








EPICS

Conference Coverage: ASCO GU 2023 Highlights

February 24, 2023

1.00 PM – 4.00 PM EST

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VIRTUAL CLOSED-DOOR ROUNDTABLE



DATE:
February 24, 2023



**DISEASE-STATE AND
DATA PRESENTATIONS**
by key experts

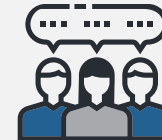


INSIGHTS REPORT
including postmeeting
analyses and actionable
recommendations



PANEL: Key experts in
GU malignancies

- > 5 from US
- > 2 from Europe



**GU CANCER-SPECIFIC
DISCUSSIONS** on
therapeutic advances and
their application in clinical
decision-making

Panel Consisting of 5 US and 2 European GU Cancer Experts

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Susan F. Slovin, MD, PhD
Memorial Sloan Kettering
Cancer Center



Leonard G. Gomella, MD, FACS
Sidney Kimmel Cancer Center



Joaquim Bellmunt, MD, PhD
Harvard Medical School



**Thomas Powles, MD,
MRCP, MBBS**
Barts Cancer Institute



CHAIR:
Daniel P. Petrylak, MD
Yale Cancer Center



**Robert Dreicer, MD,
MACP, FASCO**
University of Virginia
Cancer Center



Karim Fizazi, MD, PhD
Gustave Roussy Institute



Meeting Agenda

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Time (EDT)	Topic	Speaker/Moderator
1.00 PM – 1.05 PM	Welcome, Introductions, and Meeting Objectives	Daniel Petrylak, MD
1.05 PM – 1.15 PM	Prostate Cancer Part 1 – Localized and Castrate-Sensitive Prostate Cancers	Susan Slovin, MD, PhD
1.15 PM – 1.30 PM	Discussion	Daniel Petrylak, MD
1.30 PM – 1.35 PM	Key Takeaways	Susan Slovin, MD, PhD
1.35 PM – 1.50 PM	Prostate Cancer Part 2 – Metastatic Castration-Resistant Prostate Cancer	Karim Fizazi, MD, PhD; Robert Dreicer, MD, MACP, FASCO
1.50 PM – 2.05 PM	Discussion	Daniel Petrylak, MD
2.05 PM – 2.10 PM	Key Takeaways	Karim Fizazi, MD, PhD; Robert Dreicer, MD, MACP, FASCO
2.10 PM – 2.20 PM	Bladder Cancer Part 1 – NMIBC and MIBC	Leonard Gomella, MD, FACS
2.20 PM – 2.30 PM	Discussion	Daniel Petrylak, MD
2.30 PM – 2.35 PM	Key Takeaways	Leonard Gomella, MD, FACS
2.35 PM – 2.45 PM	<i>Break</i>	
2.45 PM – 2.55 PM	Bladder Cancer Part 2 – Metastatic Urothelial Cancer	Joaquim Bellmunt, MD, PhD
2.55 PM – 3.10 PM	Discussion	Daniel Petrylak, MD
3.10 PM – 3.15 PM	Key Takeaways	Joaquim Bellmunt, MD, PhD
3.15 PM – 3.30 PM	Renal Cell Carcinoma	Thomas Powles, MBBS, MRCP, MD
3.30 PM – 3.50 PM	Discussion	Daniel Petrylak, MD
3.50 PM – 3.55 PM	Key Takeaways	Thomas Powles, MBBS, MRCP, MD
3.55 PM – 4.00 PM	Summary and Closing Remarks	Daniel Petrylak, MD



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Congress Highlights

Prostate Cancer Part 1 – Localized and Castrate-Sensitive Prostate Cancers

FORMULA-509: Salvage radiotherapy and 6 months of GnRH agonist ± abiraterone and apalutamide post-radical prostatectomy

Nguyen et al. 2023, ASCO GU 303

STUDY POPULATION AND METHODS

> 345 pts with recurrent prostate cancer following prostatectomy

METASTASIS-FREE SURVIVAL



Darolutamide in combination with ADT and docetaxel by disease volume and disease risk in the phase 3 ARASENS study

Hussain et al. 2023, ASCO GU 15

STUDY POPULATION AND METHODS

> 1306 pts with mHSPC were randomized to darolutamide or

OVERALL SURVIVAL

STUDY POPULATION

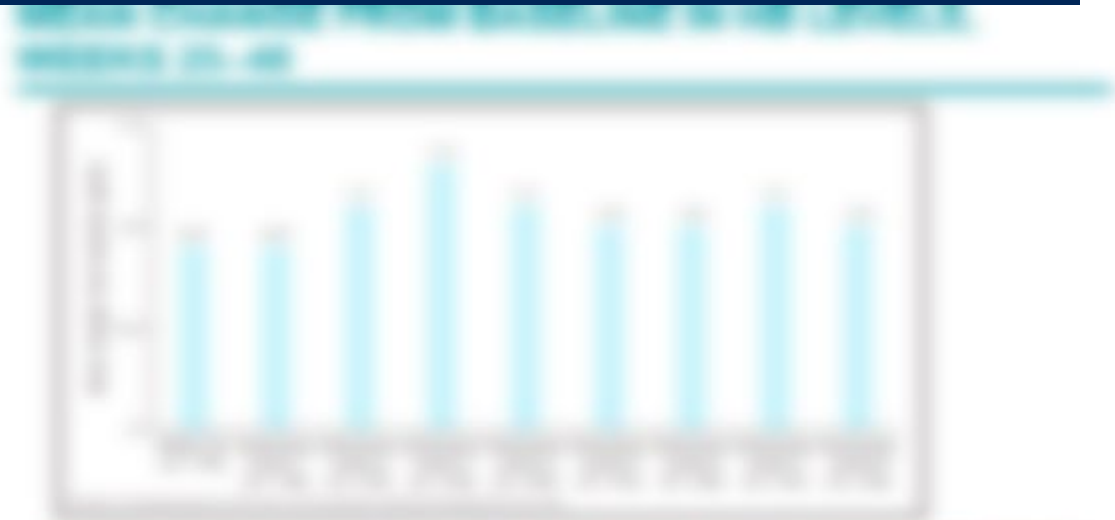
1306 pts with mHSPC were randomized to darolutamide or placebo in combination with ADT and docetaxel. The study population included all patients who were randomized and received at least one dose of study treatment. The median age was 70 years, and the median time from diagnosis to randomization was 12 months. The majority of patients had a Gleason score of 7-10 and a PSA level of 10-20 ng/mL. The study population was stratified by disease volume and disease risk.

RESULTS

The overall survival (OS) results are shown in the Kaplan-Meier plot. The median OS was significantly longer in the darolutamide group compared to the placebo group. The OS benefit was consistent across all subgroups, including patients with high and low disease volume and high and low disease risk.

CONCLUSIONS

Darolutamide in combination with ADT and docetaxel significantly improved OS in patients with mHSPC. The OS benefit was consistent across all subgroups, including patients with high and low disease volume and high and low disease risk.



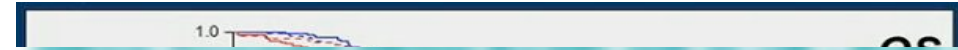
Abiraterone and ADT ± docetaxel in older patients (≥70 years) with de novo mCSPC compared to younger patients: The PEACE-1 trial

Mourey et al. 2023, ASCO GU 20

STUDY POPULATION AND METHODS

- > Pts with de novo mCSPC were randomized to receive ADT-abiraterone ± docetaxel

OVERALL SURVIVAL



Overall survival in the overall population (N=1000)



Overall survival in the older population (N=500)



Randomized phase II study of ketoconazole, hydrocortisone, and anti-PSMA antibody J591 labeled with ¹⁷⁷Lu or ¹¹¹In in nonmetastatic CRPC

Tagawa et al. 2023, ASCO GU LBA21

STUDY POPULATION AND METHODS

> 55 pts with high-risk nmCRPC with biochemical progression with

METASTASIS-FREE SURVIVAL



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Key Insights


Prostate Cancer Part 1 – Localized and Castrate-Sensitive Prostate Cancers

Experts Debated the Role of Treatment Intensification for Biochemically Recurrent PC Following Prostatectomy

FORMULA-509

Experts consider the FORMULA-509 trial to be a good proof-of-concept study, although

