APTITUDE HEALTH

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CONFERENCE COVERAGE: ESMO 2019 GU HIGHLIGHTS

September 2019

BACKGROUND

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- On 30 September, adjacent to the European Society for Medical Oncology (ESMO) Congress 2019, Aptitude Health convened a group of experts in genitourinary (GU) cancers to a small closed-session panel

- The goal of the panel was to discuss recent select studies presented at ESMO, and their possible impact on real-world clinical practice

FACULTY

CHAIR

Daniel Petrylak, MD
Yale Cancer Center
New Haven, USA

ATTENDEES

Gerhardt Attard, MD, PhD
University College London
London, UK

Jorge A. García, MD
Cleveland Clinic Taussig Cancer Institute
Cleveland, USA

David Quinn, MD, PhD
University of Southern California
Los Angeles, USA

Oliver Sartor, MD
Tulane University
New Orleans, USA

Scott Tagawa, MD
Weill Cornell Medicine-Cornell University
New York, USA

AGENDA

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Time	Topic	Speaker/Moderator
18.30 – 18.35	Welcome and Introductions	Daniel Petrylak, MD
18.35 – 18.40	Hormonal Approaches for Prostate Cancer	David Quinn, MD, PhD
18.40 – 19.00	Discussion – Hormonal Approaches for Prostate Cancer	Gerhardt Attard, MD, PhD
19.00 – 19.10	Castration-Resistant Prostate Cancer – Targeted and Immunotherapies	Gerhardt Attard, MD, PhD
19.10 – 19.30	Discussion – Castration-Resistant Prostate Cancer – Targeted and Immunotherapies	Oliver Sartor, MD
19.30 – 19.40	Updates in Renal Cell Carcinoma	Jorge A. Garcia, MD
19.40 – 20.00	Discussion – Updates in Renal Cell Carcinoma	David Quinn, MD, PhD
20.00 – 20.05	Novel Agents for Urothelial/Bladder Cancers	Scott Tagawa, MD
20.05 – 20.25	Discussion – Novel Agents for Urothelial/Bladder Cancers	David Quinn, MD, PhD
20.25 – 20.30	Summary and Closing Remarks	Daniel Petrylak, MD

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Hormonal Approaches for Prostate Cancer

DAVID QUINN, MD, PHD

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Hormone-Sensitive Prostate Cancer

HORMONAL APPROACHES FOR PROSTATE CANCER

LBA53 – Health-related quality of life (HRQL) in a randomized phase 3 trial of enzalutamide with standard first line therapy for metastatic, hormone sensitive prostate cancer (mHSPC): ENZAMET (ANZUP 1304), an ANZUP-led, international, cooperative group trial. M. Stockler, et al

HORMONAL APPROACHES FOR PROSTATE CANCER

844O – Docetaxel for hormone-naive prostate cancer: results from long-term follow-up of metastatic (M1) patients in the STAMPEDE randomised trial (NCT00268476) and sub-group analysis by metastatic burden. N. Clarke, et al

HORMONAL APPROACHES FOR PROSTATE CANCER

853P – ARCHES – the role of androgen deprivation therapy (ADT) with enzalutamide (ENZA) or placebo (PBO) in metastatic hormone-sensitive prostate cancer (mHSPC): Post hoc analyses of high and low disease volume and risk groups. A. Stenzl, et al

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Castration-Resistant Prostate Cancer

HORMONAL APPROACHES FOR PROSTATE CANCER

854P – Updated survival analyses of a multicentric phase II randomized trial of docetaxel (D) plus enzalutamide (E) versus docetaxel (D) as first line chemotherapy for patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) (CHEIRON study). O. Caffo, et al

HORMONAL APPROACHES FOR PROSTATE CANCER

851PD – Patient-Reported Outcomes (PROs) From TITAN: a Phase 3, Randomized, Double-Blind Study of Apalutamide (APA) Versus Placebo (PBO) Added to Androgen Deprivation Therapy (ADT) in Patients (pts) With Metastatic Castration-Sensitive Prostate Cancer (mCSPC). N. Agarwal, et al

HORMONAL APPROACHES FOR PROSTATE CANCER

853P – ARCHES – the role of androgen deprivation therapy (ADT) with enzalutamide (ENZA) or placebo (PBO) in metastatic hormone-sensitive prostate cancer (mHSPC): Post hoc analyses of high and low disease volume and risk groups. A. Stenzl, et al

