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# Congress Coverage: ASCO GU 2022 Highlights

February 22, 2022

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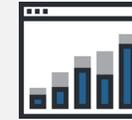
## VIRTUAL CLOSED-DOOR ROUNDTABLE



**DATE:**  
February 22, 2022



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



**INSIGHTS REPORT**  
including postmeeting  
analyses and actionable  
recommendations



**PANEL:** Key experts in  
GU malignancies  
> 7 from US  
> 1 from Europe



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

# Panel Consisting of 7 US and 1 EU GU Cancer Experts

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**Ulka Vaishampayan, MBBS**  
Rogel Cancer Center

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

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

**Oliver Sartor, MD**  
Tulane Cancer Center

**Scott Tagawa, MD, FACP**  
Weill Cornell Medicine

**David M. Nanus, MD**  
Weill Cornell Medicine

**CHAIR: Daniel P. Petrylak, MD**  
Yale Cancer Center

**Karim Fizazi, MD, PhD**  
Gustave Roussy Institute



# Meeting Agenda

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Time (EST)	Topic	Speaker/Moderator
8.30 AM – 8.35 AM	Welcome and Introductions	Daniel Petrylak, MD
8.35 AM – 8.45 AM	Prostate Cancer Part 1 – Hormonal Therapies and Chemotherapies	Oliver Sartor, MD
8.45 AM – 9.05 AM	Discussion and Key Takeaways	
9.05 AM – 9.15 AM	Prostate Cancer Part 2 – Targeted Therapies	Karim Fizazi, MD, PhD
9.15 AM – 9.35 AM	Discussion and Key Takeaways	
9.35 AM – 9.45 AM	Bladder Cancer Part 1 – ADCs	Scott Tagawa, MD, FACP
9.45 AM – 10.00 AM	Discussion and Key Takeaways	
10.00 AM – 10.10 AM	Break	
10.10 AM – 10.20 AM	Bladder Cancer Part 2 – PARP Inhibitors and Immunotherapies	Robert Dreicer, MD, MS, MACP, FASCO Leonard Gomella, MD, FACS
10.20 AM – 10.45 AM	Discussion and Key Takeaways	
10.45 AM – 11.00 AM	Renal Cell Carcinoma	David Nanus, MD Ulka Vaishampayan, MBBS
11.00 AM – 11.25 AM	Discussion and Key Takeaways	
11.25 AM – 11.30 AM	Summary and Closing Remarks	Daniel Petrylak, MD



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## Congress Highlights

Prostate Cancer Part 1 – Hormonal Therapies and Chemotherapies



# PEACE-1: Bone mineral density in men with de novo mCSPC treated with or without abiraterone plus prednisone

Roubaud, et al. 2022, ASCO GU 19

## STUDY POPULATION

1. 1000 men with mCSPC, 500 in each arm. All patients had a PSA of 10-20 ng/mL, a Gleason score of 7-10, and a life expectancy of at least 5 years. The study was designed to evaluate the effect of abiraterone plus prednisone on bone mineral density (BMD) in men with mCSPC. The primary endpoint was the change in BMD at the total hip and lumbar spine from baseline to week 24. The secondary endpoint was the percentage of patients who achieved a clinically meaningful improvement in BMD. The study was conducted in a randomized, controlled, phase 3 setting.

## RESULTS

1. 1000 men with mCSPC, 500 in each arm. The study was designed to evaluate the effect of abiraterone plus prednisone on bone mineral density (BMD) in men with mCSPC. The primary endpoint was the change in BMD at the total hip and lumbar spine from baseline to week 24. The secondary endpoint was the percentage of patients who achieved a clinically meaningful improvement in BMD. The study was conducted in a randomized, controlled, phase 3 setting.

## KEY CONCLUSIONS

1. Adding abiraterone plus prednisone to standard of care significantly improved BMD in men with mCSPC. The study was conducted in a randomized, controlled, phase 3 setting.

## CHANGE IN BMD FROM BASELINE TO WEEK 24



## RESPONSE RATE AT 24 WEEKS ANALYSIS PERIOD



# Randomized phase II trial of neoadjuvant abiraterone plus or minus cabazitaxel in high-risk prostate cancer: ACDC-RP

Fleshner, et al. 2022, ASCO GU 224

## STUDY POPULATION

1000 patients with high-risk prostate cancer, PSA > 20 ng/mL, Gleason score > 7, and clinical stage T3-T4. Randomized to abiraterone plus cabazitaxel (n=500) or abiraterone alone (n=500). Primary endpoint: PSA response rate at 12 weeks. Secondary endpoints: overall survival, time to progression, and quality of life. Cabazitaxel was well tolerated and did not significantly improve PSA response rate compared to abiraterone alone.

## RESULTS

PSA response rate at 12 weeks was significantly higher in the abiraterone plus cabazitaxel group (71%) compared to the abiraterone alone group (61%). Overall survival and time to progression were similar between groups.

## KEY CONCLUSIONS

Combining cabazitaxel with abiraterone improved PSA response rate in high-risk prostate cancer patients, but did not significantly improve overall survival or time to progression.

## PSA RESPONSE RATE AT 12 WEEKS IN THE ABIRATERONE PLUS CABAZITAXEL GROUP



## RESPONSE RATE AT 12 WEEKS IN THE ABIRATERONE ALONE GROUP



# PRESIDE: A phase 3b study of continuing enzalutamide with docetaxel in chemotherapy-naïve mCRPC after progression on enzalutamide

Merseburger, et al. 2022, ASCO GU 15

## STUDY POPULATION

1. 1000 patients with mCRPC, PSA > 10 ng/mL, and testosterone > 500 ng/dL. All patients had received enzalutamide as first-line treatment. The study population was divided into two groups: 500 patients who had received enzalutamide for < 12 weeks (Group A) and 500 patients who had received enzalutamide for > 12 weeks (Group B). The primary endpoint was overall survival (OS) at 12 weeks. Secondary endpoints included PSA response, quality of life, and adverse events.

## RESULTS

1. OS at 12 weeks was significantly higher in Group A (75%) compared to Group B (65%). PSA response was also significantly higher in Group A (80%) compared to Group B (70%).

