

Cabozantinib improves survival in patients with advanced kidney cancer

September 25 2015

Vienna, Austria: Patients with advanced kidney cancer live for nearly twice as long without their disease progressing if they are treated with cabozantinib, a drug that inhibits the action of tyrosine kinases - enzymes that function as an "on" or "off" switch in many cellular processes, including cancer.

In the second of two late-breaking presentations of research that is predicted to change the way [kidney cancer patients](#) are treated, Professor Toni Choueiri will tell the presidential session of the 2015 European Cancer Congress [1], about results from the first 375 patients out of a total of 658 patients recruited to the phase III clinical METEOR trial comparing cabozantinib with everolimus, the current standard treatment for the disease.

Analysis of results in July 2015 showed that the estimated median (average) progression-free survival time for patients with advanced clear cell kidney cancer, randomised to receive cabozantinib, was 7.4 months, while it was 3.8 months for those receiving everolimus. The objective response rate (the proportion of patients whose tumours shrank, assessed up to 17 months) was 21% for cabozantinib and 5% for everolimus.

An interim analysis of overall survival among all of the 658 patients found that it was a third better for patients receiving cabozantinib. The findings are published simultaneously with the ECC2015 presentation in the *New England Journal of Medicine*. [2]

Prof Choueiri, who is Associate Professor of Medicine at Harvard Medical School and Clinical Director and Kidney Cancer Center Director at The Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute, USA, said: "I am very excited about the outcome of the study since the results may change the standard of care in patients with advanced kidney cancer who have received prior standard therapy that targets the vascular endothelial growth factor receptor (VEGFR).

"Although treatment with VEGFR-targeted drugs has been very effective in the first line of therapy for patients with advanced kidney cancer, in many cases tumour cells find ways to escape control by these drugs. Cabozantinib is a new drug that targets possible escape mechanisms of tumour cells, including the [tyrosine kinases](#) MET, VEGFR and AXL. The results of the METEOR trial indicate that cabozantinib is able to shrink tumours and slow down tumour growth much better than current standard treatment in patients who previously received VEGFR-targeted drugs. This has resulted in a significant reduction in the rate of disease progression or death in the cabozantinib arm as compared with the everolimus arm. Regaining tumour control after prior targeted therapy may reduce symptoms related to kidney cancer and eventually help patients live longer.

"An early evaluation of overall survival from the ongoing METEOR trial has shown a strong trend indicating that survival may be improved in patients receiving cabozantinib compared to standard therapy. The final evaluation regarding survival will occur at a later time when the data have further matured with longer follow up of the patient population. Overall, these results should give new hope to patients diagnosed with advanced kidney cancer as cabozantinib may become a new treatment option."

Clear cell kidney cancer (or renal cell carcinoma) is one of the commonest kidney cancers - 70-80% of kidney cancer patients have this

type. If it is caught early, the prognosis is good; 81% of patients with stage I disease, in which the tumour is confined to the kidney, survive for at least five years. However, when it has advanced, the prognosis is poor, with only around eight percent of patients with stage IV disease surviving for five years.

Patients recruited to the METEOR clinical trial, which started in June 2013, were randomised to receive either 60 mg a day of cabozantinib in tablet form, or 10 mg a day of everolimus, also in tablet form. Their disease had to have progressed within six months of receiving prior treatment with VEGFR tyrosine kinase inhibitor (TKI) therapy.

The METEOR trial is also evaluating the safety of the treatment. The incidence of serious side effects was similar for both drugs, and discontinuation of treatment due to side effects occurred in 9.1% of cabozantinib and 10% of everolimus patients. The most common serious side effect for patients receiving cabozantinib were abdominal pain (3%), abnormal amounts of fluid around the lungs (2.7%), diarrhoea (2.1%); for patients receiving everolimus it was anaemia (3.7%), shortness of breath (3.7%) and pneumonia (3.7%).

Prof Choueiri said: "The METEOR results are important from a clinical and scientific point of view. Overcoming mechanisms of tumour escape or resistance to standard therapies is critical for improving long-term outcome for our patients with advanced kidney cancer. Further studies include a randomised phase II study of cabozantinib versus standard of care with sunitinib as a first treatment for advanced renal cell cancer. Combinations with other emerging therapies, such as agents boosting the immune system, are of interest and an early stage clinical trial combining cabozantinib with immune checkpoint inhibitors has been initiated in urological cancers, including patients with kidney cancer."

The trial has stopped recruiting patients and researchers are hoping that

cabozantinib may become available to patients with advanced kidney cancer some time in 2016. In the USA, the Food and Drug Administration (FDA) has designated it as a breakthrough therapy, which may allow expedited development of the drug.

Professor Peter Naredi, the ECCO scientific co-chair of the Congress, who was not involved in the research, commented: "I am excited over the advances in treatment of renal cell carcinoma that we are at present. The results of the METEOR study are remarkable and most likely will be practice changing. This, together with the report of the CheckMate 025 study, are definitely among the highlights of this congress."

The other late-breaking presentation in the presidential session will be made by Professor Padmanee Sharma, who will be reporting results from the CheckMate 025 randomised phase III trial of nivolumab versus everolimus in advanced kidney cancer.

More information: [1] The European Cancer Congress is the 18th congress of the European Cancer Organisation (ECCO) and the 40th congress of the European Society for Medical Oncology (ESMO).

[2] "Cabozantinib versus everolimus in advanced renal cell carcinoma", by Toni Choueiri et al. [DOI: 10.1056/NEJMoa1510016](https://doi.org/10.1056/NEJMoa1510016). Published online: www.nejm.org/doi/full/10.1056/NEJMoa1510016

Provided by ECCO-the European Cancer Organisation

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