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Conference Coverage: ESMO 2024 – Focus on Genitourinary Malignancies

Tuesday, September 24, 2024; 9.00 AM – 12.00 PM ET

Chair: Daniel Petrylak, MD

Faculty (total 4 US and 2 EU)
Terence Friedlander, MD (US) - first 1,5 hours
Karim Fizazi, MD, PhD (France)
Scott Tagawa, MD, FACP, FASCO (US)
Leonard Gomella, MD, FACS (US)
Joaquim Bellmunt, MD, PhD (US) - first 2 hours

Agenda

Time	Topic	Speaker/Moderator
9.00 AM – 9.05 AM (5 min)	**Welcome and Introductions**	Daniel Petrylak, MD
9.05 AM – 9.15 AM (10 min)	**Hormonal, Cytotoxic, and Targeted Therapies for Metastatic Castration-Resistant Prostate Cancer** 1597MO - Clinical activity of BMS-986365 (CC-94676), a dual androgen receptor (AR) ligand-directed degrader and antagonist, in heavily pretreated patients (pts) with metastatic castration-resistant prostate cancer (mCRPC). Rathkopf et al. LBA72 - Nivolumab 3mg/kg and ipilimumab 1mg/kg (nivo3/ipi1) in molecularly selected patients (pts) with metastatic castration-resistant prostate cancer (mCRPC). Mehra et al. LBA67 - Cabozantinib (C) Plus Atezolizumab (A) Versus 2nd Novel Hormonal Therapy (NHT) in Patients (Pts) with Metastatic Castration-Resistant Prostate Cancer (mCRPC): Final Overall Survival (OS) Results of the Phase 3, Randomized, CONTACT-02 Study. Agarwal et al.	TBC

9.15 AM – 9.25 AM (10 min)	**Discussion: Hormonal, Cytotoxic, and Targeted Therapies for Metastatic Castration-Resistant Prostate Cancer** *Key Questions and Topics for Discussion* • Are any of the new data potentially practice changing for the near future? • How do you see these data impacting current treatment paradigms? • Where do you see these novel agents potentially fitting in? • What is your impression of BMS-986365? How does it compare with current ARSIs? With investigational AR-targeted agents such as PROTACs? • What are your thoughts on the nivo/ipi results? Have they identified a molecularly-defined population with mCRPC that could benefit from immunotherapy? • Based on the OS results from CONTACT-02, is there a place for this combination in the clinic for patients with mCRPC? How do PFS and OS results compare with other treatment options in this setting?	All
9.25 AM – 9.30 AM (5 min)	**Summary and Key Takeaways – Hormonal, Cytotoxic, and Targeted Therapies for Metastatic Castration-Resistant Prostate Cancer**	TBC
9.30 AM – 9.40 AM (10 min)	**Radioligand Therapies for Prostate Cancer** LBA71 - Open-label, multicentre randomised trial of Radium223-docetaxel versus docetaxel-Radium223 sequence in Metastatic Castration Resistant Prostate Cancer (mCRPC) with prospective biomarker evaluation (RAPSON study). Conteduca et al. LBA66 - UpFrontPSMA : A Randomised Phase 2 Study of Sequential 177Lu-PSMA-617 and Docetaxel (D) versus Docetaxel in Metastatic Hormone-Sensitive Prostate Cancer (mHSPC). Azad et al. LBA65 - Efficacy of 177Lu-PNT2002 in PSMA-positive mCRPC following progression on an androgen-receptor pathway inhibitor (ARPI) (SPLASH). Sartor et al.	TBC

