APTITUDE HEALTH®

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Conference Coverage: AUA 2024 and ASCO 2024 – Focus on GU Malignancies

June 11, 2024

Report Contents

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Meeting Snapshot

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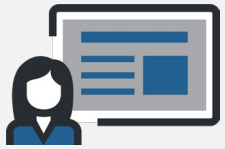
VIRTUAL CLOSED-DOOR ROUNDTABLE

DATE:
June 11, 2024



DISEASE-STATE AND DATA PRESENTATIONS by key experts

INSIGHTS REPORT including postmeeting analyses and actionable recommendations

PANEL: Key experts in GU malignancies

- 6 from US
- 1 from the UK

BLADDER AND PROSTATE CANCER-SPECIFIC DISCUSSIONS on therapeutic advances and their application in clinical decision-making

Panel Consisting of 7 Global GU Cancer Experts

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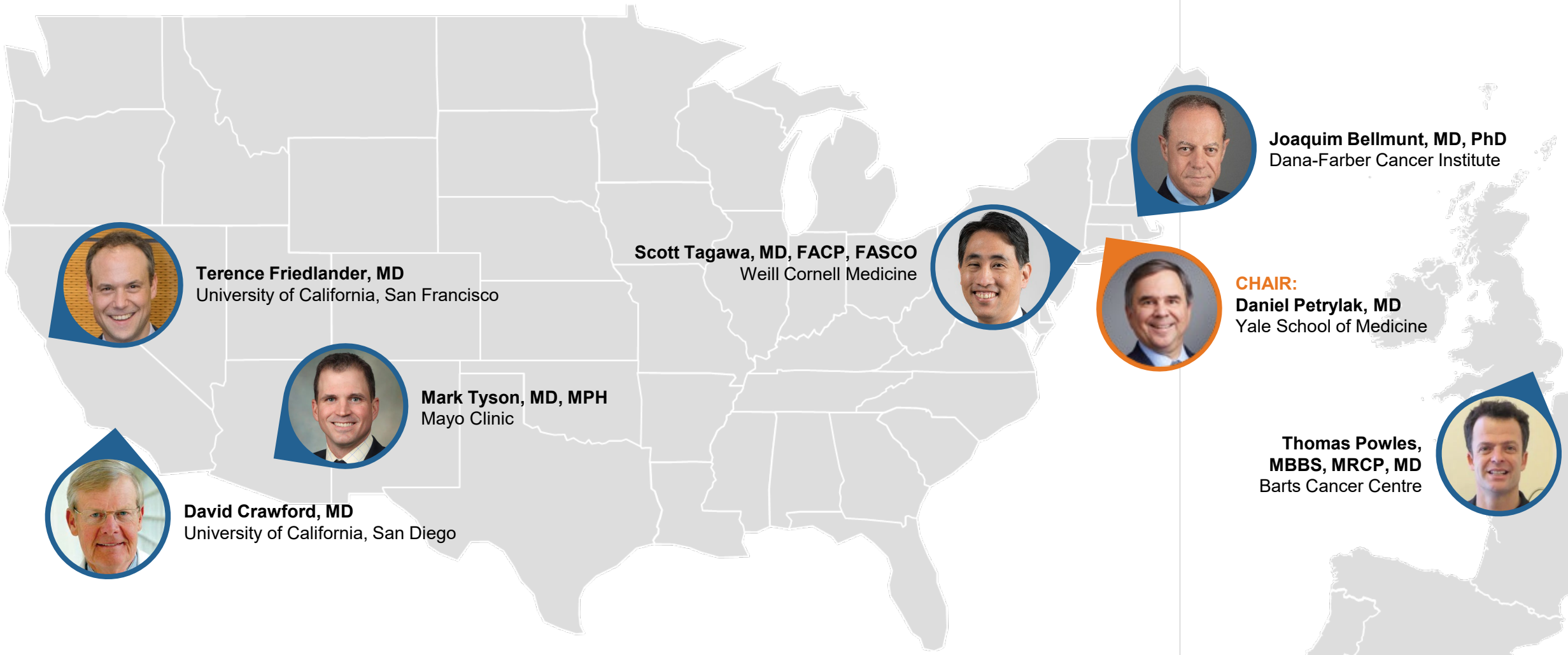

