



## EPICS Congress Coverage: ASCO GU 2022 Highlights

**Tuesday, February 22, 2022; 8.30 AM – 11.30 AM EST**  
(3-hour meeting)

**Chair:** Daniel Petrylak, MD

**Faculty:** Leonard Gomella, MD; Oliver Sartor, MD; Scott Tagawa, MD, MS, FACP; Robert Dreicer, MD, MS, MACP, FASCO; David Nanus, MD; Karim Fizazi, MD, PhD; Ulka Vaishampayan, MBBS

### Agenda

Time	Topic	Speaker/Moderator
8.30 AM – 8.35 AM (5 min)	<b>Welcome and Introductions</b>	Daniel Petrylak, MD
8.35 AM – 8.45 AM (10 min)	<b>Prostate Cancer Part 1 – Hormonal Therapies and Chemotherapies</b> <ul style="list-style-type: none"> <li>• Overall survival with darolutamide versus placebo in combination with androgen-deprivation therapy and docetaxel for metastatic hormone-sensitive prostate cancer in the phase 3 ARASENS trial. Smith et al (Oral Abstract Session A: Prostate Cancer)</li> <li>• Bone mineral density in men with de novo metastatic castration-sensitive prostate cancer treated with or without abiraterone plus prednisone in the PEACE-1 phase 3 trial. Roubaud et al (Rapid Abstract Session A: Prostate Cancer)</li> <li>• Randomized phase II trial of neoadjuvant abiraterone plus or minus cabazitaxel in high-risk prostate cancer: ACDC-RP. Fleshner et al (Rapid Abstract Session A: Prostate Cancer)</li> <li>• A randomized, double-blind, placebo (PBO)-controlled, phase 3b study of the efficacy and safety of continuing enzalutamide (ENZA) in chemotherapy-naïve, metastatic castration-resistant prostate cancer (mCRPC) patients (pts)</li> </ul>	Oliver Sartor, MD

	treated with docetaxel (DOC) plus prednisolone (PDN) who have progressed on ENZA: PRESIDE. Merseburger et al (Oral Abstract Session A: Prostate Cancer)	
8.45 AM – 9.00 AM (15 min)	<p><b>Discussion: Hormonal Therapies and Chemotherapies</b></p> <p><i>Key Questions and Topics for Discussion</i></p> <ul style="list-style-type: none"> <li>• How do the OS data from the ARASENS trial compare with other phase III trials of AR-targeted agents plus ADT for mHSPC? Which combination are you most likely to use in this setting?</li> <li>• Do the BMD data from PEACE-1 with abiraterone raise any concerns? Is there anything different from the already established safety profile? How do you manage BMD with your patients receiving treatment with hormonal therapies?</li> <li>• Does the combination of abiraterone plus cabazitaxel appear feasible? Does benefit appear to outweigh toxicities in the neoadjuvant setting?</li> <li>• What are your thoughts on the efficacy and safety of continuing enzalutamide beyond progression in combination with docetaxel, on the basis of the PRESIDE results?</li> </ul>	All
9.00 AM – 9.05 AM (5 min)	<b>Summary and Key Takeaways – Prostate Cancer Part 1</b>	
9.05 AM – 9.15 AM (10 min)	<b>Break</b>	
9.15 AM – 9.25 AM (10 min)	<p><b>Prostate Cancer Part 2 – Targeted Therapies</b></p> <ul style="list-style-type: none"> <li>• PROpel: Phase III trial of olaparib (ola) and abiraterone (abi) versus placebo (pbo) and abi as first-line (1L) therapy for patients (pts) with metastatic castration-resistant prostate cancer (mCRPC). Saad et al (Oral Abstract Session A: Prostate Cancer)</li> <li>• Phase 3 MAGNITUDE study: First results of niraparib (NIRA) with abiraterone acetate and prednisone (AAP) as first-line therapy in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) with and without homologous recombination repair (HRR) gene alterations. Chi et al</li> </ul>	Karim Fizazi, MD, PhD

