

# Cabozantinib improves progression-free survival in metastatic renal cell carcinoma

10 October 2016

Cabozantinib significantly improves progression-free survival and response rate in patients with metastatic renal cell carcinoma compared to sunitinib, according to research presented today at the ESMO 2016 Congress in Copenhagen.

Cabozantinib targets a class of enzymes called [tyrosine kinases](#) but, unlike sunitinib which targets the vascular endothelial growth factor receptors (VEGFR), cabozantinib additionally inhibits the action of MET and AXL.

"Both MET and AXL seem to be associated with tumour progression but more importantly, animal models showed that the development of resistance to VEGFR inhibitors like sunitinib can be mediated through AXL and MET," said principal investigator Dr. Toni Choueiri, director of the Lank Center for Genitourinary Oncology at the Dana-Farber Cancer Institute in Boston, US.

In this phase II multicenter trial, 157 patients with untreated clear-cell metastatic renal cell carcinoma of intermediate or poor risk, were randomized either to oral cabozantinib (60mg once daily) or sunitinib (50mg once daily, 4 weeks on, 2 weeks off).

Patients treated with cabozantinib showed a 31% reduction in the median rate of progression or death compared to those treated with sunitinib (8.2 months vs. 5.6 months,  $p = 0.012$ ). The objective response rate was also significantly higher in the cabozantinib arm compared to the sunitinib arm (46% vs. 18%).

Researchers observed a similar rate of adverse events between the two arms of the study, with the incidence of grade 3 or higher adverse events being 70.5% in the cabozantinib arm and 72.2% in the sunitinib arm. The most common adverse events for both treatments included diarrhoea, fatigue, hypertension, palmar-plantar erythrodysesthesia, hematological events, and 16

patients in each arm terminated their treatment early due to toxicity.

The study did not include good-risk patients, but Choueiri said there was no biological or clinical rationale to think that cabozantinib would not be equally effective in that population.

"Cabozantinib is currently approved for second or later lines of therapies, after patients have progressed on a VEGFR tyrosine kinase inhibitor, but this data shows that cabozantinib has the potential to become a first-line standard treatment," Choueiri said.

Commenting on the study, Dr Bernard Escudier, chairman of the renal cancer unit at Institut Gustave-Roussy, France, said, "For many years, sunitinib has been the most commonly used standard of care for first line metastatic renal cell carcinoma, and recently, cabozantinib was proven to be active in second line, especially after sunitinib failure."

"Obviously, this study will raise a lot of questions, such as whether these results are expandable to all metastatic renal cell carcinoma patients, including the good prognosis group; whether cabozantinib should become a new standard of care in the first line setting; and how we should interpret all the ongoing phase III first-line studies which selected [sunitinib](#) as the control arm."

"While more mature data and additional studies using cabozantinib in the first line setting will be required, this study raises a lot of new expectations for the treatment of metastatic [renal cell carcinoma](#)," Escudier concluded.

**More information:** CABOzantinib versus SUNitinib (CABOSUN) as initial targeted therapy for patients with metastatic renal cell carcinoma (mRCC) of poor and intermediate risk groups: Results from ALLIANCE A031203 trial, presented by Dr Toni Choueiri during Presidential Symposium

3 on Monday, 10 October, 16:30 to 18:10 (CEST).

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