

# Ramucirumab plus docetaxel improves progression-free survival in urothelial cancer

September 11 2017

---

Ramucirumab plus docetaxel improves progression-free survival in patients with advanced or metastatic urothelial cancer who have progressed on platinum-based chemotherapy, according to late-breaking results from the phase III RANGE trial presented today at the ESMO 2017 Congress in Madrid (1) to be published in *The Lancet*. (2)

Checkpoint inhibitors are effective in about 25% of patients with platinum-refractory advanced or metastatic urothelial [cancer](#), but there are few options for those who progress or are ineligible. A phase II study found that adding the vascular endothelial growth factor receptor 2 (VEGFR-2) antibody ramucirumab to [docetaxel](#) nearly doubled progression-free survival compared to docetaxel alone in patients with platinum-refractory advanced or metastatic urothelial cancer. (3)

The findings provided the rationale for the phase III RANGE trial presented today. The trial included 530 patients with advanced or metastatic urothelial cancer who had progressed on first line [platinum-based chemotherapy](#) within the previous 14 months. Patients were randomised 1:1 to ramucirumab plus docetaxel (263 patients) versus placebo plus docetaxel (267 patients).

The primary endpoint of investigator-assessed progression-free survival was significantly prolonged with ramucirumab plus docetaxel compared to placebo plus docetaxel (4.07 months versus 2.76 months; hazard ratio, 0.757). Results were slightly more favourable in a blinded central analysis, with a progression-free survival of 4.04 months with

ramucirumab/docetaxel compared to 2.46 months with placebo/docetaxel (hazard ratio, 0.672).

The objective response rate was 24.5% in the ramucirumab/docetaxel arm compared to 14.0% in the placebo/docetaxel arm. Overall survival data is still maturing.

Toxicities were similar between groups, with slightly less anaemia with ramucirumab/docetaxel compared to placebo/docetaxel. Treatment was discontinued, primarily due to progressive disease, in 209 patients on ramucirumab/docetaxel and 229 patients on placebo/docetaxel. Quality of life did not change during the study, and there were no differences between treatment arms.

"Ramucirumab reduced the risk of disease progression by 24% and this was consistent across patient subgroups," said lead author Professor Daniel P. Petrylak, professor of medicine and urology, Yale School of Medicine and Yale Cancer Center, New Haven, CT, US. "The objective response rate nearly doubled with ramucirumab and there were no significant differences in toxicities between treatments."

He concluded: "Ramucirumab plus docetaxel could become a standard of care in patients with platinum-refractory advanced or metastatic urothelial cancer who have either progressed on checkpoint inhibitors or are not eligible to receive them."

Commenting on the results, Dr Richard Cathomas, deputy chief physician of oncology and haematology, Kantonsspital Graubünden, Chur, Switzerland, said: "This is the first trial to show a progression-free survival benefit compared to chemotherapy alone in [patients](#) with platinum-refractory urothelial cancer. However, the magnitude of benefit was 1.3 months and, while statistically significant, it raises the question of whether it is clinically relevant."

"We need to know if the improvement in progression-free survival translates into an overall survival benefit," continued Cathomas. "We have seen from other trials combining chemotherapy with angiogenesis inhibitors in different cancers that such a small progression-free survival benefit often does not translate into overall survival."

He concluded: "It is too early for these results alone to change the standard of care second line treatment, which is immune checkpoint inhibition. But the improvement in response rate shows that [ramucirumab](#) does have an impact on the disease, so in future, angiogenesis inhibition may become part of the treatment armamentarium for urothelial cancer."

**More information:** References:

1 Abstract LBA4\_PR 'RANGE: a randomized, double-blind, placebo-controlled phase 3 study of docetaxel (DOC) with or without ramucirumab (RAM) in platinum-refractory advanced or metastatic urothelial carcinoma' will be presented by Dr Daniel Petrylak during Presidential Symposium II, on Sunday, 10 September, 16:30 to 18:20 (CEST), in Madrid Auditorium.

2 Ramucirumab plus docetaxel versus placebo plus docetaxel in patients with locally advanced or metastatic urothelial carcinoma after platinum-based therapy (RANGE): a randomised, double-blind, phase 3 trial Dr Daniel P Petrylak et al. The Lancet. Published Online September, 12 2017. [DOI: 10.1016/S0140-6736\(17\)32365-6](https://doi.org/10.1016/S0140-6736(17)32365-6) The full paper will be available online from 12 September 00:30 CEST, here: [www.thelancet.com/journals/lan...ulltext?elsca1=tlxpr](http://www.thelancet.com/journals/lan...ulltext?elsca1=tlxpr)

3 Petrylak DP, et al. Docetaxel As Monotherapy or Combined With Ramucirumab or Icrucumab in Second-Line Treatment for Locally Advanced or Metastatic Urothelial Carcinoma: An Open-Label, Three-

Arm, Randomized Controlled Phase II Trial. J Clin Oncol. 2016;34(13):1500-1509. [DOI: 10.1200/JCO.2015.65.0218](https://doi.org/10.1200/JCO.2015.65.0218).

Provided by European Society for Medical Oncology

Citation: Ramucirumab plus docetaxel improves progression-free survival in urothelial cancer (2017, September 11) retrieved 13 May 2024 from <https://medicalxpress.com/news/2017-09-ramucirumab-docetaxel-progression-free-survival-urothelial.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.