PRESS RELEASE

Health Canada approves Ipsen's Somatuline® Autogel® for the treatment of carcinoid syndrome in adult patients with neuroendocrine tumours (NETs)

Somatuline Autogel is the first and only somatostatin analog (SSA) approved in Canada to treat enteropancreatic neuroendocrine tumours and carcinoid syndrome[1]

Mississauga, ON – February 13, 2018 – Ipsen Biopharmaceuticals Canada Inc., the Canadian affiliate of Ipsen (Euronext: IPN; ADR: IPSEY), today announced the Health Canada approval for Somatuline® Autogel® (lanreotide injection) 120 mg for the treatment of carcinoid syndrome; when used, Somatuline Autogel reduces the administrative frequency of short-acting somatostatin analog rescue therapy.[2]

Somatuline Autogel is also approved for the treatment of enteropancreatic neuroendocrine tumours in adult patients with Grade 1 or a subset of Grade 2 (equivalent to Ki67<10%) unresectable, locally advanced or metastatic disease, to delay progression.[3]

Carcinoid syndrome occurs when rare cancerous neuroendocrine tumours called carcinoid tumours release proteins into the bloodstream, causing signs and symptoms, including diarrhea and flushing.[4] Carcinoid tumours generally occur in the esophagus, stomach, intestines, appendix, and lungs.[5]

"The additional indication for Somatuline Autogel allows me to offer patients a valuable option that not only treats enteropancreatic neuroendocrine tumours, but also treats carcinoid syndrome. This is a positive development for the NETs community," says Dr. Simron Singh, Medical Oncologist and Co-Founder, Susan Leslie NETs Clinic at Odette Cancer Centre, Sunnybrook Health Sciences Centre in Toronto.

Enteropancreatic neuroendocrine tumours are growths that have developed from endocrine cells in the gastrointestinal tract (the stomach, intestines and appendix) or the pancreas. Some symptoms come about because some neuroendocrine tumours produce and secrete small proteins in excess – overloading the system.[6]

"NET cancer can be difficult to diagnose because symptoms are often vague, including diarrhea, flushing and nausea," says Jacqueline Herman, President and Director of Treatment Access & Health Policy of CNETS (Carcinoid-Neuroendocrine Tumour Society) Canada. "This treatment provides an additional option that allows physicians to individualize therapy for Canadians with neuroendocrine tumours who present with carcinoid syndrome."

“This new indication for Somatuline Autogel reinforces Ipsen's commitment to developing research-driven treatments that provide physicians and patients in Canada with new treatment options for fighting cancer,” says Paul Reider, General Manager, Ipsen Biopharmaceuticals Canada, Inc.

About the Health Canada Approval
The additional Somatuline Autogel Health Canada approval for carcinoid syndrome was based on the phase III results of the Evaluation of Lanreotide autogel Efficacy and safety as a Carcinoid-syndrome Treatment (ELECT) study. Results of the ELECT study were published in *Endocrine Practice.*[7]

The ELECT study was a 16-week, randomized, double-blind, placebo-controlled, phase III trial. The purpose of the study was to evaluate the efficacy and safety of lanreotide injection 120 mg for the control of carcinoid syndrome in patients with NETs. Patients with/without prior somatostatin analog (SSA) use were randomized to lanreotide injection 120 mg or placebo every 4 weeks, with access to short-acting octreotide as rescue medication. The primary endpoint was the percentage of days in which short-acting octreotide was used.

The ELECT study confirms the positive benefit-risk profile of lanreotide injection 120 mg every 4 weeks in patients with carcinoid syndrome associated with NETs by demonstrating a reduced need for rescue medication for breakthrough symptoms with lanreotide injection 120 mg compared with placebo. Overall, the therapeutic value of lanreotide injection 120 mg every 4 weeks in patients with NETs comprises symptomatic efficacy in relieving carcinoid syndrome combined with proven antitumour effects, and a favourable tolerability profile. The ELECT extension study confirms the long-term safety profile.[8]

Adverse reactions occurring in greater than 5% of patients who received Somatuline Autogel in the carcinoid syndrome trial and occurring at least 5% greater than placebo were headache (12%), dizziness (7%) and muscle spasm (5%).

About Ipsen Biopharmaceuticals Canada Inc.
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., or to obtain full prescribing information for Somatuline Autogel, visit www.ipsen.ca.

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.ipsen.com.

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[1] Somatuline Autogel (lanreotide) Product Monograph Canada. Version number: 203094; Date of Revision: February 1, 2018.
[2] Ibid.
[3] Ibid.
[4] Ibid.
[5] Ibid.
[6] Ibid.
[7] *Endocrine Practice*, September 2016, Vol. 22, No. 9, pp. 1068-1080.
[8] Somatuline Autogel (lanreotide) Product Monograph Canada. Version number: 203094; Date of Revision: February 1, 2018.