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HORMONAL APPROACHES FOR PROSTATE CANCER

843O – Apalutamide (APA) and Overall Survival (OS) in Patients (pts) With Nonmetastatic Castration Resistant Prostate Cancer (nmCRPC): Updated Results From the Phase 3 SPARTAN Study. M. Smith, et al

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Discussion

HORMONE-SENSITIVE PROSTATE CANCER
STAMPEDE TRIAL

EPICS

HORMONE-SENSITIVE PROSTATE CANCER
STAMPEDE TRIAL (CONT)

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HORMONE-SENSITIVE PROSTATE CANCER
TRIPLE THERAPIES IN PHASE III TRIALS

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CASTRATION-RESISTANT PROSTATE CANCER
PRO AND QOL DATA

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CASTRATION-RESISTANT PROSTATE CANCER
CHEIRON TRIAL

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Castration-Resistant Prostate Cancer – Targeted and Immunotherapies

GERHARDT ATTARD, MD, PHD

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Checkpoint Inhibitors

CASTRATION-RESISTANT PROSTATE CANCER – IMMUNOTHERAPIES

LBA52 – Efficacy and Safety of Nivolumab in Combination With Docetaxel in Men With Metastatic Castration-Resistant Prostate Cancer in CheckMate 9KD. K. Fizazi, et al

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CASTRATION-RESISTANT PROSTATE CANCER – IMMUNOTHERAPIES

LBA51 – CCTG IND 232: A Phase II Study of Durvalumab With or Without Tremelimumab in Patients with Metastatic Castration Resistant Prostate Cancer (mCRPC). S. Hotte, et al

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PARP Inhibitors

CASTRATION-RESISTANT PROSTATE CANCER – TARGETED THERAPIES

LBA12 – PROfound: Phase 3 study of olaparib versus enzalutamide or abiraterone for metastatic castration-resistant prostate cancer (mCRPC) with homologous recombination repair (HRR) gene alterations. M. Hussain, et al

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CASTRATION-RESISTANT PROSTATE CANCER – TARGETED THERAPIES

846PD – Preliminary results from the TRITON2 study of rucaparib in patients (pts) with DNA damage repair (DDR)-deficient metastatic castration-resistant prostate cancer (mCRPC): updated analyses. W.

CASTRATION-RESISTANT PROSTATE CANCER – TARGETED THERAPIES

LBA50 – Pre-specified interim analysis of GALAHAD: phase 2 study of niraparib in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) and biallelic DNA-repair gene defects (DRD).

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ADT-Targeted Therapies

CASTRATION-RESISTANT PROSTATE CANCER – TARGETED THERAPIES

LBA13 – CARD: Randomized, open-label study of cabazitaxel (CBZ) vs abiraterone (ABI) or enzalutamide (ENZ) in metastatic castration-resistant prostate cancer (mCRPC). R. De Wit, et al

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Radionucleotide Therapy

CASTRATION-RESISTANT PROSTATE CANCER – TARGETED THERAPIES

49PD – Preliminary results of a phase I/II dose-escalation study of fractionated dose ^{177}Lu-PSMA-617 for progressive metastatic castration resistant prostate cancer (mCRPC). S.T. Tagawa, et al

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Discussion

CRPC – PARP INHIBITORS
PROFOUND TRIAL

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CRPC – PARP INHIBITORS
PROFOUND TRIAL

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CRPC – PARP INHIBITORS
BRCA ALTERATIONS

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CRPC – PARP INHIBITORS
BRCA TESTING

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CRPC – PARP INHIBITORS
COMBINATIONS

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CRPC – ADT
CARD TRIAL

EPICS

CRPC – IMMUNE CHECKPOINT INHIBITORS

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CRPC – RADIONUCLEOTIDE THERAPY

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PROSTATE CANCER (LBA48_PR DATA NOT PRESENTED)

ADJUVANT VS SALVAGE RADIOTHERAPY

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Updates in Renal Cell Carcinoma

