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EPICS

# CONFERENCE COVERAGE: ESMO 2019 GU HIGHLIGHTS

September 2019

- > 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

## CHAIR

**Daniel Petrylak, MD**

Yale Cancer Center  
New Haven, USA

## ATTENDEES

**Gerhardt Attard, MD, PhD**

University College London  
London, UK

**Oliver Sartor, MD**

Tulane University  
New Orleans, USA

**Jorge A. García, MD**

Cleveland Clinic Taussig Cancer Institute  
Cleveland, USA

**Scott Tagawa, MD**

Weill Cornell Medicine-Cornell University  
New York, USA

**David Quinn, MD, PhD**

University of Southern California  
Los Angeles, USA

# AGENDA

EPICS

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

EPICS

## Hormonal Approaches for Prostate Cancer

DAVID QUINN, MD, PHD

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EPICS

## 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

### Background

- 1. mHSPC is a common cancer with a high burden of disease. Standard first line therapy includes androgen deprivation therapy (ADT) and androgen receptor signaling inhibitors (ARSI).
- 2. The ENZAMET trial is a randomized phase 3 trial comparing enzalutamide (ENZA) with standard first line therapy (ADT + ARSI) for mHSPC. The primary endpoint is overall survival (OS).
- 3. The ENZAMET trial is an ANZUP-led, international, cooperative group trial. The trial is currently ongoing.

### Methods

- 1. The ENZAMET trial is a randomized phase 3 trial comparing enzalutamide (ENZA) with standard first line therapy (ADT + ARSI) for mHSPC. The primary endpoint is overall survival (OS).
- 2. The ENZAMET trial is an ANZUP-led, international, cooperative group trial. The trial is currently ongoing.
- 3. The ENZAMET trial is a randomized phase 3 trial comparing enzalutamide (ENZA) with standard first line therapy (ADT + ARSI) for mHSPC. The primary endpoint is overall survival (OS).

# HORMONAL APPROACHES FOR PROSTATE CANCER

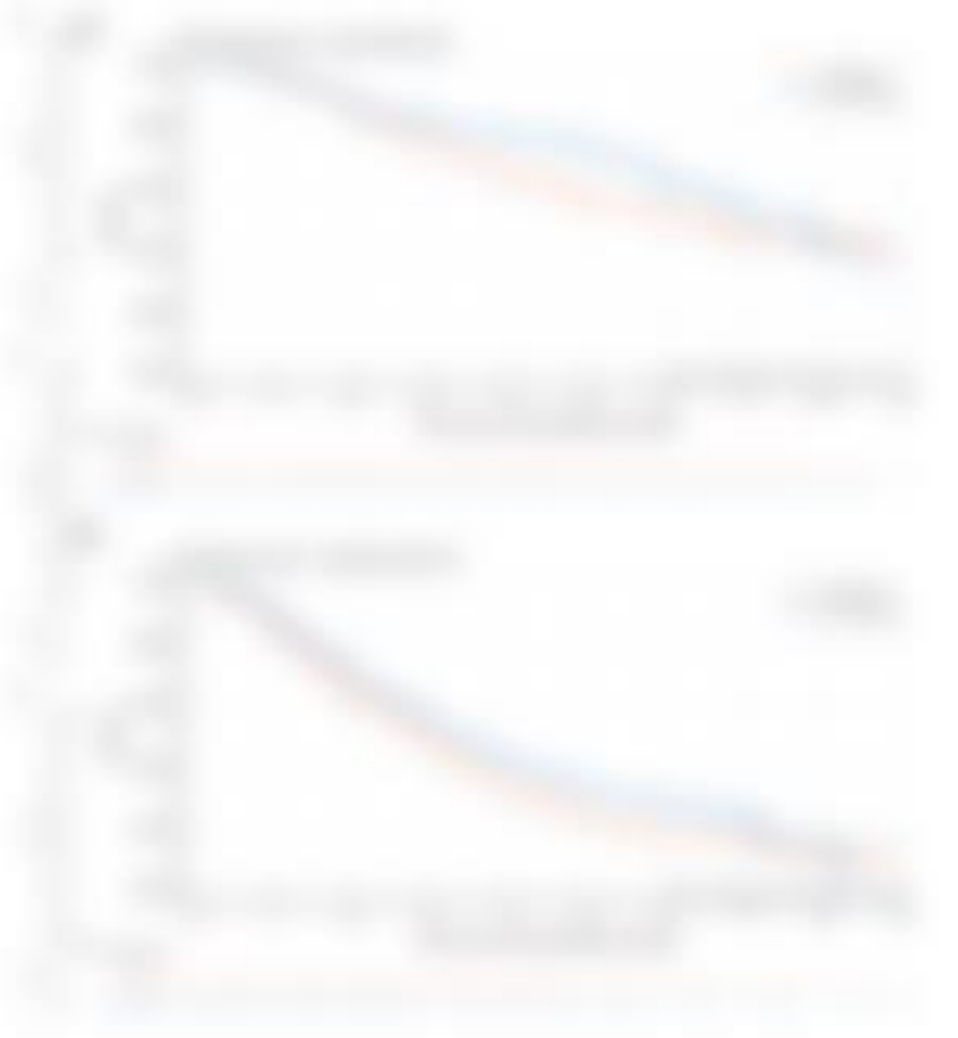
844O – Docetaxel for hormone-naïve prostate cancer: results from long-term follow-up of metastatic (M1) patients in the STAMPEDE randomised trial (NCT00268476) and sub-group analysis by metastatic burden. N. Clarke, et al

**Background:** The STAMPEDE trial (NCT00268476) compared docetaxel plus enzalutamide (DT+ENZ) with enzalutamide alone (ENZ) in hormone-naïve metastatic prostate cancer. The primary endpoint was overall survival (OS). The secondary endpoint was time to progression (TTP). The results of the primary endpoint were published in 2017. The results of the secondary endpoint are presented here.

**Methods:** The STAMPEDE trial was a randomised, controlled, phase III trial. Patients were randomised to DT+ENZ or ENZ. The primary endpoint was OS. The secondary endpoint was TTP. The results of the primary endpoint were published in 2017. The results of the secondary endpoint are presented here.

**Results:** The results of the secondary endpoint (TTP) are presented here. The results show that DT+ENZ significantly improved TTP compared to ENZ. The results are presented in the following table:

Group	TTP (months)
DT+ENZ	18.5
ENZ	15.2





## 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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EPICS

# 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

### Background

- 1. Docetaxel (D) plus enzalutamide (E) versus docetaxel (D) as first line chemotherapy for patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) (CHEIRON study).
- 2. Updated survival analyses of the trial.
- 3. The trial was a multicentric phase II randomized trial.
- 4. The trial compared docetaxel (D) plus enzalutamide (E) versus docetaxel (D) as first line chemotherapy for patients (pts) with metastatic castration-resistant prostate cancer (mCRPC).
- 5. The trial was conducted in a multicentric setting.
- 6. The trial was a phase II randomized trial.
- 7. The trial compared docetaxel (D) plus enzalutamide (E) versus docetaxel (D) as first line chemotherapy for patients (pts) with metastatic castration-resistant prostate cancer (mCRPC).
- 8. The trial was conducted in a multicentric setting.
- 9. The trial was a phase II randomized trial.
- 10. The trial compared docetaxel (D) plus enzalutamide (E) versus docetaxel (D) as first line chemotherapy for patients (pts) with metastatic castration-resistant prostate cancer (mCRPC).