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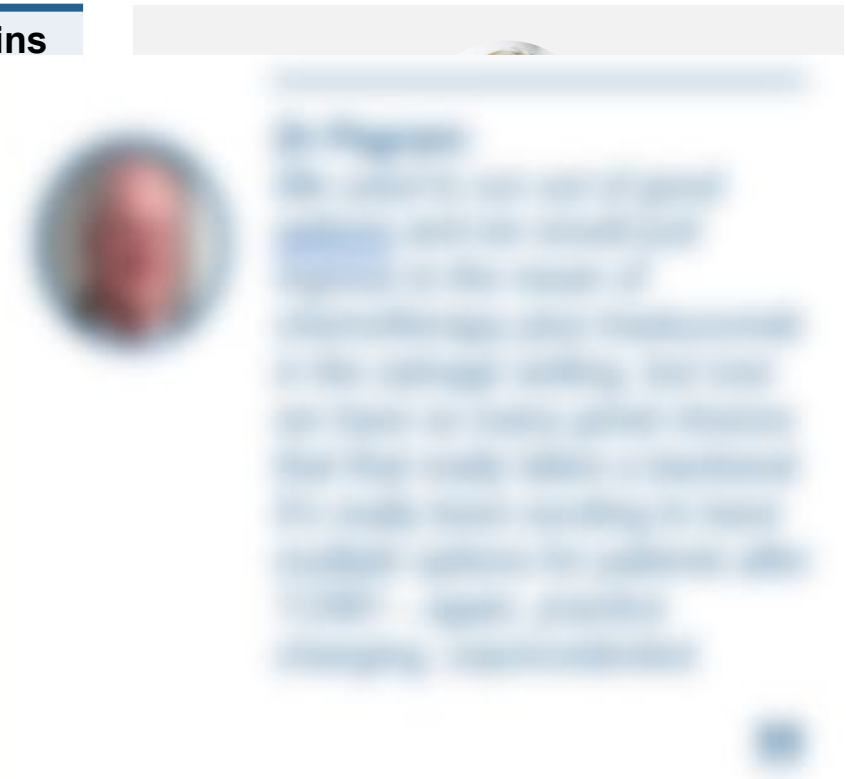
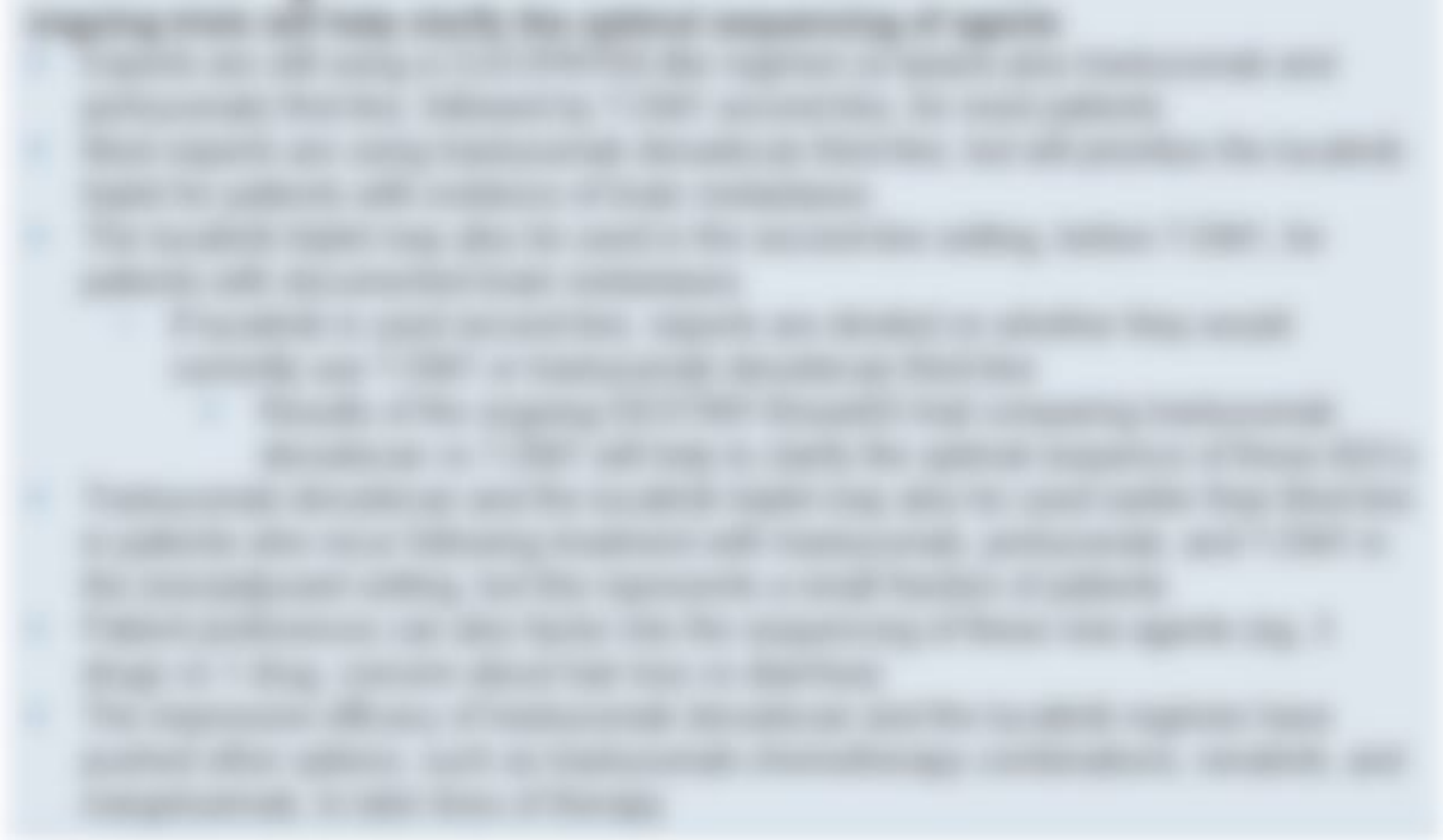


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Experts Considered Areas for Future Investigation in Nonmetastatic Prostate Cancer

RADIOLABELED ANTI-PSMA ANTIBODIES

Radiolabeled PSMA-directed mAbs are moving into earlier stages of disease, but it remains

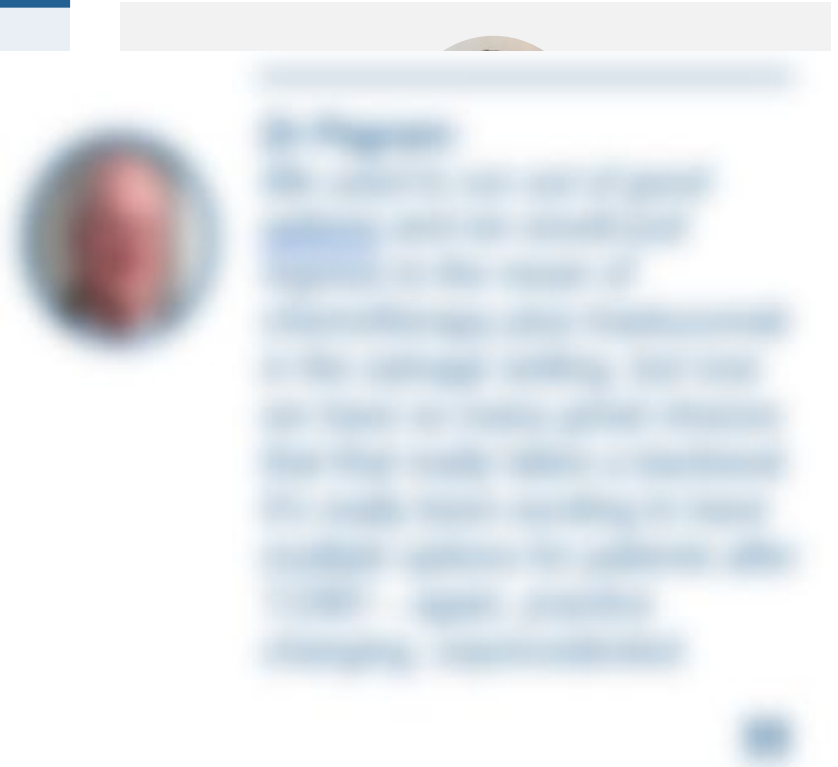


Experts Discussed Treatment Intensification for mCSPC

PEACE-1 AND ARASENS

Results from ARASENS and PEACE-1 are consistent, showing an OS benefit for triplet

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Prostate Cancer Part 2 – Metastatic Castration-Resistant Prostate Cancer

Rucaparib for mCRPC: TRITON3 interim OS and efficacy of rucaparib vs docetaxel or second-generation androgen pathway inhibitor therapy

Bryce et al. 2023, ASCO GU 18

STUDY POPULATION AND METHODS

> 405 pts with chemotherapy-naive mCRPC previously treated with

PROGRESSION-FREE SURVIVAL

PROGRESSION-FREE SURVIVAL IN THE INTENT-TO-TREAT POPULATION



RESPONSE RATES IN THE INTENT-TO-TREAT POPULATION



Niraparib + abiraterone in mCRPC and homologous recombination repair (HRR) gene alterations: Second interim analysis of MAGNITUDE

Efstathiou et al. 2023, ASCO GU 170

STUDY POPULATION AND METHODS

> 423 pts with mCRPC eligible for first-line therapy (≤ 4 mo prior

PROGRESSION-FREE SURVIVAL



Final OS in PROpel: Abiraterone ± olaparib as first-line therapy for mCRPC

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Clarke et al. 2023, ASCO GU LBA16

STUDY POPULATION AND METHODS

- > 398 pts with mCRPC, no prior chemotherapy or next-generation

OVERALL SURVIVAL



TALAPRO-2: Phase 3 study of enzalutamide ± talazoparib as first-line treatment for mCRPC

Agarwal et al. 2023, ASCO GU LBA17

STUDY POPULATION AND METHODS

> 805 pts with mCRPC (prior abiraterone and docetaxel allowed in

PROGRESSION-FREE SURVIVAL



Phase 1/2 study of co-stimulatory bispecific PSMaxCD28 antibody REGN5678 in patients with mCRPC

Stein et al. 2023, ASCO GU 154

STUDY POPULATION AND METHODS

- > 35 pts with mCRPC with ≥ 2 lines of systemic therapy, including ≥ 1

MECHANISM OF ACTION

Figure 1: Mechanism of Action of REGN5678



Figure 2: Response Rate by Line of Therapy



Early dose escalation of LAVA-1207, a novel PSMA-targeted bispecific gamma-delta T-cell engager (Gammabody), in patients with mCRPC

Mehra et al. 2023, ASCO GU 153

STUDY POPULATION AND METHODS

> 16 pts with refractory mCRPC received treatment with escalating

PSA RESPONSE

STUDY POPULATION

16 patients with mCRPC, median age 72 years, ECOG performance grade 1-2, PSA > 10 ng/mL, and refractory to standard of care. All patients had a confirmed diagnosis of mCRPC. The median time from diagnosis to study entry was 1.7 years. The median PSA at study entry was 20.5 ng/mL. All patients received treatment through week 16.