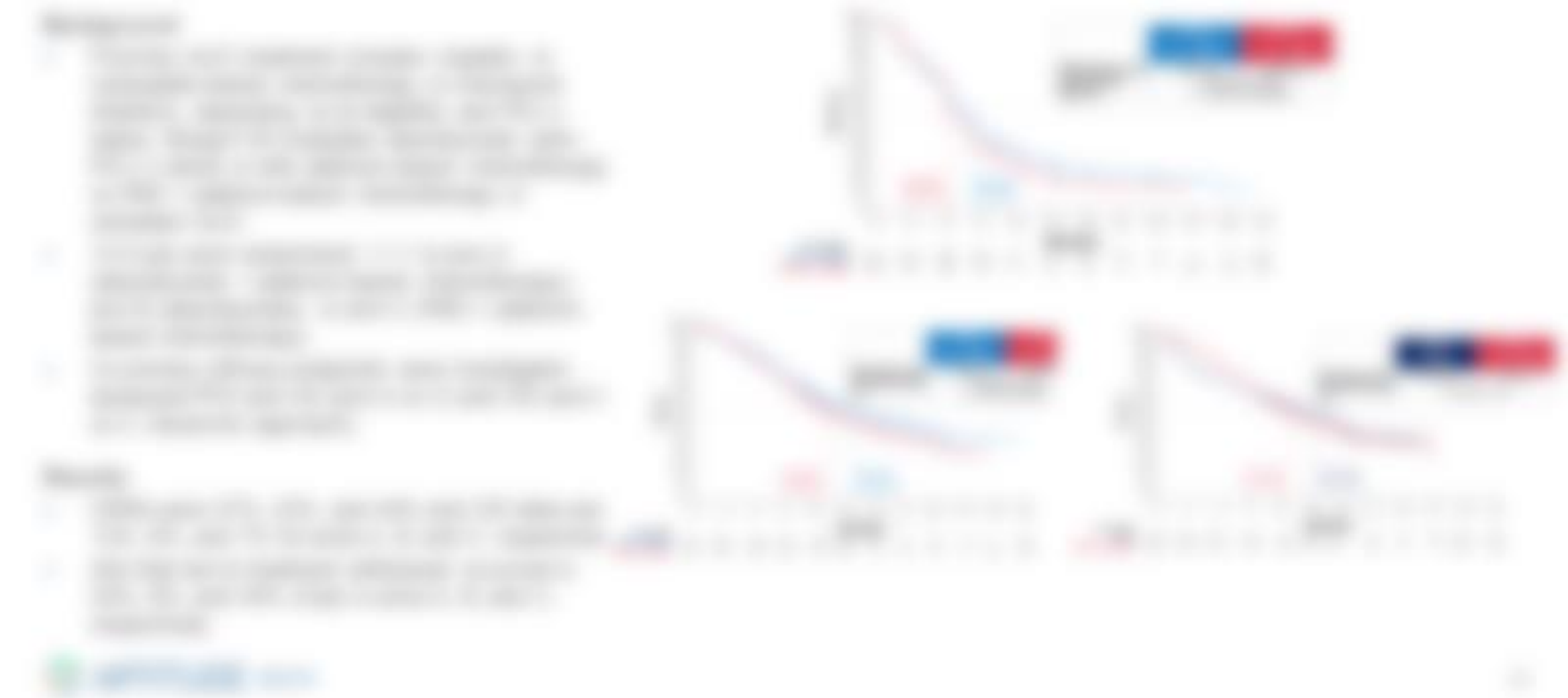
JORGE A. GARCÍA, MD

RCC – ADJUVANT

LBA56 – Primary efficacy analysis results from the SORCE trial (RE05): Adjuvant sorafenib for renal cell carcinoma at intermediate or high risk of relapse: an international, randomised double-blind phase III trial

RCC – MONOTHERAPY

11PDA – First-in-human phase I/II trial of the oral HIF-2a inhibitor PT2977 in patients with advanced RCC. E. Jonasch, et al



RCC – MONOTHERAPY

LBA57 –Tailored ImmunoTherapy Approach with Nivolumab in advanced Renal Cell Carcinoma (TITAN-RCC). M.O. Grimm, et al

RCC – MONOTHERAPY

907PD – ADAPTeR: A phase II study of anti-PD1 (nivolumab) therapy as pre- and post-operative therapy in metastatic renal cell carcinoma. L. Au, et al

RCC – MONOTHERAPY

948P – First-Line Pembrolizumab (pembro) Monotherapy for Advanced Non–Clear Cell Renal Cell Carcinoma (nccRCC): Updated Follow-Up for KEYNOTE-427 Cohort B.C. Suárez, et al

RCC – MONOTHERAPY

949P – First-line pembrolizumab (pembro) monotherapy in advanced clear cell renal cell carcinoma (ccRCC): Updated follow-up for KEYNOTE-427 cohort A.J. Larkin, et al