### Methods

- 1. The trial was a multicentric phase II randomized trial.
- 2. The trial compared docetaxel (D) plus enzalutamide (E) versus docetaxel (D) as first line chemotherapy for patients (pts) with metastatic castration-resistant prostate cancer (mCRPC).
- 3. The trial was conducted in a multicentric setting.
- 4. The trial was a phase II randomized trial.
- 5. The trial compared docetaxel (D) plus enzalutamide (E) versus docetaxel (D) as first line chemotherapy for patients (pts) with metastatic castration-resistant prostate cancer (mCRPC).
- 6. The trial was conducted in a multicentric setting.
- 7. The trial was a phase II randomized trial.
- 8. The trial compared docetaxel (D) plus enzalutamide (E) versus docetaxel (D) as first line chemotherapy for patients (pts) with metastatic castration-resistant prostate cancer (mCRPC).
- 9. The trial was conducted in a multicentric setting.
- 10. The trial was a phase II randomized trial.

# 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

## Background

- 1. TITAN is a Phase 3, randomized, double-blind study comparing the efficacy and safety of apalutamide (APA) plus ADT versus placebo (PBO) plus ADT in patients with mCSPC. The primary endpoint is overall survival (OS). Secondary endpoints include time to next androgen deprivation therapy (TADT), time to symptomatic progression (TSP), and time to death from prostate cancer (TDPC).
- 2. Patient-reported outcomes (PROs) are an important component of clinical trials, providing information on the quality of life and patient experience. The PROs collected in TITAN include the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30, EORTC QLQ-PR25, and the Patient Health Questionnaire (PHQ-9).
- 3. The results of the TITAN study will provide valuable information on the efficacy and safety of APA plus ADT versus PBO plus ADT in patients with mCSPC, as well as the impact of treatment on patient-reported outcomes.

## Methods

- 1. The TITAN study is a Phase 3, randomized, double-blind study comparing the efficacy and safety of APA plus ADT versus PBO plus ADT in patients with mCSPC. The study is conducted in a multicenter setting across several countries.
- 2. The primary endpoint is OS, defined as the time from randomization to death from any cause. Secondary endpoints include TADT, TSP, and TDPC. The study also collects PROs using the EORTC QLQ-C30, EORTC QLQ-PR25, and the PHQ-9.
- 3. The results of the TITAN study will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in 2020.



# 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

## Background

- 1. nmCRPC is a clinical entity characterized by a rising PSA level, but without radiographic evidence of metastasis.
- 2. The SPARTAN study is a phase 3, randomized, controlled trial comparing the efficacy and safety of enzalutamide (ENZA) and apalutamide (APA) in nmCRPC.
- 3. The primary endpoint of the study is OS. Secondary endpoints include time to radiographic progression, time to biochemical progression, and quality of life.
- 4. The study has shown that both ENZA and APA significantly improve OS compared to placebo in nmCRPC.
- 5. The study also showed that APA has a higher rate of adverse events compared to ENZA.

## Methods

- 1. The study included 1,917 patients with nmCRPC who were randomized to receive ENZA, APA, or placebo.
- 2. The study was conducted in a double-blind, randomized, controlled manner.
- 3. The study included a prespecified interim analysis.
- 4. The study included a prespecified subgroup analysis.
- 5. The study included a prespecified sensitivity analysis.

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EPICS

Discussion

# HORMONE-SENSITIVE PROSTATE CANCER

## STAMPEDE TRIAL

- 1. The STAMPEDE trial is a phase III, randomized, controlled trial comparing the effectiveness of two treatment strategies for hormone-sensitive prostate cancer. The trial is designed to evaluate the impact of adding docetaxel to androgen deprivation therapy (ADT) on overall survival and quality of life. The trial is currently ongoing and has recruited over 1,000 patients.
- 2. The trial is designed to evaluate the impact of adding docetaxel to ADT on overall survival and quality of life. The trial is currently ongoing and has recruited over 1,000 patients.
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# HORMONE-SENSITIVE PROSTATE CANCER

## STAMPEDE TRIAL (CONT)

# HORMONE-SENSITIVE PROSTATE CANCER

## TRIPLE THERAPIES IN PHASE III TRIALS

- The first phase III trial comparing a combination of enzalutamide, abiraterone, and androgen deprivation therapy (ADT) to ADT alone in hormone-sensitive prostate cancer was the PROSPER trial. The results of this trial showed that the combination of enzalutamide and abiraterone significantly improved overall survival compared to ADT alone in patients with hormone-sensitive prostate cancer.
- The second phase III trial comparing a combination of enzalutamide, abiraterone, and ADT to ADT alone was the PROSPER trial. The results of this trial showed that the combination of enzalutamide and abiraterone significantly improved overall survival compared to ADT alone in patients with hormone-sensitive prostate cancer.
- The third phase III trial comparing a combination of enzalutamide, abiraterone, and ADT to ADT alone was the PROSPER trial. The results of this trial showed that the combination of enzalutamide and abiraterone significantly improved overall survival compared to ADT alone in patients with hormone-sensitive prostate cancer.
- The fourth phase III trial comparing a combination of enzalutamide, abiraterone, and ADT to ADT alone was the PROSPER trial. The results of this trial showed that the combination of enzalutamide and abiraterone significantly improved overall survival compared to ADT alone in patients with hormone-sensitive prostate cancer.
- The fifth phase III trial comparing a combination of enzalutamide, abiraterone, and ADT to ADT alone was the PROSPER trial. The results of this trial showed that the combination of enzalutamide and abiraterone significantly improved overall survival compared to ADT alone in patients with hormone-sensitive prostate cancer.

# CASTRATION-RESISTANT PROSTATE CANCER

## PRO AND QOL DATA

- 1. The primary objective of this study is to evaluate the efficacy and safety of the study treatment compared to the control treatment in terms of overall survival, progression-free survival, and quality of life.
- 2. The secondary objectives of this study are to evaluate the efficacy and safety of the study treatment compared to the control treatment in terms of overall survival, progression-free survival, and quality of life.
- 3. The tertiary objectives of this study are to evaluate the efficacy and safety of the study treatment compared to the control treatment in terms of overall survival, progression-free survival, and quality of life.
- 4. The study will be conducted in a randomized, controlled, phase III manner.