Terence Friedlander, MD
University of California, San Francisco

Mark Tyson, MD, MPH
Mayo Clinic

David Crawford, MD
University of California, San Diego

Scott Tagawa, MD, FACP, FASCO
Weill Cornell Medicine

Joaquim Bellmunt, MD, PhD
Dana-Farber Cancer Institute

CHAIR:
Daniel Petrylak, MD
Yale School of Medicine

Thomas Powles, MBBS, MRCP, MD
Barts Cancer Centre

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Meeting Agenda

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Time (EDT)	Topic	Presenter
10.00 AM – 10.05 AM	**Welcome and Introductions**	Daniel Petrylak, MD
10.05 AM – 10.10 AM	**Bladder Cancer Part 1 – Non–Muscle-Invasive Disease**	Mark Tyson, MD, MPH
10.10 AM – 10.25 AM	Discussion and Key Takeaways	Moderator: Daniel Petrylak, MD
10.25 AM – 10.35 AM	**Bladder Cancer Part 2 – Muscle-Invasive Disease**	Joaquim Bellmunt, MD, PhD
10.35 AM – 10.55 AM	Discussion and Key Takeaways	Moderator: Daniel Petrylak, MD
10.55 AM – 11.05 AM	**Bladder Cancer Part 3 – Advanced/Metastatic Disease**	Thomas Powles, MBBS, MRCP, MD
11.05 AM – 11.30 PM	Discussion and Key Takeaways	Moderator: Daniel Petrylak, MD
11.30 AM – 11.40 AM	**BREAK**	
11.40 AM – 11.55 AM	**Prostate Cancer Part 1 – Hormonal, Cytotoxic, and Targeted Therapies**	David Crawford, MD
11.55 AM – 12.20 PM	Discussion and Key Takeaways	Moderator: Daniel Petrylak, MD
12.20 PM – 12.30 PM	**Prostate Cancer Part 2 – Radioligands**	Scott Tagawa, MD, FACP, FASCO
12.30 PM – 12.55 PM	Discussion and Key Takeaways	Moderator: Daniel Petrylak, MD
12.55 PM – 1.00 PM	**Wrap-Up and Closing Remarks**	Daniel Petrylak, MD

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Conference Highlights

Bladder Cancer Part 1 – Non–Muscle-Invasive Disease

CORE-001: Phase II Study of Cretostimogene Grenadenorepvec (CG) + Pembrolizumab in BCG-Unresponsive, High-Risk NMIBC With CIS

Li R, et al. ASCO 2024. Abstract 4601

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BOND-003: Phase 3 Study of Intravesical Cretostimogene Grenadenorepvec for BCG-Unresponsive, High-Risk, NMIBC With CIS

Tyson MD, et al. AUA 2024. Abstract P25-2

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TAR-200 in Patients With BCG-Unresponsive High-Risk Nonmuscle-Invasive Bladder Cancer: Results From SunRISe-1 Study

Jacob J, et al. AUA 2024. Abstract P25-1

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Key Insights

Bladder Cancer Part 1 – Non–Muscle-Invasive Disease

Experts Discussed Emerging Data From Trials of Novel Intravesical Agents and Combinations for NMIBC

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CRETOSTIMOGENE GRENADENOREPVEC

Experts Considered the Landscape of BCG-Resistant NMIBC and the Evolving Role of Intravesical Therapies

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AN EXPANDING ARMAMENTARIUM

Experts Speculated on the Potential of Novel Intravesical Agents in BCG-Naive NMIBC

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CHALLENGING BCG

Dr Pogrom

We used to run out of good options and we would just default to the mean of chemotherapy plus trastuzumab in the salvage setting, but now we have so many great choices that that really takes a backseat. It's really been exciting to have multiple options for patients after TURBT — again, practice changing, unprecedented.

