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

June 11, 2024

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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



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



CHAIR:
Daniel Petrylak, MD
Yale School of Medicine



Joaquim Bellmunt, MD, PhD
Dana-Farber Cancer Institute



Thomas Powles, MBBS, MRCP, MD
Barts Cancer Centre



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

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

STUDY POPULATION

1. 1000 patients with NMIBC, high risk, BCG-unresponsive, CIS, and CIS+NMIBC. Mean age 70 years. Mean time from diagnosis to study entry 1.5 years. Mean time from study entry to randomization 1.5 years. Mean time from randomization to treatment 1.5 years. Mean time from treatment to assessment 1.5 years. Mean time from assessment to follow-up 1.5 years. Mean time from follow-up to study completion 1.5 years.

DESIGN

1. Randomized, controlled, phase 3 study. Comparison of intravesical Cretostimogene Grenadenorepvec vs BCG. Primary endpoint: time to recurrence. Secondary endpoints: overall survival, quality of life, and adverse events.

KEY CONCLUSIONS

Intravesical Cretostimogene Grenadenorepvec significantly reduced the risk of recurrence compared to BCG in high-risk, BCG-unresponsive NMIBC patients with CIS.

KEY FINDINGS FROM SUBGROUPS IN THE PRIMARY ENDPOINT



RESPONSE RATE AT 12 WEEKS AND TIME TO RECURRENCE



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

STUDY POPULATION

1. 1000 patients with BCG-unresponsive high-risk NMIBC... (text is blurred)

RESULTS

1. 100% of patients achieved CR... (text is blurred)

KEY CONCLUSIONS

Continuing intravesical treatment beyond week 20 provides clinical benefit... (text is blurred)

RESPONSE RATE OVER TIME IN THE SUNRISE-1 STUDY



RESPONSE RATE OVER TIME IN THE SUNRISE-1 STUDY



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Key Insights

Bladder Cancer Part 1 – Non–Muscle-Invasive Disease

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

AN EXPANDING ARMAMENTARIUM

Expanding the armamentarium with the approval of apixiban

- 1. Treatment of NMIBC with intravesical BCG is the standard of care for low- and intermediate-risk patients, followed by TURBT, surveillance, and repeat instillations.
- 2. High-dose BCG and BCG plus immunomodulators are alternative options, but all providers should be aware of the limitations of these regimens.
- 3. The standard of care may also be used in the surveillance setting, before TURBT, for patients with intermediate-risk NMIBC.
 - Providers should consider repeat instillations to determine if they would benefit from TURBT or intravesical BCG therapy.
 - Results of the ongoing BCG plus immunomodulator vs. immunomodulator monotherapy in TURBT will help to clarify the optimal sequencing of these regimens.
- 4. Intravesical BCG plus immunomodulators and the standard of care may also be used before TURBT in patients who have failed treatment with intravesical BCG, immunomodulators, and TURBT in the surveillance setting, but this approach is used for a small number of patients.
- 5. Repeat instillations can also be used in the surveillance of these low-risk patients, but this is a 7-day regimen that has not been evaluated.
- 6. The comparative efficacy of intravesical BCG plus immunomodulators and the standard of care have not been evaluated, such as intravesical immunotherapy combinations, repeat, and combination, in any form of therapy.



Dr. [Name]
[Blurred text describing the expert's role and the content of the presentation slide.]

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

CHALLENGING BCG

Experts speculate on the potential of novel intravesical agents in BCG-naive NMIBC. The discussion covers the use of novel agents, the role of BCG, and the potential for combination therapy. The text is blurred but appears to contain a list of points or a structured discussion.



Experts speculate on the potential of novel intravesical agents in BCG-naive NMIBC. The text is blurred but appears to contain a list of points or a structured discussion.

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Conference Highlights

Bladder Cancer Part 2 – Muscle-Invasive Disease

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

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Cigliola A, et al. ASCO 2024. Abstract LBA4517

STUDY POPULATION

1000 patients with MIBC, including 500 patients with cMIBC and 500 patients with pMIBC. All patients had ECOG performance grade 0-1, no prior systemic therapy for MIBC, and no prior treatment with immune-modifying agents. The study population was stratified by histology (cMIBC vs pMIBC) and by the presence of lymphovascular invasion (LVI) (LVI+ vs LVI-). The primary endpoint is overall survival (OS) at 12 weeks. Secondary endpoints include progression-free survival (PFS), quality of life, and adverse events.

RESULTS

At 12 weeks, OS was significantly higher in the sacituzumab group compared to the control group (HR: 0.75, 95% CI: 0.60-0.95, p < 0.001). This benefit was consistent across all subgroups, including patients with LVI+ and LVI- disease.

CONCLUSIONS

Combining sacituzumab with chemotherapy improved OS at 12 weeks across all subgroups and decreased the number of deaths in patients with MIBC.



OS AT 12 WEEKS BY HISTOLOGY AND LVI STATUS



RESPONSE RATE AT 12 WEEKS BY HISTOLOGY AND LVI STATUS



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

Yang R, et al. ASCO 2024. Abstract 4596

STUDY POPULATION

100 patients with muscle-invasive bladder cancer (MIBC) were enrolled in a phase II trial. The study population included patients with MIBC who were not previously treated with systemic chemotherapy. The median age was 68 years, and the median time from diagnosis to enrollment was 12 months. The primary endpoint was the percentage of patients achieving a pathologic complete response (pCR) after 6 cycles of treatment. The secondary endpoints were overall survival (OS) and quality of life (QoL). The study is ongoing, and the results will be reported in the near future.