RESULTS

16 patients were enrolled in the study. The median PSA at study entry was 20.5 ng/mL. The median PSA at week 16 was 1.5 ng/mL. The median PSA reduction was 92.7%.

CONCLUSIONS

Early dose escalation of LAVA-1207 in patients with refractory mCRPC resulted in a high PSA response rate and acceptable toxicity profile.



A phase 2 expansion study of ARV-766, a PROTAC androgen receptor degrader, in mCRPC

Petrylak et al. 2023, ASCO GU TPS290

BACKGROUND

> ARV-766 is a novel, potent, orally bioavailable proteolysis

STUDY DESIGN

> 2 doses of ARV-766 (100 mg and 300 mg administered orally once

Oral innate immune activator BXCL701 + pembrolizumab in patients with mCRPC of small cell neuroendocrine phenotype: Phase 2a final results

Aggarwal et al. 2023, ASCO GU 176

STUDY POPULATION AND METHODS

- > 32 pts with mCRPC with the small cell neuroendocrine phenotype

MECHANISM OF ACTION



Figure 1: Overall survival (OS) in the overall population. The y-axis represents OS in months, ranging from 0 to 48. The x-axis shows time points from 0 to 36 months. The graph shows a series of blue bars representing OS at various intervals.



Figure 2: Response rate (RR) in the overall population. The y-axis represents RR in percentage, ranging from 0 to 100. The x-axis shows time points from 0 to 36 months. The graph shows a series of blue bars representing RR at various intervals.



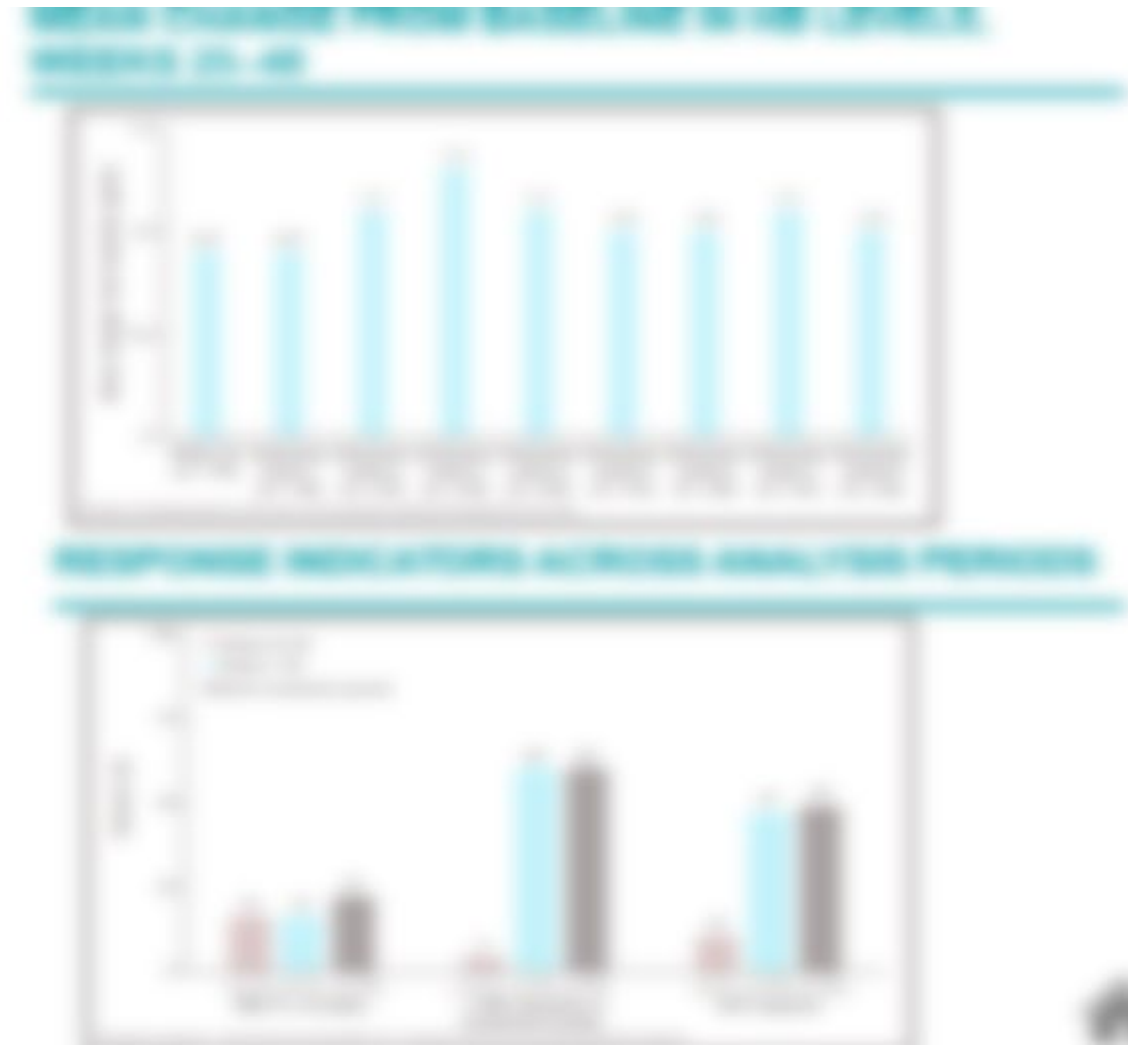
Pembrolizumab + docetaxel for mCRPC: Randomized, double-blind, phase 3 KEYNOTE-921 study

Petrylak et al. 2023, ASCO GU 19

STUDY POPULATION AND METHODS

> 1030 pts with mCRPC that progressed on ADT, and who had

OVERALL SURVIVAL



Nivolumab + ipilimumab for post-chemotherapy mCRPC: Additional results from the randomized phase 2 CheckMate 650 trial

Sharma et al. 2023, ASCO GU 22

STUDY POPULATION AND METHODS

> 259 pts with mCRPC previously treated with docetaxel

STUDY SCHEMA



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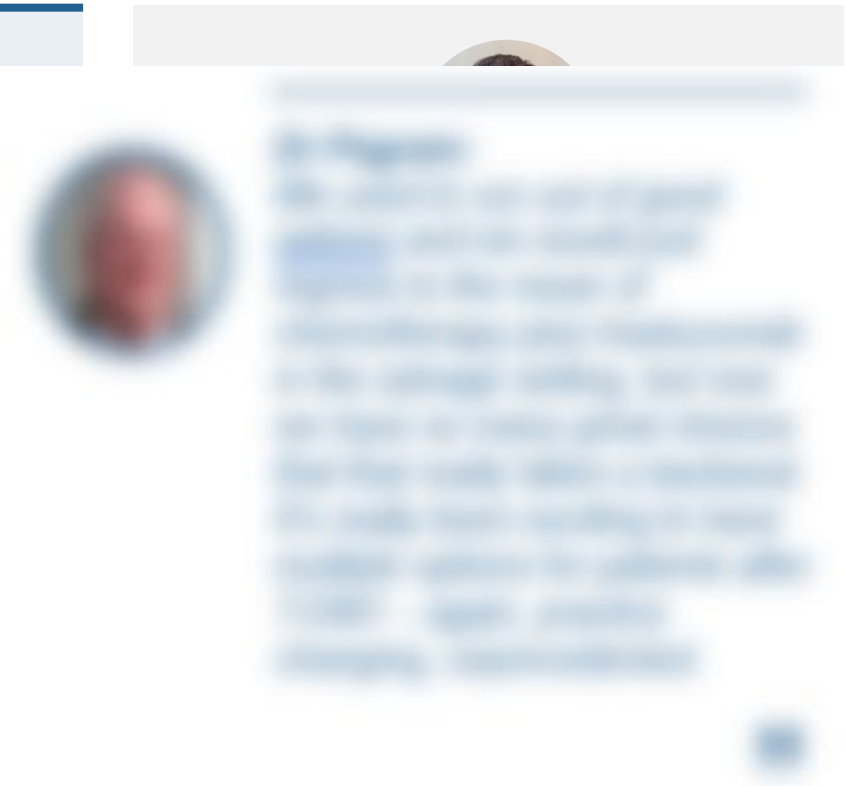
Key Insights