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Conference Highlights

Bladder Cancer Part 2 – Muscle-Invasive Disease

Avelumab as Neoadjuvant Therapy in Muscle-Invasive Urothelial Carcinoma (MIUC): Survival Data of AURA Trial, Oncodistinct 004

Blanc J, et al. ASCO 2024. Abstract 4516

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Perioperative Sacituzumab Govitecan ± Pembrolizumab for Patients With MIBC: SURE-01/02 Interim Results

Cigliola A, et al. ASCO 2024. Abstract LBA4517

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EV-103: Neoadjuvant Enfortumab Vedotin Monotherapy in Cisplatin-Ineligible Patients With MIBC – 2-Year EFS and Safety Data for Cohort H

O'Donnell PH, et al. ASCO 2024. Abstract 4564

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A Phase II Trial of Toripalimab Combined With Cisplatin Plus Gemcitabine as Neoadjuvant Treatment for Muscle-Invasive Bladder Cancer

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Yang R, et al. ASCO 2024. Abstract 4596

Atezolizumab Concurrently With Radiotherapy in Patients With MIBC: Interim Analysis of the ATEZOBLADDER-PRESERVE Phase II Trial

Calvo OF, et al. ASCO 2024. Abstract 4592

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Comparing Treatment Modalities for T2N0M0 MIBC: A Propensity Score Analysis With the National Cancer Database

Pieretti A, et al. ASCO 2024. Abstract 4604

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Key Insights

Bladder Cancer Part 2 – Muscle-Invasive Disease

Experts Discussed Data From Perioperative Trials for MIBC

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NOVEL NEOADJUVANT APPROACHES

Experts Considered a Potential Role for Enfortumab Vedotin for MIBC

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EV – EFFICACY

ongoing trials will help clarify the optimal sequencing of agents

- Experts are still using a CG/GP/NT2K-like regimen (a taxane plus trastuzumab and pertuzumab) first-line, followed by T-DM1 second-line, for most patients.
- Most experts are using trastuzumab deruxtecan third-line, but will prioritize the tucatinib triplet for patients with evidence of brain metastases.
- The tucatinib triplet may also be used in the second-line setting, before T-DM1, for patients with documented brain metastases.
  - If tucatinib is used second-line, experts are divided on whether they would currently use T-DM1 or trastuzumab deruxtecan third-line.
    - Results of the ongoing DESTINY-Breast03 trial comparing trastuzumab deruxtecan vs T-DM1 will help to clarify the optimal sequence of these ADCs.
- Trastuzumab deruxtecan and the tucatinib triplet may also be used earlier than third-line in patients who recur following treatment with trastuzumab, pertuzumab, and T-DM1 in the (neo)adjuvant setting, but this represents a small fraction of patients.
- Patient preferences can also factor into the sequencing of these new agents (eg, 3 drugs vs 1 drug, concern about hair loss vs diarrhea).
- The impressive efficacy of trastuzumab deruxtecan and the tucatinib regimen have pushed other options, such as trastuzumab-chemotherapy combinations, neratinib, and margetuximab, to later lines of therapy.

Dr Pegram:
We used to run out of good options and we would just regress to the mean of chemotherapy plus trastuzumab in the salvage setting, but now we have so many great choices that that really takes a backseat. It's really been exciting to have multiple options for patients after T-DM1 — again, practice changing, unprecedented.