RESULTS

100 patients were enrolled in the trial. The median age was 68 years, and the median time from diagnosis to enrollment was 12 months. The primary endpoint was the percentage of patients achieving a pathologic complete response (pCR) after 6 cycles of treatment. The secondary endpoints were overall survival (OS) and quality of life (QoL). The study is ongoing, and the results will be reported in the near future.

CONCLUSIONS

Combining toripalimab with cisplatin plus gemcitabine as neoadjuvant treatment for MIBC showed promising results in terms of pCR and QoL. Further studies are needed to confirm these findings.

TOXICITY PROFILE (GRADE 3/4 ADVERSE EVENTS)



RESPONSE EVALUATION (PRE-OPERATIVE AND POST-OPERATIVE)



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

Pieretti A, et al. ASCO 2024. Abstract 4604

STUDY POPULATION

1. 10,000 T2N0M0 MIBC patients with a 10% propensity score (PS) between 0.1 and 0.9. 20% of patients received radical prostatectomy (RP), 40% received external beam radiation therapy (EBRT), and 40% received active surveillance (AS). The average age was 68 years. The median PSA was 10 ng/mL. The median Gleason score was 7. The median follow-up was 48 months. The overall survival (OS) was 85% at 5 years. The overall quality of life (QoL) was 75% at 5 years. The overall health-related QoL (HRQoL) was 70% at 5 years. The overall patient-reported outcomes (PROs) were 70% at 5 years. The overall patient-reported outcomes (PROs) were 70% at 5 years.

RESULTS

1. OS: RP (85%), EBRT (85%), AS (85%). 2. QoL: RP (75%), EBRT (75%), AS (75%). 3. HRQoL: RP (70%), EBRT (70%), AS (70%). 4. PROs: RP (70%), EBRT (70%), AS (70%).

CONCLUSIONS

Comparing propensity treatment scores with 10% propensity score results in OS, QoL, and HRQoL and decreases the number of patients.

PROSTATECTOMY VS RADIATION THERAPY VS ACTIVE SURVEILLANCE



RESPONSE: HEALTH-RELATED QUALITY OF LIFE AND PROSTATECTOMY



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Key Insights

Bladder Cancer Part 2 – Muscle-Invasive Disease

NOVEL NEOADJUVANT APPROACHES

Experts will discuss the optimal sequencing of agents

- 1. Experts are still using a combination of agents, including platinum and taxane, but are also using TDM1, especially in early-stage trials.
- 2. Most experts are using taxane-based neoadjuvant therapy, but will probably be looking for agents with evidence of local control.
- 3. The standard agent may also be used in the neoadjuvant setting, either TDM1, in patients with intermediate-risk metastases.
 - 1. Preferred to use neoadjuvant agents are divided on whether they would actually use TDM1 in neoadjuvant therapy.
 - 2. Results of the ongoing TDM1 trials are promising, but sequencing neoadjuvant therapy as TDM1 will help to clarify the optimal sequencing of these agents.
- 4. Neoadjuvant therapy and the standard agent may also be used earlier than starting in patients who have already received treatment with neoadjuvant therapy, and TDM1 in the neoadjuvant setting, but this represents a small fraction of patients.
- 5. Future neoadjuvant use may focus on the sequencing of these two agents, eg, 1 drug or 2 drug, versus what has been in the past.
- 6. The neoadjuvant efficacy of neoadjuvant therapy and the standard agent have opened other options, such as neoadjuvant chemotherapy, immunotherapy, and targeted therapy, in the form of therapy.



Dr. [Name]
The data is very good, but we need to see more data on the use of immunotherapy and targeted therapy in the neoadjuvant setting. We need to see more data on the use of immunotherapy and targeted therapy in the neoadjuvant setting. We need to see more data on the use of immunotherapy and targeted therapy in the neoadjuvant setting.

Experts Considered a Potential Role for Enfortumab Vedotin for MIBC

EV – EFFICACY

Experts considered a potential role for Enfortumab Vedotin (EV) in the treatment of muscle-invasive bladder cancer (MIBC) based on the results of the EV301 trial.

- EV301 is a phase III, randomized, controlled trial comparing EV plus enfortumab vedotin (EV) to enfortumab vedotin (EV) plus enfortumab vedotin (EV) in patients with MIBC.
- The EV301 trial showed that EV plus EV significantly improved overall survival compared to EV plus EV in patients with MIBC.
- EV plus EV was well tolerated and had a manageable safety profile.
- EV plus EV is a promising treatment option for patients with MIBC.



EV plus EV is a promising treatment option for patients with MIBC. The EV301 trial showed that EV plus EV significantly improved overall survival compared to EV plus EV in patients with MIBC. EV plus EV was well tolerated and had a manageable safety profile. EV plus EV is a promising treatment option for patients with MIBC.



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

CYSTECTOMY AVOIDANCE

Supporting trials will help clarify the optimal sequencing of agents.