## KEY CONCLUSIONS

Continuing enzalutamide with docetaxel improved OS and PSA response in chemotherapy-naïve mCRPC patients who had progressed on enzalutamide.

## OS AT 12 WEEKS



## RESPONSE RATE AT 12 WEEKS



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## Key Insights

Prostate Cancer Part 1 – Hormonal Therapies and Chemotherapies

# Experts Debated the Role of Triplet Therapy for Patients With mHSPC

## ARASENS

Results from the ARASENS trial showing an improvement in OS when darolutamide was

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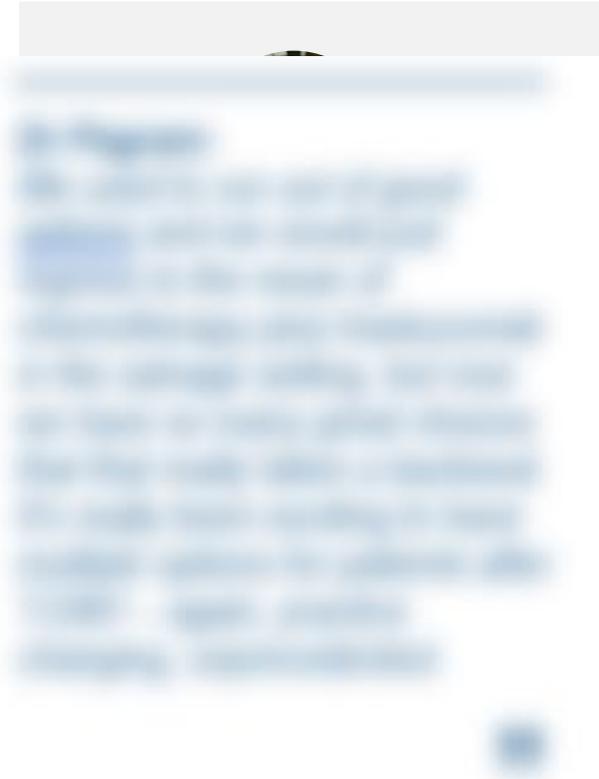


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# Experts Discussed the Broader Implications of the ARASENS and PEACE-1 Trials

## POTENTIAL BIOMARKERS

Experts would like to see the data from PEACE-1 and ARASENS analyzed by whether patients



# Experts Discussed Investigational Strategies Combining Chemotherapy With Hormonal Agents

## NEOADJUVANT CABAZITAXEL PLUS ABIRATERONE

The randomized phase II neoadjuvant trial investigating the addition of cabazitaxel to

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## Congress Highlights

Prostate Cancer Part 2 – Targeted Therapies

# Phase 3 MAGNITUDE study: Niraparib + abiraterone as 1L therapy in mCRPC with and without HRR gene alterations

Chi, et al. 2022, ASCO GU 12

## STUDY POPULATION

1000 patients with mCRPC, 500 with HRR gene alterations and 500 without. All patients received 1L therapy with abiraterone + niraparib. The study was a phase 3, randomized, controlled trial comparing the combination of niraparib + abiraterone to abiraterone monotherapy. The primary endpoint was overall survival (OS) at 24 weeks. The secondary endpoint was progression-free survival (PFS) at 24 weeks. The study was conducted in a multicenter setting across several countries. The results showed that the combination of niraparib + abiraterone significantly improved OS and PFS compared to abiraterone monotherapy in both groups of patients.

## RESULTS

OS at 24 weeks was significantly higher in the combination group (70%) compared to the monotherapy group (55%). PFS at 24 weeks was also significantly higher in the combination group (75%) compared to the monotherapy group (60%). The combination group also had a significantly lower rate of adverse events compared to the monotherapy group.

## KEY CONCLUSIONS

Combining niraparib + abiraterone as 1L therapy significantly improved OS and PFS in mCRPC patients with and without HRR gene alterations.

## OS AT 24 WEEKS IN THE COMBINATION GROUP VS MONOTHERAPY GROUP



## RESPONSE RATE AT 24 WEEKS IN THE COMBINATION GROUP VS MONOTHERAPY GROUP





# Phase 1/2 study of ARV-110, an androgen receptor PROTAC degrader, in mCRPC

Gao, et al. 2022, ASCO GU 17

## STUDY POPULATION

100 patients with mCRPC, 50 patients with a PSA velocity  $\geq 0.75$  ng/mL/year or a PSA  $\geq 10$  ng/mL, 50 patients with a PSA  $\geq 10$  ng/mL and a PSA velocity  $\geq 0.75$  ng/mL/year. All patients had a Gleason score  $\geq 7$  and were not on androgen deprivation therapy (ADT) at baseline. The median age was 70 years (range 58-82). The median time from diagnosis to study entry was 1.5 years. The median time from study entry to treatment was 1.5 years. The median time from study entry to treatment was 1.5 years. The median time from study entry to treatment was 1.5 years.

## DESIGN

100 patients were randomized 1:1 to ARV-110 (n=50) or enzalutamide (n=50). The primary endpoint was overall survival (OS) at 12 weeks. Secondary endpoints include PSA response rate, time to next treatment, and quality of life.

## KEY RESULTS

At 12 weeks, the median OS was 12.5 weeks in the ARV-110 group and 11.5 weeks in the enzalutamide group. The PSA response rate was 45% in the ARV-110 group and 40% in the enzalutamide group.

