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**Associate Professor Brian Costello**

Division of Medical Oncology,  
Genitourinary Tumour Group, Mayo Clinic, USA

**HIGHLIGHTS ON RENAL CELL CARCINOMA**

**CHECKMATE 214: EFFICACY AND SAFETY  
OF NIVOLUMAB + IPILIMUMAB  
V SUNITINIB FOR TREATMENT-NAÏVE  
ADVANCED OR mRCC, INCLUDING IMDC  
RISK AND PD-L1 EXPRESSION SUBGROUPS**

Escudier B et al. LBA5. ESMO Madrid 2017

# CHECKMATE 214

- Efficacy and safety of nivolumab + ipilimumab vs sunitinib for treatment-naïve advanced or metastatic renal cell carcinoma (mRCC)
- Inclusion:
  - Measurable clear cell histology
  - KPS  $\geq$  70
  - Available tumor tissue
  - No prior treatment
- Randomized 1:1

# CHECKMATE 214

## Treatment arm 1:

- Nivolumab 3 mg/kg IV + ipilimumab 1 mg/kg IV
  - Every 3 weeks for 4 cycles
- Then nivolumab 3 mg/kg IV every 2 weeks

## Treatment arm 2:

- Sunitinib 50 mg orally
  - 4 weeks on, 2 weeks off

## Co-primary endpoints (intermediate/poor risk)

- Overall response rate
- Progression free survival
- Overall survival

# CHECKMATE 214

## Results:

- 1096 randomized (nivo/ipi – 550; sunitinib – 546)
- Planned interim analysis
- Overall response rate
  - Nivo/ipi: 42%
  - Sunitinib: 27%
- Median progression free survival (did not reach statistical significance)
  - Nivo/ipi: 11.6 months
  - Sunitinib: 8.4 months
- Overall survival
  - Nivo/ipi: 2 year OS 67%, median OS not reached
  - Sunitinib: median OS 26.0 months

## Conclusions:

- Statistically significant benefit from nivo/ipi in intermediate/poor risk patients
  - 37% reduction in risk of death
  - Improved overall response rate with nivo/ipi
- Tumor PD-L1  $\geq 1\%$ 
  - Higher overall response rate with nivo/ipi
  - Improved progression free survival
- Safety profile consistent with previous studies

**Look for this combination to move toward regulatory approval in the future**

**SPAZO2 (SOGUG): COMPARATIVE  
EFFECTIVENESS OF PAZOPANIB IN  
METASTATIC RENAL CARCINOMA (MRC):  
INELIGIBLE (I) VS ELIGIBLE (E) PATIENTS  
FOR CLINICAL TRIALS**

J. Arranz Arija et al. 884P. ESMO Madrid 2017



Comparative effectiveness of pazopanib in metastatic renal carcinoma; ineligible vs eligible patients for clinical trials

## Population:

- 530 patients treated with pazopanib off-study
- Patients evaluated using standard clinical trial criteria
- 217 patients would have been ineligible for a clinical trial

## Results:

- Compared to clinical trial eligible patients, ineligible patients had:
  - Lower response rates
  - Shorter progression free and overall survival
  - Safety similar

## Conclusions:

- “Real-world” eligible patients had similar outcomes to those in clinical trials
- “Real-world” ineligible patients had poorer outcomes
- Study highlights the challenges of applying clinical trial data to real world practice

# **EFFICACY AND SAFETY DATA IN ELDERLY PATIENTS WITH mRCC INCLUDED IN THE NIVOLUMAB EXPANDED ACCESS PROGRAM (EAP) IN ITALY**

**Sabbatini R et al. 897P. ESMO Madrid 2017**

# EFFICACY AND SAFETY DATA IN ELDERLY PATIENTS WITH mRCC INCLUDED IN THE NIVOLUMAB EXPANDED ACCESS PROGRAM IN ITALY

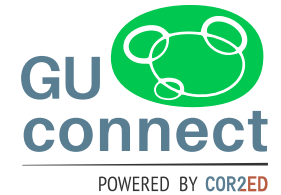
## Patients:

- At least 1 prior treatment
- Total of all ages = 389
- $\geq 70$  years (elderly) = 125

## Results for elderly patients:

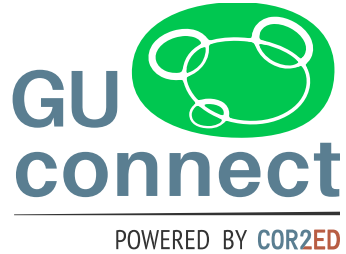
- Disease control rate = 58%
- 6-month OS = 87.2%
- 12-month OS = 77.8%
- Safety profile consistent with observations in general population

# EFFICACY AND SAFETY DATA IN ELDERLY PATIENTS WITH mRCC INCLUDED IN THE NIVOLUMAB EXPANDED ACCESS PROGRAM IN ITALY



## Conclusions:

- Elderly patients benefit from nivolumab
- Safety is similar to the general population
- Data supports use of nivolumab for mRCC in the elderly population



GU CONNECT  
Bodenackerstrasse 17  
4103 Bottmingen  
SWITZERLAND

Dr. Antoine Lacombe  
Pharm D, MBA  
Phone: +41 79 529 42 79  
[antoine.lacombe@cor2ed.com](mailto:antoine.lacombe@cor2ed.com)

Dr. Froukje Sosef  
MD  
Phone: +31 6 2324 3636  
[froukje.sosef@cor2ed.com](mailto:froukje.sosef@cor2ed.com)