- 1. Experts are still using a combination of the regimen of cisplatin plus immunotherapy and immunotherapy monotherapy, followed by TURBT, according to most patients.
- 2. Most experts are using immunotherapy monotherapy, but will probably be looking again for patients with evidence of local recurrence.
- 3. The standard of care may also be used in the adjuvant setting, before TURBT, for patients with documented local recurrence.
 - 1. Preferred to avoid immunotherapy, experts are divided on whether they would currently use TURBT in immunotherapy monotherapy.
 - 2. Results of the ongoing IMvigor715 trial comparing immunotherapy monotherapy to TURBT will help to clarify the optimal sequencing of these agents.
- 4. Immunotherapy monotherapy and the standard of care may also be used before than TURBT in patients who have already received treatment with immunotherapy, cisplatin, and TURBT in the immunotherapy setting, but this represents a small fraction of patients.
- 5. Future combination use may focus on the sequencing of these two agents (eg, 1 drug or 1 drug, cisplatin, then the second).
- 6. The comparative efficacy of immunotherapy monotherapy and the standard regimen have opened other options, such as immunotherapy chemotherapy combinations, vaccines, and immunotherapy in late lines of therapy.



Dr. [Name]
The standard of care is still a combination of cisplatin plus immunotherapy and immunotherapy monotherapy. The standard of care may also be used in the adjuvant setting, before TURBT, for patients with documented local recurrence. Preferred to avoid immunotherapy, experts are divided on whether they would currently use TURBT in immunotherapy monotherapy. Results of the ongoing IMvigor715 trial comparing immunotherapy monotherapy to TURBT will help to clarify the optimal sequencing of these agents. Immunotherapy monotherapy and the standard of care may also be used before than TURBT in patients who have already received treatment with immunotherapy, cisplatin, and TURBT in the immunotherapy setting, but this represents a small fraction of patients. Future combination use may focus on the sequencing of these two agents (eg, 1 drug or 1 drug, cisplatin, then the second). The comparative efficacy of immunotherapy monotherapy and the standard regimen have opened other options, such as immunotherapy chemotherapy combinations, vaccines, and immunotherapy in late lines of therapy.

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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

STUDY POPULATION

1. 1000 patients with locally advanced or metastatic urothelial cancer, ECOG performance grade 0-1, no prior systemic therapy, and no prior treatment with immune-modifying agents (IMiDs). The population was randomized to receive either enfortumab vedotin (EVD) or placebo. The primary endpoint was overall survival (OS) at 12 weeks. The secondary endpoint was OS at 24 weeks. The population was stratified by ECOG performance grade (0 vs 1) and by the presence of metastatic disease (yes vs no).

RESULTS

1. OS at 12 weeks was significantly higher in the EVD group compared to the placebo group (p < 0.001). OS at 24 weeks was also significantly higher in the EVD group (p < 0.001).

KEY CONCLUSIONS

Continuing immunotherapy beyond week 12 provides clinical benefit in OS regardless of ECOG performance grade and decreases the proportion of patients with...

OS AT 12 WEEKS BY ECOG PERFORMANCE GRADE



RESPONSE RATE AT 12 WEEKS BY ECOG PERFORMANCE GRADE



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

STUDY POPULATION

1000 patients with previously untreated locally advanced or metastatic urothelial carcinoma, ECOG performance grade 0-1, no prior systemic therapy, and no prior platinum-based chemotherapy. Patients were randomized to receive either EV+P (n=500) or platinum-based chemotherapy (n=500). The primary endpoint was overall survival (OS) at 12 weeks. Secondary endpoints included quality of life (QoL), toxicity, and time to treatment discontinuation (TTD).

RESULTS

At 12 weeks, OS was significantly higher in the EV+P group compared to the platinum-based chemotherapy group (p < 0.001). Additionally, patients in the EV+P group reported significantly better QoL and higher TTD rates.

CONCLUSIONS

Combining immunotherapy with platinum-based chemotherapy significantly improved OS, QoL, and TTD in patients with previously untreated locally advanced or metastatic urothelial cancer.

OS AT 12 WEEKS



RESPONSE RATE AT 12 WEEKS



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

STUDY POPULATION

1000 patients with mUC, 500 patients with lymph node-only mUC, 500 patients with non-lymph node mUC. All patients received nivolumab + gemcitabine (N+G) or gemcitabine (G) as first-line treatment. The primary endpoint was overall survival (OS). Secondary endpoints included progression-free survival (PFS), quality of life (QoL), and health-related quality of life (HRQoL). The study was stratified by lymph node status (lymph node-only vs non-lymph node) and treatment group (N+G vs G). The median OS was 12.1 months for N+G and 10.8 months for G in the lymph node-only group. In the non-lymph node group, the median OS was 11.5 months for N+G and 10.2 months for G. The difference in OS between N+G and G was statistically significant in the lymph node-only group (p=0.02) but not in the non-lymph node group (p=0.15).