## PSA RESPONSE RATE



## OS AT 12 WEEKS



# Phase 1 results of the ODM-208 first-in-human phase 1-2 trial in patients with mCRPC (CYPIDES)

Fizazi, et al. 2022, ASCO GU 18

## STUDY POPULATION

100 patients with mCRPC, 50 patients with a PSA, any metastases or a PSA rise of 20% or more, 45% PSA rise in 3 months, non-castrate, PSA, testosterone > 200 ng/dL, or PSA average 100 ng/mL. Excluded: prior or concurrent treatment with docetaxel, enzalutamide, abiraterone, or androgen deprivation therapy. 100 patients were randomized to 1:1 ODM-208 or placebo. The primary endpoint was PSA response rate at week 24. Secondary endpoints: PSA response rate at week 48, PSA response rate at week 72, PSA response rate at week 96, PSA response rate at week 120, PSA response rate at week 144, PSA response rate at week 168, PSA response rate at week 192, PSA response rate at week 216, PSA response rate at week 240, PSA response rate at week 264, PSA response rate at week 288, PSA response rate at week 312, PSA response rate at week 336, PSA response rate at week 360, PSA response rate at week 384, PSA response rate at week 408, PSA response rate at week 432, PSA response rate at week 456, PSA response rate at week 480, PSA response rate at week 504, PSA response rate at week 528, PSA response rate at week 552, PSA response rate at week 576, PSA response rate at week 600, PSA response rate at week 624, PSA response rate at week 648, PSA response rate at week 672, PSA response rate at week 696, PSA response rate at week 720, PSA response rate at week 744, PSA response rate at week 768, PSA response rate at week 792, PSA response rate at week 816, PSA response rate at week 840, PSA response rate at week 864, PSA response rate at week 888, PSA response rate at week 912, PSA response rate at week 936, PSA response rate at week 960, PSA response rate at week 984, PSA response rate at week 1008, PSA response rate at week 1032, PSA response rate at week 1056, PSA response rate at week 1080, PSA response rate at week 1104, PSA response rate at week 1128, PSA response rate at week 1152, PSA response rate at week 1176, PSA response rate at week 1200.

## RESULTS

100 patients were randomized to 1:1 ODM-208 or placebo. The primary endpoint was PSA response rate at week 24. Secondary endpoints: PSA response rate at week 48, PSA response rate at week 72, PSA response rate at week 96, PSA response rate at week 120, PSA response rate at week 144, PSA response rate at week 168, PSA response rate at week 192, PSA response rate at week 216, PSA response rate at week 240, PSA response rate at week 264, PSA response rate at week 288, PSA response rate at week 312, PSA response rate at week 336, PSA response rate at week 360, PSA response rate at week 384, PSA response rate at week 408, PSA response rate at week 432, PSA response rate at week 456, PSA response rate at week 480, PSA response rate at week 504, PSA response rate at week 528, PSA response rate at week 552, PSA response rate at week 576, PSA response rate at week 600, PSA response rate at week 624, PSA response rate at week 648, PSA response rate at week 672, PSA response rate at week 696, PSA response rate at week 720, PSA response rate at week 744, PSA response rate at week 768, PSA response rate at week 792, PSA response rate at week 816, PSA response rate at week 840, PSA response rate at week 864, PSA response rate at week 888, PSA response rate at week 912, PSA response rate at week 936, PSA response rate at week 960, PSA response rate at week 984, PSA response rate at week 1008, PSA response rate at week 1032, PSA response rate at week 1056, PSA response rate at week 1080, PSA response rate at week 1104, PSA response rate at week 1128, PSA response rate at week 1152, PSA response rate at week 1176, PSA response rate at week 1200.

## KEY CONCLUSIONS

Continuing treatment beyond week 24 provides clinical benefit in PSA response and decreases the proportion of patients with PSA response.