# CASTRATION-RESISTANT PROSTATE CANCER

## CHEIRON TRIAL

- The trial was designed to test the effect of the combination of enzalutamide and abiraterone, compared with enzalutamide alone, on overall survival in men with castration-resistant prostate cancer who had not received prior hormonal therapy. The primary endpoint was overall survival. Secondary endpoints included time to progression, time to next systemic therapy, quality of life, and safety. The trial was conducted in a randomized, controlled, open-label manner. The results of the trial are presented below.
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**EPICS**

## **Castration-Resistant Prostate Cancer – Targeted and Immunotherapies**

GERHARDT ATTARD, MD, PHD

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EPICS

**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

- The primary endpoint was overall survival (OS) in the intention-to-treat population. Secondary endpoints included time to progression (TTP), time to symptomatic progression (TSP), and time to death due to prostate cancer (TTPC).
- In the primary analysis, OS was significantly improved in the combination group compared with docetaxel monotherapy (HR 0.78, 95% CI 0.65-0.94, P = 0.011). TTP, TSP, and TTPC were also significantly improved in the combination group.
- In the secondary analysis, OS was significantly improved in the combination group compared with docetaxel monotherapy (HR 0.78, 95% CI 0.65-0.94, P = 0.011). TTP, TSP, and TTPC were also significantly improved in the combination group.
- The combination of nivolumab and docetaxel is a promising treatment option for men with metastatic CRPC.

# 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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EPICS

**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

## Background

- mCRPC is the leading cause of cancer death in men
- Standard of care for mCRPC is androgen deprivation therapy (ADT) and androgen receptor (AR) targeted therapies (enzalutamide or abiraterone)
- PARP inhibitors (olaparib) are a novel class of targeted therapies that inhibit the DNA repair pathway known as homologous recombination repair (HRR)

## Methods

- PROfound was a phase 3, randomized, controlled trial comparing olaparib to enzalutamide or abiraterone in men with mCRPC and HRR gene alterations
- The primary endpoint was overall survival (OS)
- Secondary endpoints included time to progression (TTP), quality of life (QoL), and adverse events
- The trial was stratified by HRR gene alteration status (HRR vs. non-HRR)
- The results showed that olaparib significantly improved OS compared to enzalutamide or abiraterone in the HRR group



# 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.

- The TRITON2 study is a phase 1b/2a study evaluating the safety, tolerability, and efficacy of rucaparib in patients with mCRPC who have a germline or somatic mutation in a DNA repair gene (BRCA1, BRCA2, PALB1, or ATM). The study is ongoing, and preliminary results from the phase 1b portion of the study have been reported.
- In the phase 1b study, rucaparib was administered at doses of 100 mg, 200 mg, and 400 mg twice daily. The most common adverse events (AEs) were fatigue, nausea, and diarrhea. The study also evaluated the efficacy of rucaparib in terms of PSA response and time to next anti-androgen therapy.
- Preliminary results from the phase 1b study showed that rucaparib was well-tolerated at doses up to 400 mg twice daily. The most common AEs were fatigue, nausea, and diarrhea. The study also showed that rucaparib was effective in terms of PSA response and time to next anti-androgen therapy.
- The phase 2a portion of the study is currently ongoing, and will evaluate the efficacy of rucaparib in terms of PSA response and time to next anti-androgen therapy in a larger population of patients with mCRPC who have a germline or somatic mutation in a DNA repair gene.

# 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).

- The study was designed to evaluate the efficacy and safety of niraparib in patients with mCRPC and DRD. The primary endpoint was overall survival (OS). Secondary endpoints included progression-free survival (PFS), time to next treatment (TTNT), and quality of life (QoL). The study was conducted in a randomized, controlled manner, comparing niraparib to a placebo. The results of the study showed that niraparib significantly improved OS compared to placebo in patients with mCRPC and DRD. The median OS was significantly longer in the niraparib group than in the placebo group. The results also showed that niraparib was well-tolerated, with a manageable safety profile. The study was well-powered to detect a difference in OS between the two groups. The results of the study are consistent with the hypothesis that niraparib is effective in patients with mCRPC and DRD. The study was well-conducted and the results are reliable. The study was well-powered to detect a difference in OS between the two groups. The results of the study are consistent with the hypothesis that niraparib is effective in patients with mCRPC and DRD.
- The study was designed to evaluate the efficacy and safety of niraparib in patients with mCRPC and DRD. The primary endpoint was overall survival (OS). Secondary endpoints included progression-free survival (PFS), time to next treatment (TTNT), and quality of life (QoL). The study was conducted in a randomized, controlled manner, comparing niraparib to a placebo. The results of the study showed that niraparib significantly improved OS compared to placebo in patients with mCRPC and DRD. The median OS was significantly longer in the niraparib group than in the placebo group. The results also showed that niraparib was well-tolerated, with a manageable safety profile. The study was well-powered to detect a difference in OS between the two groups. The results of the study are consistent with the hypothesis that niraparib is effective in patients with mCRPC and DRD.
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- The study was designed to evaluate the efficacy and safety of niraparib in patients with mCRPC and DRD. The primary endpoint was overall survival (OS). Secondary endpoints included progression-free survival (PFS), time to next treatment (TTNT), and quality of life (QoL). The study was conducted in a randomized, controlled manner, comparing niraparib to a placebo. The results of the study showed that niraparib significantly improved OS compared to placebo in patients with mCRPC and DRD. The median OS was significantly longer in the niraparib group than in the placebo group. The results also showed that niraparib was well-tolerated, with a manageable safety profile. The study was well-powered to detect a difference in OS between the two groups. The results of the study are consistent with the hypothesis that niraparib is effective in patients with mCRPC and DRD.



**EPICS**

**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

- The CARD trial was a randomized, open-label, phase III study comparing cabazitaxel (CBZ) plus prednisone (P) versus abiraterone (ABI) plus prednisone (P) or enzalutamide (ENZ) plus prednisone (P) in patients with metastatic castration-resistant prostate cancer (mCRPC). The primary endpoint was overall survival (OS). The study was stratified by prior docetaxel treatment. In the docetaxel-naïve population, the median OS was significantly longer in the CBZ+P group compared to the ABI+P group (14.1 months vs 11.6 months, p=0.0004). In the docetaxel-pretreated population, the median OS was significantly longer in the CBZ+P group compared to the ENZ+P group (11.1 months vs 8.4 months, p=0.0004). The study was terminated early due to the significant difference in OS between the CBZ+P group and the ABI+P group in the docetaxel-naïve population.
- The study was terminated early due to the significant difference in OS between the CBZ+P group and the ABI+P group in the docetaxel-naïve population.
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- The study was terminated early due to the significant difference in OS between the CBZ+P group and the ABI+P group in the docetaxel-naïve population.

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EPICS

**Radionuclide Therapy**

# CASTRATION-RESISTANT PROSTATE CANCER – TARGETED THERAPIES

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

- Objective: To evaluate the efficacy and toxicity of fractionated dose <sup>177</sup>Lu-PSMA-617 in patients with progressive mCRPC.
- Design: Phase I/II dose-escalation study.
- Setting: Memorial Sloan-Kettering Cancer Center, New York.
- Participants: 20 patients with progressive mCRPC.
- Interventions: Fractionated dose <sup>177</sup>Lu-PSMA-617.
- Measurements and Main Results: Preliminary results show that fractionated dose <sup>177</sup>Lu-PSMA-617 is well-tolerated and effective in patients with progressive mCRPC.
- Conclusions: Fractionated dose <sup>177</sup>Lu-PSMA-617 is a promising treatment for progressive mCRPC.
- Limitations: Small sample size, preliminary results.
- Future Research: Larger phase III study.



