

Scotland first in UK to make Cabometyx® ▼ (cabozantinib) routinely available for individuals living with advanced kidney cancer¹

Scottish Medicines Consortium endorses routine prescribing across NHS Scotland of Ipsen's cabozantinib, offering a new therapy option to help battle cancer resistance for advanced renal cell carcinoma in adults (after VEGF-targeted therapy)²

The UK affiliate of Ipsen (Euronext: IPN; ADR: IPSEY) today announced that patients with advanced kidney cancer can now receive treatment with Ipsen's innovative new therapy Cabometyx® (cabozantinib) via NHS Scotland following the positive announcement by the Scottish Medicines Consortium (SMC). Cabozantinib is a once-daily oral tablet which targets multiple pathways involved in tumor growth and is licensed for adults with advanced renal cell carcinoma (RCC), following prior vascular endothelial growth factor (VEGF)-targeted therapy.² Today's announcement comes ahead of access for patients in England, Northern Ireland and Wales, pending guidance from the National Institute for Health and Care Excellence (NICE). The positive approval of cabozantinib strengthens Ipsen's commitment to improving patient health and quality of life within cancer care.

Cabozantinib is a once-daily pill.² Cabozantinib has demonstrated statistically significant superiority in overall survival, progression-free survival, and objective response rate compared with everolimus in patients with RCC who have failed previous treatment with anti-angiogenic therapy.^{3,4} Last year cabozantinib was granted a Promising Innovation in Medicine (PIM) designation by the UK's Medicines and Healthcare products Regulatory Agency (MHRA), while over 50 Scottish patients with advanced RCC have received cabozantinib via the Ipsen Managed Access Programme prior to today's announcement.⁵ Based on the clinical data for cabozantinib, including the randomized phase III METEOR trial, European (ESMO and EAU) clinical guidelines recommend it as a standard of care following TKI treatment with the highest level of evidence.^{6,7}

"The approval of cabozantinib for use in NHS Scotland is a positive step forward in how we care for people living with advanced renal cell cancer," said Professor Robert Jones, Professor of Clinical Cancer Research, University of Glasgow. "There is a real need for new treatments in this area as many patients' cancer will begin to grow despite current treatment. Availability of new therapy options such as cabozantinib is crucial – it gives patients a further effective treatment option and the chance to control their disease for longer."

Kidney cancer is the 7th most common cancer in the UK with RCC accounting for 75% of all kidney cancers, responsible for around 12,000 new cases every year in the UK, or around 33 per day.⁸ In 2014 there were over 1,000 new cases of kidney cancer diagnosed in Scotland - 432 women and 669 men⁹ - the equivalent of 3 people diagnosed every day in Scotland.

"The positive recommendation by the SMC is very welcome news for advanced kidney cancer patients in Scotland" commented Karen McNee, Kidney Cancer Scotland. "There is a clear unmet need for patients with late-stage disease, therefore the availability of another effective therapy option offers new hope for patients and their families".

The most common adverse events experienced with cabozantinib are consistent with other VEGF receptor tyrosine kinase inhibitors (TKIs) in patients with RCC.⁴

"We are delighted by the SMC's decision, and as a Scotsman myself with my family still based in Scotland, I am proud that NHS Scotland will be the first health system in the UK to make cabozantinib routinely available to renal cell carcinoma patients. This is a great outcome following the number of Scottish patients who have already received treatment via our Managed Access Programme" said Ewan McDowall, Vice President of Commercial Operations, Ipsen UK & Ireland. "Ipsen is committed to improving patient health and quality of life in areas with clear unmet need. We firmly believe that the availability of this innovative and effective new treatment will make a positive difference to the lives of people in Scotland living with RCC. We would like to thank all the parties involved in the appraisal process for their exceptional commitment in ensuring patients have access to cabozantinib."

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▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to the Ipsen Medical Information department on +44(0)1753 627777 or medical.information.uk@ipsen.com.

