

PRESS RELEASE

Health Canada approves CABOMETRYX™ (cabozantinib) Giving Physicians and Adult Patients a New Second-Line Option in the Fight Against Advanced Hepatocellular Carcinoma

CABOMETRYX™ slows disease progression and improves survival for patients with advanced liver cancerⁱ previously treated with sorafenibⁱⁱ

Mississauga, ON – November 12, 2019 – Ipsen Biopharmaceuticals Canada Inc. today announced the Health Canada approval of CABOMETRYX™ (cabozantinib) for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.ⁱⁱⁱ

HCC is the most common form of liver cancer^{iv} and the second most common cause of cancer-related mortality worldwide.^v This combined with limited treatment options and a high unmet^{vi} medical need makes this approval an important milestone for Canadian patients living with the disease.

“Advanced liver cancer patients have a poor prognosis and historically there have been limited treatment options once their disease has progressed, which is why oncologists and patients are eager for new treatments to consider,” says Dr. Jennifer Knox, Medical Oncologist, University Health Network, Princess Margaret Cancer Centre. “The results of the CELESTIAL trial are clinically significant and position cabozantinib as an important new therapy in our efforts to slow disease progression and improve treatment outcomes for this complex disease.”

The Health Canada approval was based on results from the CELESTIAL phase 3 pivotal trial which randomized patients who previously received sorafenib to either CABOMETRYX™ or placebo. Results showed that treatment with CABOMETRYX™ led to a statistically significant improvement in overall survival (OS) compared with placebo (10.2 months vs 8.0 months; hazard ratio [HR] 0.76, 95% CI, 0.63–0.92; P =.0049).^{vii} In addition, CABOMETRYX™ led to a statistically significant improvement in progression free survival (PFS), with a median PFS of 5.2 months in the CABOMETRYX™ group vs 1.9 months in the placebo arm (HR 0.44, 95% CI, 0.36–0.52; P <.0001).^{viii} The most common adverse events reported in the trial included diarrhea, decreased appetite, palmar-plantar erythrodysesthesia, fatigue, nausea, hypertension and vomiting.^{ix}

“Liver cancer is one of the fastest rising forms of cancer in Canada, unfortunately, it can be the end result of many forms of liver disease,” says Dr. Morris Sherman, emeritus professor at the University of Toronto and Chairman of the Canadian Liver Foundation. “The key to reducing the incidence of liver cancer lies in early detection, intervention and prevention. Sadly, many Canadians who develop hepatocellular carcinoma don’t get diagnosed until it is too late for early intervention, so it becomes even more important for patients and their physicians to have access to a broad range of treatment options for a more promising outcome.”

“The results of the CELESTIAL trial provide further validation for the efficacy of CABOMETYX™,” says Ed Dybka, General Manager, Ipsen Canada. “CABOMETYX™ was previously approved by Health Canada for the treatment of renal cell carcinoma. The new expanded indication for patients with hepatocellular carcinoma underscores our commitment to continuously expanding the use of CABOMETYX™ in the treatment of solid tumors.”

About CABOMETYX™ (cabozantinib)

CABOMETYX™ is the first multi-targeted tyrosine kinase inhibitor (TKI) to target VEGFR, MET and AXL pathways that are involved in tumour progression. CABOMETYX™ is a multi-kinase inhibitor. It works by blocking the action of proteins called receptor tyrosine kinases (RTKs). RTKs are involved in cell growth and the development of new blood vessels. These proteins can be present in high amounts in cancer cells. By blocking their action, CABOMETYX™ can slow down how fast the tumour grows, help to block the blood supply that the cancer needs and may increase the length of time before the cancer gets worse.^x

In February of 2016, Exelixis and Ipsen jointly announced an exclusive licensing agreement for the commercialization and further development of CABOMETYX™ 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.

Following a priority review by Health Canada, CABOMETYX™ was first approved in Canada in September 2018 for the treatment of adult patients with advanced renal cell carcinoma (aRCC) who had received prior VEGF targeted therapy,^{xi} and in October 2019 it received Health Canada approval for treatment naïve adults with aRCC and intermediate or poor risk.^{xii}

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.ipsen.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 5,700 employees worldwide. Ipsen is listed in Paris (Euronext: IPN) and in the United States through a Sponsored Level I American Depository Receipt program (ADR: IPSEY). For more information on Ipsen, visit www.ipsen.com.

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- ⁱ Abou-Alpha G, Meyer T, Cheng A et al. Cabozantinib in Patients with Advanced and Progressing Hepatocellular Carcinoma. NEJM. 2018; 379:54-63
- ⁱⁱ Insert Product Monograph (to be updated when final PM is available).
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- ^{iv} Canadian Liver Foundation, <https://www.liver.ca/patients-caregivers/liver-diseases/liver-cancer/>, Last accessed September 4th 2019
- ^v Clinical and Molecular Hepatology (published March 4 2019), <https://www.e-cmh.org/m/journal/view.php?number=1452>, Last accessed September 4th 2019
- ^{vi} Kudo M, Targeted and immune therapies for hepatocellular carcinoma: Predictions for 2019 and beyond. World Journal of Gastroenterology. 21; 25(7):789-807.
- ^{vii} Insert Product Monograph (to be updated when final PM is available).
- ^{viii} Insert Product Monograph (to be updated when final PM is available).
- ^{ix} Abou-Alpha G, Meyer T, Cheng A et al. Cabozantinib in Patients with Advanced and Progressing Hepatocellular Carcinoma. NEJM. 2018; 379:54-63
- ^x Insert Product Monograph (to be updated when final PM is available).
- ^{xi} Health Canada, <https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-detail.php?lang=en&linkID=RDS00492>, Accessed August 23, 2019
- ^{xii} Newswire. Health Canada Approves Ipsen's CABOMETYX™ (cabozantinib) for the First-Line Treatment of Adults with Advanced Renal Cell Carcinoma. <https://www.newswire.ca/news-releases/health-canada-approves-ipesen-s-cabometryx-tm-cabozantinib-for-the-first-line-treatment-of-adults-with-advanced-renal-cell-carcinoma-806937354.html>, Accessed November 2019