Experts Debated Implications of the SURE-01/02 Trial and Sacituzumab Govitecan for Bladder Cancer

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CYSTECTOMY AVOIDANCE

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Conference Highlights

Bladder Cancer Part 3 – Advanced/Metastatic Disease

Impact of Exposure on Outcomes With Enfortumab Vedotin in Patients With Locally Advanced or Metastatic Urothelial Cancer

Petrylak DP, et al. ASCO 2024. Abstract 4503

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PROs From a Phase III trial of EV+P vs Platinum-Based Chemotherapy in Previously Untreated Locally Advanced or Metastatic Urothelial Cancer

Gupta S, et al. ASCO 2024. Abstract 4502

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Characterization of Complete Responders to Nivolumab + Gem-Cis vs Gem-Cis and Patients With Lymph Node-Only mUC From CheckMate 901

Galsky MD, et al. ASCO 2024. Abstract 4509

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Quantitative ctDNA in Patients With Advanced UC Treated With Pembrolizumab or Platinum-Based Chemotherapy From KEYNOTE-361

Powles T, et al. ASCO 2024. Abstract 4518

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Key Insights

Bladder Cancer Part 3 – Advanced/Metastatic Disease

Experts Discussed Enfortumab Vedotin (EV) for mUC

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EV: TOXICITY MANAGEMENT AND QOL

ongoing trials will help clarify the optimal sequencing of agents

- Experts are still using a CISPLATIN-like regimen (a taxane plus trastuzumab and pertuzumab) first-line, followed by T-DM1 second-line, for most patients.
- Most experts are using trastuzumab deruxtecan third-line, but will prioritize the tucatinib triplet for patients with evidence of brain metastases.
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Experts Speculated on Recent Data With Sacituzumab Govitecan (SG) in mUC

TROPiCS-04 PRESS RELEASE

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Experts Discussed Alternative Chemotherapy + IO Regimens for mUC

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CheckMate 901

ongoing trials will help clarify the optimal sequencing of agents

- Experts are still using a GC/CP/NT/N-like regimen (a taxane plus trastuzumab and pertuzumab) first-line, followed by T-DM1 second-line, for most patients.
- Most experts are using trastuzumab deruxtecan third-line, but will prioritize the tucatinib triplet for patients with evidence of brain metastases.
- The tucatinib triplet may also be used in the second-line setting, before T-DM1, for patients with documented brain metastases.
  - If tucatinib is used second-line, experts are divided on whether they would currently use T-DM1 or trastuzumab deruxtecan third-line.
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- Trastuzumab deruxtecan and the tucatinib triplet may also be used earlier than third-line in patients who recur following treatment with trastuzumab, pertuzumab, and T-DM1 in the (neo)adjuvant setting, but this represents a small fraction of patients.
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Experts Considered the Use of Cytotoxic Chemotherapy by Urologists

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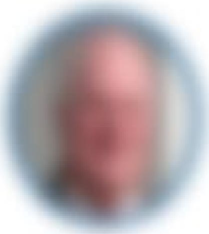
TEAM-BASED APPROACHES



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Conference Highlights

Prostate Cancer Part 1 – Hormonal, Cytotoxic, and Targeted Therapies

Cabazitaxel + Abiraterone vs Abiraterone Alone for Extensive Disease Following Docetaxel: The CHAARTED2 Trial (EA8153)

Kyriakopoulos C, et al. ASCO 2024. Abstract LBA5000

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Nivolumab and Ipilimumab for mPC With an Immunogenic Signature: The NEPTUNES Multicentre Two-Cohort, Biomarker-Selected Phase 2 Trial

Linch MD, et al. ASCO 2024. Abstract 5013

EPICS

ARV-766, a PROTAC AR Degrader, in mCRPC: Initial Results of a Phase I/II Study

Petrylak DP, et al. ASCO 2024. Abstract 5011

EPICS

CYCLONE 2: A Phase 3 Study of Abemaciclib With Abiraterone in Patients With Metastatic Castration-Resistant Prostate Cancer

Smith MR, et al. ASCO 2024. Abstract 5001

EPICS

The MAST (Metformin Active Surveillance Trial) Study: Metformin in Men on Expectant Management for Low-Risk Prostate Cancer

Joshua A, et al. 2024, ASCO LBA5002

EPICS

Phase 1b Study of Tarlatamab in De Novo or Treatment-Emergent Neuroendocrine Prostate Cancer (NEPC)