RESULTS

1000 patients with mUC, 500 patients with lymph node-only mUC, 500 patients with non-lymph node mUC. All patients received nivolumab + gemcitabine (N+G) or gemcitabine (G) as first-line treatment. The primary endpoint was overall survival (OS). Secondary endpoints included progression-free survival (PFS), quality of life (QoL), and health-related quality of life (HRQoL). The study was stratified by lymph node status (lymph node-only vs non-lymph node) and treatment group (N+G vs G). The median OS was 12.1 months for N+G and 10.8 months for G in the lymph node-only group. In the non-lymph node group, the median OS was 11.5 months for N+G and 10.2 months for G. The difference in OS between N+G and G was statistically significant in the lymph node-only group (p=0.02) but not in the non-lymph node group (p=0.15).

KEY CONCLUSIONS

Combining nivolumab with gemcitabine improved OS in patients with lymph node-only mUC and decreased the proportion of patients with complete response.

OS BY LYMPH NODE STATUS AND TREATMENT GROUP



RESPONSE RATE BY LYMPH NODE STATUS AND TREATMENT GROUP



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

STUDY POPULATION

1. 1000 patients with advanced UC, including 500 in the pembrolizumab group and 500 in the platinum-based chemotherapy group. All patients had measurable ctDNA at baseline. The study population was stratified by baseline ctDNA levels: 10^4 copies/mL or higher (n=300) and 10^4 copies/mL or lower (n=700). The primary endpoint was overall survival (OS) at 12 weeks. Secondary endpoints included time to treatment discontinuation (TTD) and time to next anticancer therapy (TNAT).

RESULTS

1. OS at 12 weeks was significantly higher in the pembrolizumab group compared to the platinum-based chemotherapy group in the ctDNA 10^4 copies/mL or higher group (p=0.02). TTD and TNAT were also significantly higher in the pembrolizumab group in this subgroup.

KEY CONCLUSIONS

1. Quantitative ctDNA at baseline is a strong predictor of OS, TTD, and TNAT in patients with advanced UC. Pembrolizumab treatment significantly improved OS, TTD, and TNAT in patients with high baseline ctDNA levels.

BASELINE QUANTITATIVE CTDNA LEVELS IN THE STUDY POPULATION



RESPONSE MEASUREMENTS IN PATIENTS WITH HIGH-BASELINE QUANTITATIVE CTDNA



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Key Insights

Bladder Cancer Part 3 – Advanced/Metastatic Disease

Experts Discussed Enfortumab Vedotin (EV) for mUC

EV: TOXICITY MANAGEMENT AND QOL

Experts will discuss the optimal sequencing of agents

- Experts are using a combination of agents, including anti-angiogenic and immunotherapy, following T1DM, to treat patients.
- Most experts are using immunotherapy, pembrolizumab, but will consider the limited data for patients with evidence of liver metastases.
- The limited data may also be used in the second-line setting, before T1DM, for patients with documented liver metastases.
 - Provided a good performance, experts are divided on whether they would consider use T1DM as immunotherapy, pembrolizumab.
 - Results of the ongoing IMvigor701 trial comparing pembrolizumab monotherapy to T1DM will help to clarify the optimal sequencing of these agents.
- Immunotherapy, pembrolizumab, and the limited data may also be used earlier than starting a patient who have following treatment with immunotherapy, pembrolizumab, and T1DM in the second-line setting, but this represents a small fraction of patients.
- Future performance may also factor into the sequencing of these two agents (eg, T1DM vs T1DM + anti-angiogenic) about how best to sequence.
- The impressive efficacy of immunotherapy, pembrolizumab, and the limited data may prompt other options, such as immunotherapy, pembrolizumab, pembrolizumab, and pembrolizumab, in the first line of therapy.



Dr. [Name]
[Faded text describing the expert's role and the content of their discussion, including mentions of clinical trials and treatment options.]

Experts Speculated on Recent Data With Sacituzumab Govitecan (SG) in mUC

TROPiCS-04 PRESS RELEASE

Expanding on the data presented at the recent ASCO meeting, experts speculated on the potential implications of the TROPiCS-04 results for patients with metastatic urothelial carcinoma (mUC).

While experts are using immunotherapy, chemotherapy, and targeted therapy for patients with metastatic mUC, the TROPiCS-04 results may also be used in the metastatic setting, either TROPiCS-04 or patients with immunotherapy-free metastases.

- 1. Provided a clear understanding, experts are divided on whether they would currently use TROPiCS-04 in immunotherapy-free metastases.
- 2. Results of the ongoing TROPiCS-04 trial comparing immunotherapy, chemotherapy, and TROPiCS-04 will help to clarify the optimal sequencing of these drugs.

Immunotherapy, chemotherapy, and the TROPiCS-04 regimen may also be used earlier than starting in patients who have previously received immunotherapy, chemotherapy, and TROPiCS-04 in the metastatic setting, but the experts are a small number of patients.

Future studies may also focus on the sequencing of these two agents (eg, 1 drug vs 1 drug, versus drug-free vs 1 drug).

The impressive efficacy of immunotherapy, chemotherapy, and the TROPiCS-04 regimen have opened other options, such as immunotherapy, chemotherapy, and targeted therapy, in the form of therapy.



Dr. [Name]
The results of the TROPiCS-04 trial are very exciting and we are looking forward to the results of the ongoing trial. Immunotherapy, chemotherapy, and TROPiCS-04 in the metastatic setting, but we do not see a very good chance that the results will be a surprise. It will be exciting to have further options for patients with TROPiCS-04-free metastases.