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EPICS

Discussion

# CRPC – PARP INHIBITORS PROFOUND TRIAL



# CRPC – PARP INHIBITORS

## PROFOUND TRIAL

- 1. The PROFOUND trial is a phase III, randomized, controlled trial comparing the efficacy and safety of olaparib versus placebo in combination with enzalutamide and abiraterone in patients with castration-resistant prostate cancer (CRPC) who have not received prior systemic therapy for CRPC. The trial is designed to evaluate the impact of PARP inhibition on overall survival and progression-free survival in this population.
- 2. The trial is currently recruiting patients and is expected to complete enrollment by late 2023. The primary endpoint is overall survival, and the secondary endpoints include progression-free survival, quality of life, and adverse events.

# CRPC – PARP INHIBITORS

## BRCA ALTERATIONS

- PARP inhibitors are a class of drugs that block the function of the PARP enzyme, which is involved in DNA repair. In the context of cancer, PARP inhibitors are used to treat certain types of cancer, including breast cancer, ovarian cancer, and pancreatic cancer.
- PARP inhibitors are most effective in cancers that have a deficiency in the BRCA1 or BRCA2 genes. These genes are responsible for a type of DNA repair called homologous recombination. When there is a deficiency in these genes, the cancer cells are more vulnerable to the effects of PARP inhibitors.
- PARP inhibitors are used in combination with other treatments, such as chemotherapy and radiation therapy, to improve outcomes in cancer patients. They are also being studied in clinical trials for the treatment of other types of cancer.
- PARP inhibitors are generally well-tolerated, but they can cause side effects such as fatigue, nausea, and hair loss. They can also interact with other medications, so it is important to discuss all medications with your healthcare provider.

# CRPC – PARP INHIBITORS

## BRCA TESTING

- 1. PARP inhibitors are a class of drugs that block the action of the PARP enzyme, which is involved in DNA repair. They are used to treat certain types of cancer, including ovarian, breast, and pancreatic cancer.
- 2. PARP inhibitors are most effective in patients with BRCA1 or BRCA2 gene mutations. These mutations increase the risk of developing certain types of cancer, including breast and ovarian cancer. PARP inhibitors work by blocking the repair of DNA damage, which can lead to the death of cancer cells.
- 3. PARP inhibitors are also used to treat certain types of cancer in patients who have already received other treatments, such as chemotherapy and radiation therapy. They are often used in combination with other drugs to improve outcomes.
- 4. PARP inhibitors are generally well-tolerated, but they can cause side effects, including fatigue, nausea, and hair loss. They are also contraindicated in patients with certain types of blood disorders and liver disease.
- 5. PARP inhibitors are a promising new class of cancer drugs, and they are being studied in many clinical trials. They are expected to play an important role in the treatment of certain types of cancer in the future.

# CRPC – PARP INHIBITORS COMBINATIONS

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- 1. The first line of treatment for metastatic CRPC is androgen deprivation therapy (ADT). ADT is the most effective treatment for CRPC and is the standard of care for all patients with CRPC.
- 2. The second line of treatment for metastatic CRPC is androgen receptor signaling inhibitors (ARSIs). ARSIs are a class of drugs that block the androgen receptor, which is the protein that allows androgens to stimulate the growth of CRPC cells. ARSIs are the most effective treatment for CRPC after ADT and are the standard of care for all patients with CRPC.
- 3. The third line of treatment for metastatic CRPC is androgen receptor signaling inhibitors (ARSIs). ARSIs are a class of drugs that block the androgen receptor, which is the protein that allows androgens to stimulate the growth of CRPC cells. ARSIs are the most effective treatment for CRPC after ADT and are the standard of care for all patients with CRPC.
- 4. The fourth line of treatment for metastatic CRPC is androgen receptor signaling inhibitors (ARSIs). ARSIs are a class of drugs that block the androgen receptor, which is the protein that allows androgens to stimulate the growth of CRPC cells. ARSIs are the most effective treatment for CRPC after ADT and are the standard of care for all patients with CRPC.
- 5. The fifth line of treatment for metastatic CRPC is androgen receptor signaling inhibitors (ARSIs). ARSIs are a class of drugs that block the androgen receptor, which is the protein that allows androgens to stimulate the growth of CRPC cells. ARSIs are the most effective treatment for CRPC after ADT and are the standard of care for all patients with CRPC.