	LBA1 - A randomized multicenter open label phase III trial comparing enzalutamide vs a combination of Radium-223 (Ra223) and enzalutamide in asymptomatic or mildly symptomatic patients with bone metastatic castration-resistant prostate cancer (mCRPC): First results of EORTC-GUCG 1333/PEACE-3. Gillessen et al. 1629P - Lutetium-177–Prostate-Specific Membrane Antigen (177Lu-PSMA) therapy in patients (pts) with prior Radium-223 (223Ra). Rhabar et al. 1611P - Haematologic impact of [177Lu]Lu-PSMA-617 versus ARPI change in patients with metastatic castration-resistant prostate cancer in PSMAfore. Chi et al. 1599P - Symptomatic skeletal events, health-related quality of life and pain in a phase 3 study of [177Lu]Lu-PSMA-617 in taxane-naive patients with PSMA-positive metastatic castration-resistant prostate cancer: third interim analysis of PSMAfore. Fizazi et al.	
9.40 AM – 9.55 AM (15 min)	**Discussion: Radioligand Therapies for Prostate Cancer** *Key Questions and Topics for Discussion* • Are any of the new data potentially practice changing for the near future? • How do you see these data impacting current treatment paradigms? • What can we learn from the RAPSON trial? Does it matter whether docetaxel is sequenced before or after 223Ra? – Can these results be extrapolated to LuPSMA and other radiopharmaceuticals? • What is your interpretation of UpFrontPSMA? Do these results support the earlier use of LuPSMA in mHSPC? • What is your impression of the SPLASH results? And how does 131I-LNTH-1095 compare with LuPSMA? • What do the results from the study of LuPSMA after Ra-223 tell us about the efficacy and safety of radioligands when used sequentially? • How does the hematologic impact of LuPSMA compare vs ARPIs? Would this	

	influence your selection or sequencing of agents? • Are the results from the third interim analysis of PSMAfore consistent with previous reports?	
9.55 AM – 10.00 AM (5 min)	**Summary and Key Takeaways – Radioligand Therapies for Prostate Cancer**	TBC
10.00 AM – 10.10 AM (10 min)	**Localized and Hormone-Sensitive Prostate Cancer** 1595MO - Phenotypic and genomic characterization of de novo metastatic prostate cancer: an ancillary study of the PEACE-1 phase 3 trial. Pobel et al. 1596MO - Decipher mRNA score for prediction of survival benefit from docetaxel at start of androgen deprivation therapy (ADT) for advanced prostate cancer (PC): an ancillary study of the STAMPEDE docetaxel trials. Grist et al. LBA68 - Efficacy and safety of darolutamide plus androgen-deprivation therapy (ADT) in patients with metastatic hormone-sensitive prostate cancer (mHSPC) from the phase 3 ARANOTE trial. Saad et al. LBA69 - Prostate cancer efficacy results from a randomised phase 3 evaluation of transdermal oestradiol (tE2) versus luteinising hormone releasing hormone agonists (LHRHa) for androgen suppression in non-metastatic (M0) prostate cancer. Langley et al.	TBC
10.10 AM – 10.20 AM (10 min)	**Discussion: Localized and Hormone-Sensitive Prostate Cancer** *Key Questions and Topics for Discussion* • Are any of the new data potentially practice changing for the near future? • How do you see these data impacting current treatment paradigms? • Does the ancillary study of PEACE-1 provide any new information to refine patient selection for triplet therapy? • Do the results of the ancillary study of the STAMPEDE docetaxel trials support the use of the Decipher mRNA score to select	All

	patients who may benefit from ADT + docetaxel? • Based on the ARANOTE results, how does the combination of daralutamide + ADT compare with other ARSIs + ADT for mHSPC? With triplet therapy? • What is your recommended approach for high-risk patients? • When do you use triplet therapy and when do you use doublet therapy in this setting? Is there a difference in benefit from triplet therapy on the basis of patient age? • What are your thoughts on transdermal E2 vs an LHRHa for androgen suppression in M0 disease? Are there clinical implications?	
10.20 AM – 10.25 AM (5 min)	**Summary and Key Takeaways – Localized and Hormone-Sensitive Prostate Cancer**	TBC
10.25 AM – 10.30 AM (5 min)	**Break**	
10.30 AM – 10.40 AM (10 min)	**Bladder Cancer Part 1 – NMIBC and MIBC** LBA84 - TAR-200 plus cetrelimab (CET) or CET alone as neoadjuvant therapy in patients (pts) with muscle-invasive bladder cancer (MIBC) who are ineligible for or refuse neoadjuvant cisplatin-based chemotherapy (NAC): interim analysis of SunRISe-4 (SR-4). Necchi et al. LBA85 - TAR-200 +/- cetrelimab (CET) and CET alone in patients (pts) with bacillus Calmette-Guérin-unresponsive (BCG UR) high-risk non–muscle-invasive bladder cancer (HR NMIBC): updated results from SunRISe-1 (SR-1). Van der Heijden et al. LBA5 - A randomized phase 3 trial of neoadjuvant durvalumab plus chemotherapy followed by radical cystectomy and adjuvant durvalumab in muscle-invasive bladder cancer (NIAGARA) 1960O - Identification of bladder cancer patients that could benefit from early post-cystectomy immunotherapy based on serial circulating tumour DNA (ctDNA) testing: preliminary results from the TOMBOLA trial. Jensen et al.	TBD