Prostate Cancer Part 2 – Metastatic Castration-Resistant Prostate Cancer

Experts Discussed the Role for PARP Inhibitors in *BRCA*-Mutated mCRPC

TRITON-3 AND PROFOUND

Cumulative data from TRITON-3 and PROFOUND strongly support using a single-agent

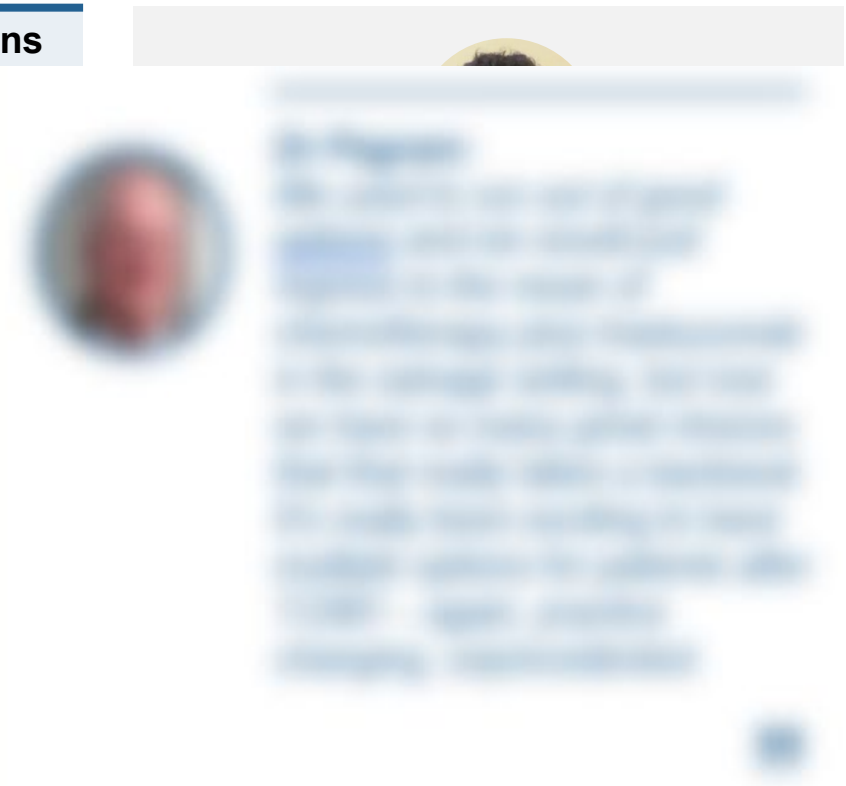


Experts Debated the Potential Role for PARP Inhibitors in *BRCA*-Nonmutated mCRPC

PROpel AND TALAPRO

Both PROpel and TALAPRO showed a modest rPFS benefit for PARPi + ARSI combinations

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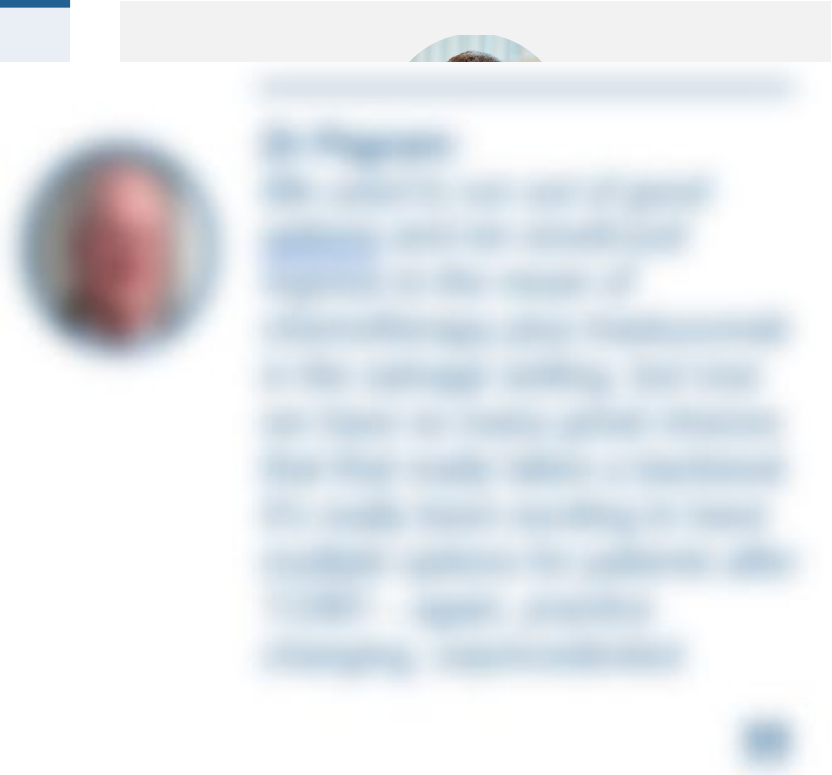


Experts Reviewed Investigational Agents for the Treatment of mCRPC

IMMUNE CHECKPOINT INHIBITORS

Negative results from KEYNOTE-921 and CheckMate 650 further confirm that ICIs rarely

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Bladder Cancer Part 1 – NMIBC and MIBC

Pembrolizumab monotherapy for high-risk NMIBC unresponsive to BCG: Results from Cohort B of the phase 2 KEYNOTE-057 trial

Necchi et al. 2023, ASCO GU LBA442

STUDY POPULATION AND METHODS

> Pts with BCG-unresponsive, high-risk NMIBC

OVERALL SURVIVAL

Overall Survival (OS) in Cohort B of the KEYNOTE-057 Trial



Response Evaluation in Cohort B of the KEYNOTE-057 Trial



HCRN GU 16-257: Phase 2 trial of gemcitabine, cisplatin, + nivolumab with selective bladder sparing in patients with MIBC

Galsky et al. 2023, ASCO GU 447

STUDY POPULATION AND METHODS

- > 76 pts with cisplatin-eligible with cT2-T4aN0M0 bladder cancer

OVERALL SURVIVAL

Overall Survival (Landmark Analysis)



Response, Relapse-Free Survival, and Time to Progression



HCRN GU14-188: Phase Ib/II study of neoadjuvant pembrolizumab and chemotherapy for T2-4aN0M0 urothelial cancer

Brown et al. 2023, ASCO GU 448

STUDY POPULATION AND METHODS

> Pts were surgical candidates with clinical stage T2-4aN0M0 UC,

RELAPSE-FREE AND OVERALL SURVIVAL

STUDY POPULATION

1. 100 patients with clinical stage T2-4aN0M0 UC, ECOG performance grade 0-1, and no prior systemic therapy. Median age 68 years (range 50-85). 50% were white, 30% black, 10% hispanic, and 10% other. 50% were married, 30% were widowed, 10% were divorced, and 10% were single. 50% were employed, 30% were retired, 10% were on disability, and 10% were unemployed. 50% were insured, 30% were self-pay, 10% were Medicaid, and 10% were Medicare. 50% were on a diet, 30% were not on a diet, 10% were on a low-carb diet, and 10% were on a low-fat diet. 50% were on a low-sodium diet, 30% were not on a low-sodium diet, 10% were on a low-sugar diet, and 10% were not on a low-sugar diet. 50% were on a low-cholesterol diet, 30% were not on a low-cholesterol diet, 10% were on a low-fiber diet, and 10% were not on a low-fiber diet. 50% were on a low-calcium diet, 30% were not on a low-calcium diet, 10% were on a low-potassium diet, and 10% were not on a low-potassium diet. 50% were on a low-sodium diet, 30% were not on a low-sodium diet, 10% were on a low-sugar diet, and 10% were not on a low-sugar diet. 50% were on a low-cholesterol diet, 30% were not on a low-cholesterol diet, 10% were on a low-fiber diet, and 10% were not on a low-fiber diet. 50% were on a low-calcium diet, 30% were not on a low-calcium diet, 10% were on a low-potassium diet, and 10% were not on a low-potassium diet.

RESULTS

1. 100 patients were enrolled in the study. 50 patients were in the pembrolizumab group and 50 patients were in the chemotherapy group. The median age was 68 years (range 50-85). 50% were white, 30% black, 10% hispanic, and 10% other. 50% were married, 30% were widowed, 10% were divorced, and 10% were single. 50% were employed, 30% were retired, 10% were on disability, and 10% were unemployed. 50% were insured, 30% were self-pay, 10% were Medicaid, and 10% were Medicare. 50% were on a diet, 30% were not on a diet, 10% were on a low-carb diet, and 10% were on a low-fat diet. 50% were on a low-sodium diet, 30% were not on a low-sodium diet, 10% were on a low-sugar diet, and 10% were not on a low-sugar diet. 50% were on a low-cholesterol diet, 30% were not on a low-cholesterol diet, 10% were on a low-fiber diet, and 10% were not on a low-fiber diet. 50% were on a low-calcium diet, 30% were not on a low-calcium diet, 10% were on a low-potassium diet, and 10% were not on a low-potassium diet.

CONCLUSIONS

1. The study showed that pembrolizumab plus chemotherapy is a promising treatment for T2-4aN0M0 urothelial cancer. The combination of pembrolizumab and chemotherapy significantly improved overall survival compared to chemotherapy alone. The combination of pembrolizumab and chemotherapy also significantly improved relapse-free survival compared to chemotherapy alone. The combination of pembrolizumab and chemotherapy was well tolerated, with no significant increase in adverse events compared to chemotherapy alone.