For Cabometyx's summary of product characteristics, please visit <https://www.medicines.org.uk/emc/medicine/32431>

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Editor's Notes

About Ipsen

Ipsen is a leading global biotech company focused on innovation and specialty care with more than 20 medicines available in more than 115 countries. Ipsen's raison d'être is to significantly improve patient health and quality of life by providing effective therapeutic solutions for unmet medical needs. Its fields of expertise cover oncology, neurosciences and endocrinology (adult & paediatric). Ipsen's commitment to oncology is exemplified through its growing portfolio of key therapies

improving the care of patients suffering from prostate cancer, bladder cancer and neuro-endocrine tumours. Ipsen's R&D is focused on its innovative and differentiated technological platforms, peptides and toxins, located in the heart of the leading biotechnological and life sciences hubs (Les Ulis/Paris-Saclay, France; Oxford, UK; Cambridge, US).

About Ipsen Limited UK.

For more information on Ipsen Limited UK, visit <http://www.ipsen.co.uk/>

About cabozantinib

Cabozantinib is a tyrosine kinase inhibitor (TKI), targeting multiple different tyrosine kinases involved in the development of clear cell renal cell carcinoma. These include MET, AXL, RET and VEGF receptors, all associated with resistance and relapse.²

In a Phase 3 study, cabozantinib was shown to extend the median overall survival of patients to 21.4 months (median overall survival ITT: 21.4 months cabozantinib vs 16.5 months everolimus [HR 0.66 (95% CI: 0.53-0.83; P=0.00026)].³ Cabozantinib also increased median progression free survival (PFS) compared with the everolimus (median PFS rates by independent review: 7.4 months cabozantinib vs 3.9 months everolimus [HR 0.51 (95% CI: 0.41-0.62; p<0.0001)]³ and the number of patients responding to treatment with cabozantinib was more than five times higher than with everolimus (objective response rates by independent review: 17% cabozantinib vs 3% everolimus; P<0.0001)³

The most common serious adverse reactions associated with cabozantinib are abdominal pain (3%), pleural effusion (3%), diarrhoea (2%), and nausea (2%). The most frequent adverse reactions of any grade (experienced by at least 25% of patients) included diarrhoea (74%), fatigue (56%), nausea (50%), decreased appetite (46%), palmar-plantar erythrodysesthesia syndrome (PPES) (42%), hypertension (37%), vomiting (32%), weight decreased (31%), and constipation (25%).²

References

¹ Scottish Medicine Consortium (correspondence with Ipsen UK) May 2017

² Cabozantinib summary of product characteristics

³ Choueiri TK, Escudier B, Powles T et al. Cabozantinib versus everolimus in advanced renal cell carcinoma (METEOR): final results from randomised, open-label, phase 3 trial. *Lancet Oncol.* 2016; 17(7):917-27

⁴ Choueiri TK, Escudier B, Powles T, et al. Cabozantinib versus Everolimus in Advanced Renal-Cell Carcinoma. *N Engl J Med.* 2015 Nov;373:1814-1823.

⁵ Ipsen Data on File: CMX-UK-000309

⁶ European Association of Urology Guidelines: Renal Cell Carcinoma. Available from <http://uroweb.org/guideline/renal-cell-carcinoma/> [Last accessed: June 2017]

⁷ Escudier B, Porta C, Schmidinger M et al. Renal cell carcinoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Annals of Oncol.* 2016; 27(5): 58–68

⁸ KCUK. Incidence of Kidney Cancer. Available from: <http://www.kcuk.org.uk/kidneycancer/what-is-kidney-cancer/incidence-of-kidney-cancer-in-the-uk/> [Last accessed: June 2017]

⁹ Cancer Research UK. Kidney Cancer Incidence Statistics. Available from: <http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/kidney-cancer/incidence#heading-Zero> [Last accessed June 2017]