RCC – COMBINATIONS

LBA54 – ENTRATA: Randomized, double-blind, phase 2 study of telaglenastat (tela; CB-839) + everolimus (E) vs. placebo (pbo) + E in patients (pts) with advanced/metastatic renal cell carcinoma (mRCC). R. Motzer, et al

RCC – COMBINATIONS

1187PD – Phase II study of lenvatinib plus pembrolizumab for disease progression after PD-1/PD-L1 immune checkpoint inhibitor in metastatic clear cell renal cell carcinoma (mccRCC): Results of an interim

RCC – COMBINATIONS

912PD – Results of the Phase 2 TRAXAR Study: A Randomized Phase 2 Trial of Axitinib and TRC105 (TRAX) versus AXitinib (AX) Alone in Patients with Advanced or Metastatic Renal Cell Carcinoma

RCC – COMBINATIONS

947P – TiNivo: Tivozanib combined with nivolumab results in prolonged progression free survival in patients with metastatic renal cell carcinoma (mRCC). Final Results. P. Barthelemy, et al

RCC – COMBINATIONS

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950P – Association Between Depth of Response and Overall Survival: Exploratory Analysis in Patients With Previously Untreated Advanced Renal Cell Carcinoma (aRCC) in CheckMate 214. V. Grünwald, et al

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Discussion

OVERALL IMPRESSIONS ON RCC TRIAL DATA

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RCC
TKI IN ADJUVANT THERAPY

EPICS

RCC
HIF-2α INHIBITOR – MONOTHERAPY

EPICS

RCC
IMMUNE CHECKPOINT INHIBITORS – MONOTHERAPY

EPICS

RCC
COMBINATION THERAPY WITH TKI

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COMBINATION THERAPY WITH TKI

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RCC
COMBINATION THERAPY WITH IMMUNOTHERAPY

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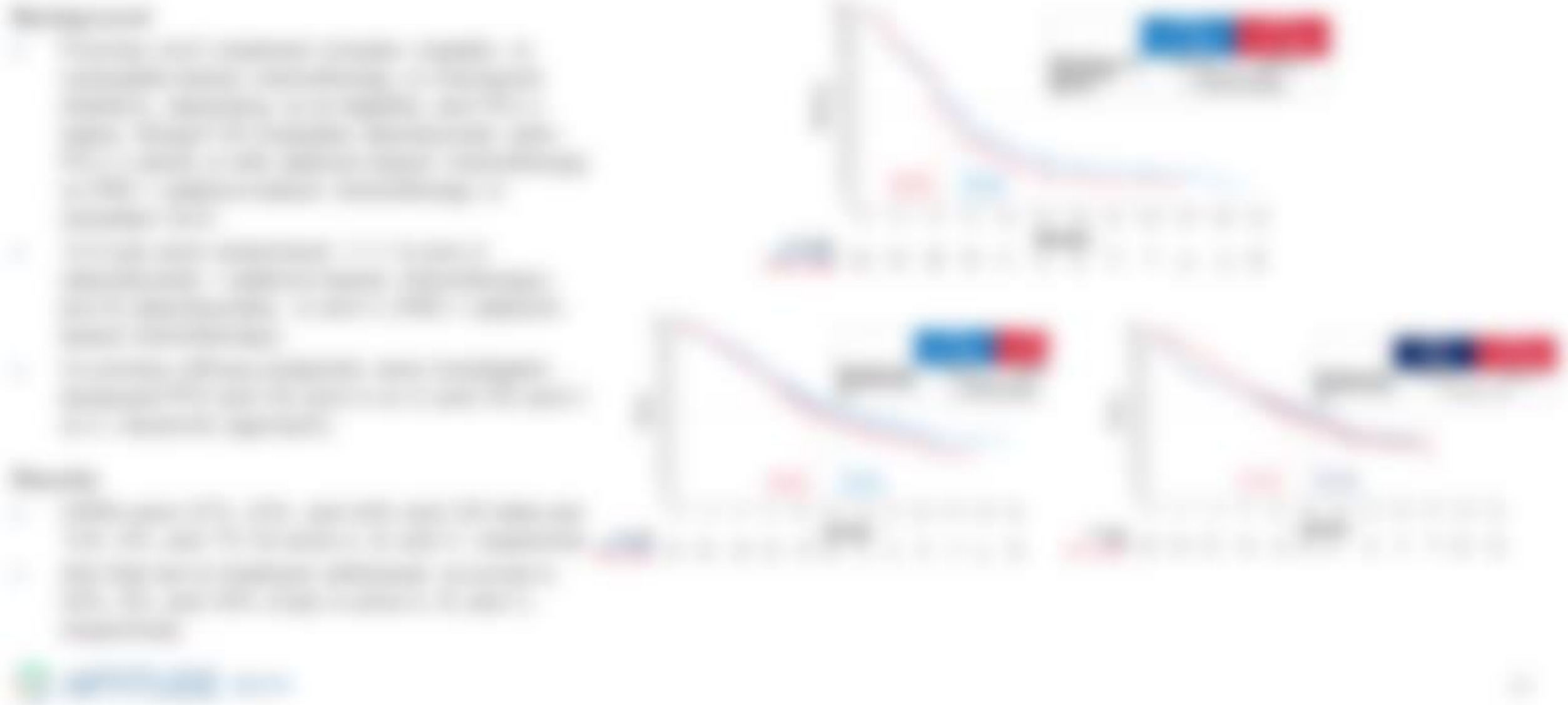
Novel Agents for Urothelial/Bladder Cancers

