastatic TNBC that is PD-L1-negative?



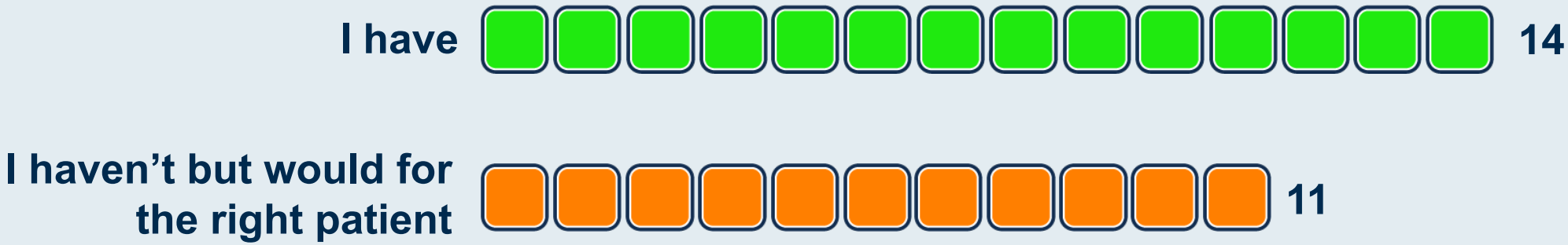
Survey of 25 breast cancer clinical investigators

Regulatory and reimbursement issues aside, have you attempted or would you attempt to access a PARP inhibitor for a patient with metastatic TNBC and a germline PALB2 mutation?



Survey of 25 breast cancer clinical investigators

Regulatory and reimbursement issues aside, have you attempted or would you attempt to access a PARP inhibitor for a patient with metastatic TNBC and a somatic BRCA mutation?



Survey of 25 breast cancer clinical investigators

Agenda

Module 1: Case Presentations

- An 88-year-old woman with triple-negative lobular carcinoma
- A 66-year-old woman with triple-negative, node-positive breast cancer
- A 31-year-old woman with triple-negative, node-negative IDC

Module 2: San Antonio Breast Cancer Symposium Review – Part 1

Module 3: Case Presentations

- A 40-year-old woman with metastatic TNBC
- A 61-year-old woman with a germline BRCA1 mutation and locally advanced breast cancer

Module 4: San Antonio Breast Cancer Symposium Review – Part 2

Module 5: Case Presentations

- A 46-year-old woman with triple-negative small cell carcinoma of the breast
- A 37-year-old woman with triple-negative IDC
- A 68-year-old woman with triple-negative, node-negative IDC

Module 6: San Antonio Breast Cancer Symposium Review – Part 3

RTP RESEARCH TO PRACTICE

Case Presentation – Dr Astrow: A 46-year-old woman with a 3.8-cm triple-negative, node-positive small cell carcinoma of the left breast

Dr Alan Astrow

- Large left breast mass and axillary nodes
- Core biopsy: Grade 3 IDC, triple-negative, Ki67: 70-80%
- Patient refused neoadjuvant chemotherapy
- Lumpectomy: 3.8-cm, Grade 3 small cell carcinoma, synaptophysin- and chromogranin-negative
- 3/18 positive axillary lymph nodes

Questions

- What chemotherapy would you recommend for this highly aggressive breast cancer? Should I just give standard dose-dense AC/paclitaxel?
- Should I give carbo/paclitaxel, or carbo/etoposide, or cisplatin/etoposide? If I give the patient carbo/etoposide, should I follow that with an anthracycline?

RTP RESEARCH TO PRACTICE

Case Presentation – Dr Astrow: A 37-year-old woman with TNBC and persistent neuropathy after neoadjuvant AC → paclitaxel

Dr Alan Astrow

- Left 3-cm Grade 3 IDC, triple-negative
- Neoadjuvant dose-dense AC x 4 → Paclitaxel (q2 wk) x 1 discontinued due to allergic reaction
  - BP elevated, trouble breathing, skin rash
- *Nab* paclitaxel x 6 of 9 completed but discontinued due to neuropathy
- Surgery, with CR
- One year later, neuropathy persists

Questions

- Is there anything that can be done for her persistent neuropathy?
- For future patients, do you recommend using gloves with ice in them? Other recommendations?