## PSA RESPONSE RATE OVER TIME IN THE PLACEBO AND ODM-208 GROUPS



## RESPONSE RATE AT WEEK 24 AND WEEK 48



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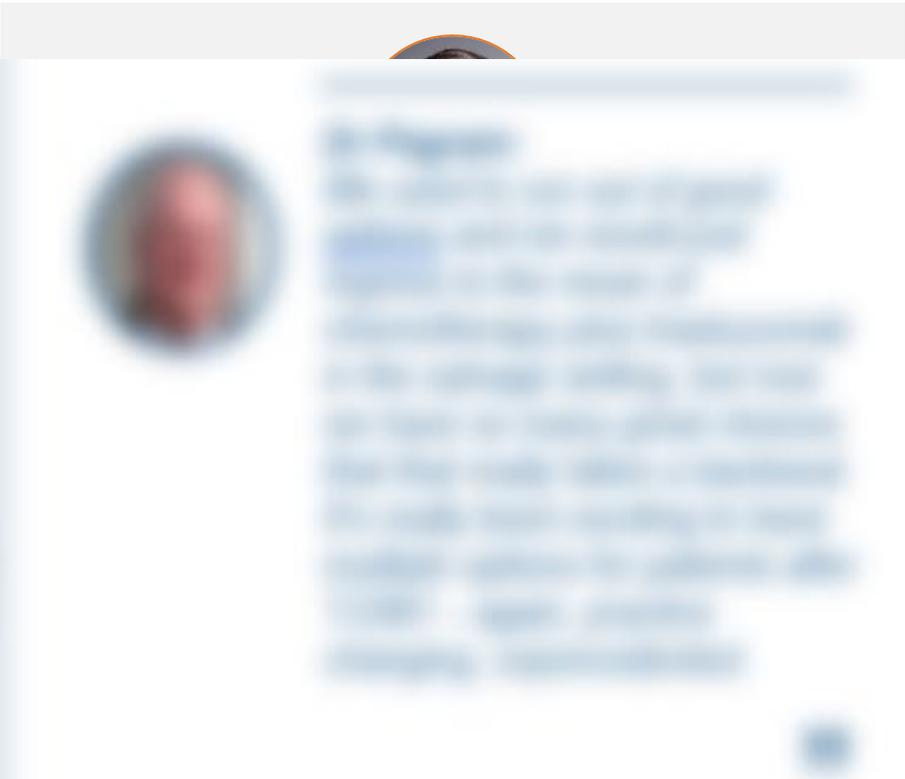
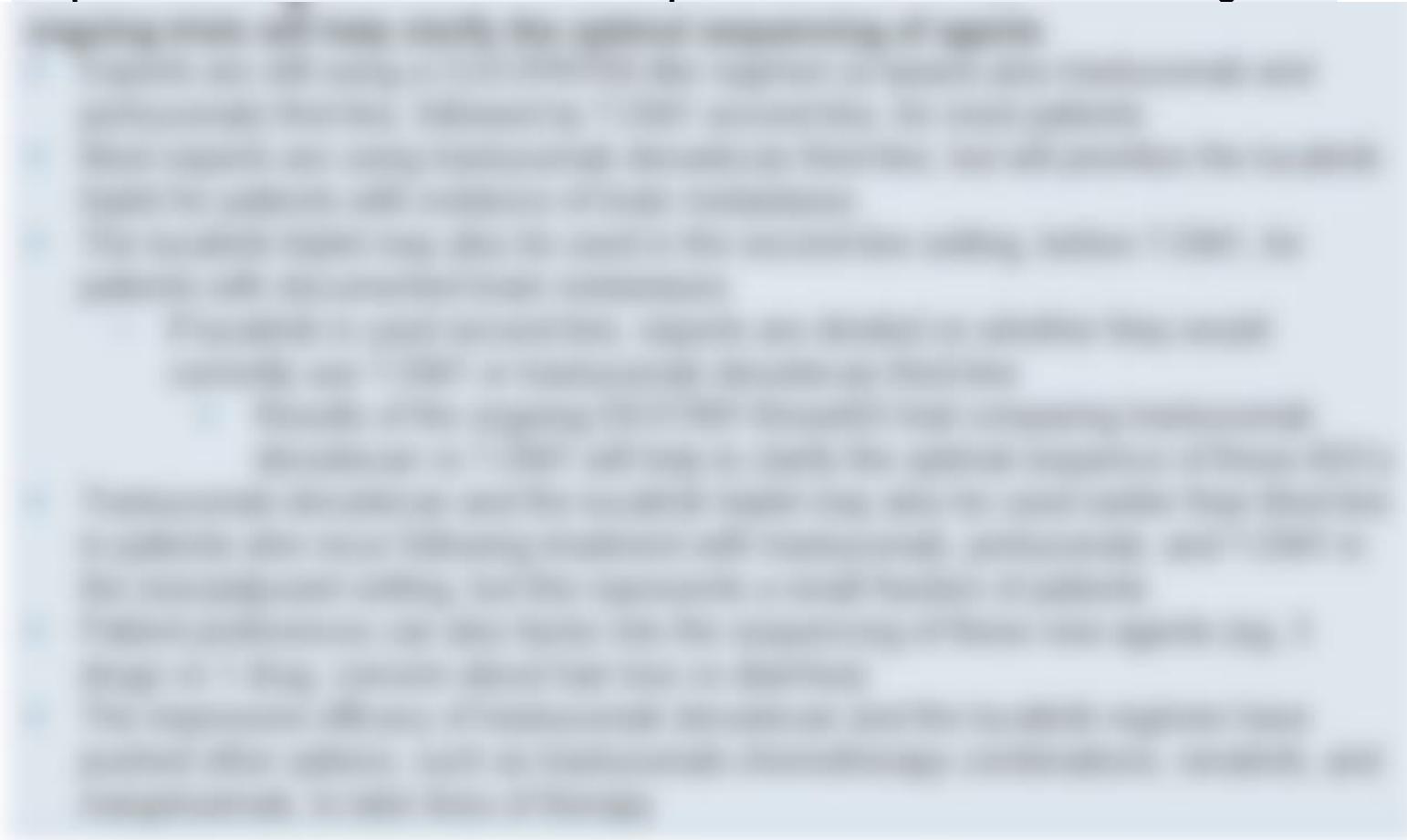
## Key Insights