Extended follow-up results from the CheckMate 274 trial

Galsky et al. 2023, ASCO GU LBA443

STUDY POPULATION AND METHODS

- > 353 pts with high-risk MIBC after radical resection

DISEASE-FREE SURVIVAL

Figure 1: Disease-Free Survival (DFS) in the Overall Population



Figure 2: Response Evaluation in the Overall Population



Quality of life in QUILT 3.032 study: Patients with BCG-unresponsive NMIBC receiving IL-15R α Fc superagonist N-803 + BCG

Chamie et al. 2023, ASCO GU 495

STUDY POPULATION AND METHODS

> Pts with BCG-unresponsive NMIBC

QUALITY-OF-LIFE MEASURES

STUDY POPULATION

1. 100 patients with BCG-unresponsive NMIBC... (text is blurred)

RESULTS

1. 100 patients with BCG-unresponsive NMIBC... (text is blurred)

CONCLUSIONS

1. 100 patients with BCG-unresponsive NMIBC... (text is blurred)



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Key Insights

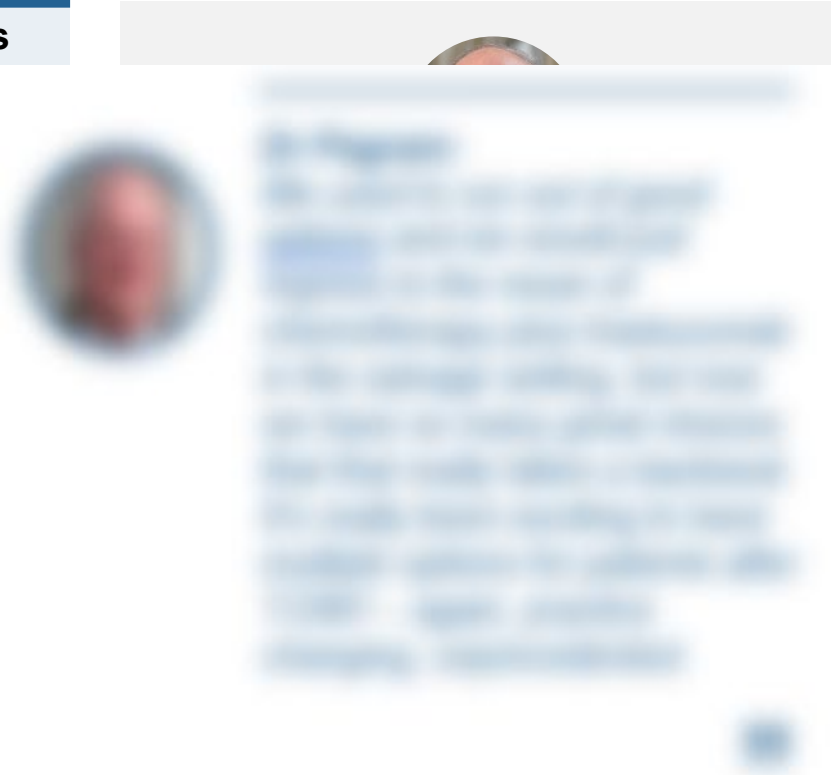
Bladder Cancer Part 1 – NMIBC and MIBC

Experts Discussed the Management of NMIBC

QUILT 3.032

Experts had positive perceptions of the intravesical IL-15 superagonist N-803 on the basis

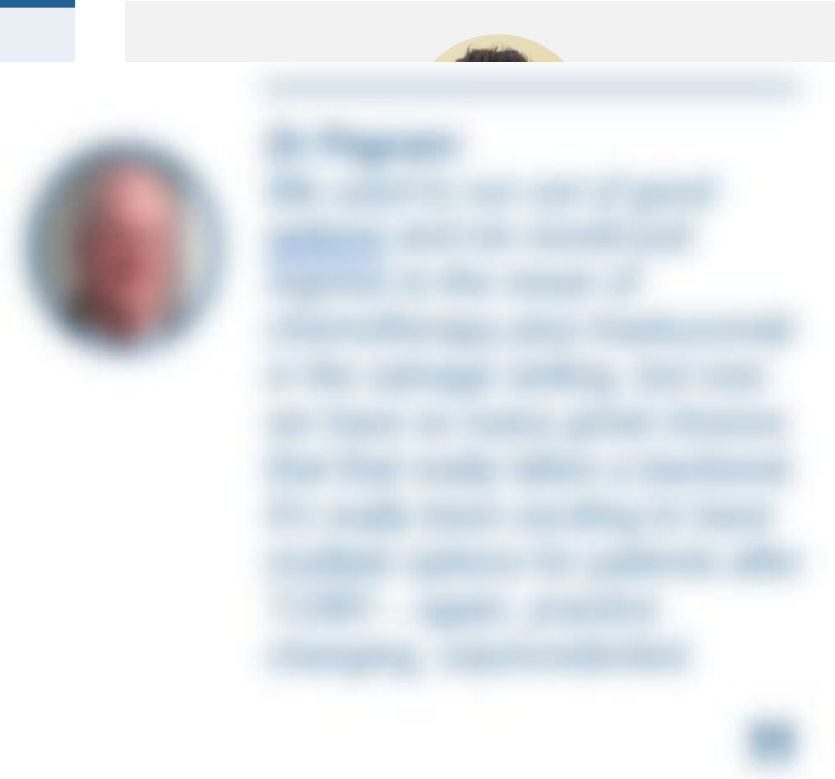
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Experts Considered Results From Trials for MIBC

CheckMate 274

An updated analysis of CheckMate 274 showed that the DFS and DMFS advantages



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Bladder Cancer Part 2 – Metastatic Urothelial
Cancer

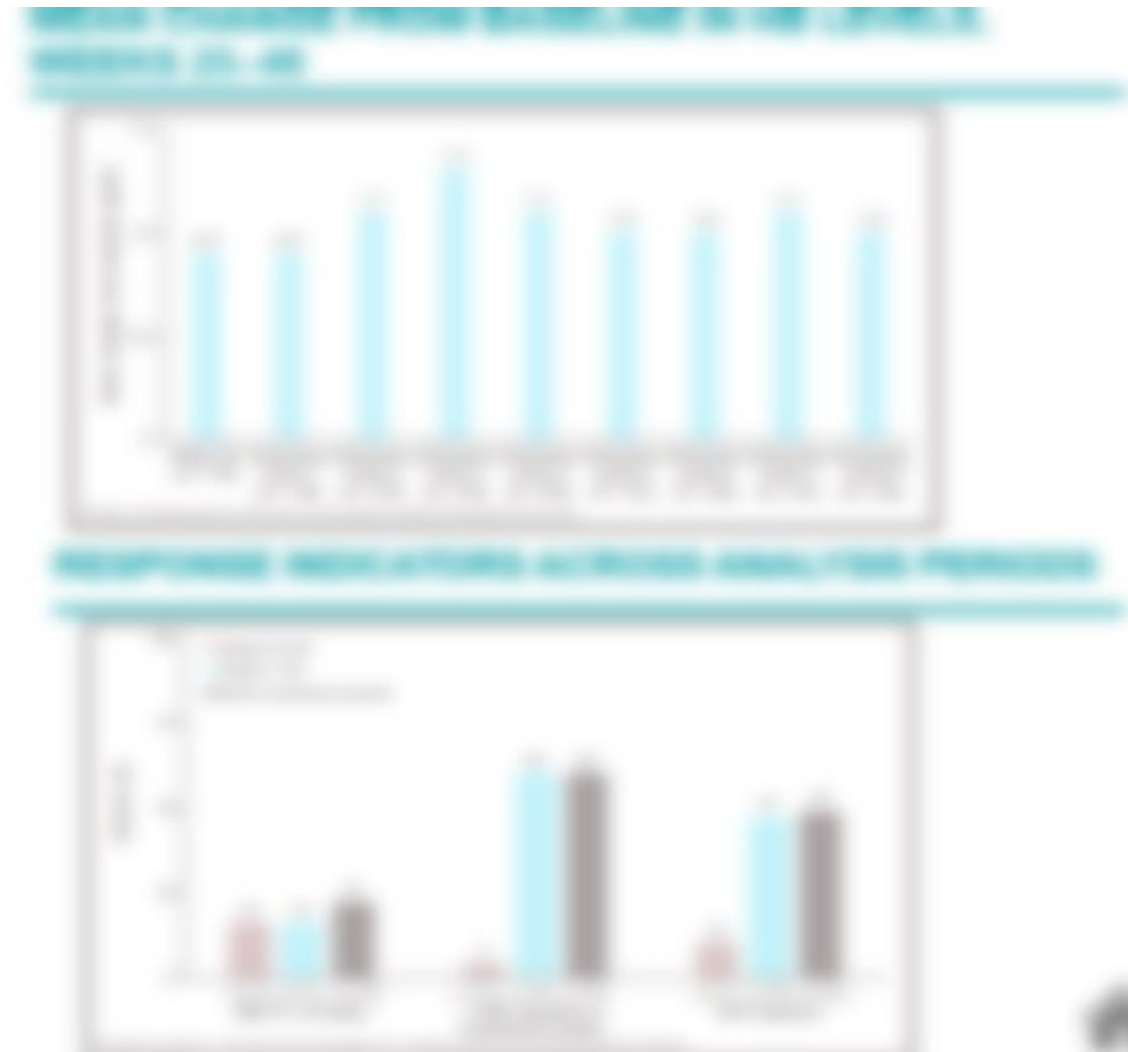
TROPHY-U-01 cohort 2, a phase 2 study of sacituzumab govitecan in platinum-ineligible mUC that progressed after prior CPI therapy

Petrylak et al. 2023, ASCO GU 520

STUDY POPULATION AND METHODS

> 38 pts with platinum-ineligible mUC that progressed after prior ICI

OVERALL SURVIVAL



Platinum/gemcitabine ± atezolizumab as first-line treatment of locally advanced or mUC: Final OS from phase 3 IMvigor130 study

Galsky et al. 2023, ASCO GU LBA440

STUDY POPULATION AND METHODS

> Pts with mUC previously untreated for metastatic disease

OVERALL SURVIVAL

STUDY POPULATION

1. 1000 patients with mUC, previously untreated for metastatic disease, were randomized to receive platinum/gemcitabine (PG) or platinum/gemcitabine/atezolizumab (PG+ATE) as first-line treatment. The primary endpoint was overall survival (OS). The study population included all patients who were randomized and received at least one cycle of treatment.

RESULTS

1. The median OS was significantly longer in the PG+ATE group compared to the PG group (18.5 months vs 15.5 months, respectively, P < 0.001).

CONCLUSIONS

1. The addition of atezolizumab to platinum/gemcitabine significantly improved OS in patients with mUC previously untreated for metastatic disease.