RTP RESEARCH TO PRACTICE

Case Presentation – Dr Astrow: A 68-year-old woman with an 8-mm triple-negative, node-negative IDC – Oncotype DX® RS: 57 (ER-negative)

Dr Alan Astrow

- Diagnosed with an 8-mm, Grade 3 IDC
- SLNB: Negative
- IHC: ER: 20%, PR: Negative, HER2: Negative
- RT-PCR via Oncotype DX assay: Triple-negative
- Oncotype DX RS: 57

Questions

- Would you suggest TC chemotherapy, particularly in light of her high RS of 57? What about dose-dense AC-paclitaxel?
- Should I offer her an aromatase inhibitor or tamoxifen after completion of chemotherapy, since she is triple-negative by RT-PCR with the Oncotype DX assay but ER-positive by IHC?

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Module 6: San Antonio Breast Cancer Symposium Review – Part 3

RTP RESEARCH TO PRACTICE

Low Levels of Interleukin-6 at Baseline Were Significantly Associated with Improved Overall Survival of Patients Treated with Eribulin for Locally Advanced or Metastatic Breast Cancer

Bun A et al.

SABCS 2020;Abstract PS4-20.

Conclusion

Patients treated with eribulin demonstrated a significantly longer OS if their baseline IL-6 levels were within the normal range. This predictive efficacy for eribulin was more accurate than that of NLR or ALC. As there was no significant association between IL-6 levels and NLR or ALC, IL-6 appears to predict whether the tumor microenvironment is favorable or unfavorable for eribulin treatment, mediated through different mechanisms. Therefore, IL-6 levels may be useful for selecting patients who will benefit from the administration of eribulin in terms of improved OS.

Bun A et al. SABCS 2020;Abstract PS4-20.

Biomarker Evaluation in the Phase 3 ASCENT Study of Sacituzumab Govitecan Versus Chemotherapy in Patients With Metastatic Triple-Negative Breast Cancer

Sara A. Hurvitz,[1] Sara M. Tolaney,[2] Kevin Punie,[3] Delphine Loirat,[4] Mafalda Oliveira,[5] Kevin Kalinsky,[6] Amelia Zelnak,[7] Philippe Aftimos,[8] Florence Dalenc,[9] Sagar Sardesai,[10] Erika Hamilton,[11] Priyanka Sharma,[12] Sabela Recalde,[13] Eva Ciruelos Gil,[14] Tiffany Traina,[15] Joyce O'Shaughnessy,[16] Javier Cortes,[17] Michaela Tsai,[18] Linda Vahdat,[19] Véronique Diéras,[20] Lisa Carey,[21] Hope S. Rugo,[22] David M. Goldenberg,[23] Quan Hong,[23] Martin Olivo,[23] Loretta M. Itri,[23] and Aditya Bardia[24]

[1]Medical Oncology, University of California, Los Angeles, Jonsson Comprehensive Cancer Center, Los Angeles, CA, USA; [2]Dana-Farber Cancer Institute, Boston, MA, USA; [3]Department of General Medical Oncology, University Hospitals Leuven, Leuven, Belgium; [4]Institut Curie, Paris, France; [5]Hospital Universitari Vall d'Hebron, Barcelona, Spain; [6]Winship Cancer Institute, Emory University, Atlanta, GA, USA; [7]Northside Hospital, Atlanta, GA, USA; [8]Institut Jules Bordet, Brussels, Belgium; [9]Institut Claudius Regaud, Toulouse, France; [10]The Ohio State University Wexner Medical Center, Columbus, OH, USA; [11]Sarah Cannon Research Institute/Tennessee Oncology, Nashville, TN, USA; [12]University of Kansas Cancer Center - The Richard and Annette Bloch Cancer Care Pavilion, Kansas City, KS, USA; [13]Institut Catala d'Oncologia Hospitalet, Barcelona, Spain; [14]Hospital Universitario 12 de Octubre, Madrid, Spain; [15]Memorial Sloan Kettering Cancer Center, New York, NY, USA; [16]Texas Oncology - Baylor Charles A. Sammons Cancer Center, Dallas, TX, USA; [17]IOB Institute of Oncology, Quiron Group, Madrid & Barcelona, Spain; [18]VPCI Oncology Research, Minneapolis, MN, USA; [19]Memorial Sloan Kettering Cancer Center, New York, NY, USA; [20]Centre Eugène-Marquis, Rennes, France; [21]University of North Carolina Lineberger Comprehensive Cancer Center, Chapel Hill, NC, USA; [22]University of California San Francisco Comprehensive Cancer Center, San Francisco, CA, USA; [23]Immunomedics, Morris Plains, NJ, USA; and [24]Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA

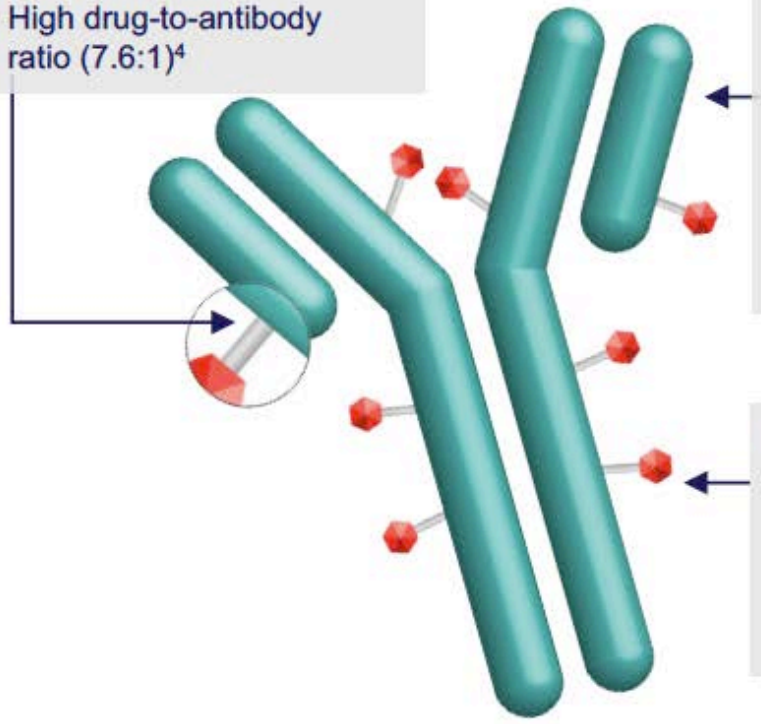
To obtain presentation, https://bit.ly/2020hurvitzgs3-06

ClinicalTrials.gov Number: NCT02574455

Sacituzumab Govitecan (SG) Is a First-in-Class Trop-2–Directed ADC

- SG is distinct from other ADCs[1-4]
  - Antibody highly specific for Trop-2
  - High drug-to-antibody ratio (7.6:1)
  - Internalization and enzymatic cleavage by tumor cell not required for SN-38 liberation from antibody
  - Hydrolysis of the linker also releases SN-38 extracellularly in the tumor microenvironment (bystander effect)
- Granted FDA accelerated approval for mTNBC[5]
- Landmark ASCENT study demonstrated a significant survival improvement of SG over chemotherapy, with a tolerable safety profile in pretreated mTNBC[6]
  - Median PFS of 5.6 vs 1.7 months (HR 0.41, *P*<0.0001)
  - Median OS of 12.1 vs 6.7 months (HR 0.48, *P*<0.0001)

Linker for SN-38
- Hydrolyzable linker for payload release
- High drug-to-antibody ratio (7.6:1)[4]



Humanized anti–Trop-2 antibody
- Directed toward Trop-2, an epithelial antigen expressed on many solid cancers