Prostate Cancer Part 2 – Targeted Therapies

# Experts Debated Results of First-Line Trials of PARP Inhibitors Plus Abiraterone for mCRPC

## MAGNITUDE AND PROpel

Experts consider the results of the PROpel and MAGNITUDE trials showing that

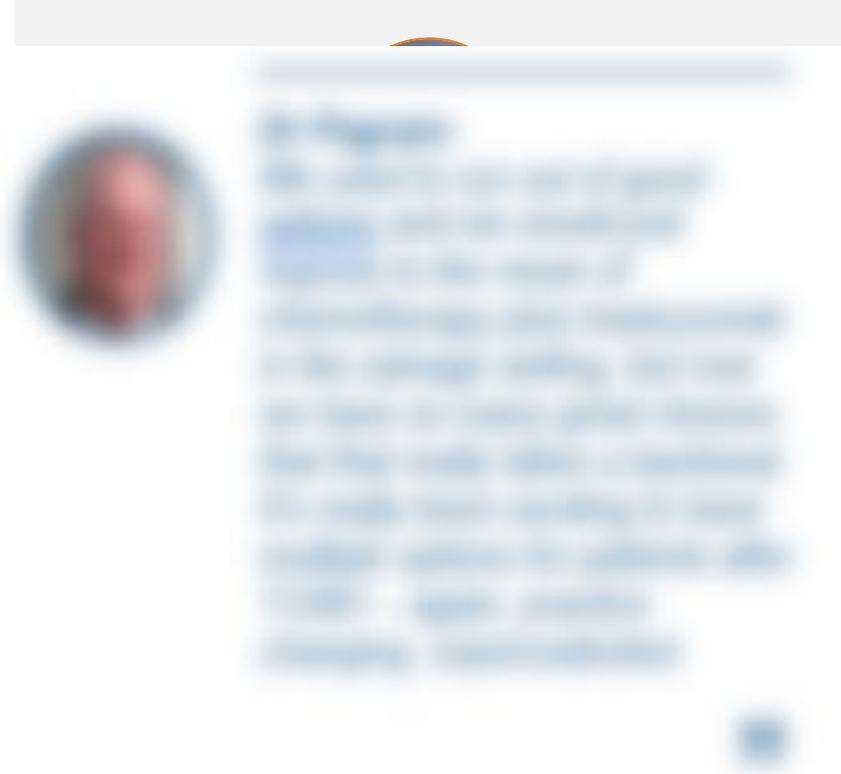


# Experts Discussed Considerations for Future First-Line Hormonal Therapy Trials for mCRPC

## FUTURE STUDIES AND PRACTICAL IMPLICATIONS

### First-line hormonal therapy trials for antiandrogen-naïve mCRPC such as MAGNITUDE

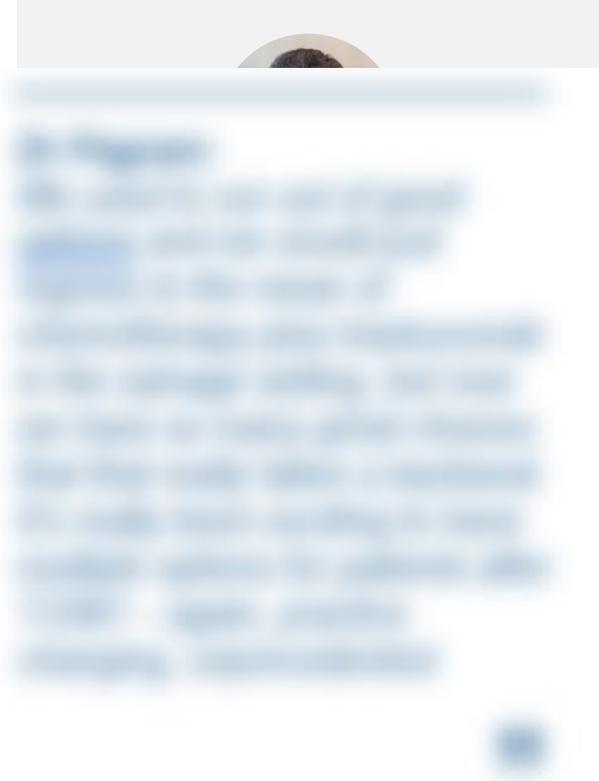
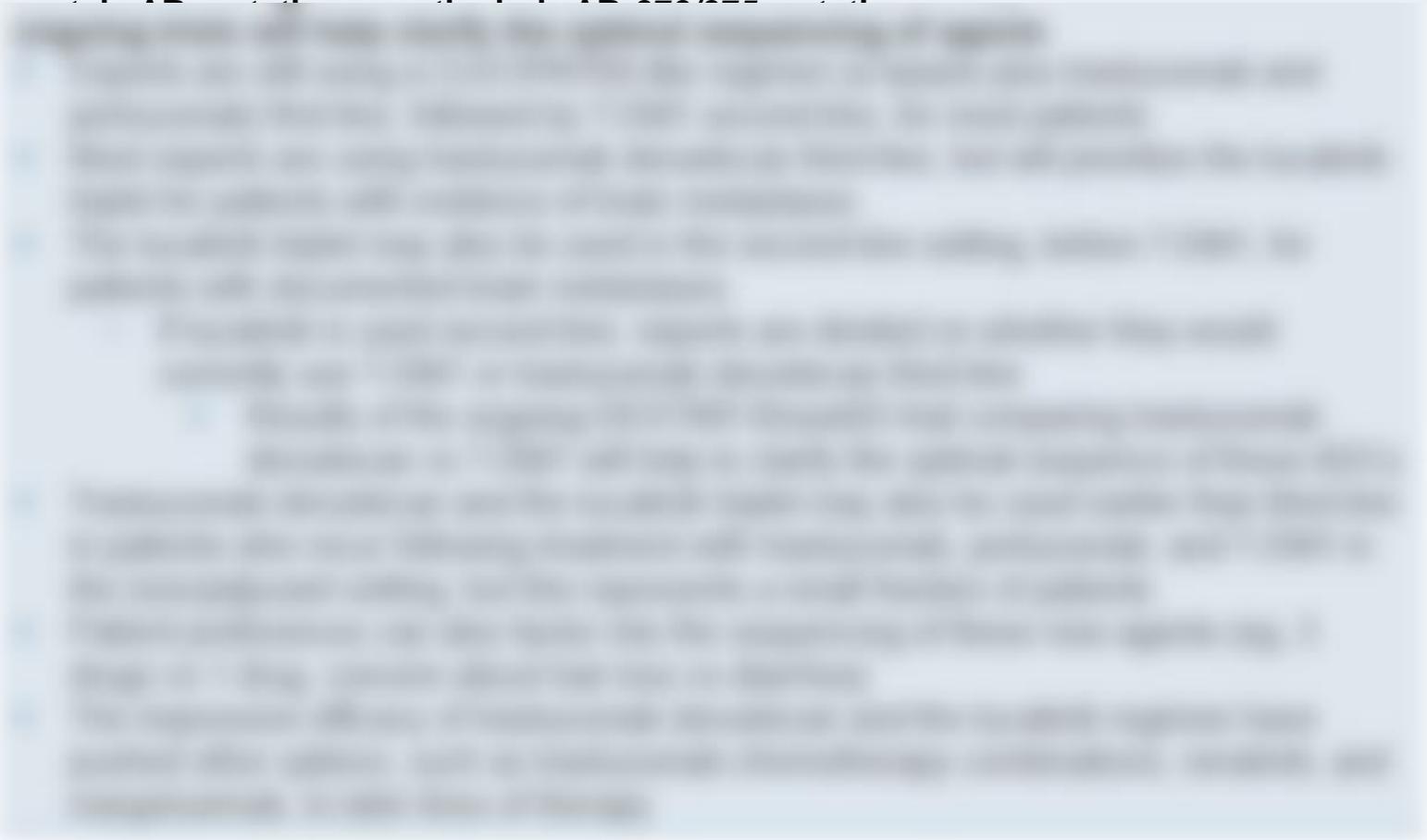
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# Experts Assessed Novel AR-Targeted Agents for mCRPC

## ARV-110

Experts were enthusiastic about the activity ARV-110, noting it appears to be more active against



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# Congress Highlights

Bladder Cancer Part 1 – ADCs



# Study EV-103 Cohort H: Neoadjuvant treatment with enfortumab vedotin monotherapy in patients with MIBC who are cisplatin-ineligible

Petrylak, et al. 2022, ASCO GU 435

## STUDY POPULATION

100 patients with MIBC who were cisplatin-ineligible and had ECOG performance grade 0-1, no prior systemic therapy, and no prior bladder cancer surgery. The patients were randomized to receive enfortumab vedotin (n=50) or placebo (n=50). The enfortumab vedotin group had a median overall survival of 12.1 months compared to 10.1 months in the placebo group. The most common adverse events were fatigue, nausea, and diarrhea.

