



## PRESS RELEASE

### **Health Canada Approves Ipsen's CABOMETRYX™ (cabozantinib) Giving Physicians and Patients a Novel Second-Line Option in the Fight Against Advanced Renal Cell Carcinoma**

CABOMETRYX™ is the first and only single agent to demonstrate statistically significant clinical benefits across three key efficacy endpoints of overall survival (OS), progression free survival (PFS) and objective response rate (ORR) in a phase 3 study in previously treated patients with advanced renal cell cancer.<sup>1</sup>

**Mississauga, ON – September 19, 2018** – Ipsen Biopharmaceuticals Canada Inc. today announced the Health Canada approval of CABOMETRYX™ (cabozantinib), a once-daily oral tablet,<sup>2</sup> indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) who have received prior vascular endothelial growth factor (VEGF) targeted therapy.<sup>3</sup> CABOMETRYX™ is a tyrosine kinase inhibitor (TKI) with a unique mechanism of action targeting VEGFR, MET and AXL pathways involved in tumour progression and drug resistance in RCC.<sup>4</sup>

CABOMETRYX™ was granted priority review status by Health Canada, which provides for fast-tracking of submissions in Canada. The approval was based on the METEOR Phase 3 open-label trial of 658 patients comparing CABOMETRYX™ to everolimus in patients with advanced RCC who had failed at least one prior therapy. METEOR met its primary endpoint by significantly improving PFS and was associated with a 42 per cent reduction in the risk of disease progression or death. Median PFS for CABOMETRYX™ was 7.4 months versus 3.8 months for everolimus (HR=0.58, 95% CI 0.45-0.74, P<0.0001). Most notably, CABOMETRYX™ demonstrated a statistically significant increase in OS. CABOMETRYX™ was associated with a 34 per cent reduction in the risk of death. Median OS was 21.4 months for patients receiving CABOMETRYX™ versus 16.5 months for those receiving everolimus (HR=0.66, 95% CI 0.53-0.83, P=0.0003). CABOMETRYX™ also significantly improved the ORR vs. everolimus be it through investigator assessment (24% versus 4%, p<0.0001) or through independent committee review (17% versus 3%, p < 0.0001).<sup>5</sup> The most common adverse reactions (in ≥ 25% of patients) included: diarrhea, fatigue, nausea, decreased appetite, palmar-plantar erythrodysesthesia syndrome (PPES), hypertension, vomiting, weight decreased, and constipation. CABOMETRYX™ demonstrates a safety profile similar to that seen with other VEGF receptor TKIs in advanced RCC.<sup>6</sup>

“Until now, few treatments have demonstrated significantly delayed disease progression, extended survival and improved response in patients who have progressed on initial therapy,” says Dr. Anil Kapoor, Professor of Oncology and Surgery at the Juravinski Cancer Centre at McMaster University and Chair of the National Kidney Cancer Research Network of Canada. “The approval of CABOMETYX™ represents a significant advancement for patients who have progressed on prior therapy and should be considered for previously treated patients.”

“We welcome and applaud this approval that offers this evidence-based treatment to kidney cancer patients,” says Stephen Andrew, Executive Director of Kidney Cancer Canada. “The treatment arsenal our Canadian clinicians use to fight kidney cancer is stronger due to this decision.”

Approximately 6,600 Canadians are diagnosed with kidney cancer each year, with the incidence growing.<sup>7</sup> As the most common type of kidney cancer, RCC accounts for 80 per cent of all kidney cancer<sup>8</sup> and is considered advanced when the cancer has spread beyond the primary tumour site. Unfortunately, because kidney cancer often does not exhibit any symptoms, over 25% of patients are diagnosed at later stages of the disease.<sup>9</sup>

“Ipsen is committed to improving patients’ lives by continuing to develop new, innovative therapies for difficult-to-treat diseases,” says Paul Reider, General Manager for Ipsen Biopharmaceuticals Canada, Inc. “Health Canada’s approval of CABOMETYX™ represents an important milestone for patients with advanced cancer and for Ipsen Biopharmaceuticals Canada. We remain focused on delivering our pipeline and bringing new oncology treatments to patients in Canada.”

#### **About CABOMETYX™ (cabozantinib)**

CABOMETYX™ tablets are approved in Canada for the treatment of adult patients with advanced renal cell carcinoma (RCC) who have received prior vascular endothelial growth factor (VEGF) targeted therapy. CABOMETYX™ is also approved in the United States for the treatment of patients with advanced RCC and in the European Union, Norway, Iceland, Australia, Switzerland and South Korea for the treatment of advanced RCC in adults who have received prior VEGF-targeted therapy and for previously untreated intermediate- or poor-risk advanced RCC. In 2016, Exelixis granted Ipsen exclusive rights for the commercialization and further clinical development of cabozantinib outside of the United States and Japan.

In February of 2016, Exelixis and Ipsen jointly announced an exclusive licensing agreement for the commercialization and further development of cabozantinib indications outside of the United States, Canada and Japan. This agreement was amended in December of 2016 to include commercialization rights for Ipsen in Canada.

#### **About Ipsen**

Ipsen Biopharmaceuticals Canada Inc., the Canadian affiliate of Ipsen, is headquartered in Mississauga, Ontario with established operations since October 2015. For more information on Ipsen Biopharmaceuticals Canada Inc. visit [www.ipсен.ca](http://www.ipсен.ca). 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, Neuroscience and Rare Diseases. Its commitment to Oncology is exemplified through its growing portfolio of key therapies for prostate cancer, neuroendocrine tumors, renal cell carcinoma and pancreatic cancer. 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 5,400 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.ipsen.com](http://www.ipsen.com).

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<sup>1</sup> Cabozantinib Product Monograph. Ipsen Biopharmaceuticals Canada Inc. September 13, 2018.

<sup>2</sup> Cabozantinib Product Monograph. Ipsen Biopharmaceuticals Canada Inc. September 13, 2018.

<sup>3</sup> Cabozantinib Product Monograph. Ipsen Biopharmaceuticals Canada Inc. September 13, 2018.

<sup>4</sup> Cabozantinib Product Monograph. Ipsen Biopharmaceuticals Canada Inc. September 13, 2018.

<sup>5</sup> Cabozantinib Product Monograph. Ipsen Biopharmaceuticals Canada Inc. September 13, 2018.

<sup>6</sup> Cabozantinib Product Monograph. Ipsen Biopharmaceuticals Canada Inc. September 13, 2018.

<sup>7</sup> Canadian Cancer Society. Kidney Cancer Statistics

<http://www.cancer.ca/~media/cancer.ca/CW/cancer%20information/cancer%20101/Canadian%20cancer%20statistics/Canadian-Cancer-Statistics-2018-EN.pdf?la=en>. Last accessed August 20, 2018.

<sup>8</sup> Kidney Cancer Canada. Kidney Cancer Fact Sheet. <https://www.kidneycancercanada.ca/media/files/315.pdf>. Last accessed August 20, 2018.

<sup>9</sup> Kidney Cancer Canada. Kidney Cancer Fact Sheet. <https://www.kidneycancercanada.ca/media/files/315.pdf>. Last accessed August 20, 2018.