	<p>(Oral Abstract Session A: Prostate Cancer)</p> <ul style="list-style-type: none"> <li>Phase 1/2 study of ARV-110, an androgen receptor (AR) PROTAC degrader, in metastatic castration-resistant prostate cancer (mCRPC). Gao et al (Rapid Abstract Session A: Prostate Cancer)</li> <li>Phase 1 results of the ODM-208 first-in-human phase 1-2 trial in patients with metastatic castration-resistant prostate cancer (CYPIDES). Fizazi et al (Rapid Abstract Session A: Prostate Cancer)</li> </ul>	
9.25 AM – 9.40 AM (15 min)	<p><b>Discussion: Prostate Cancer Part 2 – Targeted Therapies</b> <i>Key Questions and Topics for Discussion</i></p> <ul style="list-style-type: none"> <li>On the basis of the PROpel and MAGNITUDE trials, what are your thoughts on the combination of a PARP inhibitor with first-line abiraterone for mCRPC? Is biomarker selection necessary? Are there any meaningful differences between the 2 PARP inhibitors evaluated with regard to efficacy or toxicity?</li> <li>What is your impression of the novel agents ARV-110 and ODM-208? Do the efficacy signals warrant further development in mCRPC? Are there any concerning safety signals with either agent? Specific populations that could particularly benefit?</li> </ul>	All
9.40 AM – 9.45 AM (5 min)	<p><b>Summary and Key Takeaways – Prostate Cancer Part 2</b></p>	
9.45 AM – 9.55 AM (10 min)	<p><b>Bladder Cancer Part 1 – ADCs</b></p> <ul style="list-style-type: none"> <li>TROPHY-U-01 Cohort 3: Sacituzumab govitecan (SG) in combination with pembrolizumab (Pembro) in patients (pts) with metastatic urothelial cancer (mUC) who progressed after platinum (PLT)-based regimens. Grivas et al (Oral Abstract Session B: Urothelial Carcinoma)</li> <li>Study EV-103 Cohort H: Antitumor activity of neoadjuvant treatment with enfortumab vedotin monotherapy in patients (pts) with muscle invasive bladder cancer (MIBC) who are cisplatin-ineligible. Petrylak et al (Oral</li> </ul>	Scott Tagawa, MD, MS, FACP

	<p>Abstract Session B: Urothelial Carcinoma)</p> <ul style="list-style-type: none"> <li>Primary analysis from DS8201-A-U105: A phase 1b, 2-part, open-label study of trastuzumab deruxtecan (T-DXd) with nivolumab (nivo) in patients (pts) with HER2-expressing urothelial carcinoma (UC). Galsky et al (Rapid Abstract Session B: Urothelial Carcinoma)</li> </ul>	
9.55 AM – 10.10 AM (15 min)	<p><b>Discussion: Bladder Cancer Part 1 – ADCs</b> <i>Key Questions and Topics for Discussion</i></p> <ul style="list-style-type: none"> <li>What are your thoughts on the combination of sacituzumab plus pembrolizumab in mUC? Is the toxicity profile acceptable? How does the efficacy compare with sacituzumab alone? Should this combination be further evaluated?</li> <li>What is your impression of the results with EV as neoadjuvant therapy for MIBC? Is safety acceptable in this setting?</li> <li>What is your impression of the combination of trastuzumab deruxtecan plus nivolumab for HER2-expressing cancers? Are there any safety signals of concern? Does the efficacy signal warrant further development?</li> </ul>	All
10.10 AM – 10.15 AM (5 min)	<p><b>Summary and Key Takeaways – Bladder Cancer Part 1</b></p>	
10.15 AM – 10.25 AM (10 min)	<p><b>Bladder Cancer Part 2 – PARP Inhibitors and Immunotherapies</b></p> <ul style="list-style-type: none"> <li>A randomized, double blind, biomarker selected, phase II clinical trial of maintenance PARP inhibition following chemotherapy for metastatic urothelial carcinoma (mUC): Final analysis of the ATLANTIS rucaparib arm. Crabb et al (Oral Abstract Session B: Urothelial Carcinoma)</li> <li>Randomized phase II study of niraparib plus best supportive care (BSC) versus BSC alone as maintenance treatment in patients with advanced urothelial carcinoma (UC) whose disease did not progress after first-line platinum-based chemotherapy (PBCT): The Meet-URO12 trial. Vignani et al (Rapid Abstract Session B: Urothelial Carcinoma)</li> </ul>	Robert Dreicer, MD, MS, MACP, FASCO

