

Oncology Q&A: Discussing Common Questions Posed by Patients with Metastatic Triple-Negative Breast Cancer

A CME/MOC- and NCPD-Accredited Webinar Developed in Partnership with the Triple Negative Breast Cancer Foundation

Tuesday, January 7, 2025

5:00 PM – 6:00 PM ET

Faculty

Lisa A Carey, MD, ScM, FASCO

Rita Nanda, MD

Moderator

Neil Love, MD

Faculty



Lisa A Carey, MD, ScM, FASCO
L Richardson and Marilyn Jacobs Preyer
Distinguished Professor for
Breast Cancer Research
Deputy Director for Clinical Sciences
Lineberger Comprehensive Cancer Center
University of North Carolina
Chapel Hill, North Carolina



MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida



Rita Nanda, MD
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Associate Professor of Medicine
Section of Hematology/Oncology
The University of Chicago
Chicago, Illinois

Survey Participants



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Division of Medical Oncology, Department of
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Drug Discovery, Delivery and Experimental
Therapeutics Program
The University of Kansas Cancer Center
Westwood, Kansas



Joyce O'Shaughnessy, MD
Celebrating Women Chair in Breast
Cancer Research
Baylor University Medical Center
Chair, Breast Disease Committee
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Seth Wander, MD, PhD
Assistant Professor of Medicine
Harvard Medical School
Attending Physician
Massachusetts General Hospital
Boston, Massachusetts

Commercial Support

This activity is supported by an educational grant from Gilead Sciences Inc.

Dr Love — Disclosures

Dr Love is president and CEO of Research To Practice. Research To Practice receives funds in the form of educational grants to develop CME activities from the following companies: AbbVie Inc, Adaptive Biotechnologies Corporation, ADC Therapeutics, Agios Pharmaceuticals Inc, Alexion Pharmaceuticals, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Arvinas, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, BeiGene Ltd, BeyondSpring Pharmaceuticals Inc, Black Diamond Therapeutics Inc, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol Myers Squibb, Celgene Corporation, Clovis Oncology, Coherus BioSciences, CTI BioPharma, a Sobi Company, Daiichi Sankyo Inc, Eisai Inc, Elevation Oncology Inc, EMD Serono Inc, Epizyme Inc, Exact Sciences Corporation, Exelixis Inc, Five Prime Therapeutics Inc, Foundation Medicine, G1 Therapeutics Inc, Genentech, a member of the Roche Group, Genmab US Inc, Geron Corporation, Gilead Sciences Inc, Grail Inc, GSK, Halozyme Inc, Helsinn Healthcare SA, Hologic Inc, ImmunoGen Inc, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Karyopharm Therapeutics, Kite, A Gilead Company, Kronos Bio Inc, Legend Biotech, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, MEI Pharma Inc, Merck, Mersana Therapeutics Inc, Mirati Therapeutics Inc, Mural Oncology Inc, Natera Inc, Novartis, Novartis Pharmaceuticals Corporation on behalf of Advanced Accelerator Applications, Novocure Inc, Nuvalent, Oncopeptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, R-Pharm US, Sanofi, Seagen Inc, Servier Pharmaceuticals LLC, SpringWorks Therapeutics Inc, Stemline Therapeutics Inc, Sumitomo Dainippon Pharma Oncology Inc, Syndax Pharmaceuticals, Taiho Oncology Inc, Takeda Pharmaceuticals USA Inc, TerSera Therapeutics LLC, Tesaro, A GSK Company, TG Therapeutics Inc, Turning Point Therapeutics Inc, Verastem Inc, and Zymeworks Inc.

Research To Practice CME Planning Committee Members, Staff and Reviewers

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

Dr Carey — Disclosures Faculty

No relevant conflicts of interest to disclose.

Dr Nanda — Disclosures Faculty

Advisory Committees	AstraZeneca Pharmaceuticals LP, Daiichi Sankyo Inc, Exact Sciences Corporation, GE Healthcare, Gilead Sciences Inc, Guardant Health, Merck, Moderna, Novartis, OBI Pharma Inc, Pfizer Inc, Sanofi, Seagen Inc, Stemline Therapeutics Inc, Summit Therapeutics
Contracted Research	Arvinas, AstraZeneca Pharmaceuticals LP, Bristol Myers Squibb, Corcept Therapeutics, Genentech, a member of the Roche Group, Gilead Sciences Inc, GSK, Merck, Novartis, OBI Pharma Inc, Pfizer Inc, Relay Therapeutics, Seagen Inc, Sun Pharmaceutical Industries Ltd, Taiho Oncology Inc

Dr Brufsky — Disclosures

Survey Participant

Consulting Agreements	Agendia Inc, AstraZeneca Pharmaceuticals LP, BriaCell, Daiichi Sankyo Inc, Genentech, a member of the Roche Group, Gilead Sciences Inc, Jazz Pharmaceuticals Inc, Lilly, Merck, Myriad Genetic Laboratories Inc, Natera Inc, Novartis, Pfizer Inc, Puma Biotechnology Inc, Sanofi
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Dr O'Shaughnessy — Disclosures

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Dr Sharma — Disclosures Survey Participant

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Data and Safety Monitoring Boards/Committees	Jazz Pharmaceuticals Inc

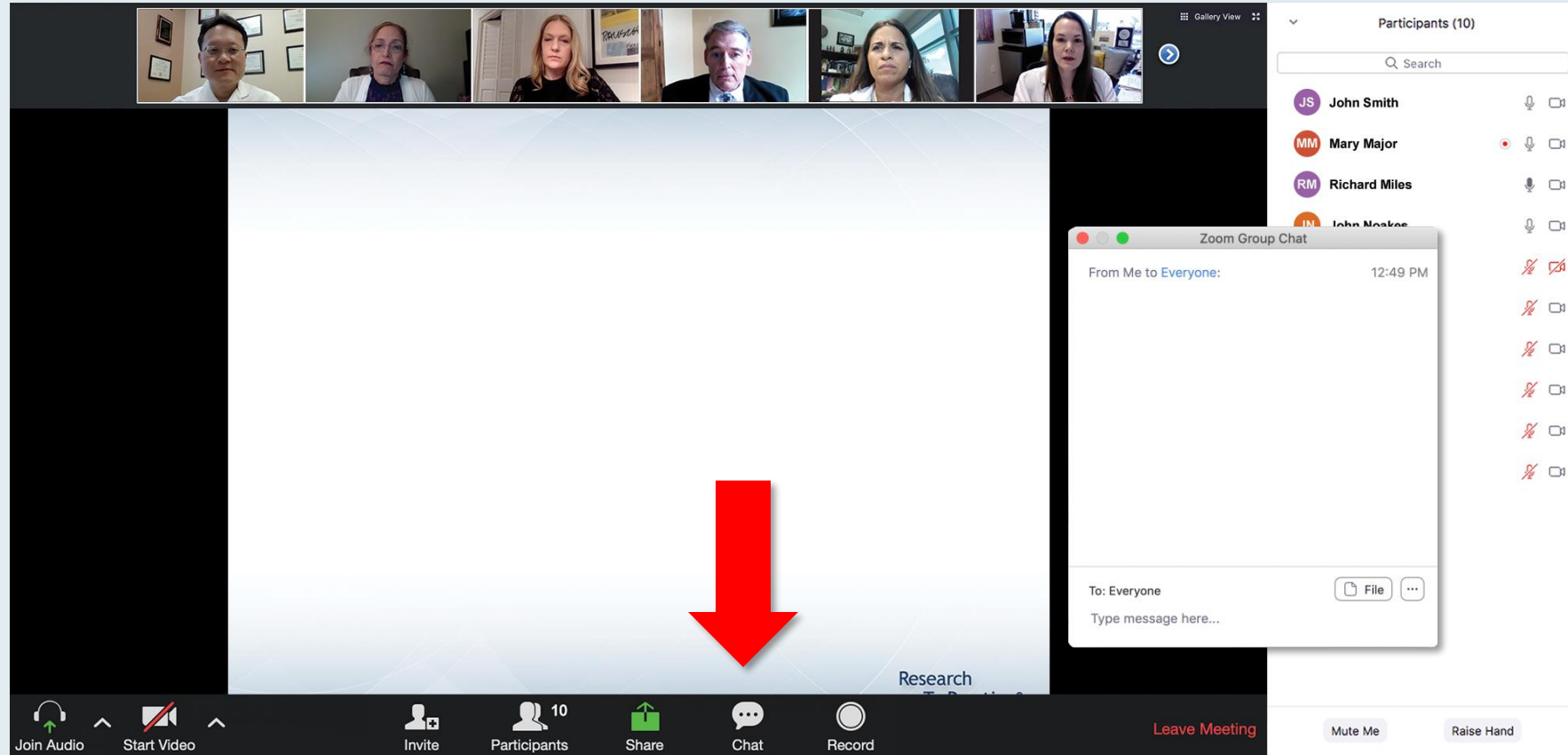
Dr Wander — Disclosures

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Data and Safety Monitoring Boards/Committees	Regor Therapeutics Group
Speakers Bureaus	Guardant Health, Lilly
Nonrelevant Financial Relationships	2nd.MD

This educational activity contains discussion of non-FDA-approved uses of agents and regimens. Please refer to official prescribing information for each product for approved indications.

We Encourage Clinicians in Practice to Submit Questions



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

Familiarizing Yourself with the Zoom Interface

Expand chat submission box

The screenshot shows a Zoom meeting interface. At the top, there are video thumbnails for participants: RTP Coordinat..., Kirsten Miller, RTP Mike Rivera, and Lisa Suarez. A 'Recording...' indicator is visible. The main content is a slide titled 'Meet The Professor Program Participating Faculty' with six faculty members listed:

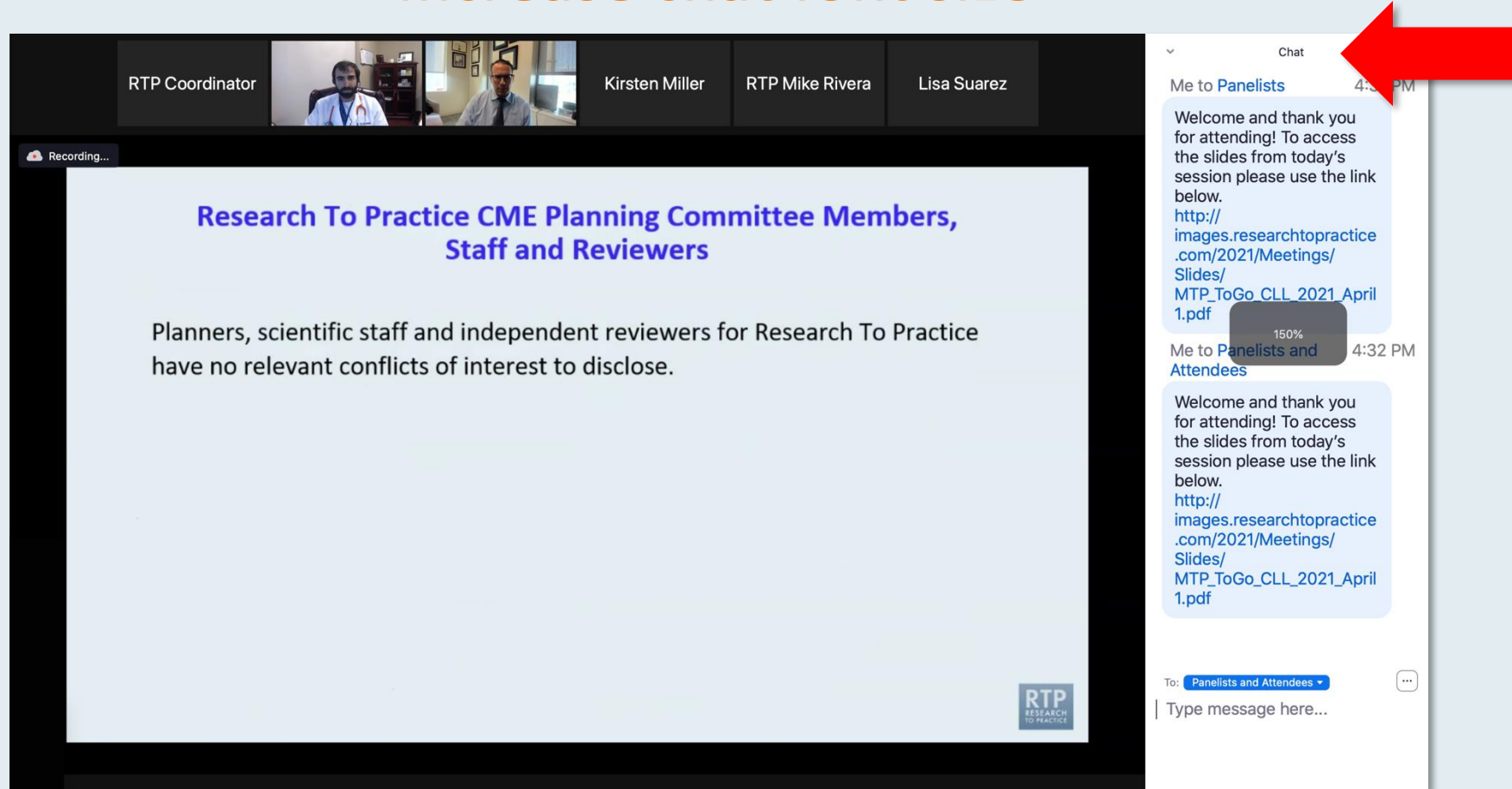
- Nancy L Bartlett, MD**
Professor of Medicine
Koman Chair in Medical Oncology
Washington University School of Medicine
St Louis, Missouri
- Jonathan W Friedberg, MD, MMSc**
Samuel E Durand Professor of Medicine
Director, James P Wilmot Cancer Institute
University of Rochester
Rochester, New York
- Carla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

The chat window on the right shows two messages from 'Me to Panelists' and 'Me to Panelists and Attendees' at 4:31 PM and 4:32 PM respectively. Each message contains a welcome message and a link to a PDF: http://images.researchtopractice.com/2021/Meetings/Slides/MTP_ToGo_CLL_2021_April1.pdf. A red arrow points to the white line above the chat submission box, indicating how to expand it.

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

Familiarizing Yourself with the Zoom Interface

Increase chat font size



The screenshot displays a Zoom meeting interface. At the top, there are video thumbnails for participants: RTP Coordinator, Kirsten Miller, RTP Mike Rivera, and Lisa Suarez. Below the thumbnails is a slide titled "Research To Practice CME Planning Committee Members, Staff and Reviewers". The slide content reads: "Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose." A "Recording..." indicator is visible in the top left corner of the slide area. On the right side, the Zoom chat window is open, showing a message from "Me to Panelists" and "Me to Panelists and Attendees". A red arrow points to the chat window, specifically to the font size adjustment icon (a small square with a plus sign) located above the chat messages. The chat messages contain a welcome message and a link to a PDF document: http://images.researchtopractice.com/2021/Meetings/Slides/MTP_ToGo_CLL_2021_April_1.pdf. The chat window also shows a "150%" font size indicator and a "To: Panelists and Attendees" dropdown menu.

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

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

The screenshot shows a Zoom meeting with a gallery view of participants at the top. The main content area displays a slide titled "Meet The Professor" with the subtitle "Optimizing the Selection and Sequencing of Therapy for Patients with Metastatic Gastrointestinal Cancer". The event is scheduled for Wednesday, August 25, from 5:00 PM to 6:00 PM. The faculty member is Wells A Messersmith, and the moderator is Neil Love, MD. A "Quick Survey" overlay is active, listing several treatment combinations with radio button options: Carfilzomib +/- dexamethasone, Pomalidomide +/- dexamethasone, Carfilzomib + pomalidomide +/- dexamethasone, Elotuzumab + lenalidomide +/- dexamethasone, Elotuzumab + pomalidomide +/- dexamethasone, Daratumumab + lenalidomide +/- dexamethasone, Daratumumab + pomalidomide +/- dexamethasone, Daratumumab + bortezomib +/- dexamethasone, and Ixazomib + Rd. A "Submit" button is at the bottom of the survey. On the right, a "Participants (10)" list shows names and icons for John Smith, Mary Major, Richard Miles, John Noakes, Alice Suarez, Jane Perez, Robert Stiles, Juan Fernandez, Ashok Kumar, and Jeremy Smith. The bottom toolbar includes icons for Join Audio, Start Video, Invite, Participants (10), Share, Chat, Record, and Leave Meeting.

The screenshot shows the same Zoom meeting with a different slide. The slide title is "Regulatory and reimbursement issues aside, which would you recommend for a 65-year-old patient with clear cell renal cell carcinoma (ccRCC) if follow-up 3 years later is found to have asymptomatic (PS 0)?" Below the title is a numbered list of eight options: 1. Nivolumab/ipilimumab, 2. Avelumab/axitinib, 3. Pembrolizumab/axitinib, 4. Pembrolizumab/lenvatinib, 5. Nivolumab/cabozantinib, 6. Tyrosine kinase inhibitor (TKI) monotherapy, 7. Anti-PD-1/PD-L1 monotherapy, and 8. Other. A "Quick Poll" overlay is active, showing the same list of options with radio button selection and a "Submit" button. The "Participants (10)" list on the right is identical to the previous screenshot. The bottom toolbar is also identical.

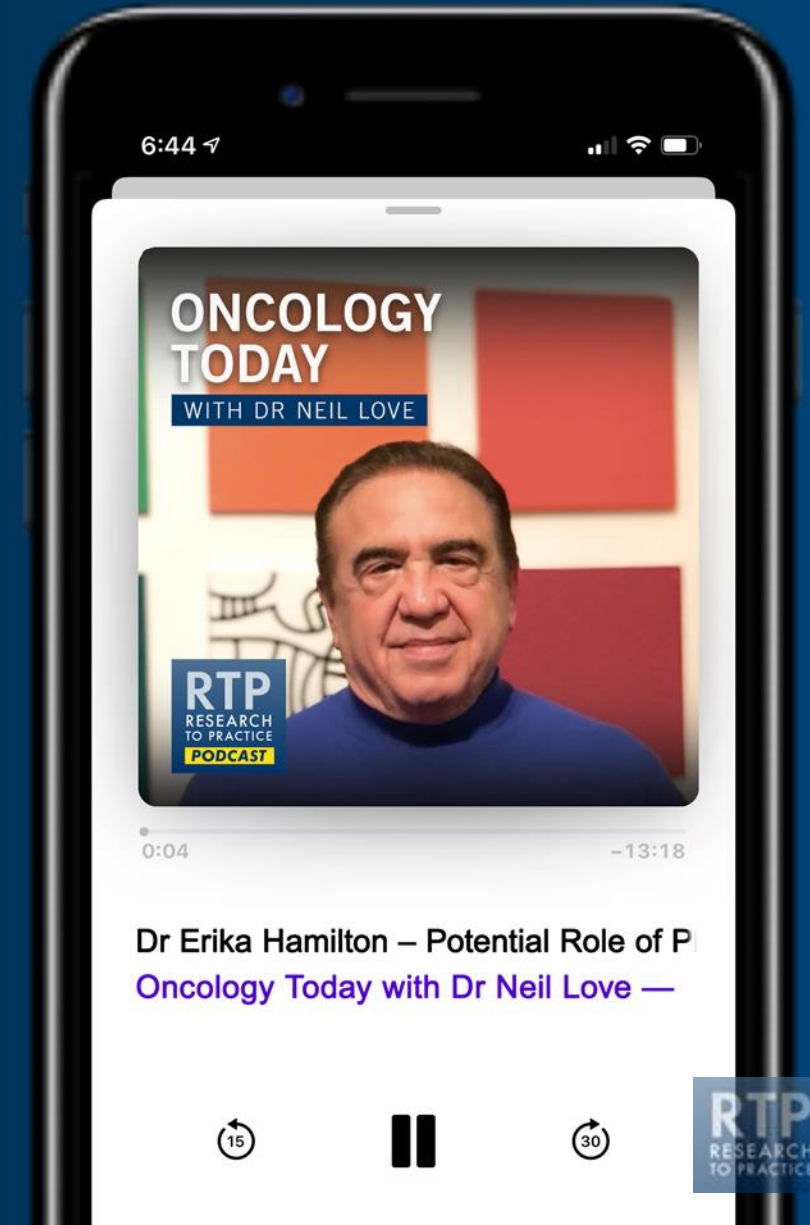
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WITH DR NEIL LOVE

Potential Role of PROTAC ER Degraders in Therapy for HR-Positive Metastatic Breast Cancer



DR ERIKA HAMILTON
SARAH CANNON RESEARCH INSTITUTE



Meet The Professor
**Optimizing the Management of
Chronic Lymphocytic Leukemia**

**Thursday, January 9, 2025
5:00 PM – 6:00 PM ET**

Faculty

Jennifer Woyach, MD

Moderator

Neil Love, MD

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

EGFR-Mutant Non-Small Cell Lung Cancer

A CME/MOC-Accredited Live Webinar

Wednesday, January 15, 2025

5:00 PM – 6:00 PM ET

Faculty

Enriqueta Felip, MD, PhD

Helena Yu, MD

Moderator

Neil Love, MD

Teaching Cases from Investigators: The Application of Available Research to the Clinical Care of Patients with Hepatocellular Carcinoma

A CME Symposium Held in Conjunction with the 2025 ASCO® Gastrointestinal Cancers Symposium

Thursday, January 23, 2025

6:15 PM – 8:15 PM PT (9:15 PM – 11:15 PM ET)

Faculty

Anthony El-Khoueiry, MD

Richard S Finn, MD

Aiwu Ruth He, MD, PhD

Stacey Stein, MD

Moderator

Stephen “Fred” Divers, MD

What Clinicians Want to Know: Biomarker Assessment and Related Treatment Decision-Making for Patients with Colorectal Cancer

*A CME Symposium Held in Conjunction with
the 2025 ASCO® Gastrointestinal Cancers Symposium*

Friday, January 24, 2025

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

Faculty

Arvind Dasari, MD, MS

Van K Morris, MD

Jenny Seligmann, MBChB, MRCP, PhD

Eric Van Cutsem, MD, PhD

Moderator

Christopher Lieu, MD

What Clinicians Want to Know: Addressing Current Questions Related to the Use of Antibody-Drug Conjugates in the Management of Bladder Cancer and Hormonal Therapy-Based Interventions in the Management of Prostate Cancer

A CME Symposium Held in Conjunction with the 2025 ASCO® Genitourinary Cancers Symposium

Thursday, February 13, 2025

7:00 PM – 9:00 PM PT (10:00 PM – 12:00 AM ET)

Faculty

Neeraj Agarwal, MD, FASCO
Andrew J Armstrong, MD, ScM

Terence Friedlander, MD
Matthew D Galsky, MD

Moderator

To be announced.