# PROSTATE CANCER (LBA48\_PR DATA NOT PRESENTED)

## ADJUVANT VS SALVAGE RADIOTHERAPY

EPICS

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**EPICS**

# **Updates in Renal Cell Carcinoma**

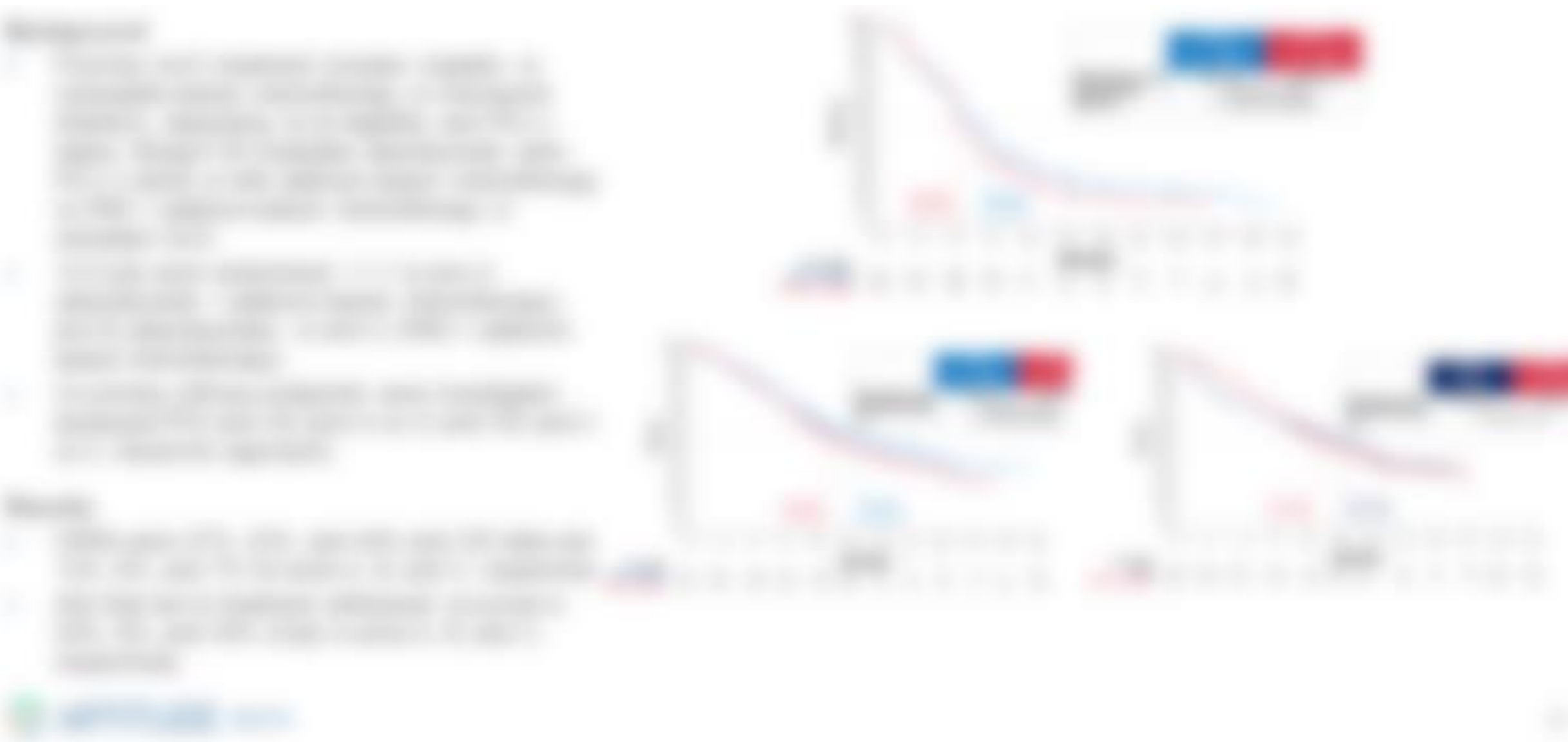
JORGE A. GARCÍA, MD

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

- The SORCE trial was a randomised, double-blind, phase III trial comparing adjuvant sorafenib with placebo in patients with renal cell carcinoma at intermediate or high risk of relapse. The primary endpoint was overall survival. The trial was conducted in 12 countries and included 1011 patients. The results showed that adjuvant sorafenib significantly improved overall survival compared with placebo in the intermediate risk group, but not in the high risk group. The trial was stopped early due to futility in the high risk group.
- The primary endpoint of overall survival was not significantly improved in the high risk group. The results showed that adjuvant sorafenib significantly improved overall survival compared with placebo in the intermediate risk group, but not in the high risk group. The trial was stopped early due to futility in the high risk group.
- The secondary endpoint of progression-free survival was not significantly improved in the high risk group. The results showed that adjuvant sorafenib significantly improved progression-free survival compared with placebo in the intermediate risk group, but not in the high risk group. The trial was stopped early due to futility in the high risk group.
- The safety profile of adjuvant sorafenib was consistent with the known safety profile of sorafenib. The most common adverse events were fatigue, diarrhoea, and hand-foot skin reaction. The trial was stopped early due to futility in the high risk group.

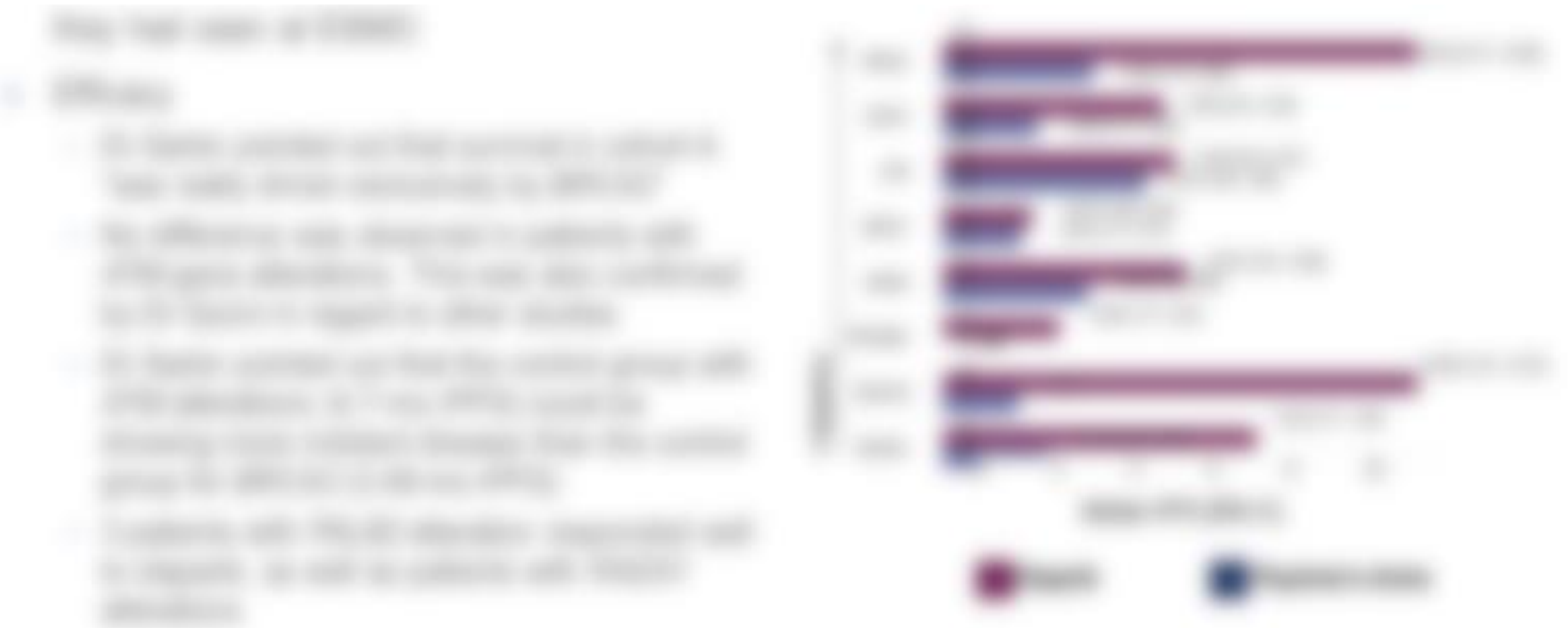
RCC – MONOTHERAPY

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

- Objective: To evaluate the efficacy and safety of nivolumab as pre- and post-operative therapy in metastatic renal cell carcinoma (mRCC). The primary endpoint is overall survival (OS) at 24 months. Secondary endpoints include progression-free survival (PFS), objective response rate (ORR), and adverse events (AE). The study is a phase II, randomized, controlled trial comparing nivolumab to placebo in patients with mRCC who have undergone partial or total nephrectomy. The study is currently recruiting patients.
- Design: Phase II, randomized, controlled trial comparing nivolumab to placebo in patients with mRCC who have undergone partial or total nephrectomy. The study is currently recruiting patients.
- Setting: Multiple sites across the United States and internationally.
- Population: Patients with mRCC who have undergone partial or total nephrectomy.
- Intervention: Nivolumab (anti-PD1) or placebo.
- Comparison: Placebo.
- Results: Preliminary results show that nivolumab is well-tolerated and has a higher ORR compared to placebo. OS and PFS are being monitored.

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

- Objective: To report the efficacy and safety of pembrolizumab monotherapy in the first-line treatment of advanced nccRCC in the KEYNOTE-427 cohort B.
- Methods: This is a phase 3, randomized, controlled trial comparing pembrolizumab monotherapy with standard of care (SOC) in the first-line treatment of advanced nccRCC. The primary endpoint was overall survival (OS). Secondary endpoints included progression-free survival (PFS), objective response rate (ORR), and safety.
- Results: The trial included 427 patients. The pembrolizumab group showed significantly improved OS compared to the SOC group (p < 0.001). The median OS was 15.1 months for the pembrolizumab group versus 11.5 months for the SOC group. The ORR was 44.1% for the pembrolizumab group versus 28.3% for the SOC group. The most common adverse events were fatigue, decreased appetite, and weight loss.
- Conclusion: Pembrolizumab monotherapy significantly improved OS and ORR compared to SOC in the first-line treatment of advanced nccRCC.