Final OS analysis of atezolizumab monotherapy vs chemotherapy in untreated locally advanced or mUC from the phase 3 IMvigor130 study

Bamias et al. 2023, ASCO GU LBA441

STUDY POPULATION AND METHODS

> Pts with mUC previously untreated for metastatic disease

OVERALL SURVIVAL

PD-1 1 IC2/3



PROs in cisplatin-ineligible mUC with enfortumab vedotin alone or with pembrolizumab in the phase 1b/2 EV-103 Cohort K study

Milowsky et al. 2023, ASCO GU 439

STUDY POPULATION AND METHODS

> Cisplatin-ineligible pts with previously untreated Ia/mUC

QUALITY OF LIFE

Mean Change From Baseline in the EQ-5D-5L Score (n=48)



Response-Related Adverse Events (RRAEs) (n=48)



Biomarkers of response to enfortumab vedotin in patients with advanced urothelial carcinoma: Analysis of the UNITE study

Jindal et al. 2023, ASCO GU 450

STUDY POPULATION AND METHODS

> 170 pts with mUC from 16 sites treated with EV and registered in

OVERALL SURVIVAL



Avelumab maintenance: Long-term follow-up from JAVELIN Bladder 100 in subgroups

Sridhar et al. 2023, ASCO GU 508

STUDY POPULATION AND METHODS

> Pts with advanced UC that had not progressed with 4–6 cycles of

OVERALL SURVIVAL FROM START OF FIRST-LINE THERAPY

STUDY POPULATION

1. 1000 patients with advanced UC who had not progressed with 4–6 cycles of first-line therapy were randomized to receive either avelumab (n=500) or placebo (n=500) as maintenance therapy. The primary endpoint was overall survival (OS) from start of first-line therapy. Secondary endpoints included progression-free survival (PFS), quality of life, and adverse events. The study was conducted in a multicenter, randomized, controlled, open-label manner. All patients provided written informed consent before starting treatment.

RESULTS

2. The median OS was significantly longer in the avelumab group compared to the placebo group (18.5 months vs 15.2 months, respectively; P<0.001). The median PFS was also significantly longer in the avelumab group (10.2 months vs 7.8 months, respectively; P<0.001).

CONCLUSIONS

3. Avelumab maintenance significantly improved OS and PFS in patients with advanced UC who had not progressed with 4–6 cycles of first-line therapy.

OS FROM START OF FIRST-LINE THERAPY



RESPONSE, TOXICITY, AND QUALITY OF LIFE



BT8009-100: A phase I/II study of novel bicyclic peptide and MMAE conjugate BT8009 in advanced malignancies associated with nectin-4

Baldini et al. 2023, ASCO GU 498

STUDY POPULATION AND METHODS

> 24 pts with heavily pretreated mUC (median 3 prior lines of

RESPONSE



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Key Insights

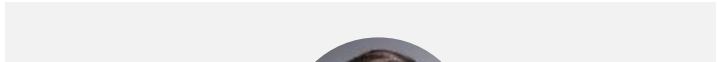
Bladder Cancer Part 2 – Metastatic Urothelial
Cancer

Experts Discussed the Cytotoxic Drug Conjugates for mUC

SACITUZUMAB GOVITECAN

Experts consider SG to be an active agent, but a head-to-head trial with EV would be

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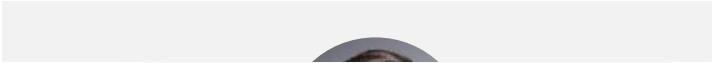
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Experts Debated the Timing of Immune Checkpoint Inhibitors for mUC

JAVELIN Bladder 100

JAVELIN Bladder 100 long-term follow-up showed that OS benefits associated with

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Congress Highlights

Renal Cell Carcinoma

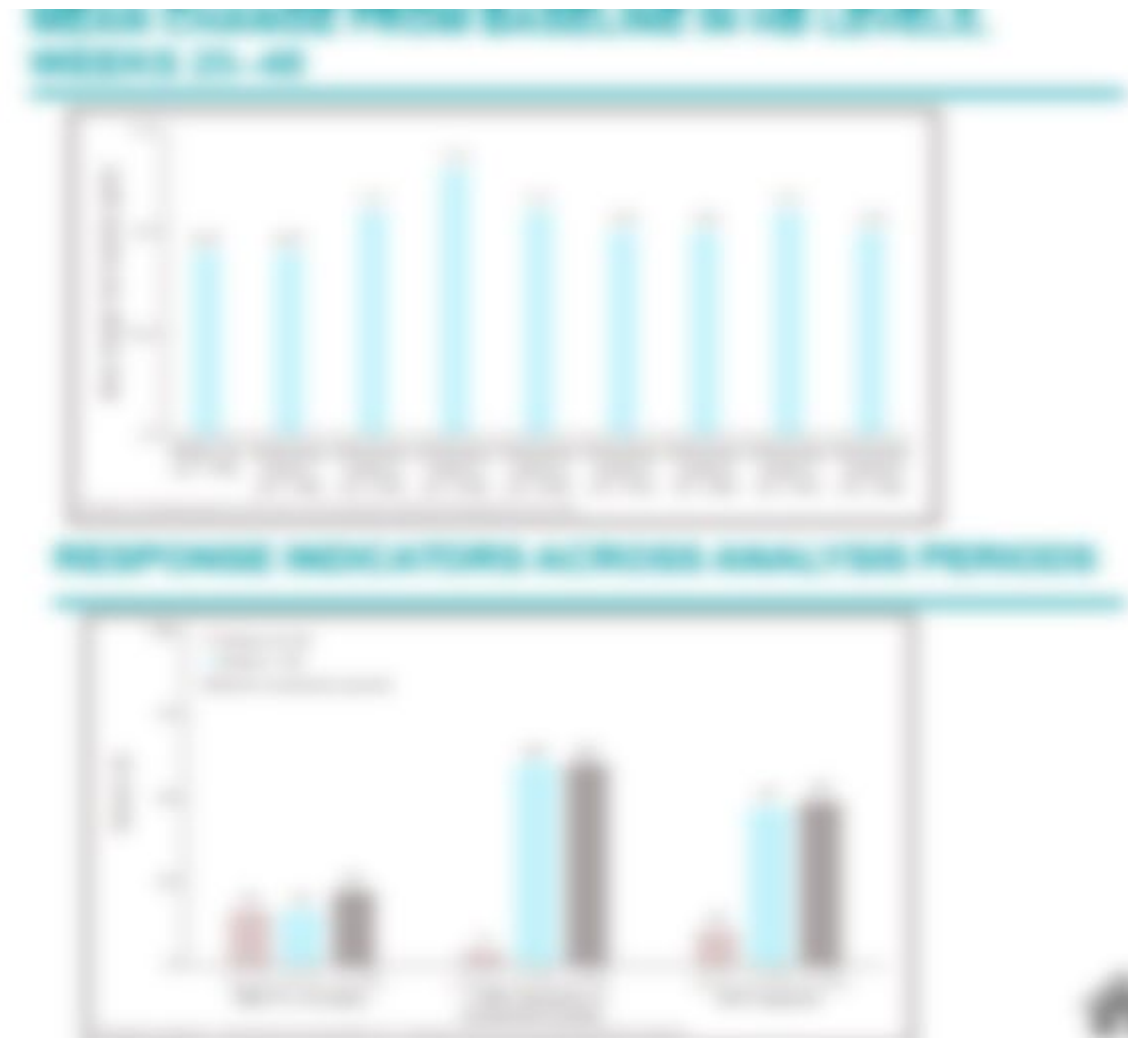
HCRN GU16-260-Cohort A: Treatment-free survival with nivolumab and salvage nivolumab + ipilimumab in advanced ccRCC