What Clinicians Want to Know: Addressing Current Questions Related to the Management of Renal Cell Carcinoma

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Tian Zhang, MD, MHS

Additional faculty to be announced.

Moderator

Sumanta Kumar Pal, MD

Save The Date

Fourth Annual National General Medical Oncology Summit

*A Multitumor CME/MOC-, NCPD- and ACPE-Accredited
Educational Conference Developed in Partnership with
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Friday to Sunday, February 28 to March 2, 2025

Fontainebleau Hotel, Miami Beach, Florida

Moderated by Neil Love, MD

Thank you for joining us!

Information on how to obtain CME, ABIM MOC, ABS and NCPD credit will be provided at the conclusion of the activity in the Zoom chat room. Attendees will also receive an email in 1 to 3 business days with these instructions.

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We're here for you

What is triple negative breast cancer?

[Learn the basics about TNBC →](#)



Thursdays with TNBC Friends

Thursday, November 21st - 7pm ET / 4pm PT

Join TNBC Foundation and fellow triple negative breast cancer thrivers for a virtual meet and greet on Zoom the last Thursday of every month.

[Register →](#)

Faculty



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Distinguished Professor for
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Section of Hematology/Oncology
The University of Chicago
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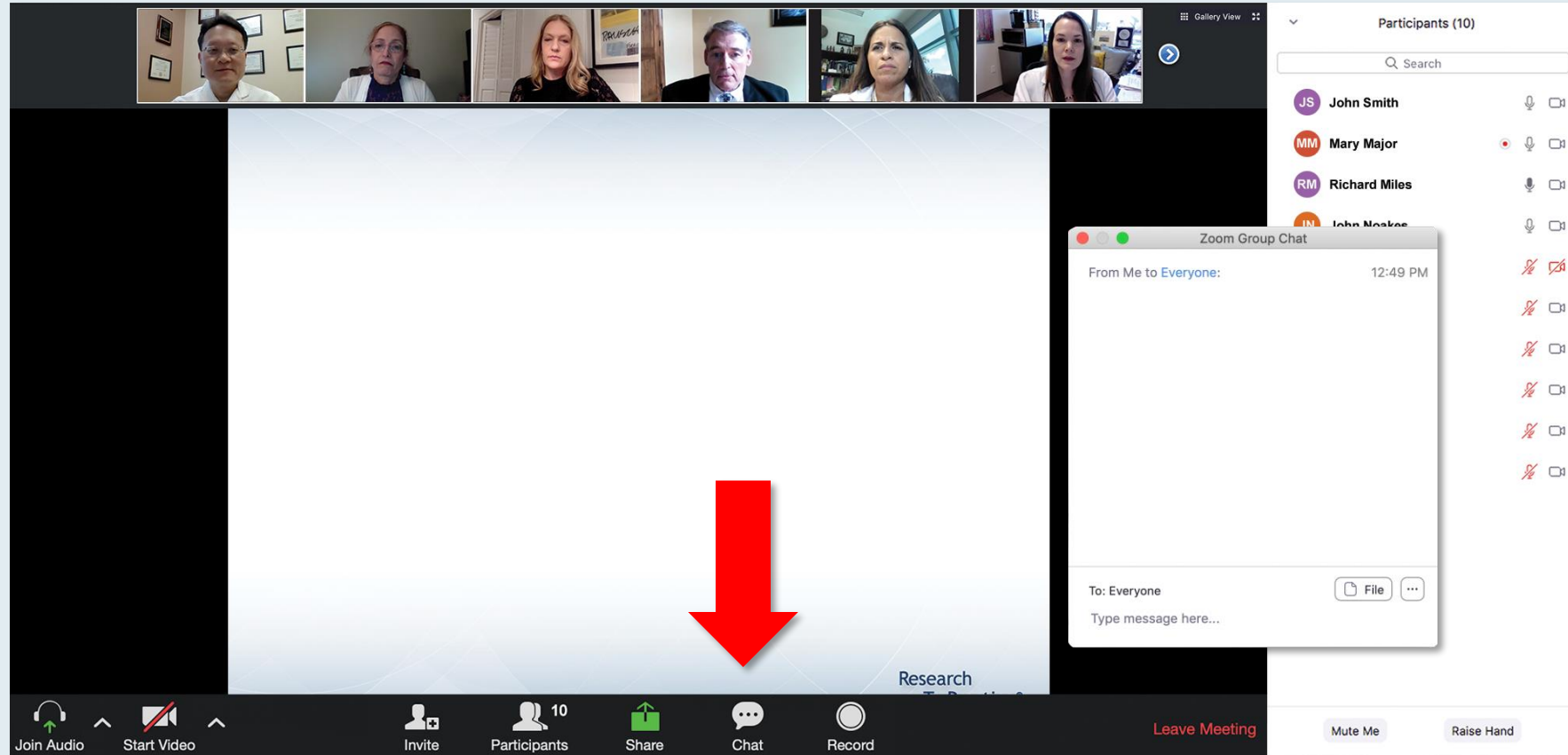


Joyce O'Shaughnessy, MD
Celebrating Women Chair in Breast
Cancer Research
Baylor University Medical Center
Chair, Breast Disease Committee
Sarah Cannon Research Institute
Dallas, Texas



Seth Wander, MD, PhD
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Harvard Medical School
Attending Physician
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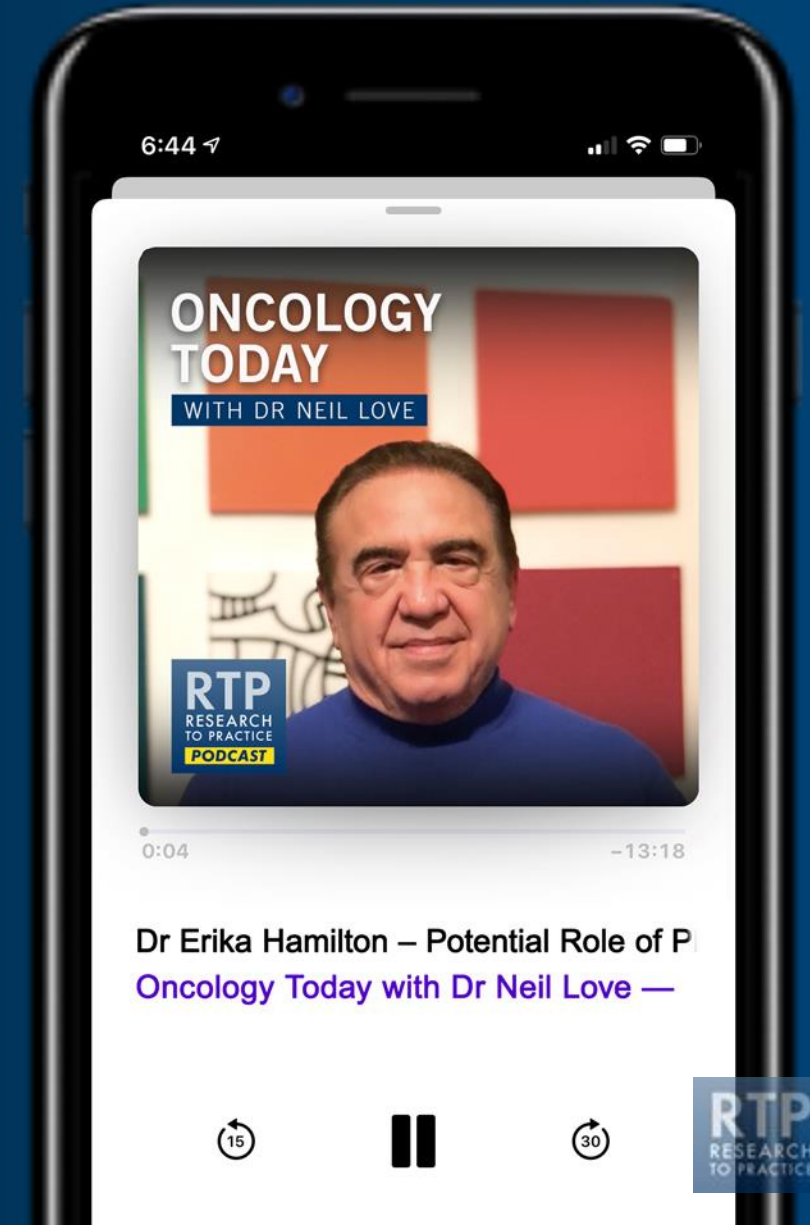
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Nonrelevant Financial Relationships	2nd.MD

Dr Love — Disclosures

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This educational activity contains discussion of non-FDA-approved uses of agents and regimens. Please refer to official prescribing information for each product for approved indications.

Agenda

Module 1: Patient Videos and Clinical Investigator Survey

Module 2: SABCS Report – Education Session on Antibody-Drug Conjugates

Module 3: Patient Videos and Clinical Investigator Survey

Module 4: SABCS Report – Abstracts of Interest

Module 5: Patient Videos and Clinical Investigator Survey

Oncology Q&A: Addressing Common Questions Posed by Patients with Metastatic Triple-Negative Breast Cancer

A Live Webinar for Patients, Developed in Partnership with the Triple Negative Breast Cancer Foundation

Wednesday, November 13, 2024

6:00 PM – 7:00 PM ET

Faculty

Lisa A Carey, MD, ScM, FASCO

Rita Nanda, MD

Moderator

Neil Love, MD

Exploring the Current Management Paradigm for Patients with Metastatic Triple-Negative Breast Cancer

A CME/MOC-Accredited Live Webinar

In Partnership with Florida Cancer Specialists & Research Institute

Monday, November 18, 2024

5:00 PM – 6:00 PM ET

Faculty

Priyanka Sharma, MD

Sara M Tolaney, MD, MPH

Moderator

Neil Love, MD



Contributing General Medical Oncologist



Maen Hussein, MD

Florida Cancer Specialists & Research Institute
The Villages, Florida

Oncology Q&A

Metastatic Triple-Negative Breast Cancer (TNBC)

- ▶ **PLAY** First diagnosis of metastatic TNBC
- ▶ **PLAY** Key elements of initial discussions
- ▶ **PLAY** Recurrence after adjuvant treatment
- ▶ **PLAY** Dose reduction or escalation?
- ▶ **PLAY** Management of chemotherapy-like side effects with antibody-drug conjugates
- ▶ **PLAY** Isn't oncology depressing?
- ▶ **PLAY** Minor children and grandchildren; complementary therapies
- ▶ **PLAY** Self advocacy; second opinions
- ▶ **PLAY** Living wills; advanced directives; palliative care

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First diagnosis of metastatic TNBC









Key elements of initial discussions



A 65-year-old woman in good health (PS 0) with no other major medical conditions is about to begin treatment for metastatic TNBC. The patient is asymptomatic. How would you respond if the patient asked, *What is the percent chance that side effects/toxicity will lead to the treatment being stopped temporarily?*

	Sacituzumab govitecan	T-DXd	PARP inhibitor
 Dr Carey	40%	30%	20%
 Dr Nanda	50%	25%	25%
 Dr Brufsky	20%	20%	20%
 Dr O'Shaughnessy	33%	33%	25%
 Dr Sharma	25%	20%	10%
 Dr Wander	20%	20%	10%

A 65-year-old woman in good health (PS 0) with no other major medical conditions is about to begin treatment for metastatic TNBC. The patient is asymptomatic. How would you respond if the patient asked, *What is the percent chance that side effects/toxicity will lead to the treatment being permanently discontinued?*







	Sacituzumab govitecan	T-DXd	PARP inhibitor
 Dr Carey	10%	15%	5%
 Dr Nanda	<5%	15%	<5%
 Dr Brufsky	5%	15%	5%
 Dr O'Shaughnessy	10%	15%	10%
 Dr Sharma	5%-6%	13%-15%	5%-6%
 Dr Wander	5%-10%	5%-10%	<5%

Recurrence after adjuvant treatment









For a patient with localized TNBC who has received preoperative chemotherapy with immunotherapy and then is monitored off treatment, do you generally order routine imaging and/or blood work?