SCOTT TAGAWA, MD

UROTHELIAL/BLADDER CANCER

LBA14_PR – IMvigor130: efficacy and safety from a Phase 3 study of atezolizumab (atezo) as monotherapy or combined with platinum-based chemotherapy (PBC) vs placebo + PBC in previously untreated locally advanced or metastatic urothelial carcinoma (mUC). E. Grande, et al



UROTHELIAL/BLADDER CANCER

LBA55 – Initial Results From TROPHY-U-01: A Phase 2 Open-Label Study of Sacituzumab Govitecan in Patients (Pts) With Metastatic Urothelial Cancer (mUC) After Failure of Platinum-Based Regimens (PLT) or Immunotherapy. S. Tagawa, et al

UROTHELIAL/BLADDER CANCER

901O – EV-103: Initial results of enfortumab vedotin plus pembrolizumab for locally advanced or metastatic urothelial carcinoma. C. Hoimes, et al

UROTHELIAL/BLADDER CANCER

904PD – Pre-operative ipilimumab and nivolumab in locoregionally advanced, stage III, urothelial cancer (NABUCCO). M. Van Der Heijden, et al

UROTHELIAL/BLADDER CANCER

917P – Clinical activity of vofatamab (V), an FGFR3 selective antibody in combination with pembrolizumab (P) in metastatic urothelial carcinoma (mUC), updated interim analysis of FIERCE-22.

A. Siefker-Radtke, et al

UROTHELIAL/BLADDER CANCER

918P – Atezolizumab (atezo) vs chemotherapy (chemo) in patients (pts) with platinum-treated locally advanced or metastatic urothelial carcinoma (mUC): a long-term overall survival (OS) and safety update from the Phase III IMvigor211 study. M. Van Der Heijden, et al

UROTHELIAL/BLADDER CANCER

919P – Three-Year Follow-Up From the Phase 3 KEYNOTE-045 Trial: Pembrolizumab (Pembro) Versus Investigator's Choice (Paclitaxel, Docetaxel, or Vinflunine) in Recurrent, Advanced Urothelial Cancer (UC). A. Necchi, et al

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UROTHELIAL/BLADDER CANCER

921P – Quality of Life of Metastatic Urothelial Cancer (mUC) Patients Treated with Enfortumab Vedotin (EV) Following Platinum-Containing Chemotherapy and a Checkpoint Inhibitor (CPI): Data from EV-201 Cohort 1. B. McGregor, et al

UROTHELIAL/BLADDER CANCER

916P – Health-Related Quality of Life (HRQoL) and Updated Follow-Up From KEYNOTE-057: Phase 2 Study of Pembrolizumab (pembro) for Patients (pts) With High-Risk (HR) Non–Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus Calmette-Guérin (BCG). R. De Wit, et al

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Discussion

UROTHELIAL/BLADDER CANCER
IMMUNOTHERAPY

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UROTHELIAL/BLADDER CANCER
IMMUNOTHERAPY

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UROTHELIAL/BLADDER CANCER
ANTIBODY-DRUG CONJUGATES

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Key Highlights and Strategic Takeaways

KEY HIGHLIGHTS AND STRATEGIC TAKEAWAYS

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