## RESULTS

100 patients were randomized to receive enfortumab vedotin (n=50) or placebo (n=50). The enfortumab vedotin group had a median overall survival of 12.1 months compared to 10.1 months in the placebo group.

## KEY CONCLUSIONS

Enfortumab vedotin monotherapy improved overall survival in cisplatin-ineligible patients with MIBC.

## TOXICITY PROFILE: GRADE 3/4 ADVERSE EVENTS



## RESPONSE: NEOADJUVANT BLADDER CANCER RESECTION



# DS8201-A-U105: A phase 1b study of trastuzumab deruxtecan (T-DXd) with nivolumab in patients with HER2-expressing urothelial carcinoma

Galsky, et al. 2022, ASCO GU 438

## STUDY POPULATION

100 patients with HER2-expressing urothelial carcinoma (UC) who had received at least one prior systemic therapy for UC. The study population included patients who had received prior systemic therapy for UC, including but not limited to platinum-based chemotherapy, taxane-based chemotherapy, and immunotherapy. The study population was stratified by prior systemic therapy for UC, including but not limited to platinum-based chemotherapy, taxane-based chemotherapy, and immunotherapy. The study population was stratified by prior systemic therapy for UC, including but not limited to platinum-based chemotherapy, taxane-based chemotherapy, and immunotherapy.

## DESIGN

100 patients with HER2-expressing UC, 100 patients with HER2-expressing UC.

## KEY CONCLUSIONS

Continuing treatment beyond week 25 provides clinical benefit in patients and decreases the proportion of patients with HER2-expressing UC.

## TOXICITY PROFILE



## RESPONSE RATE AND CLINICAL BENEFIT



# RC48-C014: Preliminary results of RC48-ADC combined with toripalimab in patients with locally advanced or metastatic urothelial carcinoma

Zhou, et al. 2022, ASCO GU 515

## STUDY POPULATION

100 patients with locally advanced or metastatic urothelial carcinoma who had not received prior systemic therapy for their urothelial carcinoma. All patients had ECOG performance grade 0-1. The median age was 68 years (range 45-85). The median time from diagnosis to study enrollment was 12 months. All patients were treated with RC48-ADC and toripalimab through week 24.

## RESULTS

100 patients were enrolled in the study. The overall response rate (ORR) was 45%. The median overall survival (OS) was 12.5 months. The median progression-free survival (PFS) was 6.5 months.

## KEY CONCLUSIONS

Combining RC48-ADC with toripalimab showed promising activity in patients with locally advanced or metastatic urothelial carcinoma.

## TOXICITY PROFILE



## RESPONSE, SURVIVAL, AND TOXICITY PROFILES



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## Key Insights

Bladder Cancer Part 1 – ADCs

# Experts Assessed Investigational Approaches Utilizing ADCs Currently in Use for mUC

## SACITUZUMAB GOVITECAN PLUS PEMBROLIZUMAB

The activity of SG plus pembrolizumab in platinum-pretreated mUC is considered interesting, but

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# Experts Discussed HER2-Targeted ADCs in Combination With Immune Checkpoint Inhibitors for HER2+ mUC

## TRASTUZUMAB DERUXTECAN AND RC48-C014

Results of the 2 studies suggest the HER2-targeted ADCs (trastuzumab deruxtecan

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## Congress Highlights

Bladder Cancer Part 2 – PARP Inhibitors and Immunotherapies

# Phase 3 results in both CIS and papillary cohorts BCG-unresponsive NMIBC after IL-15R $\alpha$ Fc superagonist N-803 and BCG infusion

Chang, et al. 2022, ASCO GU 431

## STUDY POPULATION

1000 patients with BCG-unresponsive NMIBC, including CIS and papillary NMIBC, were randomized to receive either N-803 + BCG (n=500) or BCG alone (n=500). The primary endpoint was the percentage of patients with a complete response (CR) at 24 weeks. Secondary endpoints included overall survival (OS), progression-free survival (PFS), and quality of life (QoL). The N-803 + BCG group showed a significantly higher CR rate compared to the BCG alone group.

## RESULTS

At 24 weeks, the CR rate was significantly higher in the N-803 + BCG group (55%) compared to the BCG alone group (35%). OS and PFS were similar between the two groups. QoL was maintained in both groups throughout the study.

## KEY CONCLUSIONS

Combining N-803 with BCG significantly improved the CR rate in BCG-unresponsive NMIBC patients. This combination may represent a novel therapeutic approach for this challenging disease.

## CR RATE OVER TIME



## RESPONSE RATE AT 24 WEEKS ANALYSIS





# Meet-URO 12: BSC +/- niraparib as maintenance in patients with mUC whose disease did not progress after 1L platinum-based chemotherapy

Vignani, et al. 2022, ASCO GU 442

## STUDY POPULATION

1000 patients with mUC, who had not received prior systemic therapy for mUC, and whose disease did not progress after 1L platinum-based chemotherapy. The study population was divided into two groups: 500 patients who received BSC +/- niraparib and 500 patients who received BSC +/- placebo. The study population was divided into two groups: 500 patients who received BSC +/- niraparib and 500 patients who received BSC +/- placebo. The study population was divided into two groups: 500 patients who received BSC +/- niraparib and 500 patients who received BSC +/- placebo.

## RESULTS

1000 patients with mUC, who had not received prior systemic therapy for mUC, and whose disease did not progress after 1L platinum-based chemotherapy. The study population was divided into two groups: 500 patients who received BSC +/- niraparib and 500 patients who received BSC +/- placebo. The study population was divided into two groups: 500 patients who received BSC +/- niraparib and 500 patients who received BSC +/- placebo.

## KEY CONCLUSIONS

Continuing maintenance treatment beyond week 23 provides clinical benefit in mUC patients and decreases the maintenance cost to patients.

## KEY TAKEAWAYS FROM MAINTENANCE IN THE CLINICAL TRIAL



## RESPONSE, TOXICITY, AND COST ANALYSIS RESULTS





# BAYOU: A phase II, randomized study of durvalumab plus olaparib for the 1L treatment of platinum-ineligible unresectable, stage IV UC

Rosenberg, et al. 2022, ASCO GU 437

## STUDY POPULATION

1000 patients with stage IV UC, platinum-ineligible, unresectable, ECOG PS 0-1, no prior systemic therapy for advanced UC. Randomized to durvalumab + olaparib (n=500) or durvalumab (n=500). Primary endpoint: ORR. Secondary endpoints: OS, PFS, QoL. All patients received durvalumab through week 48.