What is your usual approach to monitoring, including the duration and intervals of evaluation?

	Imaging and/or blood work?	Duration and intervals
 Dr Carey	No	N/A
 Dr Nanda	No	N/A
 Dr Brufsky	No	N/A
 Dr O'Shaughnessy	Yes	Lab work 2x per year, imaging annually
 Dr Sharma	No	N/A
 Dr Wander	Yes	Routine exam 2x per year, routine labs 1 to 2x per year, routine surveillance breast imaging

**In general, do you recommend surgery and/or radiation therapy for a single site of metastatic disease, even if the metastasis is asymptomatic?
For which sites of a single metastasis, if any, have you used this strategy?**

	Surgery and/or radiation therapy?	Sites of single metastasis
 Dr Carey	No	Only for brain metastases, symptomatic bone metastases, eroding local disease
 Dr Nanda	Yes*	Lung, liver, bone, brain, lymph nodes
 Dr Brufsky	Yes, occasionally for very long term (>12-18 months) without disease progression	Breast, lung, liver
 Dr O'Shaughnessy	Yes, occasionally	Liver, bone, chest wall, locally recurrent adenopathy
 Dr Sharma	No	Only for symptomatic metastasis
 Dr Wander	Yes, occasionally use RT for oligometastatic disease	Bone, lung, brain, liver in specific circumstances







* RT possibly for exceptional responders to immunotherapy with limited disease progression; surgery possibly for exceptional responders with de novo HER2+ breast cancer and clinical complete response and disease progression in their primary tumors only.

Dose reduction or escalation?



Dr Maen Hussein (The Villages, Florida)

A 65-year-old woman in good health (PS 0) with no other major medical conditions is about to begin treatment for metastatic triple-negative breast cancer (TNBC). The patient is asymptomatic. How would you respond if the patient asked, *If the dose of the treatment is reduced, will it be less effective?*

	Sacituzumab govitecan	T-DXd	PARP inhibitor
 Dr Carey	No	No	No
 Dr Nanda	No	No	No
 Dr Brufsky	No	No	No
 Dr O'Shaughnessy	No	Likely not	Likely not
 Dr Sharma	No	No	No
 Dr Wander	No	No	No

Management of chemotherapy-like side effects with antibody-drug conjugates



Do you use preemptive growth factors for patients with TNBC receiving sacituzumab govitecan?



Dr Carey

No, but have a low threshold



Dr Nanda

No



Dr Brufsky

Yes, pegfilgrastim (or biosimilar) on day 9



Dr O'Shaughnessy

No (I start at a reduced dose of sacituzumab govitecan unless patient is young and very healthy)



Dr Sharma

Yes, pegfilgrastim on day 9



Dr Wander

No

For patients with metastatic TNBC who are eligible to receive both sacituzumab govitecan and T-DXd, which agent do you generally use first?



Dr Carey

Sacituzumab govitecan



Dr Nanda

Sacituzumab govitecan



Dr Brufsky

Sacituzumab govitecan



Dr O'Shaughnessy

Sacituzumab govitecan



Dr Sharma

Sacituzumab govitecan



Dr Wander

Sacituzumab govitecan

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ABC of ADCs

History, Mechanism of Action, Mechanisms of Resistance

John M. Lambert, Ph.D.

- Consultant, Cambridge, Massachusetts, USA
- ImmunoGen, Inc., 1987 - 2017
 - Former Chief Scientific Officer (2008-2016)
- Honorary Professor, The Queen's University Belfast, UK

The art of developing ADCs: insights at the intersection of academia and industry

Ingrid Mayer, MD, MSCI

VP, Global Clinical Strategy Head, Breast and Gynecological Cancers
Oncology Research and Development, AstraZeneca

Treating breast cancer with ADCs: Clinical role and emerging challenges

Giuseppe Curigliano, MD PhD

European Institute of Oncology, Milano, Italy
Università degli Studi di Milano, Milano, Italy



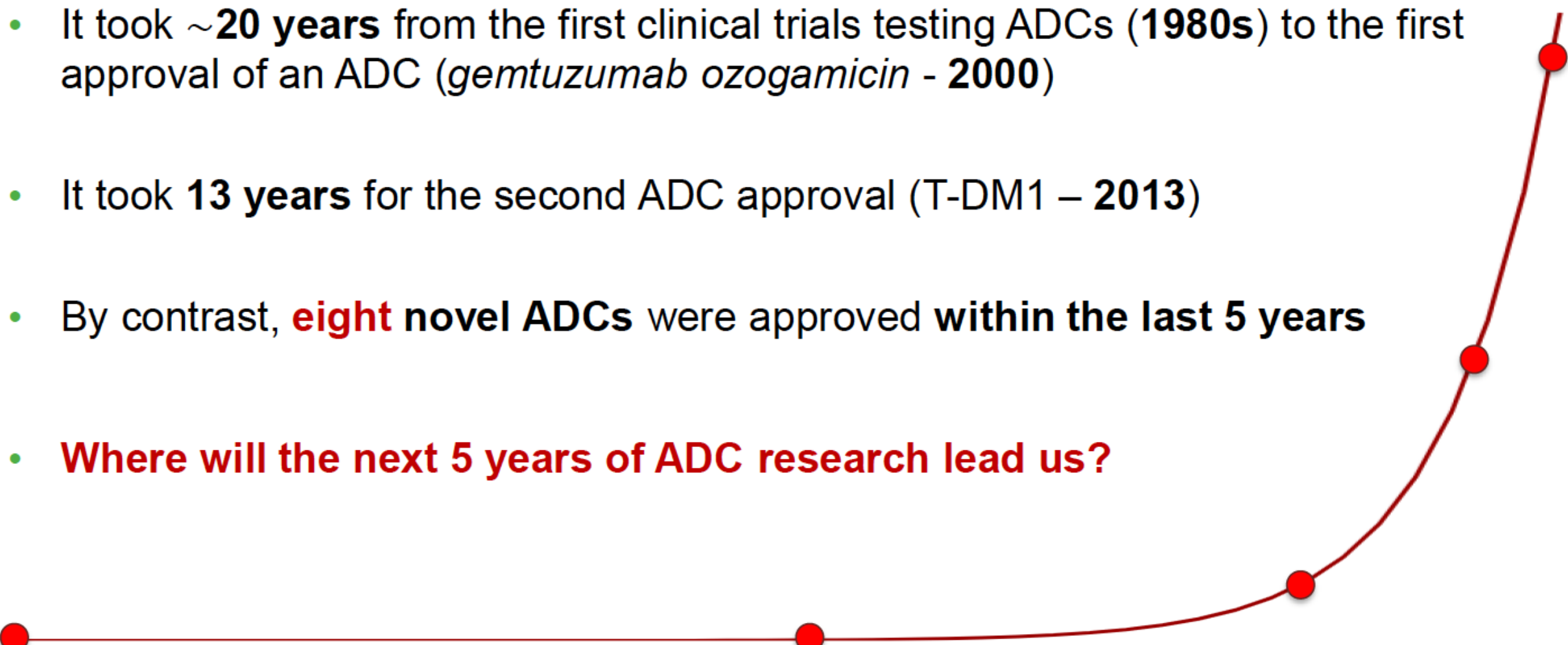
AIMING FOR THE TARGET: Increasing the precision of ADCs through novel biomarkers and constructs



Paolo Tarantino, MD

Dana-Farber Cancer Institute, Boston MA

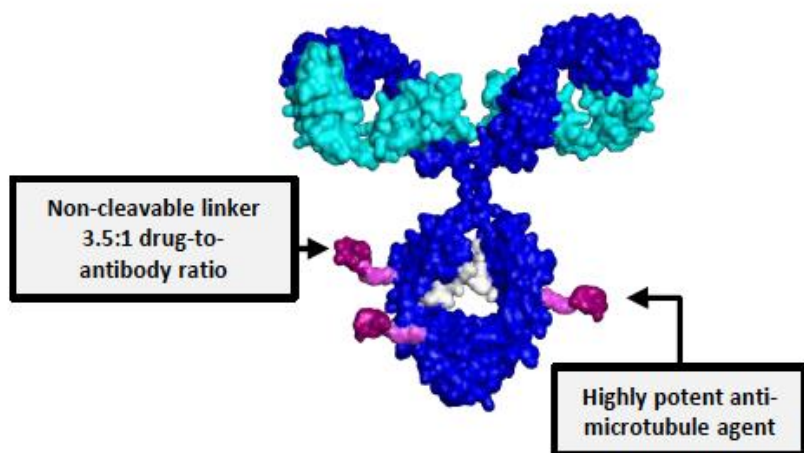
The exponential growth of the ADC field

- It took ~**20 years** from the first clinical trials testing ADCs (**1980s**) to the first approval of an ADC (*gemtuzumab ozogamicin* - **2000**)
 - It took **13 years** for the second ADC approval (T-DM1 – **2013**)
 - By contrast, **eight novel ADCs** were approved **within the last 5 years**
 - **Where will the next 5 years of ADC research lead us?**
- 

ADCs Approved for MBC

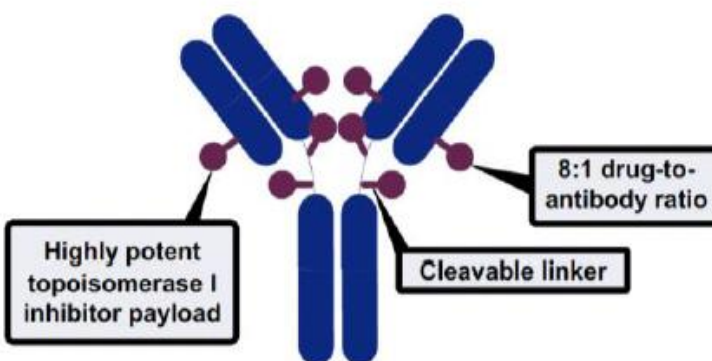
3 ADCs are currently approved to treat chemo-refractory MBC

Trastuzumab emtansine (T-DM1) anti-HER2 ADC



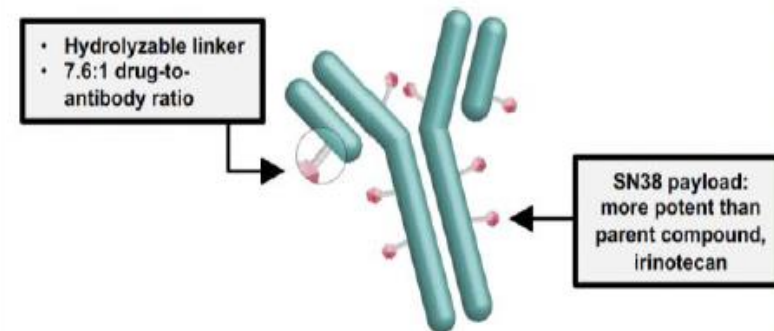
~ 15% (HER2+)