Aggarwal RR, et al. ASCO 2024. Abstract 5012

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Key Insights

Prostate Cancer Part 1 – Hormonal, Cytotoxic, and Targeted Therapies

Experts Assessed Results From Trials of Hormonal and Cytotoxic Agents for mCRPC

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CHAARTED2

ongoing trials will help clarify the optimal sequencing of agents

- Experts are still using a docetaxel-like regimen (a taxane plus trastuzumab and pertuzumab) first-line, followed by 177Lu-PSMA second-line, for most patients.
- Most experts are using trastuzumab deruxtecan third-line, but will prioritize the lutetium triplet for patients with evidence of brain metastases.
- The lutetium triplet may also be used in the second-line setting, before 177Lu-PSMA, for patients with documented brain metastases.
  - If lutetium is used second-line, experts are divided on whether they would currently use 177Lu-PSMA or trastuzumab deruxtecan third-line.
    - Results of the ongoing DESTINY-Breast03 trial comparing trastuzumab deruxtecan vs 177Lu-PSMA will help to clarify the optimal sequence of these ADCs.
- Trastuzumab deruxtecan and the lutetium triplet may also be used earlier than third-line in patients who recur following treatment with trastuzumab, pertuzumab, and 177Lu-PSMA in the (neo)adjuvant setting, but this represents a small fraction of patients.
- Patient preferences can also factor into the sequencing of these new agents (eg, 3 drugs vs 1 drug, concern about hair loss vs diarrhea).
- The impressive efficacy of trastuzumab deruxtecan and the lutetium regimen have pushed other options, such as trastuzumab-chemotherapy combinations, cabozantinib, and rucaparib/olaparib, to later lines of therapy.

Dr Pagano:
We used to run out of good options and we would just regress to the mean of chemotherapy plus trastuzumab in the salvage setting, but now we have so many great choices that that really takes a backseat. It's really been exciting to have multiple options for patients after 177Lu-PSMA—again, practice changing, unprecedented.

Experts Considered Novel AR-Targeting Agents for mCRPC

EPICS

ARV-766

ongoing trials will help clarify the optimal sequencing of agents

- Experts are still using a [redacted] regimen (a taxane plus trastuzumab and pertuzumab) first-line, followed by [redacted] second-line, for most patients.
- Most experts are using trastuzumab deruxtecan third-line, but will prioritize the tucatinib triplet for patients with evidence of brain metastases.
- The tucatinib triplet may also be used in the second-line setting, before [redacted], for patients with documented brain metastases.
  - If tucatinib is used second-line, experts are divided on whether they would currently use [redacted] or trastuzumab deruxtecan third-line.
    - Results of the ongoing DESTINY-Breast03 trial comparing trastuzumab deruxtecan vs [redacted] will help to clarify the optimal sequence of these ADCs.
- Trastuzumab deruxtecan and the tucatinib triplet may also be used earlier than third-line in patients who recur following treatment with trastuzumab, pertuzumab, and [redacted] in the (neo)adjuvant setting, but this represents a small fraction of patients.
- Patient preferences can also factor into the sequencing of these new agents (eg, 3 drugs vs 1 drug, concern about hair loss vs diarrhea).
- The impressive efficacy of trastuzumab deruxtecan and the tucatinib regimen have pushed other options, such as trastuzumab-chemotherapy combinations, neratinib, and margetuximab, to later lines of therapy.

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We used to run out of good options and we would just regress to the mean of chemotherapy plus trastuzumab in the salvage setting, but now we have so many great choices that that really takes a backseat. It's really been exciting to have multiple options for patients after [redacted] — again, practice changing, unprecedented.