## RESULTS

ORR was significantly higher in the durvalumab + olaparib group (31.2%) compared to the durvalumab group (20.8%). OS and PFS were also significantly higher in the combination group.

## KEY CONCLUSIONS

Combining durvalumab with olaparib improved overall survival, progression-free survival, and quality of life in patients with platinum-ineligible unresectable stage IV UC.

## ORR AND PFS BY LINE OF THERAPY



## RESPONSE, PROGRESSION-FREE SURVIVAL, AND QOL



# Avelumab 1L maintenance for advanced UC: Long-term follow-up results from the JAVELIN Bladder 100 trial

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Powles, et al. 2022, ASCO GU 438

## STUDY POPULATION

1000 patients with advanced UC, 500 in each arm. Median age 68 years, 75% male. 75% had prior treatment with docetaxel, irinotecan, and/or fluorouracil. 75% had prior treatment with docetaxel, irinotecan, and/or fluorouracil. 75% had prior treatment with docetaxel, irinotecan, and/or fluorouracil. 75% had prior treatment with docetaxel, irinotecan, and/or fluorouracil.

## DESIGN

Randomized, controlled, open-label, phase 3 trial. Primary endpoint: overall survival. Secondary endpoints: progression-free survival, quality of life, and adverse events.

## KEY CONCLUSIONS

Continuing maintenance treatment beyond week 25 provides clinical benefit in overall survival and decreases the proportion of patients with adverse events.

## KEY FINDINGS FROM EARLY AND LATE ANALYSES



## RESPONSE, TOXICITY, AND QUALITY OF LIFE FINDINGS



# Avelumab 1L maintenance + BSC versus BSC alone in Asian patients with advanced UC: JAVELIN Bladder 100 subgroup analysis

Eto, et al. 2022, ASCO GU 486

## STUDY POPULATION

1000 Asian patients with advanced UC, randomized to receive either Avelumab 1L maintenance + BSC (n=500) or BSC alone (n=500). The primary endpoint was overall survival (OS). The secondary endpoint was progression-free survival (PFS). The study was conducted in a double-blind, randomized, controlled manner.

## RESULTS

Median OS was significantly longer in the Avelumab 1L maintenance + BSC group compared to the BSC alone group. Median PFS was also significantly longer in the Avelumab 1L maintenance + BSC group.

## KEY CONCLUSIONS

Adding Avelumab 1L maintenance to BSC significantly improved OS and PFS in Asian patients with advanced UC.

## OS: Overall Survival in the JAVELIN Bladder 100 Subgroup



## RESPONSE: KEY CLINICAL AND BIOMARKER ANALYSIS



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## Key Insights

Bladder Cancer Part 2 – PARP Inhibitors and Immunotherapies

# Experts Discussed Investigational Strategies for BCG-Unresponsive NMIBC

## INTRAVESICAL THERAPIES

Experts found the results of the QUILT 3.032 trial evaluating the IL-15R $\alpha$ Fc superagonist N-803 plus

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# Experts Reviewed Immune Checkpoint Inhibitors for mUC

## MAINTENANCE AVELUMAB

Experts were happy to see the longer follow-up of the JAVELIN Bladder 100 trial confirming prior

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# Experts Assessed the Data With PARP Inhibitors for mUC

## ATLANTIS, Meet-URO 12, AND BAYOU

### Efficacy results from the ATLANTIS and Meet-URO 12 trials evaluating maintenance

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# Congress Highlights

Renal Cell Carcinoma





# A phase I/II study of nivolumab and axitinib in patients with advanced renal cell carcinoma

Zibelman, et al. 2022, ASCO GU 291

## STUDY POPULATION

100 patients with advanced renal cell carcinoma (RCC) were enrolled in a phase I/II study. The study was designed to evaluate the safety and efficacy of nivolumab and axitinib in patients with advanced RCC. The study population included patients with advanced RCC who had not received prior systemic therapy for advanced disease. The study was conducted in a multicenter setting and included patients from various geographic locations. The study was designed to evaluate the safety and efficacy of nivolumab and axitinib in patients with advanced RCC. The study population included patients with advanced RCC who had not received prior systemic therapy for advanced disease. The study was conducted in a multicenter setting and included patients from various geographic locations.

## RESULTS

The study results showed that the combination of nivolumab and axitinib was well-tolerated and demonstrated promising efficacy in patients with advanced RCC. The most common adverse events were fatigue, diarrhea, and hypertension. The overall response rate (ORR) was 45%, and the median progression-free survival (PFS) was 12 months. The study was designed to evaluate the safety and efficacy of nivolumab and axitinib in patients with advanced RCC. The study population included patients with advanced RCC who had not received prior systemic therapy for advanced disease. The study was conducted in a multicenter setting and included patients from various geographic locations.

## CONCLUSIONS

The combination of nivolumab and axitinib demonstrated promising efficacy and safety in patients with advanced RCC. Further studies are needed to confirm these findings and to evaluate the long-term outcomes of this treatment approach. The study was designed to evaluate the safety and efficacy of nivolumab and axitinib in patients with advanced RCC. The study population included patients with advanced RCC who had not received prior systemic therapy for advanced disease. The study was conducted in a multicenter setting and included patients from various geographic locations.