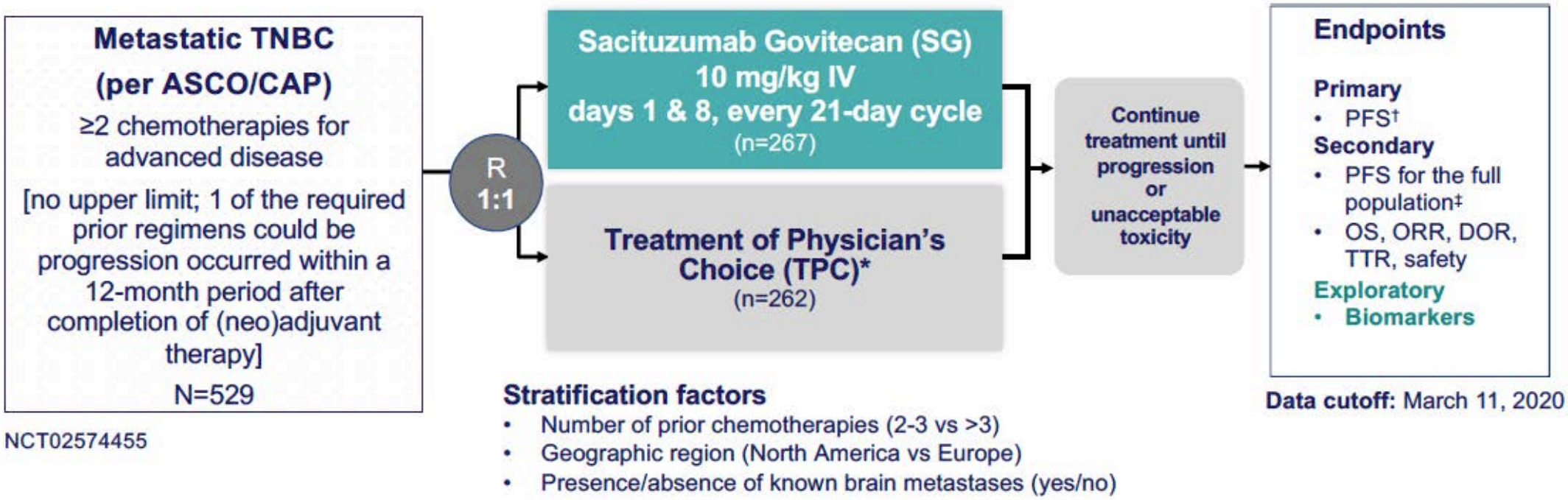
SN-38 payload
- SN-38 more potent than parent compound, irinotecan

ADC, antibody-drug conjugate; FDA, US Food and Drug Administration; OS, overall survival; PFS, progression-free survival; TNBC, triple-negative breast cancer; Trop-2, trophoblast cell surface antigen 2.

1. Goldenberg DM, et al. *Expert Opin Biol Ther.* 2020;20:871-885. 2. Nagayama A, et al. *Ther Adv Med Oncol.* 2020;12:1758835920915980. 3. Cardillo TM, et al. *Bioconjugate Chem.* 2015;26:919-931. 4. Goldenberg DM, et al. *Oncotarget.* 2015;6:22496-224512. 5. Press Release. https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-sacituzumab-govitecan-hziy-metastatic-triple-negative-breast-cancer. Accessed August 26, 2020. 6. Bardia A, et al. ESMO 2020. Abstract LBA17.

Hurvitz S et al. SABCS 2020;Abstract GS3-06.

ASCENT: A Phase 3 Confirmatory Study of Sacituzumab Govitecan in Refractory/Relapsed mTNBC



NCT02574455

Stratification factors
- Number of prior chemotherapies (2-3 vs >3)
- Geographic region (North America vs Europe)
- Presence/absence of known brain metastases (yes/no)