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

- Objective: To report the efficacy and safety of pembrolizumab monotherapy in the first-line treatment of advanced clear cell renal cell carcinoma (ccRCC) in the KEYNOTE-427 cohort. The primary endpoint was overall survival (OS) at 12 months. Secondary endpoints included progression-free survival (PFS), objective response rate (ORR), and adverse events (AEs).
- Design: A phase 3, randomized, controlled trial comparing pembrolizumab monotherapy to standard of care (SOC) in the first-line treatment of advanced ccRCC. The trial was conducted in a multicenter setting across several countries.
- Setting: The trial was conducted in a multicenter setting across several countries.
- Participants: The study included patients with advanced ccRCC who had not received prior systemic therapy for their disease. The patients were randomized to receive either pembrolizumab monotherapy or SOC.
- Interventions: The intervention group received pembrolizumab monotherapy, while the control group received SOC.
- Measurements and Main Results: The primary endpoint, OS at 12 months, was significantly higher in the pembrolizumab group compared to the SOC group. Secondary endpoints, including PFS and ORR, also showed favorable results for the pembrolizumab group. AEs were manageable and similar between the two groups.
- Conclusions: Pembrolizumab monotherapy demonstrated superior efficacy and acceptable safety in the first-line treatment of advanced ccRCC compared to SOC. These findings support the use of pembrolizumab as a first-line treatment option for patients with advanced ccRCC.

## 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



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

- The study was designed to evaluate the efficacy and safety of lenvatinib plus pembrolizumab in patients with metastatic clear cell renal cell carcinoma (mccRCC) who had previously received a PD-1/PD-L1 immune checkpoint inhibitor. The primary endpoint was overall survival (OS). Secondary endpoints included progression-free survival (PFS), objective response rate (ORR), and safety. The study was conducted in a randomized, controlled manner, comparing the combination of lenvatinib plus pembrolizumab to lenvatinib monotherapy. The results of the interim analysis showed that the combination of lenvatinib plus pembrolizumab significantly improved OS compared to lenvatinib monotherapy. The ORR and PFS were also significantly higher in the combination group. The safety profile of the combination was manageable, with no new safety signals identified.
- The study was designed to evaluate the efficacy and safety of lenvatinib plus pembrolizumab in patients with metastatic clear cell renal cell carcinoma (mccRCC) who had previously received a PD-1/PD-L1 immune checkpoint inhibitor. The primary endpoint was overall survival (OS). Secondary endpoints included progression-free survival (PFS), objective response rate (ORR), and safety. The study was conducted in a randomized, controlled manner, comparing the combination of lenvatinib plus pembrolizumab to lenvatinib monotherapy. The results of the interim analysis showed that the combination of lenvatinib plus pembrolizumab significantly improved OS compared to lenvatinib monotherapy. The ORR and PFS were also significantly higher in the combination group. The safety profile of the combination was manageable, with no new safety signals identified.
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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

- The TRAXAR study was a randomized, controlled, phase 2 trial comparing the combination of axitinib and TRC105 (TRAX) to axitinib monotherapy (AX) in patients with advanced or metastatic renal cell carcinoma (RCC). The primary endpoint was overall survival (OS). Secondary endpoints included progression-free survival (PFS), objective response rate (ORR), and safety. The study was conducted in a 1:1 ratio, with patients randomized to either the TRAX or AX group. The results of the study showed that the TRAX group had a significantly higher OS compared to the AX group. The median OS for the TRAX group was 18.5 months, while for the AX group it was 14.2 months. The difference was statistically significant (p < 0.001). Additionally, the TRAX group also showed a higher PFS and ORR compared to the AX group. The median PFS for the TRAX group was 10.2 months, while for the AX group it was 7.8 months (p < 0.001). The ORR for the TRAX group was 45.2%, compared to 38.5% for the AX group (p = 0.02). Regarding safety, the TRAX group experienced a higher rate of adverse events compared to the AX group. The most common adverse events in the TRAX group were fatigue, weight loss, and decreased appetite. In the AX group, the most common adverse events were fatigue, weight loss, and decreased appetite. The study concluded that the combination of axitinib and TRC105 (TRAX) is superior to axitinib monotherapy (AX) in terms of OS, PFS, and ORR in patients with advanced or metastatic RCC.
- The TRAXAR study was a randomized, controlled, phase 2 trial comparing the combination of axitinib and TRC105 (TRAX) to axitinib monotherapy (AX) in patients with advanced or metastatic renal cell carcinoma (RCC). The primary endpoint was overall survival (OS). Secondary endpoints included progression-free survival (PFS), objective response rate (ORR), and safety. The study was conducted in a 1:1 ratio, with patients randomized to either the TRAX or AX group. The results of the study showed that the TRAX group had a significantly higher OS compared to the AX group. The median OS for the TRAX group was 18.5 months, while for the AX group it was 14.2 months. The difference was statistically significant (p < 0.001). Additionally, the TRAX group also showed a higher PFS and ORR compared to the AX group. The median PFS for the TRAX group was 10.2 months, while for the AX group it was 7.8 months (p < 0.001). The ORR for the TRAX group was 45.2%, compared to 38.5% for the AX group (p = 0.02). Regarding safety, the TRAX group experienced a higher rate of adverse events compared to the AX group. The most common adverse events in the TRAX group were fatigue, weight loss, and decreased appetite. In the AX group, the most common adverse events were fatigue, weight loss, and decreased appetite. The study concluded that the combination of axitinib and TRC105 (TRAX) is superior to axitinib monotherapy (AX) in terms of OS, PFS, and ORR in patients with advanced or metastatic RCC.
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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

- The primary objective of the CheckMate 214 trial was to evaluate the efficacy and safety of nivolumab plus ipilimumab compared with nivolumab monotherapy in patients with previously untreated advanced renal cell carcinoma (aRCC). The trial is a phase 3, randomized, controlled study. The primary endpoint is overall survival (OS). Secondary endpoints include progression-free survival (PFS), objective response rate (ORR), and safety. The trial is ongoing, and results are being analyzed.
- The exploratory analysis of the CheckMate 214 trial evaluated the association between depth of response (DoR) and overall survival (OS) in patients with previously untreated aRCC. The analysis included patients who had achieved a partial response (PR) or better. The results showed that patients who achieved a PR or better had a significantly higher OS compared to patients who did not achieve a PR or better. This suggests that DoR is a strong predictor of OS in this population.
- The exploratory analysis also evaluated the association between DoR and other clinical outcomes, including PFS and ORR. The results showed that patients who achieved a PR or better had a significantly higher PFS and ORR compared to patients who did not achieve a PR or better. This suggests that DoR is also a strong predictor of PFS and ORR in this population.
- The exploratory analysis also evaluated the association between DoR and safety. The results showed that patients who achieved a PR or better had a similar safety profile to patients who did not achieve a PR or better. This suggests that DoR is not a strong predictor of safety in this population.