Trastuzumab deruxtecan (T-DXd) anti-HER2 ADC



~90% (HER2+, -low, -ultralow)

Sacituzumab Govitecan (SG) anti-Trop2 ADC

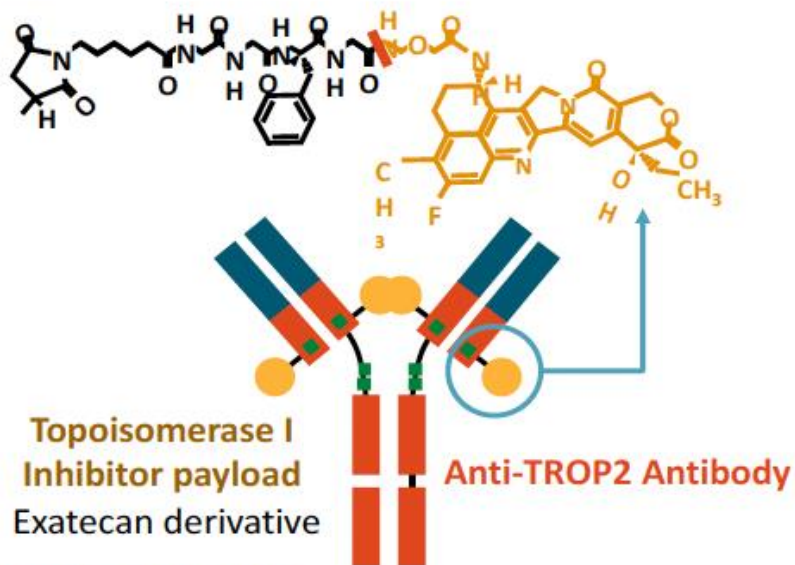


~90% (TNBC, HR+/HER2-)

Upcoming ADCs for MBC

- 2 additional Trop2 ADCs (**Dato-DXd**, **Sac-TMT**), both carrying Topo1 inhibitors, have positive phase 3 data and may join the treatment arsenal in the near future

Datopotamab Deruxtecan (Dato-DXd) anti-Trop2 ADC



BLA submitted for HR+ MBC

Sacituzumab Tirumotecan (Sac-TMT) anti-Trop2 ADC

Antibody

- hRS7, targeting TROP2 antigen
- High affinity and targeting effect

2-methylsulfonyl pyrimidine Linker

- Novel irreversible linker
- cysteine conjugation, DAR ≈ 8
- Favorable stability in circulation system for better therapeutic window.

carbonate linkage

- Releasing payload in acidic environment
- Bystander effect

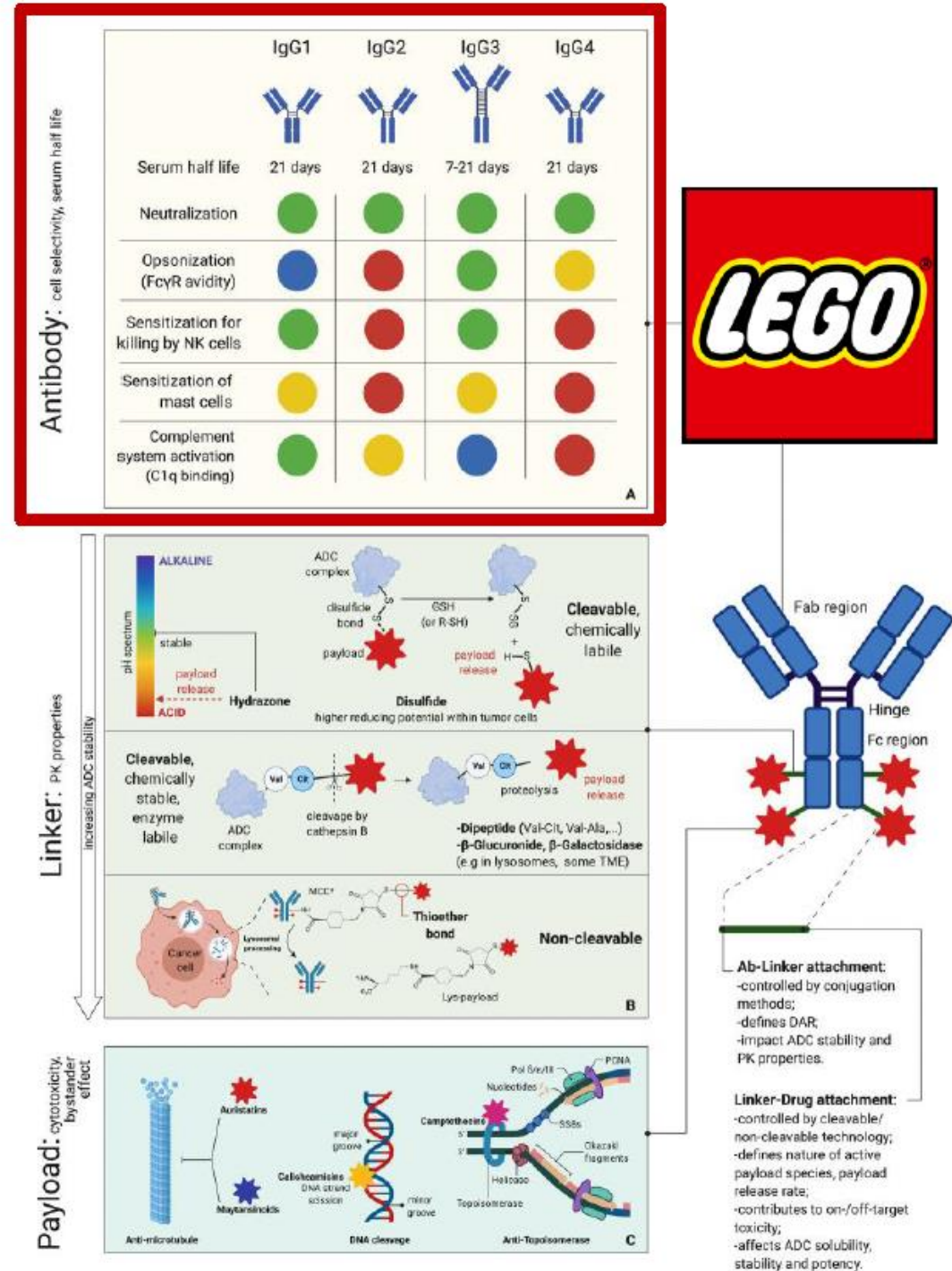
Payload (T030)

- Novel Topo I inhibitor (Belotecan derivative)
- Moderate cytotoxicity

Approved in China
for TNBC

Fine-tuning of ADCs

- ADCs are modular compounds
- Innovation in each of their key components (mAb, linker, payload) can result in improvement in their clinical profile



Ongoing Phase 3 Trials May Bring Additional ADCs to the Clinic

Neoadjuvant

Adjuvant

1L cytotoxic, pre-ChT

DESTINY-Breast11

T-DXd vs T-DXd/THP vs AC-THP

DESTINY-Breast05

T-DXd vs T-DM1

DESTINY-Breast09

T-DXd +/- pertuzumab vs THP

TROPION-Breast04

Dato-DXd/Durva vs KN522 regimen

SURVIVE-HERoes

T-DXd vs TPC

TROPION-Breast02

Dato-DXd vs. TPC

TROPION-Breast03

Dato-DXd +/- Durva vs. TPC

TROPION-Breast05

Dato-DXd/Durva vs. chemo/pembro

ASCENT-05/OptimICE-RD

SG/pembro vs pembro +/- cape

ASCENT-03

SG vs. TPC

NCT06393374

Sac-TMT/ pembro vs TPC

ASCENT-04

SG/pembro vs. TPC/pembro

SASCIA

SG vs TPC

ASCENT-07

SG vs. TPC

DYNASTY-Breast02

DB-1303 vs. TPC

TroFuse-010

Sac-TMT ± pembro vs.TPC

In the **probable future**, we will likely have **more Topo1 ADCs** approved in **earlier indications** (curative setting, 1L setting)