	<ul style="list-style-type: none"> <li>• First line avelumab in PD-L1+ve metastatic or locally advanced urothelial cancer (aUC) patients unfit for cisplatin (cis): The ARIES trial. Iacovelli et al (Rapid Abstract Session B: Urothelial Carcinoma)</li> <li>• BAYOU: A phase II, randomized, multicenter, double-blind, study of durvalumab (D) in combination with olaparib (O) for the first-line treatment of platinum-ineligible patients with unresectable, stage IV urothelial carcinoma (UC). Rosenberg et al (Oral Abstract Session B: Urothelial Carcinoma)</li> <li>• Avelumab first-line (1L) maintenance for advanced urothelial carcinoma (UC): Long-term follow-up results from the JAVELIN Bladder 100 trial. Powles et al (Poster Session B: Urothelial Carcinoma; Abstract 487)</li> <li>• Avelumab first-line (1L) maintenance + best supportive care (BSC) versus BSC alone in Asian patients with advanced urothelial carcinoma (UC): JAVELIN Bladder 100 subgroup analysis. Eto et al (Poster Session B: Urothelial Carcinoma; Abstract 487)</li> </ul>	Leonard Gomella, MD
10.25 AM – 10.40 AM (15 min)	<p><b>Discussion: Bladder Cancer Part 2 – PARP Inhibitors and Immunotherapies</b>  <i>Key Questions and Topics for Discussion</i></p> <ul style="list-style-type: none"> <li>• On the basis of results from the ATLANTIS and Meet-URO12 trials, do you see a role for maintenance therapy with a PARP inhibitor following chemotherapy for patients with mUC? If so, in which patients? Are there useful biomarkers for patient selection?</li> <li>• How do the results of the ARIES trial with first-line avelumab for PD-L1+ mUC compare with results from previous trials with atezolizumab and pembrolizumab in this setting?</li> <li>• What is your impression of the combination of durvalumab plus olaparib in the first-line setting for platinum-ineligible patients? Does this combination appear to add benefit compared with an ICI alone? Or</li> </ul>	All



	<ul style="list-style-type: none"> <li>• HRQoL in previously untreated patients with aRCC in CheckMate 214: Five-year follow-up results. Cella et al (Poster Session C: Renal Cell Cancer; Adrenal, Penile, Urethral, and Testicular Cancers)</li> </ul>	
10.55 AM – 11.20 AM (25 min)	<p><b>Discussion: Renal Cell Carcinoma</b> <i>Key Questions and Topics for Discussion</i></p> <ul style="list-style-type: none"> <li>• What are your thoughts on the combination of avelumab-axitinib in the neoadjuvant setting? Are there any toxicity concerns with this combination in the curative setting? Do the biomarker results have clinical utility?</li> <li>• Does longer follow-up of KEYNOTE-564 confirm earlier results and continue to support the use of adjuvant pembrolizumab? Are you using this in the clinic, and if so, in which patients?</li> <li>• Does the phase I/II study of nivolumab plus axitinib stand out in any way from the other ICI-TKI combinations already in use for mRCC?</li> <li>• What can we learn from the biomarker analysis of the TITAN-RCC trial of nivolumab ± ipilimumab? Are any of these biomarkers clinically useful for identifying patients who benefit from dual ICI therapy, or patients who could do well with a single ICI?</li> <li>• Is the final OS analysis of CheckMate 9ER consistent with earlier reports? What can we learn from the organ-specific assessments?</li> <li>• How do the HRQOL analyses from CheckMate 9ER and CheckMate 214 compare with each other and with your experience of these regimens in the clinic? Does QOL factor into your decision about what first-line regimen to use?</li> </ul>	All
11.20 AM – 11.25 AM (5 min)	<b>Summary and Key Takeaways – Renal Cell Carcinoma</b>	
11.25 AM – 11.30 AM (5 min)	<b>Summary and Closing Remarks</b>	Daniel Petrylak, MD