**EPICS**

**Discussion**

# OVERALL IMPRESSIONS ON RCC TRIAL DATA

Overall impressions on RCC trial data. The trial was well conducted and the data was well analyzed. The results were positive and the trial was a success. The data was well analyzed and the results were positive. The trial was a success.



# RCC

## TKI IN ADJUVANT THERAPY

- The primary aim of the study was to evaluate the efficacy and safety of the combination of sunitinib and everolimus compared with sunitinib monotherapy in patients with metastatic RCC.
- Secondary aims included:
  - To evaluate the overall survival (OS) in patients with metastatic RCC.
  - To evaluate the progression-free survival (PFS) in patients with metastatic RCC.
- The study was a phase III, randomized, controlled trial. Patients were randomized to receive either sunitinib monotherapy or the combination of sunitinib and everolimus.

## HIF-2 $\alpha$ INHIBITOR – MONOTHERAPY

- In phase 1 studies, the HIF-2 $\alpha$  inhibitor, belzutamide, was shown to be well-tolerated and to have a dose-limiting toxicity (DLT) of myelosuppression, leading to the decision to use a lower dose in phase 2 studies.
- In phase 2 studies:
  - The HIF-2 $\alpha$  inhibitor, belzutamide, was shown to have a DLT of myelosuppression, leading to the decision to use a lower dose in phase 3 studies.
  - The HIF-2 $\alpha$  inhibitor, belzutamide, was shown to have a DLT of myelosuppression, leading to the decision to use a lower dose in phase 3 studies.
- In phase 3 studies, the HIF-2 $\alpha$  inhibitor, belzutamide, was shown to have a DLT of myelosuppression, leading to the decision to use a lower dose in phase 3 studies.

# IMMUNE CHECKPOINT INHIBITORS – MONOTHERAPY

- The immune system is responsible for the body's defense against cancer cells. Immune cells, called T cells, recognize and kill cancer cells. However, cancer cells can sometimes evade the immune system by using immune checkpoint proteins to hide from T cells. Immune checkpoint inhibitors (ICIs) are drugs that block these proteins, allowing T cells to recognize and kill cancer cells more effectively.

  - ICIs are used to treat various types of cancer, including melanoma, lung cancer, kidney cancer, and bladder cancer. They are often used in combination with other treatments, such as surgery, chemotherapy, and radiation therapy.
- The most common side effects of ICIs are fatigue, muscle pain, and joint pain. These side effects are usually mild and can be managed with pain relievers. However, some patients may experience more serious side effects, such as liver damage, lung disease, and autoimmune disorders. These side effects are rare but can be life-threatening.
- ICIs are a promising new class of cancer treatment. They have shown significant improvements in survival and quality of life for many cancer patients. However, more research is needed to determine the best way to use these drugs and to identify the patients who will benefit most from them.

# RCC COMBINATION THERAPY WITH TKI

# RCC COMBINATION THERAPY WITH TKI

# RCC

## COMBINATION THERAPY WITH TKI

1. The combination of a tyrosine kinase inhibitor (TKI) with a mTOR inhibitor is a standard of care for the treatment of advanced renal cell carcinoma (RCC). This combination has been shown to improve overall survival compared to monotherapy with either agent alone. The most commonly used TKI in this combination is sunitinib, and the most commonly used mTOR inhibitor is everolimus. This combination is typically used in patients who have not received prior systemic therapy for RCC. The combination is typically used in patients who have not received prior systemic therapy for RCC.

# RCC

## COMBINATION THERAPY WITH TKI

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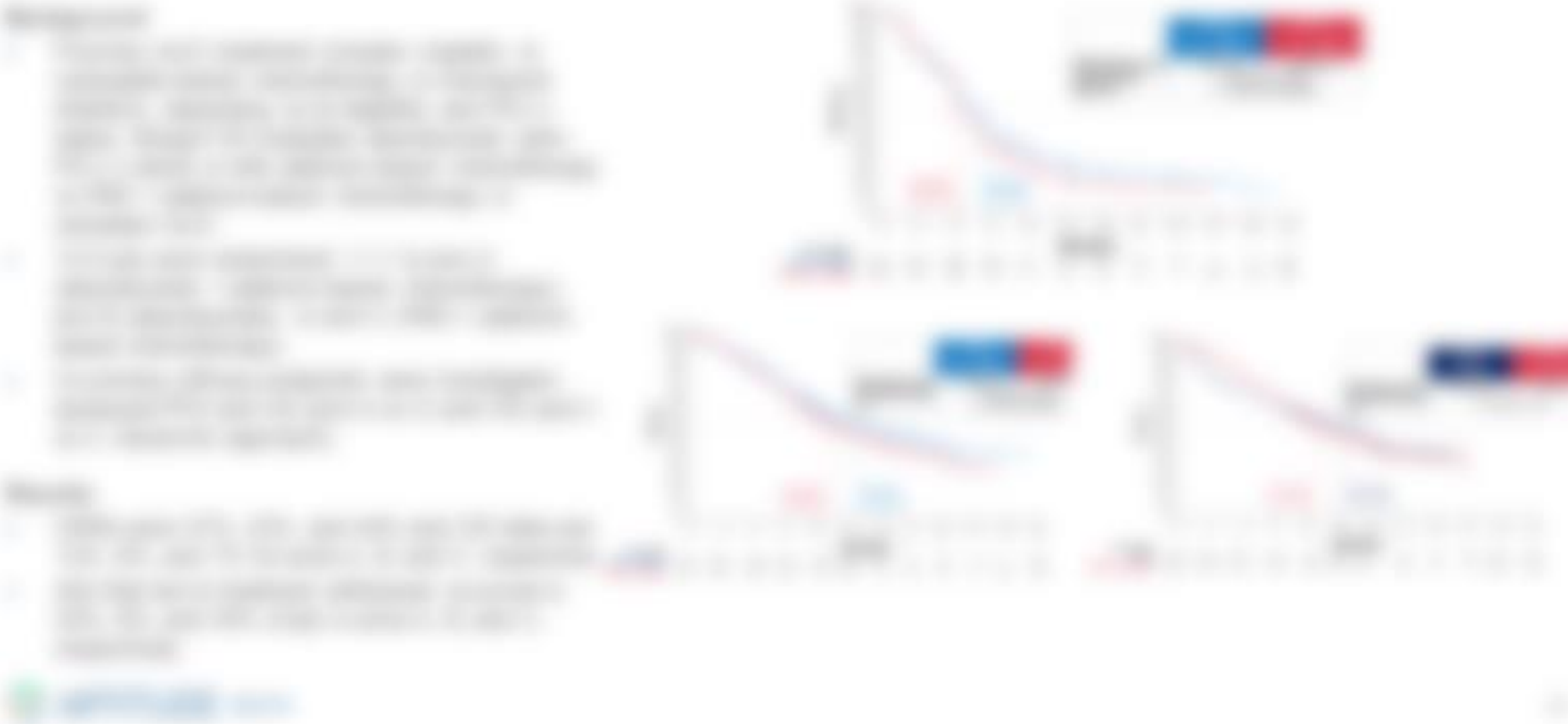
EPICS

## 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

EPICS

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

- Objective: To evaluate the efficacy and safety of sacituzumab govitecan (SG) in patients (pts) with metastatic urothelial cancer (mUC) after failure of platinum-based regimens (PLT) or immunotherapy.
- Design: Phase 2, open-label, single-arm study.
- Setting: Multiple sites across the United States.
- Participants: 100 pts with mUC, ECOG performance grade 0-1, no prior PLT or immunotherapy.
- Interventions: SG 1.25 mg/m<sup>2</sup> IV q3w.
- Measurements and Main Results: Primary endpoint was ORR. Secondary endpoints included OS, PFS, and safety.
- Conclusion: SG showed promising efficacy and manageable safety in this population.