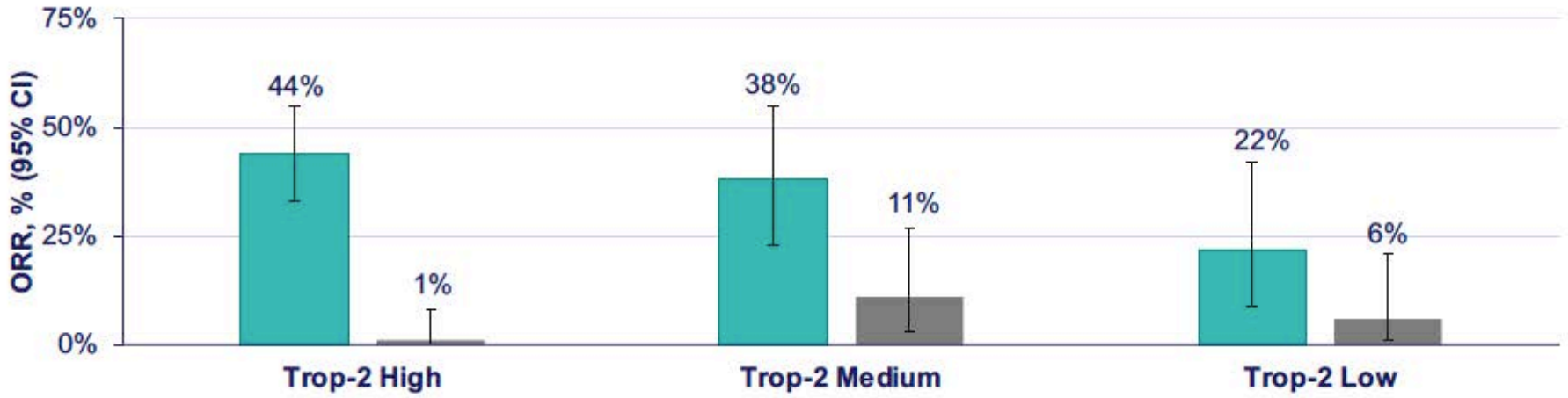
Data cutoff: March 11, 2020

We report the exploratory biomarker analysis in the brain metastases-negative (Brain Mets-Negative) population

*TPC: eribulin, vinorelbine, gemcitabine, or capecitabine. †PFS measured by an independent, centralized, and blinded group of radiology experts who assessed tumor response using RECIST 1.1 criteria in patients without brain metastasis. ‡The full population includes all randomized patients (with and without brain metastases). Baseline brain MRI only required for patients with known brain metastasis.
ASCO/CAP, American Society of Clinical Oncology/College of American Pathologists; DOR, duration of response; DSMC, Data Safety Monitoring Committee; IV, intravenous; mTNBC, metastatic triple-negative breast cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; R, randomization; RECIST, Response Evaluation Criteria in Solid Tumors; TTR, time to response.
National Institutes of Health. https://clinicaltrials.gov/ct2/show/NCT02574455.

Hurvitz S et al. SABCS 2020;Abstract GS3-06.