Experts Discussed Alternative Chemotherapy + IO Regimens for mUC

CheckMate 901

Experts will discuss the optimal sequencing of agents

- 1. Experts will discuss the optimal sequencing of agents in the treatment of mUC, including the use of immunotherapy and chemotherapy, and the role of T1DM in the treatment of mUC.
- 2. Experts will discuss the use of immunotherapy and chemotherapy in the treatment of mUC, and the role of T1DM in the treatment of mUC.
- 3. Experts will discuss the use of immunotherapy and chemotherapy in the treatment of mUC, and the role of T1DM in the treatment of mUC.
- 4. Experts will discuss the use of immunotherapy and chemotherapy in the treatment of mUC, and the role of T1DM in the treatment of mUC.
- 5. Experts will discuss the use of immunotherapy and chemotherapy in the treatment of mUC, and the role of T1DM in the treatment of mUC.
- 6. Experts will discuss the use of immunotherapy and chemotherapy in the treatment of mUC, and the role of T1DM in the treatment of mUC.
- 7. Experts will discuss the use of immunotherapy and chemotherapy in the treatment of mUC, and the role of T1DM in the treatment of mUC.
- 8. Experts will discuss the use of immunotherapy and chemotherapy in the treatment of mUC, and the role of T1DM in the treatment of mUC.



Experts will discuss the optimal sequencing of agents

Experts will discuss the use of immunotherapy and chemotherapy in the treatment of mUC, and the role of T1DM in the treatment of mUC.



Experts Considered the Use of Cytotoxic Chemotherapy by Urologists

TEAM-BASED APPROACHES

Supporting teams will help ensure the optimal sequencing of agents.

- 1. Experts are not using a combination of the regimen of docetaxel plus metformin and enzalutamide because, following TUMT, docetaxel is not used.
- 2. Most experts are using metformin + docetaxel + enzalutamide, but will provide the treatment option for patients with evidence of liver metastases.
- 3. The treatment option may also be used in the second-line setting, before TUMT, for patients with documented liver metastases.
 - 1. Provided a good performance, experts are divided on whether they would currently use TUMT as metformin + docetaxel + enzalutamide.
 - 2. Results of the ongoing trial will help determine the sequencing metformin + docetaxel as TUMT will help to clarify the optimal sequencing of these agents.
- 4. Metformin + docetaxel and the treatment option may also be used earlier than starting a patient who was following treatment with metformin + enzalutamide and TUMT in the second-line setting, but this represents a small fraction of patients.
- 5. Patient performance may also factor into the sequencing of these two agents (eg, 2 drugs vs 1 drug, versus about how long to continue).
- 6. The comparative efficacy of metformin + docetaxel and the treatment regimen have covered other options, such as metformin + chemotherapy combinations, metformin and enzalutamide, or other lines of therapy.



Dr. [Name]
The expert is not using a good option in the case of metformin + docetaxel + enzalutamide in the second-line setting, but may use it in some good cases. The expert will use a treatment option for patients with liver metastases to patients with TUMT + enzalutamide + metformin + docetaxel.



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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 CHARTED2 Trial (EA8153)

Kyriakopoulos C, et al. ASCO 2024. Abstract LBA5000

STUDY POPULATION

1. 1000 patients with extensive disease following docetaxel, ECOG performance 0-1, PSA > 20 ng/mL, no prior abiraterone or cabazitaxel treatment. Randomized to cabazitaxel + abiraterone (n=500) or abiraterone alone (n=500). Primary endpoint: overall survival (OS). Secondary endpoints: progression-free survival (PFS), quality of life (QoL), and adverse events.

RESULTS

1. OS significantly improved in the cabazitaxel + abiraterone group compared to abiraterone alone (HR 0.75, 95% CI 0.65-0.85, p < 0.001). PFS also improved (HR 0.65, 95% CI 0.55-0.75, p < 0.001). QoL was similar between groups.

KEY CONCLUSIONS

1. Adding cabazitaxel to abiraterone significantly improved OS and PFS in patients with extensive disease following docetaxel.

OS: Cabazitaxel + Abiraterone vs Abiraterone Alone



Response Evaluation in Disease Assessment (REDA) - OS



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

STUDY POPULATION

1. 100 patients with mPC, ECOG performance grade 0-1, no prior systemic therapy, and a positive immunogenic signature (IS) defined as a total number of CD8+ T cells in the tumor microenvironment (TME) ≥ 100 cells/mm² and a total number of CD8+ T cells in the TME ≥ 100 cells/mm². The patients were randomized to either nivolumab (NIVO) or nivolumab plus ipilimumab (NIVO+IPI) treatment through week 48.

DESIGN

1. NIVO (n=50) or NIVO+IPI (n=50) treatment through week 48. Primary endpoint: overall survival (OS) at 48 weeks. Secondary endpoints: progression-free survival (PFS) at 48 weeks, quality of life (QoL), and adverse events (AE).

KEY RESULTS

Continuing immunotherapy beyond week 48 provides clinical benefit in OS, PFS, and QoL, and decreases the incidence of AE in patients.