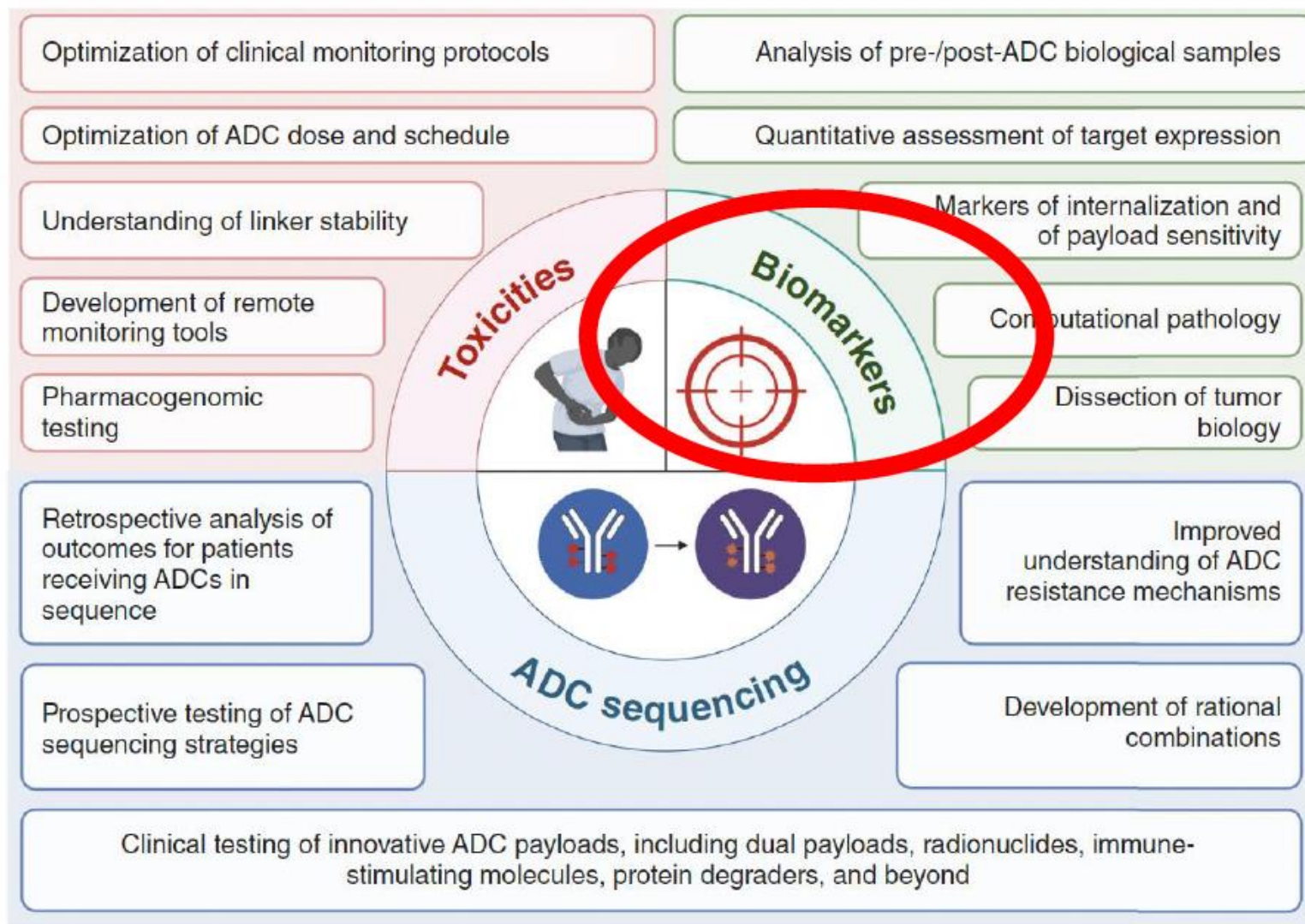
HER2+

TNBC

HR+/HER2-

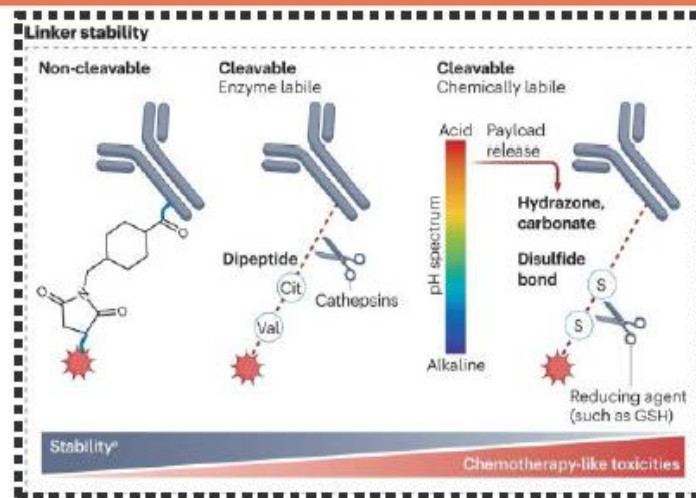
Topo1 ADC

Emerging Challenges

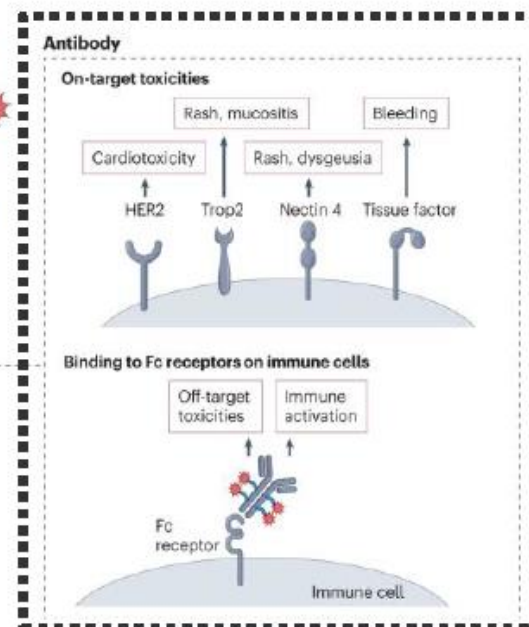
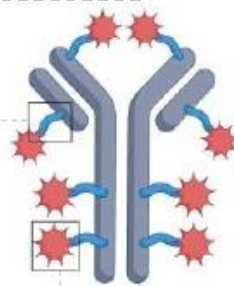
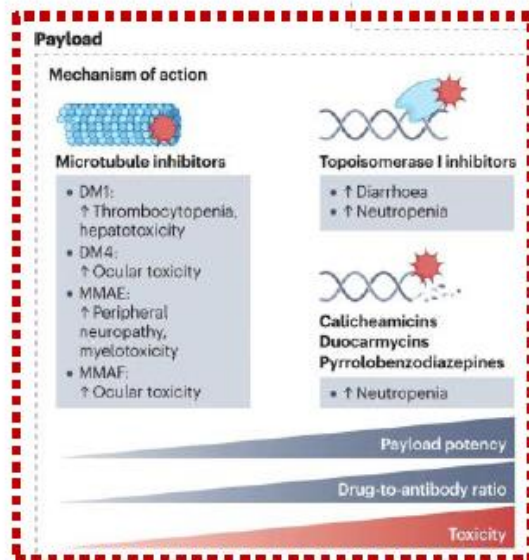


Determinants of the Toxicities of ADCs

More unstable linkers lead to more chemotherapy-related side effects.



Payload-related toxicities dominate the toxicity profile of most ADCs



Antibody-related toxicities are common, but rarely limit the tolerable dose of the ADC

Examples:

- Cardiotoxicity with T-DXd
- Mucositis with Dato-DXd

Dose Optimization Strategies

DOSE CAPPING



The dose of **enfortumab vedotin** (normally 1.25 mg/kg) was **capped to 125 mg**, after reports of fatal adverse events among patients with baseline body weight ≥ 100 kg

CAPPING OF DURATION



Polatumab vedotin is approved to be administered for a **maximum of 6 cycles**, to reduce the risk of permanent peripheral neuropathy

RESPONSE- GUIDED DOSING



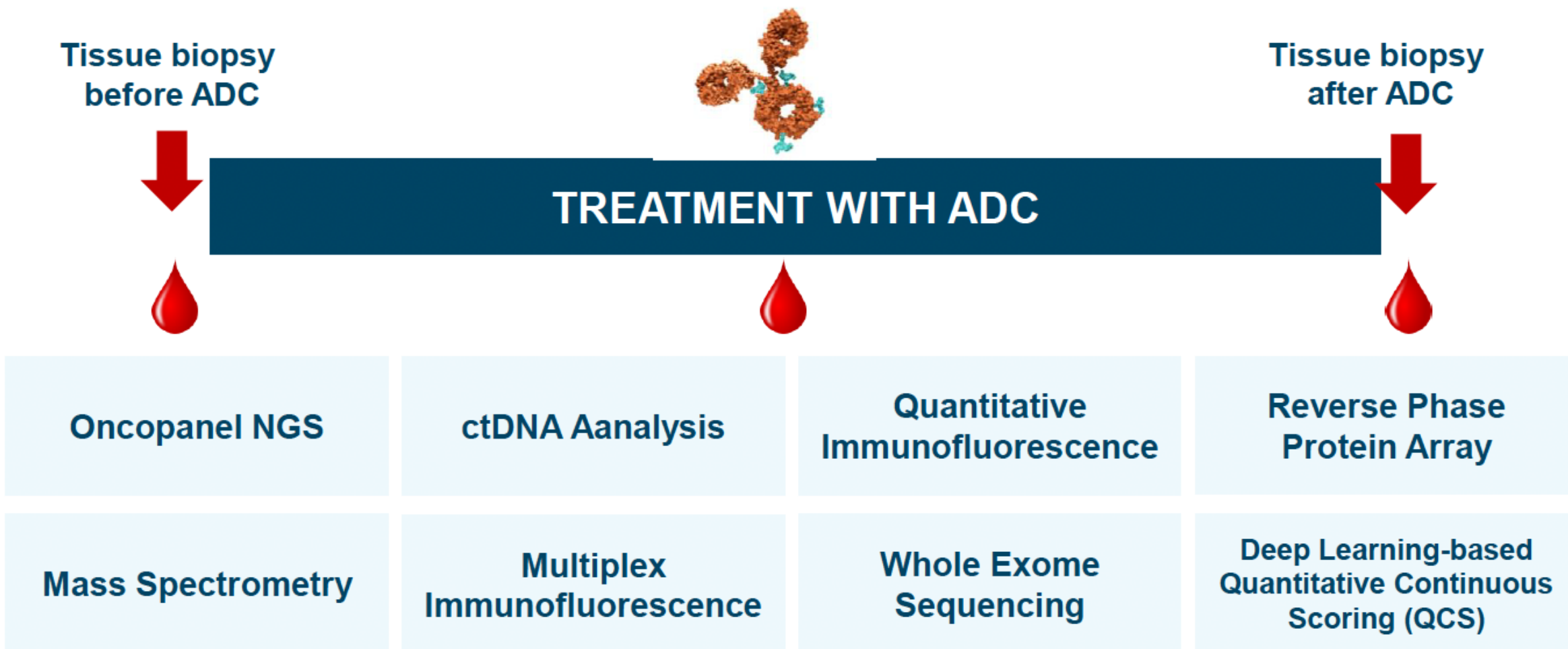
After an initial induction, the dose of **inotuzumab ozogamicin** is reduced to a **lower, maintenance dose**, among those patients that achieve CR

FRACTIONATED DOSING



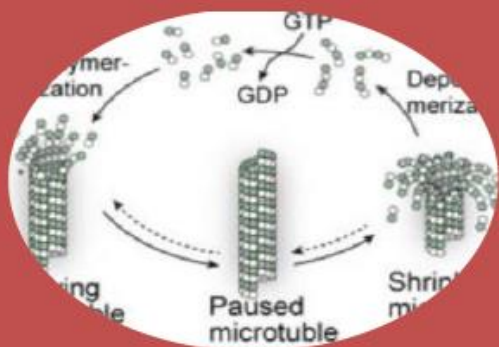
After being withdrawn from market for excessive toxicity (2010), **gemtuzumab ozogamicin** was reapproved in 2017 with a **fractionated**, less toxic dosing

DFCI efforts to improve ADC biomarkers



Predicting toxicity: Payload

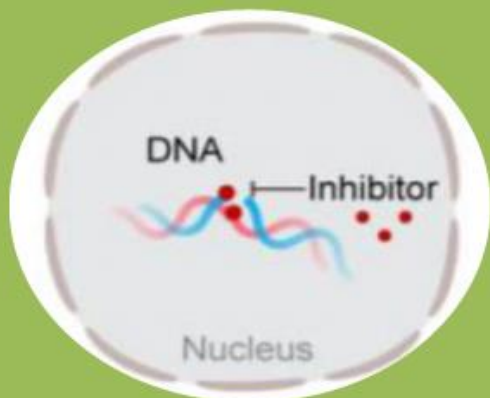
Microtubules targeting



- Tubulin polymerization inhibitors – Maytansinoids (DM1, DM4)
- Tubulin polymerization enhancers – Auristatins (MMAE, MMAF)

- **Neurotoxicity**
- Myelosuppression
- Alopecia
- GI symptoms

DNA targeting



- Antibiotics - Calicheamicins (ozogamicin)
- TOPO-I inhibitors (SN-38, exatecan, DXd)
- Alkylating (PBD, Duocarmycins)

- **Myelosuppression**
- GI symptoms
- Fatigue
- Pneumonitis
- Hepatitis

Challita-Eid PM, et al. Cancer Res. 2016

Cho Y et al, Lab Invest 2011

Rajvanshi P et al, Blood 2001

ADC clinical trial development: where academia meets industry

INDUSTRY

- Patient population, control arm, trial design, contribution of components, contribution of phases, dose optimization and statistical considerations need to be globally friendly to multiple regulatory agencies to ensure registrational success
- Need to potentially consider different biomarker cut-offs
- Need to consider development of companion diagnostic biomarker test
- Need to consider merits of development in multiple disease indications and treatment settings
- Need to consider merits of different formulations
- Need to consider pediatric development
- Need to consider manufacturing/ distribution issues
- Need to consider label, commercialization and reimbursement on a global level
- Need to consider competitors in the field: futureproofing trials, development speed, market share

- Always follow the science/ biology
- Do the right thing for patients: benefit/risk considerations are key

ACADEMIA

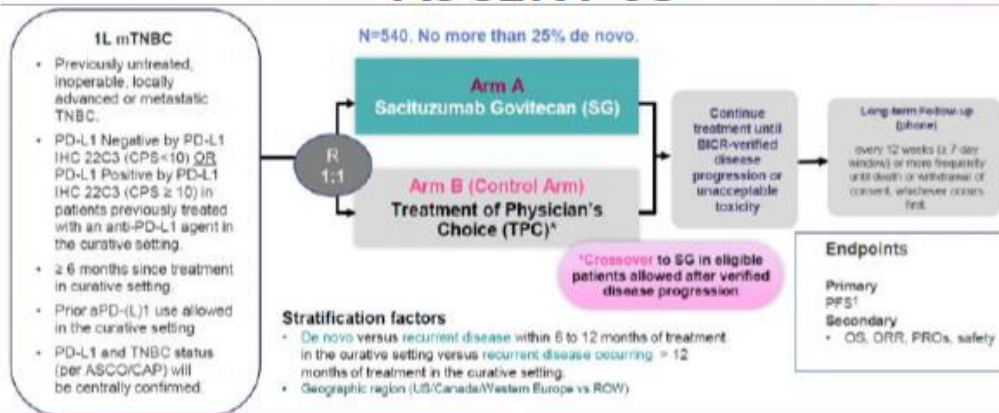
- Control arm and trial design considerations tend to be more regional
- More design/statistical flexibility as not bound by registrational/ regulatory constrains
- Smaller trials as budget is generally limited
- Development is usually disease specific

Triple-Negative Breast Cancer: what's next?