ORR by Trop-2 Expression

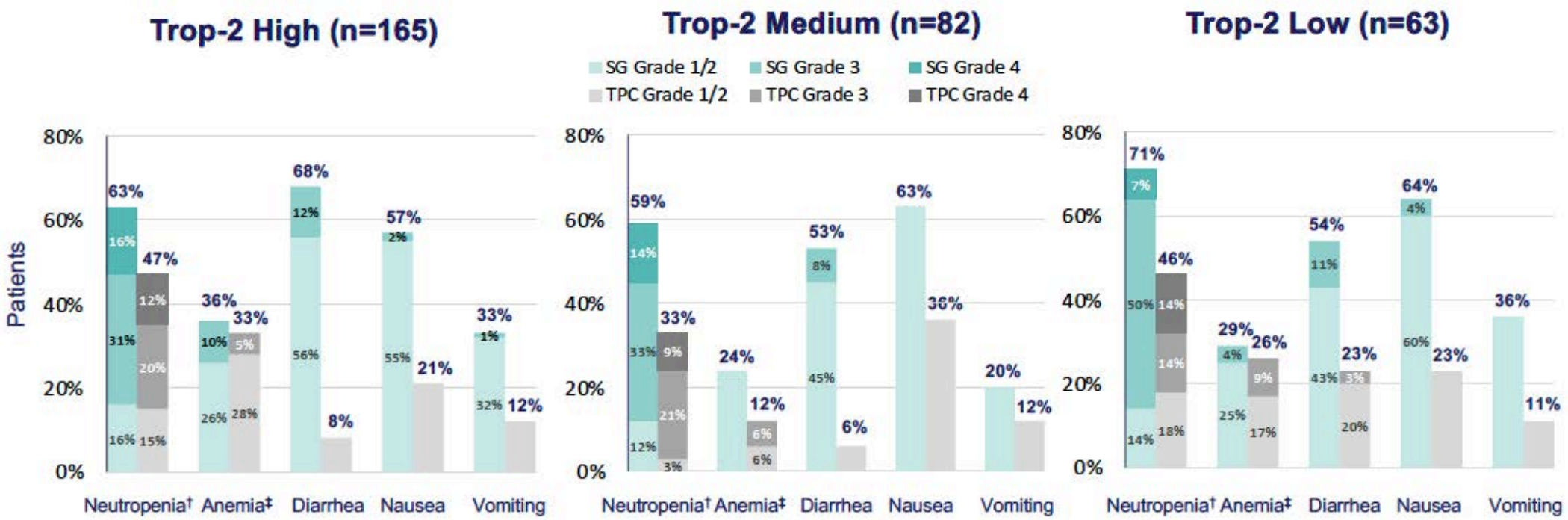


	Trop-2 High H-score: 200-300 (n=157)		Trop-2 Medium H-score: 100-200 (n=74)		Trop-2 Low H-score: <100 (n=59)	
	SG (n=85)	TPC (n=72)	SG (n=39)	TPC (n=35)	SG (n=27)	TPC (n=32)
ORR—% (no.)	44% (37)	1% (1)	38% (15)	11% (4)	22% (6)	6% (2)
95% CI	33-55	0-8	23-55	3-27	9-42	1-21

Assessed in the brain metastases-negative population. ORR and PFS are assessed by BICR. Trop-2 expression determined in archival samples by validated immunohistochemistry assay and H-scoring.
BICR, blind independent central review; H-score, histochemical-score; ORR, objective response rate; SG, sacituzumab govitecan; TPC, treatment of physician's choice; Trop-2, trophoblast cell surface antigen-2.

Hurvitz S et al. SABCS 2020;Abstract GS3-06.