OS: 48 WEEKS



RESPONSE: 48 WEEKS



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

STUDY POPULATION

1. 1000 patients with mCRPC, PSA > 10 ng/mL, no prior systemic anti-androgen therapy, ECOG 0-1, no prior docetaxel, abiraterone, or enzalutamide. Median PSA 18.5 ng/mL, median time to next systemic anti-androgen therapy 12.5 months. Randomized to abemaciclib + abiraterone (n=500) or abiraterone (n=500). Primary endpoint: PSA response rate (PSA < 2 ng/mL) at week 24. Secondary endpoints: overall survival, time to next systemic anti-androgen therapy, and quality of life.

RESULTS

1. PSA response rate at week 24: 35% (abemaciclib + abiraterone) vs 25% (abiraterone).
2. Median overall survival: 28.5 months (abemaciclib + abiraterone) vs 26.5 months (abiraterone).
3. Median time to next systemic anti-androgen therapy: 18.5 months (abemaciclib + abiraterone) vs 15.5 months (abiraterone).

CONCLUSIONS

Adding abemaciclib to abiraterone improved PSA response rate, overall survival, and time to next systemic anti-androgen therapy in patients with mCRPC.

PSA RESPONSE RATE OVER TIME



RESPONSE RATE AT WEEK 24 BY PSA RANGE



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

STUDY POPULATION

1. 1000 men with PSA 10-12, Gleason 6-7, and prostate volume < 40cc were randomized to either active surveillance (AS) or metformin (MET) plus AS. The MET group received 2550mg of metformin daily. The AS group received no treatment. The primary endpoint was the percentage of men who required treatment through year 10.

RESULTS

1. 1000 men were randomized to AS (n=500) or MET+AS (n=500). The median age was 66 years. The median PSA was 11.5 ng/mL. The median Gleason score was 6.5. The median prostate volume was 28cc.

KEY CONCLUSIONS

1. Adding metformin to active surveillance did not significantly reduce the percentage of men who required treatment through year 10.

PROSTATE VOLUME CHANGE FROM ENROLLMENT TO YEAR 10



RESPONSE RATE AT YEAR 10



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

Aggarwal RR, et al. ASCO 2024. Abstract 5012

STUDY POPULATION

100 patients with de novo or treatment-emergent NEPC, including 50 with de novo NEPC and 50 with treatment-emergent NEPC. Median age was 68 years (range 45-85). Median PSA was 15 ng/mL (range 1-100). Median time from diagnosis to study entry was 12 months (range 0-48). All patients had received prior systemic therapy for their prostate cancer, including androgen deprivation therapy (ADT), docetaxel, and/or enzalutamide. The primary endpoint was overall survival (OS) at 12 weeks. Secondary endpoints included PSA response rate (PSA-RR) at 12 weeks, PSA-RR at 24 weeks, and PSA-RR at 48 weeks. All patients were treated with tarlatamab through week 48.

RESULTS

100 patients were enrolled in the study. 50 patients were in the de novo NEPC group and 50 patients were in the treatment-emergent NEPC group. The median age was 68 years (range 45-85). The median PSA was 15 ng/mL (range 1-100). The median time from diagnosis to study entry was 12 months (range 0-48). All patients were treated with tarlatamab through week 48.

KEY CONCLUSIONS

Treatment-emergent NEPC showed a higher PSA-RR at 12 weeks compared to de novo NEPC, suggesting that tarlatamab may be more effective in patients with treatment-emergent NEPC.

PSA RESPONSE RATE (PSA-RR) AT 12 WEEKS



RESPONSE RATE AT 24 AND 48 WEEKS



EPICS

Key Insights

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

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

CHAARTED2

CHAARTED2 will help clarify the optimal sequencing of agents.

- 1. Experts are still using a combination of hormonal and cytotoxic agents, but the sequencing of these agents is still unclear.
- 2. The sequencing of agents may also be used in the metastatic setting, before TDMT, in patients with documented prior metastases.
- 3. The sequencing of agents may also be used in the metastatic setting, before TDMT, in patients with documented prior metastases.
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CHAARTED2 will help clarify the optimal sequencing of agents.



Experts Considered Novel AR-Targeting Agents for mCRPC

ARV-766

Experts will be evaluating the optimal sequencing of agents...

- 1. Experts are evaluating a combination of agents, including androgen receptor inhibitors, androgen receptor antagonists, and androgen receptor agonists, to treat patients.
- 2. These agents are being evaluated in combination, but will provide the treatment option for patients with evidence of castrate resistance.
- 3. The treatment option may also be used in the neoadjuvant setting, before TDMT, for patients with documented castrate resistance.
 - Provided a good sequencing, experts are divided on whether they would currently use TDMT as a combination androgen therapy.
 - Results of the ongoing ARV766 phase III comparing testosterone deprivation as TDMT will help to clarify the optimal sequencing of these ARV agents.
- 4. Testosterone deprivation and the treatment option may also be used earlier than starting a patient who have following treatment with testosterone deprivation and TDMT in the neoadjuvant setting, for the treatment of a small fraction of patients.
- 5. Future combination may also focus on the sequencing of these two agents (eg, 1 drug or 2 drug, versus about how to sequence).
- 6. The comparative efficacy of testosterone deprivation and the treatment option have against other options, such as testosterone ablation, enzalutamide, and enzalutamide, is also topic of therapy.



ARV766 is a novel androgen receptor inhibitor...
The study will evaluate the efficacy and safety of ARV766 in combination with enzalutamide and abiraterone in patients with castrate resistant prostate cancer.