## TOXICITY PROFILE OVER TIME IN THE STUDY



## RESPONSE RATE AND PROGRESSION-FREE SURVIVAL OVER TIME













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## Key Insights

Renal Cell Carcinoma

# Experts Reviewed Data From Adjuvant and Neoadjuvant Trials for RCC

## KEYNOTE-564

Updated results from KEYNOTE-564 show an increasing DFS benefit with adjuvant

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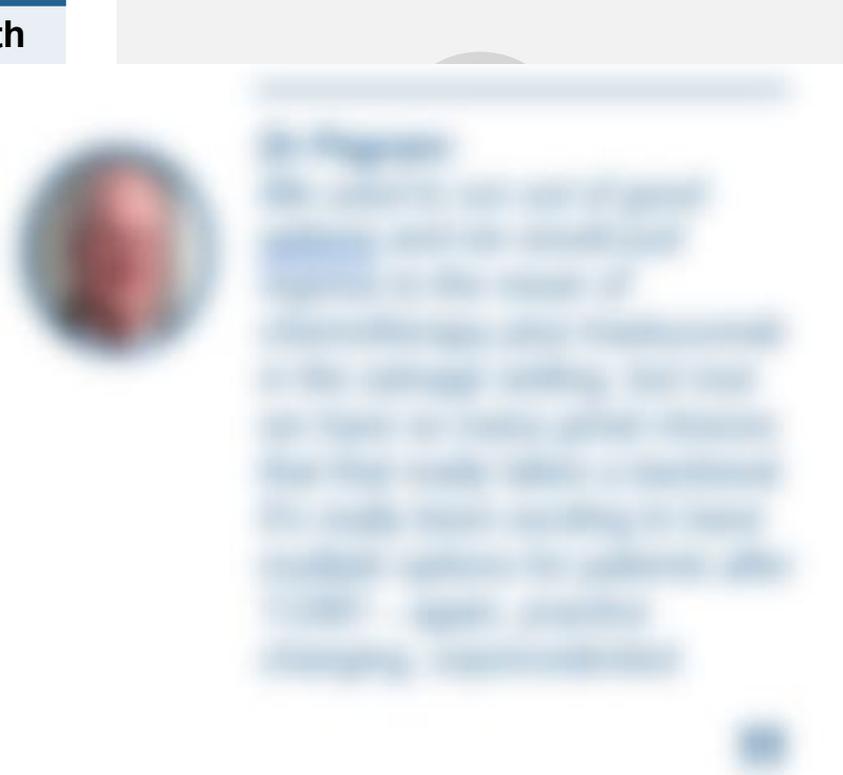
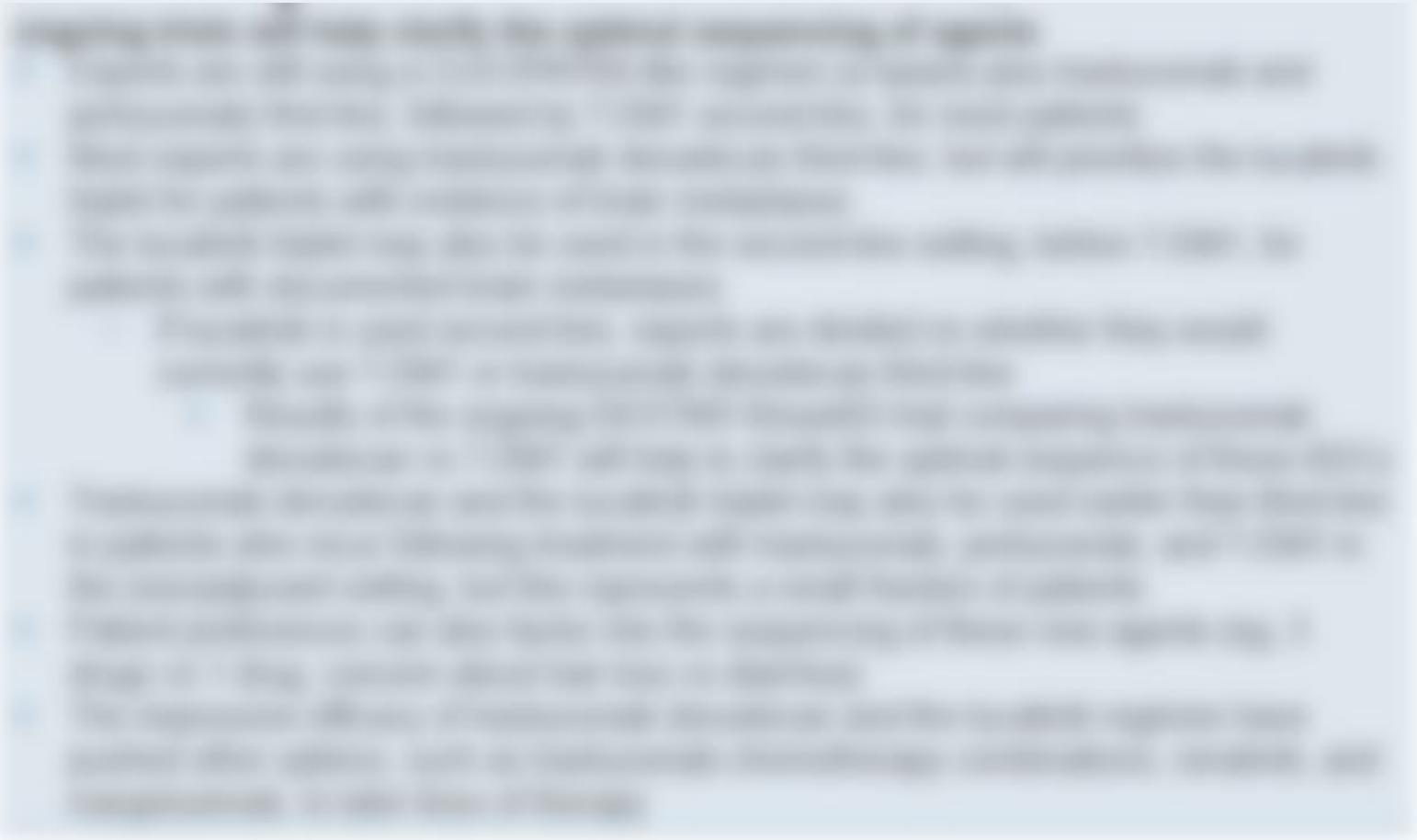
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## QUALITY OF LIFE ANALYSES

The QOL data from CheckMate 9ER and 214 show that disease-specific QOL improves with



# Experts Assessed Novel Agents and Biomarkers for mRCC

## ARO-HIF2

Preliminary data from the phase I study suggest this HIF2-alpha-targeted agent has

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