Treatment-Related AESIs by Trop-2 Expression: Key AESIs*

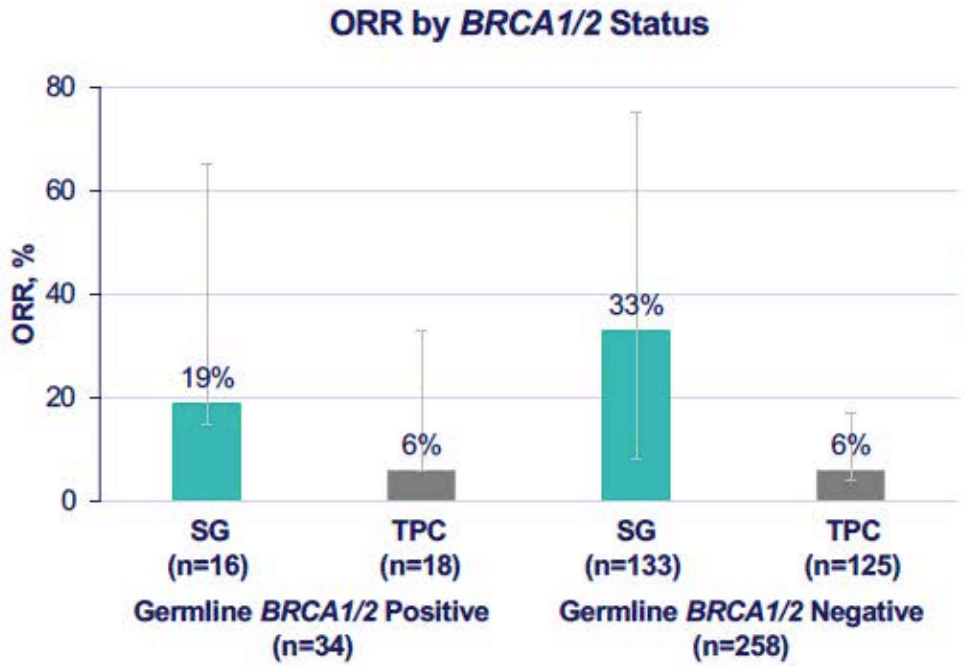


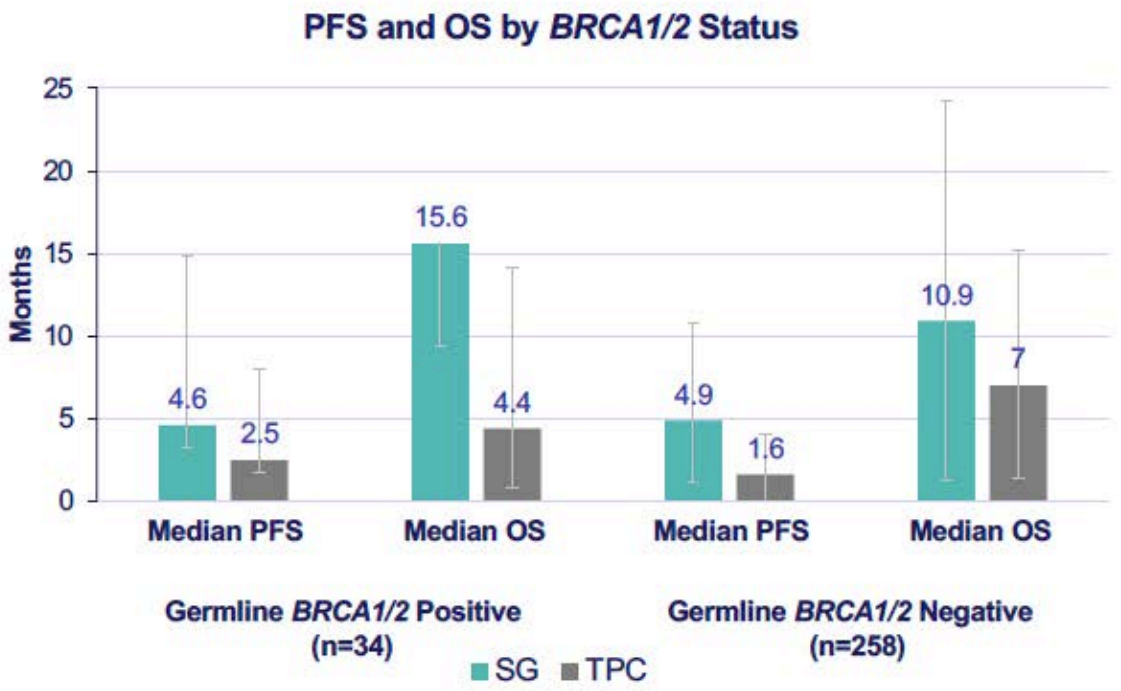
- Key grade ≥3 treatment-related AESIs for Trop-2 High (SG [n=90] vs TPC [n=70]): neutropenia (47% vs 32%), diarrhea (12% vs 0%), and anemia (10% vs 5%)

Assessed in the safety population of patients who received at ≥1 dose of SG regardless of brain metastases status and have known Trop-2 expression. Trop-2 expression determined in archival samples by validated immunohistochemistry assay and H-scoring. *Patients may report more than 1 event per preferred term. AEs were classified according to the MedDRA systems of preferred terms and system organ class and according to severity by NCI CTCAE v4.03. †Combined preferred terms of 'neutropenia' and 'decreased neutrophil count'. ‡Combined preferred terms of 'anemia,' 'hemoglobin decreased' and 'red blood cell count decreased'.
AESI, adverse event of special interest; H-score, histochemical score; MedDRA, Medical Dictionary for Regulatory Activities; NCI CTCAE v4.03, National Cancer Institute Common Terminology Criteria for AEs, version 4.03; SG, sacituzumab govitecan; TPC, treatment of physician's choice; Trop-2, trophoblast cell surface antigen-2.

Hurvitz S et al. SABCS 2020;Abstract GS3-06.

Efficacy Summary by Germline *BRCA1/2* Status





Assessed in the brain metastases-negative population. ORR and PFS are assessed by BICR.
BICR, blind independent central review; *BRCA*, breast cancer gene; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; SG, sacituzumab govitecan; TPC, treatment of physician's choice; Trop-2, trophoblast cell surface antigen-2.

Hurvitz S et al. SABCS 2020;Abstract GS3-06.

Geicam/2014-03 (RegisTEM): A Prospective Registry of Unresectable Locally Advanced or Metastatic Breast Cancer: Characteristics of a Subset of Patients with Triple Negative Subtype

Jara C et al.

SABCS 2020;Abstract PS7-25.

Conclusion

In this subset of patients with TN ABC due to recurrent disease, lung, lymph nodes and bone are the most frequent metastatic locations. The main first- and second-line therapies were CT in monotherapy.

Progression to the first-line conventional therapy (CT +/- bevacizumab) was reported in 51.1% patients with a median TTP of 4.7 mo (range 0.8-19.0) in the whole group, being similar in pts with TN in PT and PT/M1 (4.4 mo), and higher in patients with TN in M1 (7.1 mo), no statistically significant difference.