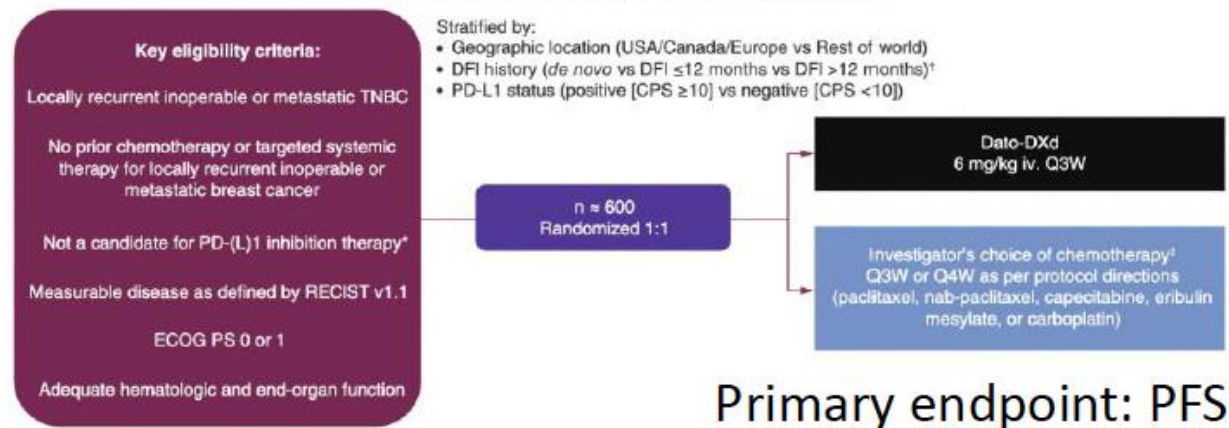
Moving anti-Trop2 ADCs in first-line setting

PD-L1 negative

ASCENT 03

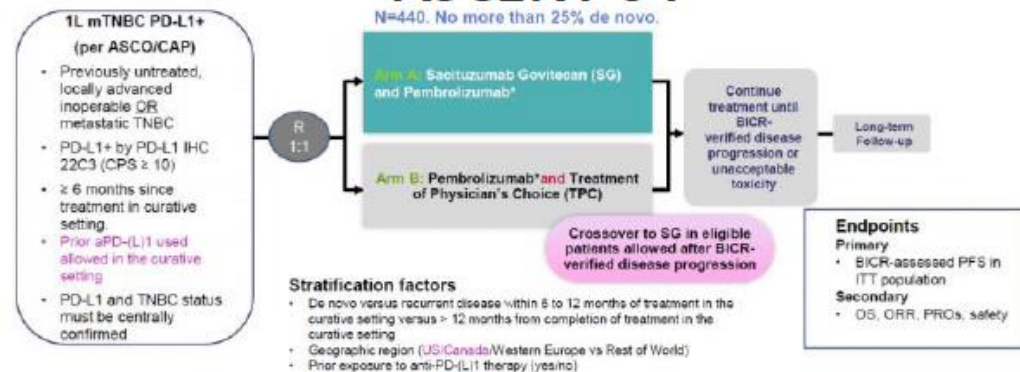


TROPION-Breast02

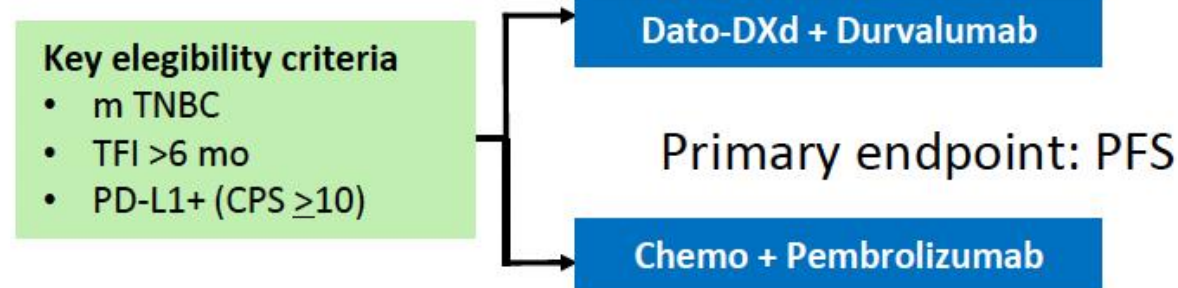


PD-L1 positive

ASCENT 04



TROPION-Breast05



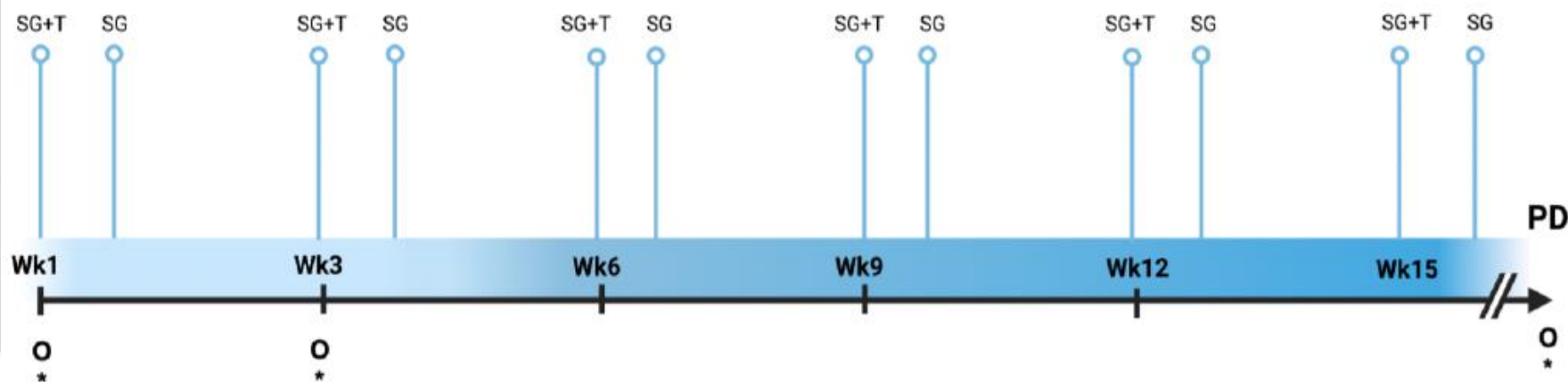
SATEEN phase 2 trial

The **SATEEN** phase 2 trial is ongoing to evaluate the activity of **SG + trastuzumab** among patients with **HER2+ MBC** that have **previously been exposed to T-DXd**

Inclusion criteria:

- Metastatic or unresectable locally advanced breast cancer
- HER2-positive disease (any HR status)
- Prior progression to taxanes, trastuzumab and T-DXd
- No limit of prior lines
- Has not previously received anti-Trop2 ADCs

Sample size: 40 patients



SG= sacituzumab govitecan; T= trastuzumab

O Tissue biopsy (mandatory at baseline, optional at C2D1 and at progression)

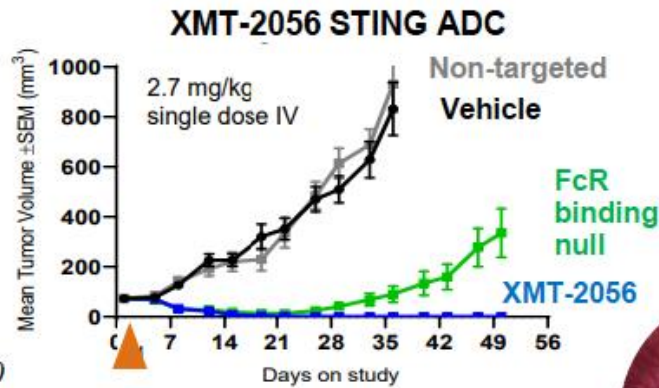
* Research bloods (cfDNA) will be collected at baseline, C2D1, and at time of progression or off protocol therapy, whichever comes first

Expanding beyond cytotoxics with the next wave of ADCs

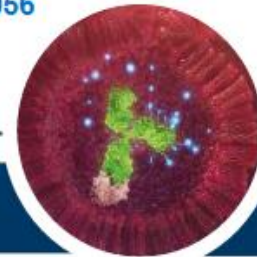
Immune-stimulating Antibody Conjugates

Immune agonist payloads:

STING
 TLR7/8
 TLR9

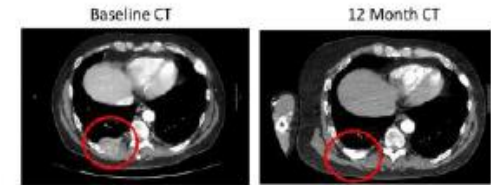
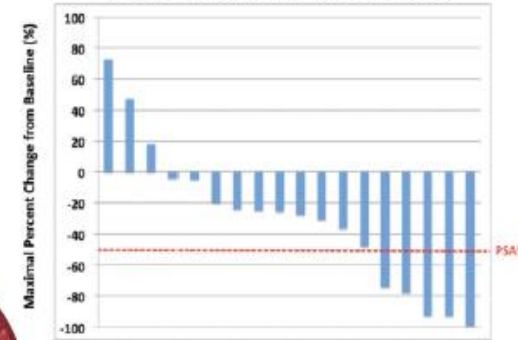


Mersana Internal Data, 2020



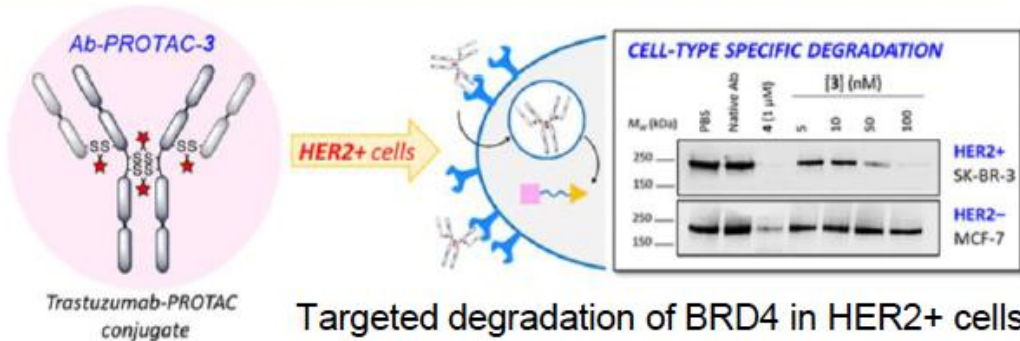
Radioconjugates

PSA Change from Baseline



44% ORR and 27% durable responses after single priming dose of ¹⁷⁷Lu-PSMA-617 followed by Pembro