Experts Discussed Other Biomarker-Directed Therapies for Prostate Cancer

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NEPTUNES

Experts Discussed Metformin and Implications of the MAST Study

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METFORMIN ACTIVE SURVEILLANCE TRIAL

ongoing trials will help clarify the optimal sequencing of agents

- Experts are still using a CLEOPATRA-like regimen (a taxane plus trastuzumab and pertuzumab) first-line, followed by T-DM1 second-line, for most patients.
- Most experts are using trastuzumab deruxtecan third-line, but will prioritize the tucatinib triplet for patients with evidence of brain metastases.
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Conference Highlights

Prostate Cancer Part 2 – Radioligands

HRQOL and Pain in a Phase 3 Study of [^{177}Lu]Lu-PSMA-617 in Taxane-Naive Patients With mCRPC (PSMAfore)

Fizazi K, et al. ASCO 2024. Abstract 5003

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Efficacy of 177Lu-PSMA-617 vs ARPI Change in Taxane-Naïve Patients With Metastatic CRPC by Pre-Randomization ARPI (PSMAfore)

Shore N, et al. AUA 2024. Abstract 0503

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STUDY POPULATION

- [illegible]

OUTCOMES

- [illegible]

EXPERT CONCLUSIONS

[illegible]

Baseline ctDNA and Outcomes in Taxane-Naive Patients With mCRPC Treated With ^{177}Lu-PSMA-617 vs Change of ARPI in PSMAfore

De Bono JS, et al. ASCO 2024. Abstract 5008

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Association of Genomic Alterations With Clinical Outcomes Following Lutetium-177-PSMA in Men With mCRPC

Gauntner T, et al. ASCO 2024. Abstract 5057

EPICS

Final Results of a Phase I/II Dose-Escalation Study of Fractionated Dose ^{177}Lu-PSMA-617 for Progressive mCRPC

Tagawa ST, et al. ASCO 2024. Abstract 5074

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A phase 1 Study of JNJ-69086420 (JNJ-6420), an Actinium-225 (^{225}Ac) - Labeled Antibody Targeting Human Kallikrein 2 (hK2), for mCRPC

Morris MJ, et al. ASCO 2024. Abstract 5010

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Key Insights

Prostate Cancer Part 2 – Radioligands

Experts Considered Recent Data With ^{177}Lu-PSMA-617 in mCRPC

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PSMAfore

Dr Pagnani

We used to run out of good options and we would just regress to the mean of chemotherapy plus trastuzumab in the salvage setting, but now we have so many great choices that that really takes a backseat. It's really been exciting to have multiple options for patients after ^{177}Lu — again, practice changing, unprecedented.

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Experts Discussed Investigational Radioligands for mCRPC

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JNJ-69086420

ongoing trials will help clarify the optimal sequencing of agents

- Experts are still using a [redacted] regimen (a taxane plus trastuzumab and pertuzumab) first-line, followed by [redacted] second-line, for most patients.
- Most experts are using trastuzumab deruxtecan third-line, but will prioritize the tucatinib triplet for patients with evidence of brain metastases.
- The tucatinib triplet may also be used in the second-line setting, before [redacted], for patients with documented brain metastases.
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- Trastuzumab deruxtecan and the tucatinib triplet may also be used earlier than third-line in patients who recur following treatment with trastuzumab, pertuzumab, and [redacted] in the (neo)adjuvant setting, but this represents a small fraction of patients.
- Patient preferences can also factor into the sequencing of these new agents (eg, 3 drugs vs 1 drug, concern about hair loss vs diarrhea).
- The impressive efficacy of trastuzumab deruxtecan and the tucatinib regimen have pushed other options, such as trastuzumab-chemotherapy combinations, neratinib, and margetuximab, to later lines of therapy.

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Experts Speculated on Future Directions in Research for mCRPC

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ctDNA

ongoing trials will help clarify the optimal sequencing of agents

- Experts are still using a [redacted] regimen (a taxane plus trastuzumab and pertuzumab) first-line, followed by T-DM1 second-line, for most patients.
- Most experts are using trastuzumab deruxtecan third-line, but will prioritize the tucatinib triplet for patients with evidence of brain metastases.
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- Trastuzumab deruxtecan and the tucatinib triplet may also be used earlier than third-line in patients who recur following treatment with trastuzumab, pertuzumab, and T-DM1 in the (neo)adjuvant setting, but this represents a small fraction of patients.
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