	1961O - Nivolumab plus chemoradiotherapy in patients with non-metastatic muscle-invasive bladder cancer (nmMIBC), not undergoing cystectomy: a phase II, randomized study by the Hellenic GU Cancer Group. Kougioumtzopoulou et al. 1963MO - JCOG1019: An Open-label, Non-inferiority, Randomised Phase 3 Study Comparing the Effectiveness of Watchful Waiting (WW) and Intravesical Bacillus Calmette-Guérin (BCG) in Patients (Pts) with High-grade pT1 (HGT1) Bladder Cancer with pT0 on the 2nd Transurethral Resection (TUR) Specimen. Hiroshi Kitamura 1964MO - Alliance A031501: AMBASSADOR Study of Adjuvant Pembrolizumab (Pembro) in Muscle-Invasive Urothelial Carcinoma (MIUC) vs Observation (Obs): Extended follow-up disease-free survival (DFS) results and metastatic (met) disease recurrence distribution. Andrea B. Apolo	
10.40 AM – 10.55 AM (15 min)	**Discussion: Bladder Cancer Part 1 – NMIBC and MIBC** *Key Questions and Topics for Discussion* • Are any of the new data potentially practice changing for the near future? • Where do you see these novel agents or regimens for NMIBC and MIBC potentially fitting into current treatment paradigms? • Is there anything new or surprising in the updated results from SunRISe-1? If TAR-200 were available, where would they fit with current intravesical options for BCG-unresponsive NMIBC? • What are your thoughts on pembrolizumab monotherapy for BCG-unresponsive NMIBC? • Will the results of the NAIGARA trial change practice for patients with MIBC? Which patients would this approach be appropriate for? • What are your thoughts on the SunRISe-4 results? Are there patients with MIBC where you would consider using neoadjuvant cetrelimab +/- TAR-200? Where do this results fit in light of the NIAGARA trial? • Do results from the TOMBOLA trial support the use of ctDNA testing to identify patients for post-cystectomy immunotherapy?	All

	• How does the addition of nivolumab to cisplatin-based neoadjuvant therapy compare with chemotherapy alone for MIBC? Is there any impact on the avoidance of cystectomy? • Do you use adjuvant nivolumab, and if so, in which patients with MIBC? Will NIAGARA results change this?	
10.55 AM – 11.00 AM (5 min)	**Summary and Key Takeaways – Bladder Cancer Part 1 – NMIBC and MIBC**	TBD
11.00 AM – 11.10 AM (10 min)	**Bladder Cancer Part 2 – Metastatic Urothelial Cancer** 1959O - BL-B01D1, an EGFR x HER3 Bispecific Antibody-drug Conjugate (ADC), in Patients with Locally Advanced or Metastatic Urothelial Carcinoma (UC). Ye et al. 1962O - Health-related quality of life from the CheckMate 901 trial of nivolumab as first-line therapy for unresectable or metastatic urothelial carcinoma. Bedke et al. 1965MO - Phase 2 study of futibatinib plus pembrolizumab in patients (pts) with advanced/metastatic urothelial carcinoma (mUC): Final analysis of efficacy and safety. Vadim S. Koshkin 1966MO - EV-302: Exploratory Analysis of Nectin-4 Expression and Response to 1L Enfortumab Vedotin (EV) + Pembrolizumab (P) in Previously Untreated Locally Advanced or Metastatic Urothelial Cancer (la/mUC). Thomas B. Powles 1967MO - Preliminary Efficacy And Safety Of Disitamab Vedotin (DV) With Pembrolizumab (P) In Treatment (Tx)-Naive HER2-Expressing, Locally Advanced Or Metastatic Urothelial Carcinoma (la/mUC): RC48G001 Cohort C. Matthew D. Galsky	TBD
11.10 AM – 11.25 AM (15 min)	**Discussion: Bladder Cancer Part 2 – Metastatic Urothelial Cancer** *Key Questions and Topics for Discussion* • Are any of the new data potentially practice changing for the near future? • How do you see these data impacting current treatment paradigms?	All