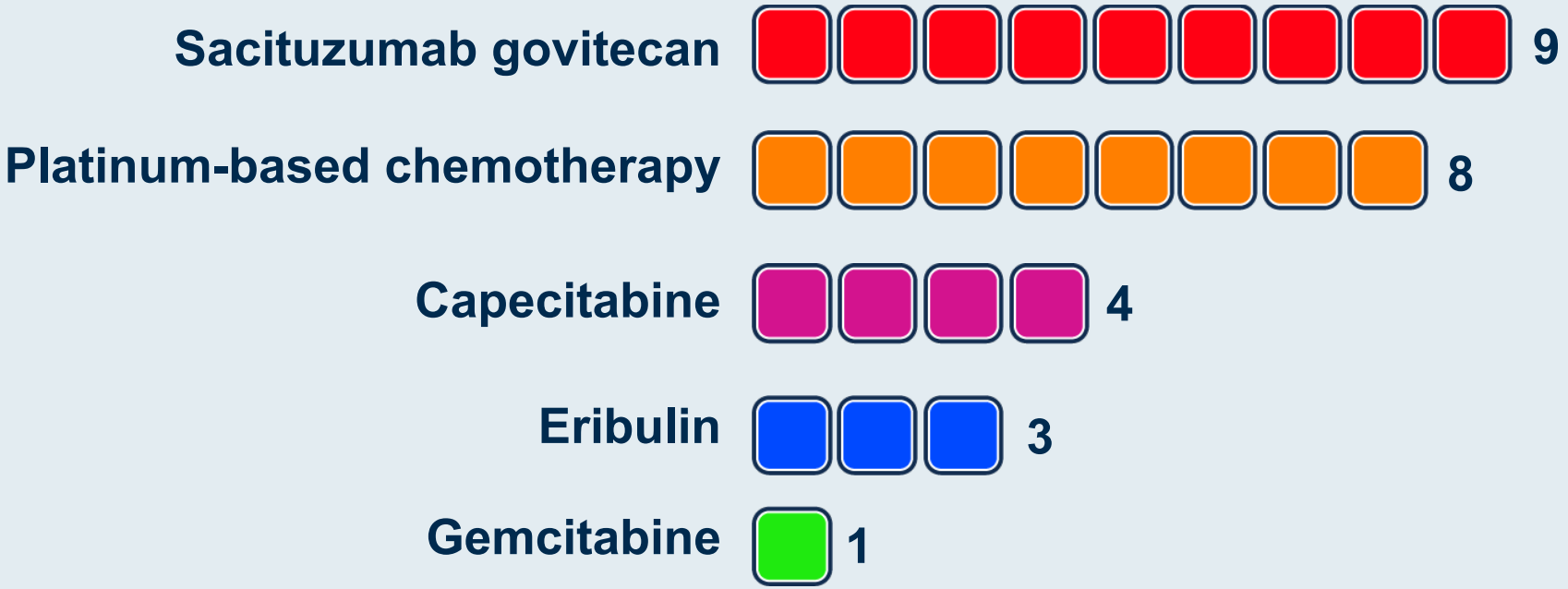
36% of the initial subset of patients reported to be treated in the third-line setting. Patients with TN only in M1 seem to have a longer time to progression from EBC.

Jara C et al. SABCS 2020;Abstract PS7-25

What treatment would you recommend next for a 60-year-old woman with metastatic TNBC (BRCA wild type, PD-L1-positive) who experiences disease progression after 7 months of first-line atezolizumab/*nab* paclitaxel?

1. Gemcitabine
2. Capecitabine
3. Vinorelbine
4. Eribulin
5. Sacituzumab govitecan
6. Platinum-based chemotherapy
7. Other chemotherapy
8. Other

What treatment would you recommend next for a 60-year-old woman with metastatic TNBC (BRCA WT, PD-L1-positive) who experiences disease progression after 7 months of first-line atezolizumab/*nab* paclitaxel?



Survey of 25 breast cancer clinical investigators

Meet The Professor
Management of Lung Cancer

Tuesday, February 23, 2021
12:00 PM – 1:00 PM ET

Faculty

Martin Reck, MD, PhD

Moderator

Neil Love, MD

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CME credit information will be emailed to each participant within 3 business days.

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