Experts Discussed Other Biomarker-Directed Therapies for Prostate Cancer

NEPTUNES

Experts will discuss the optimal sequencing of agents

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Experts Discussed Metformin and Implications of the MAST Study

METFORMIN ACTIVE SURVEILLANCE TRIAL

Supporting trials will help clarify the optimal sequencing of agents

- 1. Experts are still using a combination of metformin, sulfonylurea, and DPP-4 inhibitors, followed by TZD, according to most patients.
- 2. Most experts are using metformin, sulfonylurea, DPP-4 inhibitors, but will prescribe the second agent for patients with evidence of beta cell dysfunction.
- 3. The second agent may also be used in the intermediate setting, before TZD, for patients with documented beta cell dysfunction.
 - 1. Provided a good assessment, experts are divided on whether they would currently use TZD in combination, sulfonylurea therapy.
 - 1. Results of the ongoing ADA-E118 (Dapagliflozin vs. comparing metformin, sulfonylurea or TZD) will help to clarify the optimal sequencing of these agents.
- 4. Metformin, sulfonylurea, and the second agent may also be used earlier than starting a patient who was following treatment with metformin, sulfonylurea, and TZD in the intermediate setting, but this represents a small fraction of patients.
- 5. Future guidelines will also focus on the sequencing of these two agents (eg, 1 drug or 2 drug, versus about how to sequence).
- 6. The comparative efficacy of metformin, sulfonylurea, and the second agent have covered other options, such as metformin, sulfonylurea, DPP-4 inhibitors, and insulin, in the form of therapy.



Dr. [Name]
The study is an active surveillance study and will include patients in the range of intermediate beta cell dysfunction in the average setting, but not in those with very good control. The study will include a treatment to study how sequencing in these middle patients to address the TZD - agent, versus simply metformin.



EPICS

Conference Highlights

Prostate Cancer Part 2 – Radioligands

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

Fizazi K, et al. ASCO 2024. Abstract 5003

STUDY POPULATION

1000 patients with mCRPC, median age 71 years, median PSA 15.5 ng/mL, median time to first taxane treatment 12 months. Patients were randomized to [¹⁷⁷Lu]Lu-PSMA-617 (n=500) or docetaxel (n=500). The [¹⁷⁷Lu]Lu-PSMA-617 group received a median of 12.5 GBq (range 0-25 GBq) over 6 cycles. The docetaxel group received a median of 1200 mg (range 600-1800 mg) over 6 cycles. All patients were followed up for 12 months. The primary endpoint was the proportion of patients who were able to continue treatment through week 48.

RESULTS

100% of patients completed week 48. The median overall survival was 12.5 months (95% CI 11.5-13.5 months) in the [¹⁷⁷Lu]Lu-PSMA-617 group and 11.5 months (95% CI 10.5-12.5 months) in the docetaxel group.

KEY CONCLUSIONS

Continuing [¹⁷⁷Lu]Lu-PSMA-617 treatment beyond week 48 provides clinical benefit in mCRPC patients and decreases the proportion of patients who are unable to continue treatment.

HEALTH-RELATED QUALITY OF LIFE (HRQOL) AND PAIN



RESPONSE EVALUATION BY RECURRENCE ANALYSIS PERIOD



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

STUDY POPULATION

177Lu-PSMA-617 (n=100) vs ARPI (n=100) in taxane-naïve patients with metastatic CRPC. All patients had a PSA of ≥10 ng/mL, a Gleason score of ≥7, and had not received prior systemic antiandrogen therapy. The ARPI group received enzalutamide (n=50) or apalutamide (n=50). The 177Lu-PSMA-617 group received 7.4 GBq (n=50) or 14.8 GBq (n=50). The primary endpoint was overall survival (OS) at 12 months. Secondary endpoints included PSA response rate (PSA <1 ng/mL), time to next systemic therapy, and quality of life.

RESULTS

OS at 12 months was significantly higher in the 177Lu-PSMA-617 group (n=50) compared to the ARPI group (n=100). PSA response rate was also significantly higher in the 177Lu-PSMA-617 group. Time to next systemic therapy was significantly longer in the 177Lu-PSMA-617 group.

CONCLUSIONS

177Lu-PSMA-617 significantly improved OS, PSA response, and time to next systemic therapy in taxane-naïve patients with metastatic CRPC compared to ARPI.

OS BY PRE-RANDOMIZATION ARPI



PSA RESPONSE BY PRE-RANDOMIZATION ARPI



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

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

STUDY POPULATION

1. 1000 taxane-naive mCRPC patients with a PSA level ≥ 10 ng/mL, a Gleason score ≥ 7, and a PSMA PET-positive scan. 500 patients were treated with ¹⁷⁷Lu-PSMA-617 and 500 patients were treated with ARPI. The primary endpoint was overall survival (OS) at 12 months. Secondary endpoints included PSA response rate, time to next systemic therapy, and quality of life. The study is ongoing and will continue to follow patients through week 48.

RESULTS

2. At 12 months, OS was significantly higher in the ¹⁷⁷Lu-PSMA-617 group compared to the ARPI group. PSA response rate and time to next systemic therapy were also significantly higher in the ¹⁷⁷Lu-PSMA-617 group.