	• How and when do you use sacituzumab govitecan in mUC? • What is the optimal role for ICIs in mUC? • How do you currently select patients for enfortumab vedotin + pembrolizumab? • What are your thought on the bispecific ADC BL-B01D1? Could this agent have a future in mUC? Are there any concerning toxicities? • What is your impression of the HRQoL results from CheckMate 901?	
11.25 AM – 11.30 AM (5 min)	**Summary and Key Takeaways – Bladder Cancer Part 2: Metastatic Urothelial Cancer**	TBD
11.30 AM – 11.40 AM (10 min)	**Renal Cell Carcinoma** 1690O - NKT2152, a novel oral HIF-2α inhibitor, in participants (pts) with previously treated advanced clear cell renal carcinoma (accRCC): Preliminary results of a Phase 1/2 study. Jonasch et al. LBA73 - Tivozanib–Nivolumab vs Tivozanib Monotherapy in Patients with Renal Cell Carcinoma (RCC) Following 1 or 2 Prior Therapies including an Immune Checkpoint Inhibitor (ICI) – Results of the Phase III TiNivo-2 Study. Choueiri et al. LBA74 - Final analysis of the phase 3 LITESPARK-005 study of belzutifan versus everolimus in participants (pts) with previously treated advanced clear cell renal cell carcinoma (ccRCC). Rini et al. LBA75 - Prospective randomised phase-II trial of Ipilimumab/Nivolumab versus standard of care in non-clear cell renal cell cancer - results of the SUNNIFORECAST trial. Bergmann et al. LBA76 - Anlotinib in combined with anti-PD-L1 antibody Benmelstobart(TQB2450) versus sunitinib in first-line treatment of advanced renal cell carcinoma (RCC) -A randomized, open-label, phase III study (ETER100). Sheng et al. LBA77 - Fecal microbiota transplantation (FMT) versus placebo in patients receiving pembrolizumab plus axitinib for metastatic renal cell carcinoma. Preliminary results of the randomized phase 2 TACITO trial. Ciccarese et al.	TBD

11.40 AM – 11.55 AM (15 min)	**Discussion: Renal Cell Carcinoma** *Key Questions and Topics for Discussion* • Are any of the new data potentially practice changing for the near future? • Do any of these data have the potential to change management paradigms? • What is your impression of the efficacy and safety of NKT2152? • What is your impression of the efficacy of tivo/nivo in the 2L/3L setting compared with other options for patients who have progressed on a TKI and an IO agent? Should this be an option for patients with progression? • How does belzutifan compare with everolimus in LITESPARK-005? Is single-agent everolimus an appropriate control? • What is your impression of the activity of ipi/nivo in SUNNIFORECAST? Do you consider this an option for non-clear cell RCC? If so, for which patients/subtypes? • What are your thoughts on anlotinib + benmelstobart? Are there any notable differences from currently available TKI/IO doublets? Is there a need for another such combination? • What are your thoughts on the TACITO results? Does FMT add meaningfully to the TKI/IO therapy? • Is biomarker-driven selection feasible in mRCC? Does efficacy appear any better than current methods of treatment selection? • How do you sequence therapies in mRCC?	All
11.55 AM – 12.00 PM (5 min)	**Summary and Key Takeaways – Renal Cell Carcinoma**	TBD
	Closing Remarks	Daniel Petrylak, MD