Atkins et al. 2023, ASCO GU 604

STUDY POPULATION AND METHODS

> 128 pts with advanced ccRCC

TUMOR RESPONSE



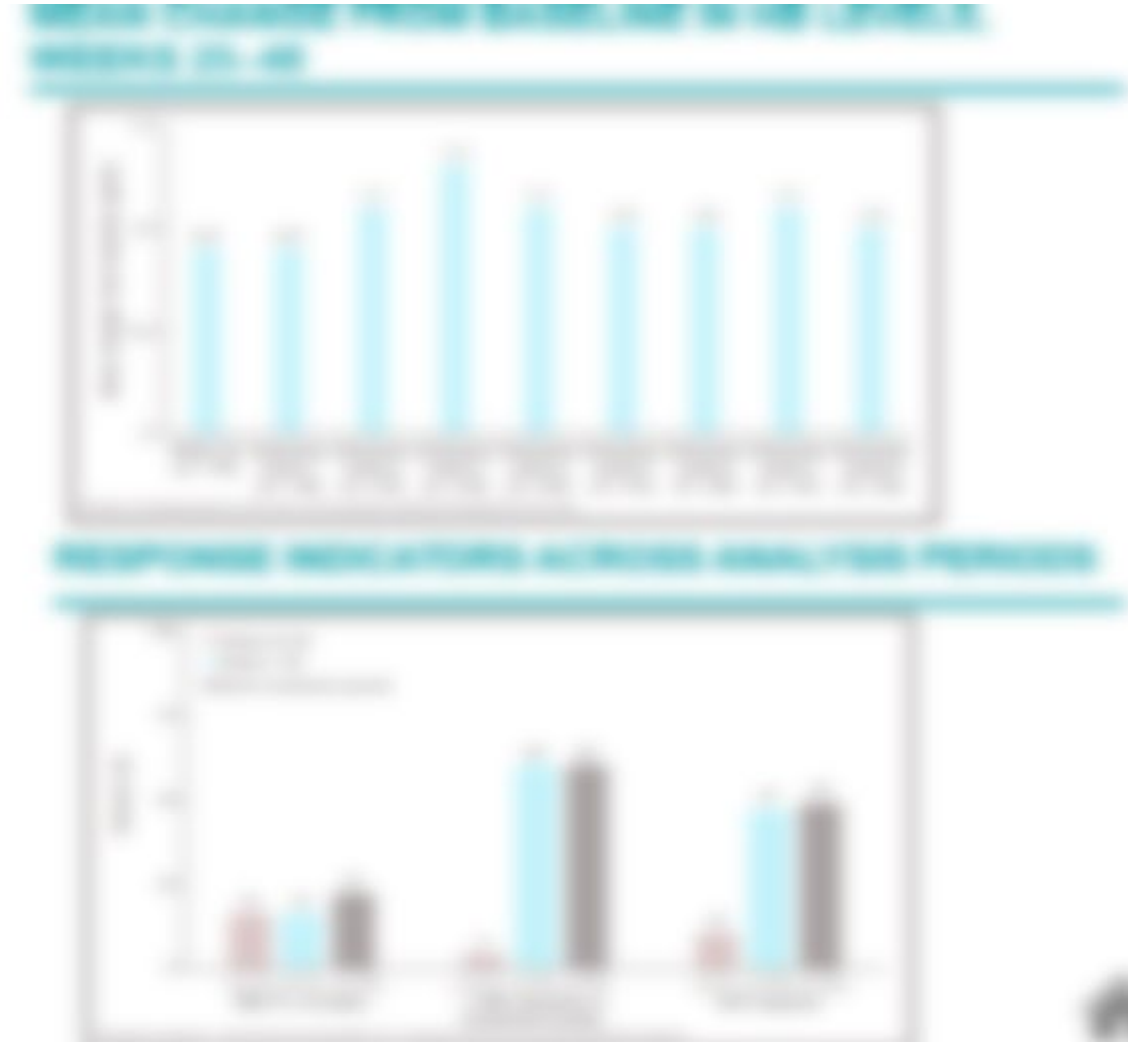
Nivolumab plus cabozantinib vs sunitinib for first-line treatment of advanced RCC: 3-year follow-up from the phase 3 CheckMate 9ER trial

Burotto et al. 2023, ASCO GU 603

STUDY POPULATION AND METHODS

> Pts with previously untreated mRCC were randomized to

OVERALL SURVIVAL BY IMDC RISK



Biomarker analysis from the phase 3 CheckMate 9ER trial of nivolumab + cabozantinib vs sunitinib for advanced renal cell carcinoma (aRCC)

Choueiri et al. 2023, ASCO GU 608

STUDY POPULATION AND METHODS

> Pts with previously untreated mRCC were randomized to

PFS OUTCOMES BY PD-L1 STATUS



COSMIC-313 phase 3 trial evaluating cabozantinib + nivolumab and ipilimumab in first-line advanced intermediate- or poor-risk RCC

Powles et al. 2023, ASCO GU 605

STUDY POPULATION AND METHODS

> 855 pts with advanced ccRCC of IMDC intermediate or poor risk

PROGRESSION-FREE SURVIVAL



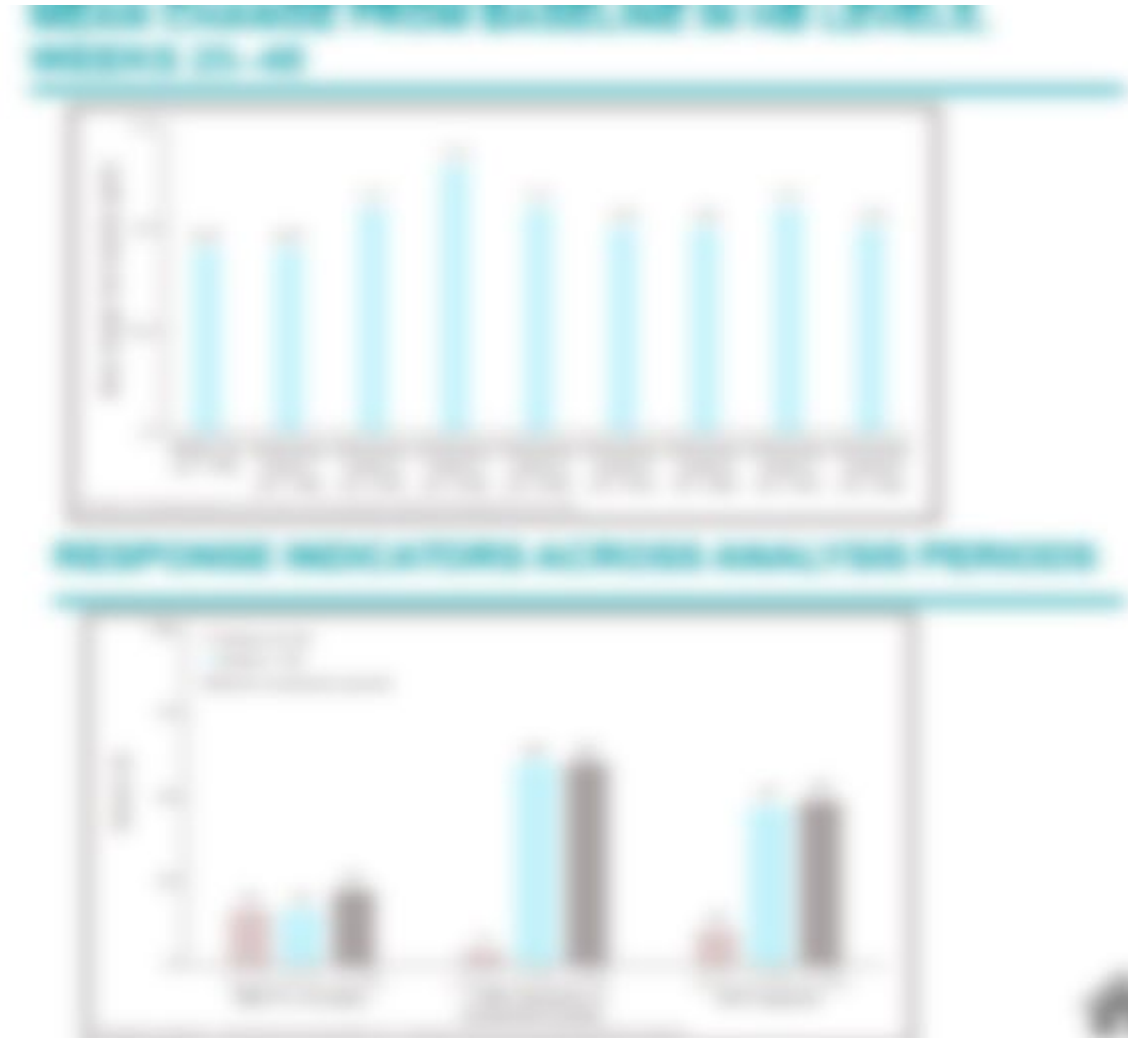
CaboPoint: Phase 2 study of cabozantinib after checkpoint inhibitor therapy in patients with advanced RCC

Albiges et al. 2023, ASCO GU 606

STUDY POPULATION AND METHODS

- > 88 pts with advanced RCC progressing after first-line ICI-based

RESPONSE RATES ACROSS SUBGROUPS



OS and efficacy of second-line treatment in patients with mRCC treated in the randomized phase II BIONIKK trial

Vano et al. 2023, ASCO GU 607

STUDY POPULATION AND METHODS

> 199 pts with previously untreated mRCC

UPDATED ORR AND PFS

[Redacted]

STUDY POPULATION

199 patients with previously untreated mRCC... median age 65 years... 50% male... 50% female... median performance status 1... median hemoglobin 12.5 g/dL... median creatinine 1.2 mg/dL... median time to treatment initiation 1.5 months... 100% patients received at least one cycle of treatment... 95% patients received at least two cycles of treatment... 85% patients received at least three cycles of treatment... 75% patients received at least four cycles of treatment... 65% patients received at least five cycles of treatment... 55% patients received at least six cycles of treatment... 45% patients received at least seven cycles of treatment... 35% patients received at least eight cycles of treatment... 25% patients received at least nine cycles of treatment... 15% patients received at least ten cycles of treatment... 5% patients received at least eleven cycles of treatment... 2% patients received at least twelve cycles of treatment... 1% patients received at least thirteen cycles of treatment... 0% patients received at least fourteen cycles of treatment... 0% patients received at least fifteen cycles of treatment... 0% patients received at least sixteen cycles of treatment... 0% patients received at least seventeen cycles of treatment... 0% patients received at least eighteen cycles of treatment... 0% patients received at least nineteen cycles of treatment... 0% patients received at least twenty cycles of treatment...

METHODS

Randomized phase II trial comparing treatment A and treatment B... primary endpoint: overall survival... secondary endpoints: objective response rate, progression-free survival... statistical significance: p < 0.05... confidence interval: 95%... hazard ratio: 0.85... p-value: 0.02...

KEY CONCLUSIONS

Treatment A demonstrated superior overall survival compared to treatment B... this finding was statistically significant... treatment B was well tolerated... quality of life was similar between groups... these results support the use of treatment A as the standard of care for patients with previously untreated mRCC...