Antibody-PROTAC Conjugates

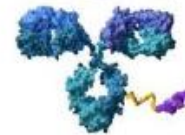


Maneiro et al, ACS Chem. Biol. 2020

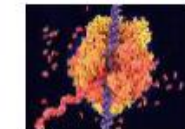
Additional Modalities



Cell death agents
 (ex. ABBV-155 BCL-xL ADC)



siRNA
 (ex. AOC1001 Avidity Bio)

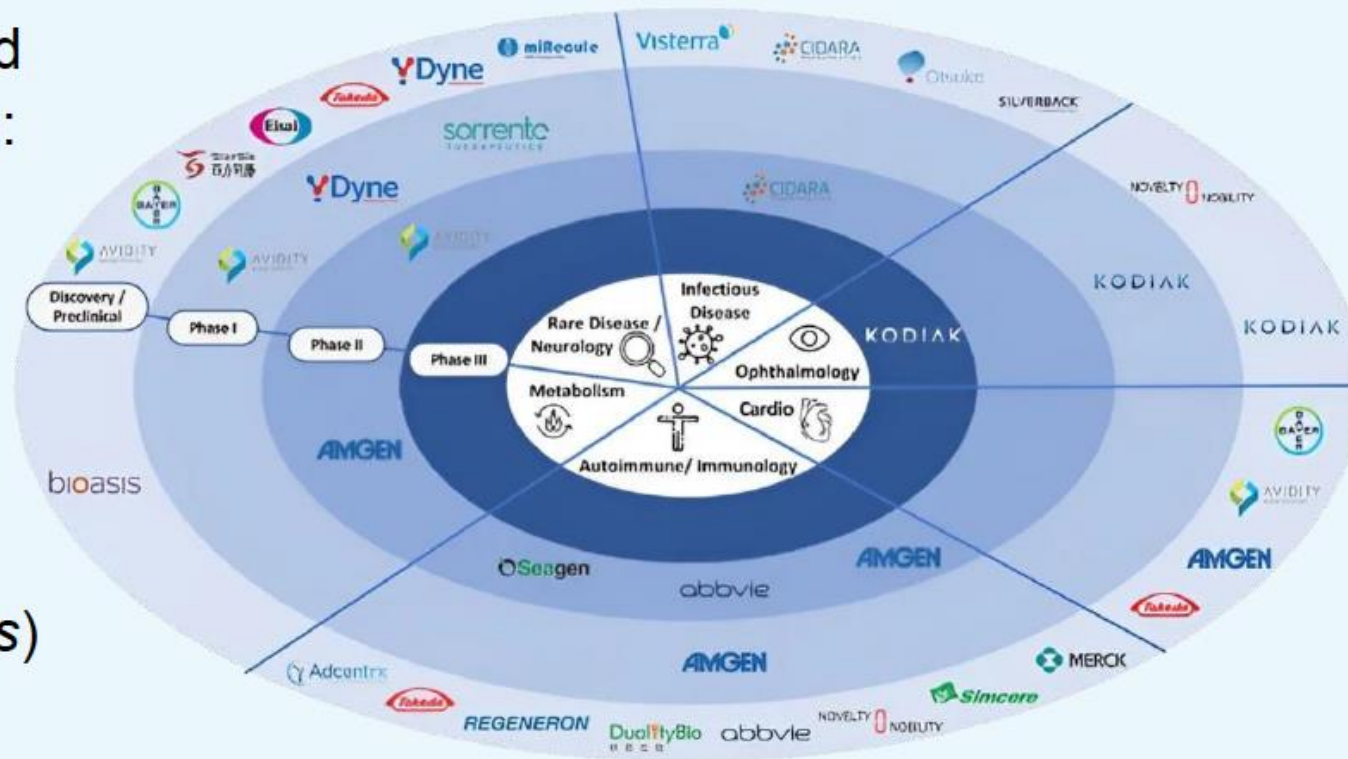


RNA polymerase II inhibitors
 (ex. Hdp-101 Heidelberg Pharma AG)

ADCs Beyond Oncology Indications

The success in oncology has ignited the development of ADCs beyond oncology indications, including in:

- **Neurology / Rare Diseases**
(*siRNA Conjugates*)
- **Immunology**
(*Dexamethasone Conjugates*)
- **Infectious Diseases**
(*Antibody-Antibiotic Conjugates*)
- Among others



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Isn't oncology depressing?



Minor children and grandchildren; complementary therapies



In general, do you recommend to patients with metastatic TNBC that they consult, either in person or virtually, with a professional outside your clinical team to discuss the following complementary strategies?

	Nutrition/diet	Exercise	Massage therapy
 Dr Carey	Yes, for select patients	Yes, for select patients	No
 Dr Nanda	Yes, for most patients	No, but support if patient wishes	No, but support if patient wishes
 Dr Brufsky	Yes, for select patients	Yes, for select patients	Yes, for select patients
 Dr O'Shaughnessy	Yes, for select patients	Yes, for select patients	No
 Dr Sharma	Yes, for select patients	Yes, for select patients	No
 Dr Wander	Yes, for select patients	No	Yes, for select patients

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Real-world treatment patterns and clinical outcomes for patients with metastatic triple-negative breast cancer in the United States: an electronic health records observational study

Tiffany Traina,¹ Sam Hillman,^{2*} Chintal H. Shah,³ Reema Tank,² Simon Collin,² Manali Bhawe⁴

¹Memorial Sloan Kettering Cancer Center, New York, NY, USA; ²AstraZeneca, Cambridge, UK; ³Astrazeneca, Gaithersburg, MD, USA;

⁴Winship Cancer Institute, Emory University School of Medicine, Atlanta, GA, USA.

*Affiliation at the time the analysis was conducted.

P1-02-06: Efficacy analysis & updated safety from the phase 2 PRIMED study of prophylactic granulocyte-colony stimulating factor (G-CSF) & loperamide for patients (pts) with HER2-negative advanced breast cancer (ABC) treated w/ sacituzumab govitecan (SG)

Presenting Author(s): Elena Lopez and Co-Author(s): María Gion, Manuel Ruiz-Borrego, Isabel Blancas, Elena López-Miranda, Salvador Blanch, Sabela Recalde, Lourdes Calvo, Xavier González, Nerea Ancizar, Serafin Morales, Patricia Cortez, Zuzanna Piwowarska, Eileen Shimizu, José Antonio Guerrero, Miguel Sampayo-Cordero, Alejandro Martínez-Bueno, Javier Cortés, Antonio Llombart-Cussac

SABCS 2024

P1-06-12: Efficacy and safety of the addition of prophylactic atropine to patients with metastatic triple-negative breast cancer treated with sacituzumab govitecan: a Spanish multicenter real-world study

Presenting Author(s): María José Echarri and Co-Author(s): Marta Santisteban, Juan David Cárdenas

SABCS 2024

P1-07-16: Real-World Duration of Sacituzumab Govitecan-hziy Treatment in Patients with Metastatic Triple-Negative Breast Cancer

Presenting Author(s): Fred Kudrik and Co-Author(s): Vikram Gorantla, MD, Rushir Choski, MD, Debra Patt, MD, PhD, MBA, Anupama Vasudevan, BDS, MPH, PhD, Erin Alwon, MS, Dawn Brenneman, MS, Mike Gart, MBA, Prateesh Varughese, PharmD, MBA, Brandon Wang, MBA, Lisa Morere, RN, MSN, ANP, Simon Blanc, MD

SABCS 2024

P1-07-27: Triple-negative breast cancer with bone marrow involvement and response after use of antibody-drug conjugate (ADC)

Presenting Author(s): Sophia Freitas and Co-Author(s): Sophia Freitas, Rafael Silva, Thales Silva, Bianca Carnevalli, Danilo Souza, Aumilto Junior, João Victor Oliveira

SABCS 2024

P1-09-17: Management of Neutropenia and Effectiveness of Sacituzumab Govitecan (SG) in Patients (pts) With Metastatic Triple-Negative Breast Cancer (mTNBC) Treated in Real-World Settings in the United States

Presenting Author(s): Rita Nanda and Co-Author(s): Clinton Yam, Laura Spring, Manali Ajay Bhave, Ioanna Ntalla, Theresa Valdez, Brian Stwalley, Chenxue Liang, Nikoleta Sjekloca, Catherine Lai, Kevin Kalinsky

SABCS 2024

P1-12-29: Extreme response to sacituzumab-govitecan in a patient with metastatic triple-negative breast cancer

Presenting Author(s): Allison Poles and Co-Author(s): Melody Cobleigh, MD, Gene Solmos, MD

SABCS 2024

Agenda

Module 1: Patient Videos and Clinical Investigator Survey

Module 2: SABCS Report – Education Session on Antibody-Drug Conjugates

Module 3: Patient Videos and Clinical Investigator Survey

Module 4: SABCS Report – Abstracts of Interest

Module 5: Patient Videos and Clinical Investigator Survey

Self advocacy; second opinions



**Dr Maen Hussein
(The Villages, Florida)**

Living wills; advanced directives; palliative care



Dr Maen Hussein (The Villages, Florida)

At what point in the treatment course do you discuss advanced directives and a “living will” with patients with metastatic TNBC?



Dr Carey

Beginning at second-line therapy



Dr Nanda

Varies, but most patients are referred to palliative care, where the subject is generally broached. I generally have a thoughtful discussion about goals of care and treatment options when disease progresses on a line of therapy.



Dr Brufsky

Second- or third-line therapy



Dr O'Shaughnessy

At diagnosis



Dr Sharma







After exhausting 1 line of therapy



Dr Wander

Typically early on, while there are no active/urgent medical issues or pending hospitalizations

How frequently does the topic of spirituality arise in your discussions with patients with metastatic TNBC? Have you prayed with patients and family? Do you refer your patients with metastatic TNBC to specific chaplain services?

	Frequency of discussion on spirituality	Prayed with patients and family?	Refer to specific chaplain services?
 Dr Carey	Occasionally	Rarely	No
 Dr Nanda	Always in context of goals of care discussion	No	Yes, if patient desires
 Dr Brufsky	20%	No	No
 Dr O'Shaughnessy	Very often	Yes, if initiated by patient or family	No
 Dr Sharma	25%	No	No
 Dr Wander	Occasionally	No	Yes, if patient desires

Contributing General Medical Oncologist



Maen Hussein, MD

Florida Cancer Specialists & Research Institute
The Villages, Florida



Thank you



Meet The Professor
**Optimizing the Management of
Chronic Lymphocytic Leukemia**

**Thursday, January 9, 2025
5:00 PM – 6:00 PM ET**

Faculty

Jennifer Woyach, MD

Moderator

Neil Love, MD

Thank you for joining us!

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The survey will remain open for 5 minutes after the meeting ends.

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