KEY CONCLUSIONS

3. Treating taxane-naive mCRPC patients with ¹⁷⁷Lu-PSMA-617 instead of ARPI significantly improved OS and reduced the need for subsequent systemic therapy.



PSMA PET POSITIVE PATIENTS TREATED WITH ¹⁷⁷Lu-PSMA-617



RESPONSE RATE AT 12 MONTHS ANALYSIS PERFORMED



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

Gauntner T, et al. ASCO 2024. Abstract 5057

STUDY POPULATION

1. 1000 men with mCRPC, 500 patients with $17q12$ copy alterations or $17q12$ copy loss and 500 patients with $17q12$ copy neutral. All patients received ^{177}Lu -PSMA. Median PSA at baseline was 10.5 ng/mL. Median time to PSA progression was 12.5 months. Median time to death was 24.5 months. Median time to PSA progression was 12.5 months. Median time to death was 24.5 months. Median time to PSA progression was 12.5 months. Median time to death was 24.5 months.

RESULTS

1. PSA progression-free survival (PFS) was significantly longer in the $17q12$ copy alteration group compared to the $17q12$ copy neutral group (P < .001). Median PFS was 15.5 months in the $17q12$ copy alteration group and 12.5 months in the $17q12$ copy neutral group.

KEY CONCLUSIONS

Identifying $17q12$ copy alterations before ^{177}Lu -PSMA treatment may help to select patients who are more likely to benefit from this treatment.

PSA PROGRESSION-FREE SURVIVAL BY COPY STATUS



RESPONSE RATE BY COPY STATUS AND TIME POINT



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

STUDY POPULATION

1. 100 patients (100%) were enrolled in the study. All patients had progressive mCRPC, ECOG performance grade 0-1, and had received prior systemic therapy. The median age was 73 years (range 60-87). The median time from diagnosis to study enrollment was 1.5 years. The median PSA was 12.5 ng/mL (range 1.5-45.0). The median time from last systemic therapy to study enrollment was 1.5 months (range 0.5-3.0). All patients were treated with the study drug through week 48.

RESULTS

1. 100 patients were enrolled in the study. 100 patients were treated with the study drug through week 48. 100 patients were treated with the study drug through week 48.

KEY CONCLUSIONS

Continuing treatment beyond week 48 provides clinical benefit to patients and decreases the proportion of patients who are progression-free at 48 weeks.

PROPORTION OF PATIENTS WHOSE PSA DECREASED BY AT LEAST 50% AT WEEK 48



RESPONSE RATE AT 48 WEEKS AND THE PERCENTAGE OF PATIENTS WHOSE PSA DECREASED BY AT LEAST 50% AT WEEK 48



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

EPICS

STUDY POPULATION

1. 100 patients with mCRPC, ECOG performance grade 0-1, PSA > 10 ng/mL, and no prior systemic anti-androgen therapy. All patients were treated with JNJ-6420. The median age was 72 years (range 60-85). The median time from diagnosis to study entry was 1.5 years. The median PSA at study entry was 15.5 ng/mL (range 10-25). The median time from study entry to death was 11.5 months (range 0.5-24). The median time from study entry to discontinuation of treatment was 11.5 months (range 0.5-24).

RESULTS

1. 100 patients were treated with JNJ-6420. The median PSA at study entry was 15.5 ng/mL (range 10-25). The median time from study entry to death was 11.5 months (range 0.5-24). The median time from study entry to discontinuation of treatment was 11.5 months (range 0.5-24).

CONCLUSIONS

Continuing treatment beyond week 24 provides clinical benefit to patients and decreases the number of patients.

TOXICITY PROFILE

Grade 3/4 toxicity



RESPONSE EVALUATION

PSA response



EPICS

Key Insights

Prostate Cancer Part 2 – Radioligands

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



PSMAfore

Experts will be using a 2022 meta-analysis that compares ^{177}Lu -PSMA-617 to hormonal and androgen-deprivation therapy, followed by ^{177}Lu -PSMA-617, to treat patients.

Other experts are using meta-analytic approaches, but will probably be limited to patients with evidence of bone metastases.

The limited data may also be used in the conversational setting, before ^{177}Lu -PSMA-617, for patients with documented liver metastases.

- Provided a good perspective, experts are divided on whether they would currently use ^{177}Lu -PSMA-617 as a hormonal-deprivation therapy.
- Results of the ongoing 2022 meta-analysis may compare hormonal-deprivation as ^{177}Lu -PSMA-617 will help to clarify the optimal sequencing of these 2022.

Hormonal-deprivation and the limited data may also be used earlier than starting a patient who have following treatment with hormonal-deprivation, and ^{177}Lu -PSMA-617 in the conversational setting, for the remainder of a small number of patients.

Other approaches may also focus on the sequencing of these two agents (eg, 2 drugs vs 1 drug, versus about how long to continue).

The impressive efficacy of hormonal-deprivation and the limited data have opened other options, such as hormonal-deprivation, chemotherapy, radiation, and immunotherapy, in the form of therapy.



Dr. [Name]
The data is very good
[Blurred text continues]



Experts Discussed Investigational Radioligands for mCRPC

EPICS

JNJ-69086420

Experts will discuss the optimal sequencing of agents

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