

**Life-extending tablet for advanced kidney cancer,  
Cabometyx® ▼ (cabozantinib), approved by NICE for routine access by  
English and Welsh patients<sup>1</sup>**

*NICE endorses prescribing across the NHS of Ipsen's tablet cabozantinib, offering a new therapy option to help battle cancer resistance in advanced renal cell carcinoma in adults (after VEGF-targeted therapy)<sup>2</sup>*

**00:01 Monday 10 July, 2017** — The UK affiliate of Ipsen (Euronext: IPN; ADR: IPSEY) today announced that eligible patients with advanced kidney cancer could now benefit from treatment with Ipsen's innovative new therapy Cabometyx® (cabozantinib) via the NHS in England and Wales, following recommendation for use by NICE in their Final Appraisal Determination (FAD). Cabozantinib is a once-daily oral tablet which targets multiple pathways involved in tumour growth and is licensed for adults with advanced renal cell carcinoma (RCC), following prior vascular endothelial growth factor (VEGF)-targeted therapy.<sup>2</sup> It has been shown to significantly extend overall survival and progression free survival compared with everolimus, with over five times more patients responding to treatment.<sup>3</sup> The committee concluded that because of its multi-targeted approach, cabozantinib would likely have additional benefits for some patients and so could be considered innovative.<sup>1</sup>

Today's announcement comes in the wake of the first annual World Kidney Cancer Day (22 June), which recently shed light on the rising need for new targeted treatments to tackle the increasing rates of kidney cancer incidence, especially as up to 30% of people diagnosed are in the late/advanced stages of the disease.<sup>4,5</sup> The approval of cabozantinib strengthens Ipsen's commitment to improving patient health and quality of life within cancer care and follows the news on 12 June that the Scottish Medicines Consortium approves routine prescribing of cabozantinib across NHS Scotland.

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.<sup>3,6</sup> Last year cabozantinib was granted a Promising Innovation in Medicine (PIM) designation by the UK's Medicines and Healthcare products Regulatory Agency (MHRA), while nearly 250 English, Welsh and Northern Irish patients with advanced RCC have received cabozantinib via the Ipsen Managed Access Programme prior to today's announcement.<sup>7</sup>

*"The approval of cabozantinib is welcome news for clinicians and people with advanced kidney cancer in England and Wales," said Professor Robert Hawkins, Consultant Oncologist at Manchester's Christie NHS Foundation Trust. "We have been fortunate enough to already see the benefits of this treatment in patients enrolled in the managed access scheme, and we are delighted that wider access means more people with kidney cancer will be able to live longer. There is a real need for new treatments among patients with advanced or relapsing kidney cancer and cabozantinib*

*has demonstrated strong potential among these patients where there is an urgent need for new advances that extend and improve lives.”*

Kidney cancer is the 7<sup>th</sup> 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.<sup>8</sup>

*“The positive recommendation by NICE represents a huge milestone for advanced kidney cancer patients in England and Wales.” commented **Nick Turkentine, CEO of Kidney Cancer UK.** “We believe it brings us one step closer to fighting kidney cancer, which is rapidly on the rise in the UK. There is a clear unmet need for treatments to patients with late-stage disease and as such the approval of this 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.<sup>6</sup>

**Ewan McDowall, Vice President of Commercial Operations, Ipsen UK & Ireland** commented on today’s announcement by NICE saying, *“At a time where the NHS is under increasing pressure we have taken our responsibility one step further by implementing an industry first of its kind: a managed access programme throughout the UK that provides cabozantinib free of charge for patients for the duration of their treatment. To date nearly 300 patients in the UK have benefited from cabozantinib through this Ipsen initiative, whilst the NICE process took place. We are delighted that now any eligible patient in the UK can benefit from cabozantinib. These patients don’t have time to wait.”*

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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](http://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](mailto: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 global specialty-driven biopharmaceutical group focused on innovation and specialty care. The group develops and commercializes innovative medicines in three key therapeutic areas - Oncology, Neurosciences and Rare Diseases. Its commitment to oncology is exemplified through its growing portfolio of key therapies for prostate cancer, neuroendocrine tumours, renal cell carcinoma and pancreatic cancer. Ipsen also has a well-established Consumer Healthcare business. With total sales close to €1.6 billion in 2016, Ipsen sells more than 20 drugs in over 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's R&D is focused on its innovative and differentiated technological platforms located in the heart of the leading biotechnological and life sciences hubs (Paris-Saclay, France; Oxford, UK; Cambridge, US). The Group has about 5,100 employees worldwide. Ipsen is listed in Paris (Euronext: IPN) and in the United States through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information on Ipsen, visit [www.ipсен.com](http://www.ipсен.com).

### About Ipsen Limited UK.

For more information on Ipsen Limited UK, visit <http://www.ipсен.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.<sup>2</sup>

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)].<sup>3</sup> 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)]<sup>3</sup> 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).<sup>3</sup>

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%).<sup>2</sup>

### References

<sup>1</sup> NICE FAD. ID931 cabozantinib. July 2017

<sup>2</sup> Cabozantinib Summary of Product Characteristics

<sup>3</sup> 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

<sup>4</sup> 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 July 2017]

<sup>5</sup> Bracarda S. Metastatic Renal Cell Carcinoma: Pathogenesis and the Current Medical Landscape. *European Urology Supplements* 8. 2009. 787-792

<sup>6</sup> 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.

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<sup>7</sup> Ipsen Data on File: CMX-UK-000372

<sup>8</sup> 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: July 2017]