UPDATED ORR AND PFS



RESPONSE, PROGRESSION-FREE SURVIVAL, AND OVERALL SURVIVAL



Results from phase 3 study of ⁸⁹Zr-DFO-girentuximab for PET/CT imaging of clear cell renal cell carcinoma (ZIRCON)

Shuch et al. 2023, ASCO GU LBA602

STUDY POPULATION AND METHODS

> 300 pts with an indeterminate renal mass (≤7 cm; tumor stage

RATIONALE FOR RADIOTRACER TARGET

MEAN TUMOR TISSUE BOUNDING IN THE LIVER, WEEKS 10-16



RESPONSE EVALUATION AT 10 WEEKS ANALYSIS PERIOD



EPICS

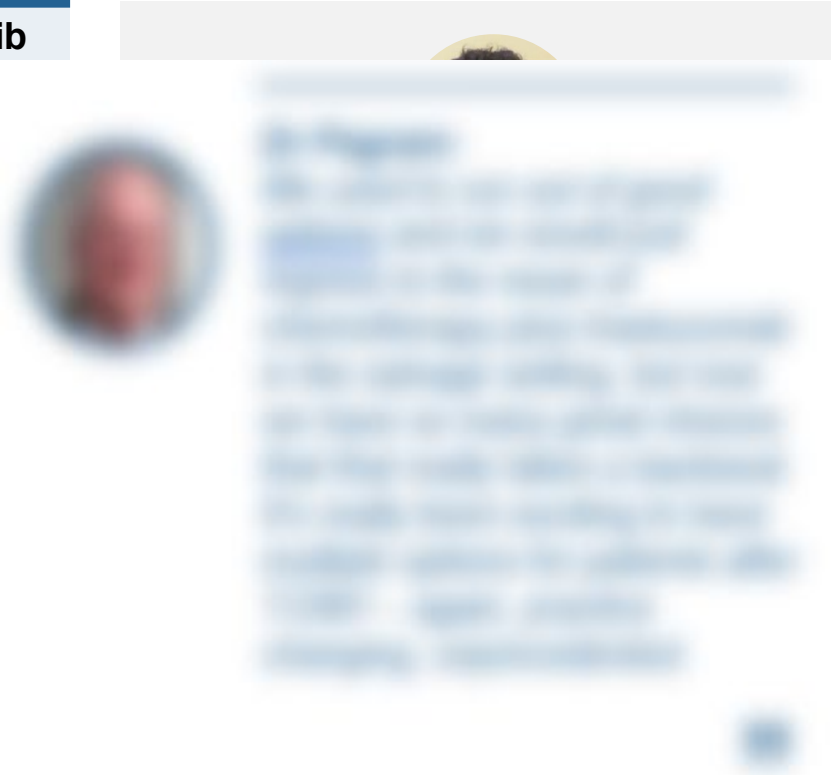
Key Insights

Renal Cell Carcinoma

CheckMate 9ER

The 44-month follow-up of CheckMate 9ER comparing cabozantinib-nivolumab vs sunitinib

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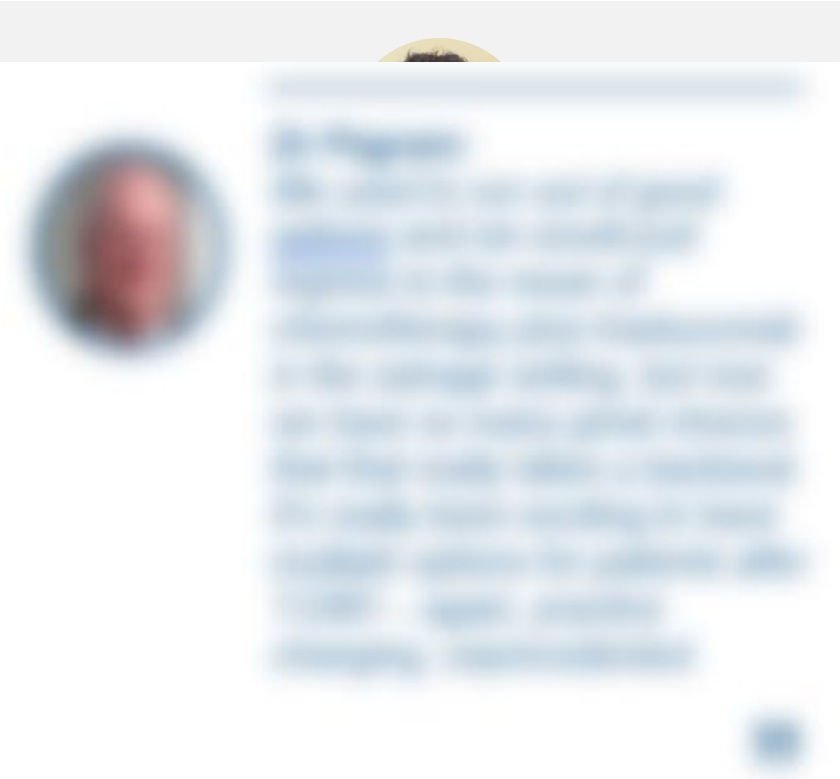


Experts Debated the Implications of Investigational First-Line Strategies

HCRN GU16-260

The HCRN GU16-260 study in treatment-naive mRCC reported that adding

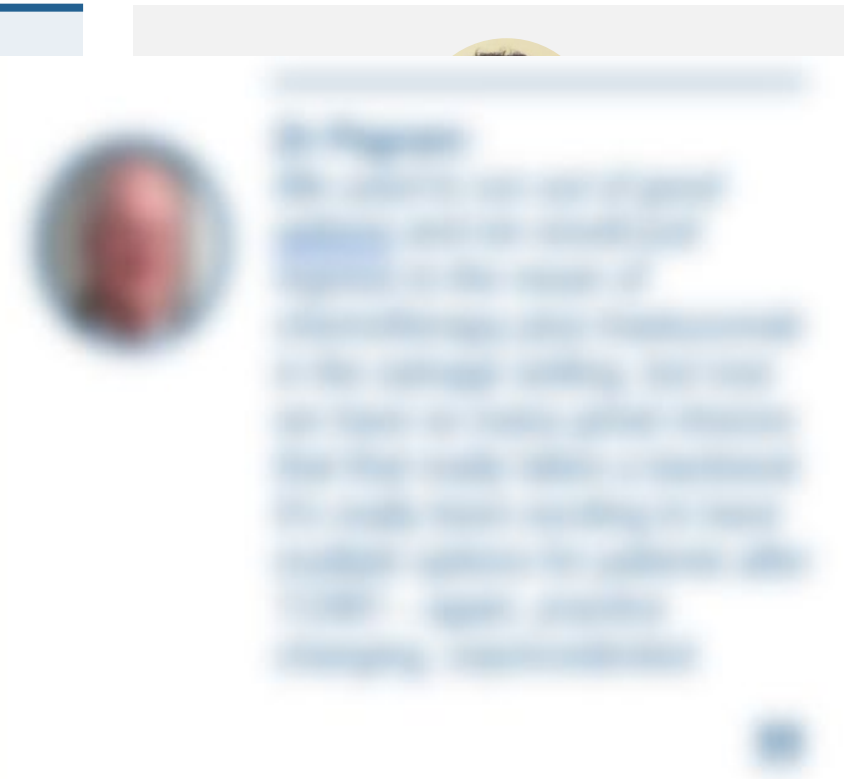
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Experts Discussed Later-Line Therapy and Biomarker-Driven Approaches for mRCC

TKIs FOLLOWING PROGRESSION ON AN ICI

The phase II CaboPoint trial reported ORRs of ~30% with single-agent cabozantinib in

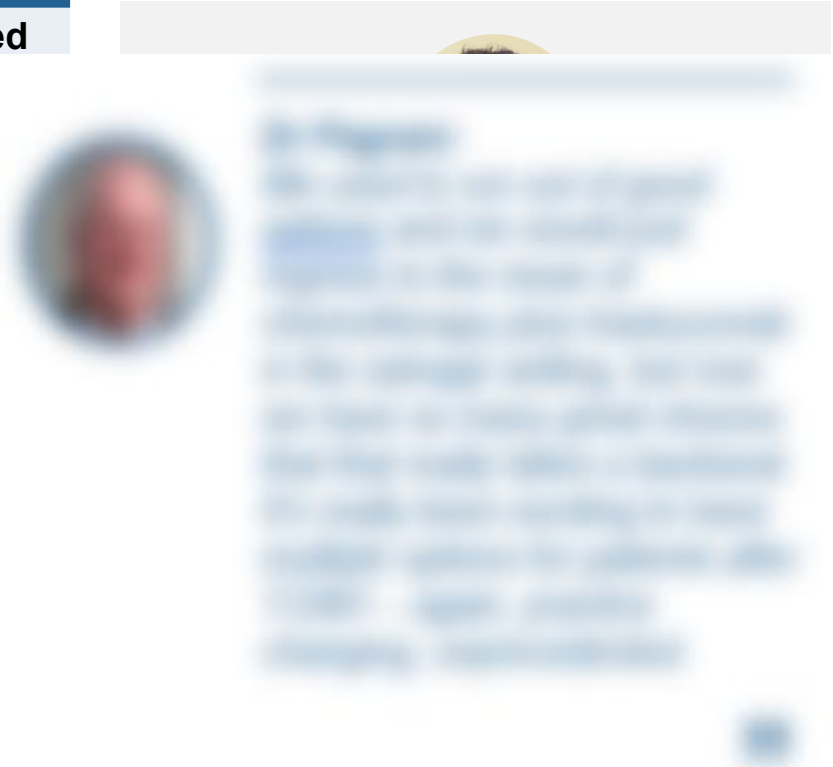


Experts Speculated on Diagnostic Imaging for ccRCC

⁸⁹Zr-DFO-GIRENTUXIMAB PET IMAGING

Data with the new CAIX-targeted PET tracer are promising, and will likely play an expanded

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