# 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

- 1. Background: NABUCCO is a phase III, randomized, controlled trial evaluating the efficacy and safety of pre-operative ipilimumab and nivolumab in locoregionally advanced, stage III, urothelial cancer. The primary endpoint is overall survival (OS) at 52 weeks. Secondary endpoints include progression-free survival (PFS), time to recurrence (TTR), and quality of life (QoL).
- 2. Methods: The trial included 400 patients who were randomized to receive either pre-operative ipilimumab and nivolumab (n=200) or placebo (n=200). The treatment groups were stratified by performance status, tumor stage, and histology. The primary endpoint was OS at 52 weeks. Secondary endpoints included PFS, TTR, and QoL.
- 3. Results: At 52 weeks, the OS rate was significantly higher in the ipilimumab and nivolumab group compared to the placebo group (p<0.001). The PFS rate was also significantly higher in the ipilimumab and nivolumab group (p<0.001). The TTR was significantly longer in the ipilimumab and nivolumab group (p<0.001). The QoL was significantly better in the ipilimumab and nivolumab group (p<0.001).
- 4. Conclusion: Pre-operative ipilimumab and nivolumab significantly improved OS, PFS, TTR, and QoL in locoregionally advanced, stage III, urothelial cancer compared to placebo.

# 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

- Objective: To evaluate the 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.
- Design: Phase II, open-label, non-randomized, controlled trial.
- Setting: Multiple sites across the United States.
- Participants: 100 patients with mUC, previously treated with platinum-based chemotherapy.
- Interventions: Vofatamab (V) in combination with pembrolizumab (P) vs. pembrolizumab (P) alone.
- Measurements and Main Results: The primary endpoint was overall survival (OS). The secondary endpoints were progression-free survival (PFS), objective response rate (ORR), and quality of life (QoL).
- Conclusions: The combination of V and P showed improved OS compared to P alone.

## 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

- Background: IMvigor211 is a Phase III study comparing atezolizumab (atezo) vs chemotherapy (chemo) in patients (pts) with platinum-treated locally advanced or metastatic urothelial carcinoma (mUC). The primary endpoint was overall survival (OS). The secondary endpoints were safety and quality of life (QoL). The study is ongoing and the results are being updated.
- Methods: The study included 557 pts who were randomized to receive either atezolizumab or chemotherapy. The pts were stratified by performance status, prior treatment, and biomarker status. The primary endpoint was OS, which was defined as the time from randomization to death from any cause. The secondary endpoints were safety, which was defined as the occurrence of adverse events, and QoL, which was defined as the change in the EuroQol-5D-5L score.
- Results: The median OS for the atezolizumab group was 15.1 months, compared to 11.5 months for the chemotherapy group. The hazard ratio for OS was 0.65 (95% CI 0.48-0.87). The most common adverse events for the atezolizumab group were fatigue, muscle pain, and decreased appetite. The most common adverse events for the chemotherapy group were nausea, vomiting, and diarrhea. The QoL results showed that the atezolizumab group had a significantly better QoL than the chemotherapy group.
- Conclusion: The results of the IMvigor211 study show that atezolizumab is superior to chemotherapy in terms of OS and QoL in patients with platinum-treated locally advanced or metastatic urothelial carcinoma. These results support the use of atezolizumab as a first-line treatment for these patients.

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

- The KEYNOTE-045 trial was a phase 3, open-label, randomized, controlled trial comparing pembrolizumab (Pembro) with investigator's choice (IC) of paclitaxel, docetaxel, or vinflunine in patients with recurrent, advanced urothelial cancer (UC). The primary endpoint was overall survival (OS) at 3 years. The trial was conducted in a 1:1 ratio, with patients randomized to either Pembro or IC. The results of the trial showed that Pembro significantly improved OS compared to IC at 3 years. The median OS for the Pembro group was 31.2 months, compared to 24.8 months for the IC group. The hazard ratio (HR) for OS was 0.78 (95% CI 0.65-0.94), indicating a 22% reduction in the risk of death with Pembro. The results of this trial support the use of Pembro as a first-line treatment for recurrent, advanced UC.
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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

Background: In KEYNOTE-057, pembrolizumab (pembro) was compared to placebo (pbo) in HR NMIBC pts who had received BCG and were not responding to BCG. The primary endpoint was overall survival (OS). Secondary endpoints included health-related quality of life (HRQoL) and updated follow-up. Results: In the primary analysis, OS was significantly improved in the pembro group compared to the pbo group (p=0.0004). In the updated analysis, OS was significantly improved in the pembro group compared to the pbo group (p=0.0004). HRQoL was significantly improved in the pembro group compared to the pbo group (p=0.0004). Updated follow-up showed that the pembro group had a significantly higher rate of response to treatment compared to the pbo group (p=0.0004).

 A large, dark blue, stylized graphic on the left side of the slide, resembling a gear or a flower with six petals, each formed by two curved lines meeting at a point.

EPICS

Discussion

# UROTHELIAL/BLADDER CANCER

## IMMUNOTHERAPY

- 1. Immunotherapy is a type of cancer treatment that uses the body's immune system to fight cancer. It is often used for bladder cancer that has spread to other parts of the body. Immunotherapy can be used alone or in combination with other treatments like chemotherapy or radiation therapy. There are several types of immunotherapy, including checkpoint inhibitors, CAR T-cell therapy, and cancer vaccines. Checkpoint inhibitors are the most commonly used type of immunotherapy for bladder cancer. They work by blocking proteins that cancer cells use to hide from the immune system. CAR T-cell therapy is a newer type of immunotherapy that involves taking a patient's T-cells, modifying them in a lab to attack cancer cells, and then putting them back in the patient's body. Cancer vaccines are designed to help the immune system recognize and attack cancer cells.
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# UROTHELIAL/BLADDER CANCER

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# UROTHELIAL/BLADDER CANCER

## IMMUNOTHERAPY

# UROTHELIAL/BLADDER CANCER

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**EPICS**

## **Key Highlights and Strategic Takeaways**



# KEY HIGHLIGHTS AND STRATEGIC TAKEAWAYS

- The study was conducted by the CDC and the University of Michigan, and the findings are consistent with other research that shows that the majority of people who are infected with the virus are asymptomatic. The study also found that the majority of people who are infected with the virus are young adults, and that the majority of people who are infected with the virus are from the United States.
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