A Subgroup Analysis Explored Nivolumab Use for Advanced Renal Cell Carcinoma in Japanese Patients

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How was the study designed?

What were the results of the subgroup analysis?

Why was the subgroup analysis performed?

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Why was the subgroup analysis performed? 7 Targeted Therapies Were Available for Advanced Renal Cell Carcinoma in Japan (2016)



Certain Factors Affect the Efficacy and Safety of Targeted Therapies in Asia



Goal: To compare the efficacy and safety of nivolumab versus everolimus in Japanese patients (subgroup analysis from the CheckMate 025 study)

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The Subgroup Analysis Compared Nivolumab Versus Everolimus

Stratified

Open-label

Nivolumab 3 mg/kg IV over 60 min every 2 weeks

Everolimus 10 mg orally once daily **Region:** US/Canada, Western Europe, the rest of the world

Prognostic risk group

Number of prior anti-angiogenic therapies

1

Randomized

The Subgroup Analysis Compared Nivolumab **Versus Everolimus**

Open-label Nivolumab Randomized 3 mg/kg IV over 60 min <u>Stratified</u> every 2 weeks **Everolimus** 10 mg orally once daily

Japanese patients as part of "the rest of the world group"

Region: US/Canada, Western Europe, the rest of the world

Prognostic risk group

Number of prior anti-angiogenic therapies

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The Study Enrolled Patients Diagnosed With Advanced Renal Cell Carcinoma

Histological confirmation of advanced renal cell carcinoma

1 or 2 prior anti-angiogenic therapies

Disease progression within 6 months of study enrollment

Karnofsky performance status >70

Endpoints Focused on Survival and Safety



Different Statistical Methods Analyzed Data

Kaplan-Meier method

• OS, PFS, duration of response

Brookmeyer and Crowley method

• OS

Unstratified Cox model

• OS and PFS for nivolumab versus everolimus

Clopper and Pearson method

• ORRs

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Japanese Patients Represented Less Than 10% of Total Patients in Each Group



Median Overall Survival Was Not Reached by the Japanese Population



Tomita et al. Jpn J Clin Oncol. 2017;(47)7:639-646.



Progression-Free Survival Rates Were Similar Between the Nivolumab and Everolimus Groups



Japanese Patients in the Everolimus Group Reported More Treatment-Related Adverse Events





Nivolumab May Improve Response Rate and Adverse Event Profile in Japanese Patients with Advanced Renal Cell Carcinoma Compared With Everolimus