

U.S. FDA Approves New Indication for Ipsen's Somatuline[®] Depot (lanreotide) Injection for the Treatment of Carcinoid Syndrome

Paris (France), September 18, 2017 – Ipsen (Euronext: IPN; ADR: IPSEY) (Ipsen), today announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental indication for Somatuline[®] Depot (lanreotide) Injection 120 mg for the treatment of carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analogue rescue therapy.

Somatuline[®] Depot is also approved for the improvement of progression-free survival (PFS) in patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs).¹

Alexandre Lebeaut, MD, Executive Vice-President, R&D, Chief Scientific Officer, Ipsen, said: *"The new indication for Somatuline[®] Depot offers patients in the U.S. a valuable treatment option for debilitating carcinoid syndrome associated with neuroendocrine tumors. It also reaffirms Ipsen's global commitment to helping to improve lives of patients with cancer."*

"This new indication for Somatuline[®] Depot gives doctors the only somatostatin analog approved by the FDA in adults for both improving progression-free survival in patients with unresectable, well- or moderately- differentiated, locally advanced or metastatic GEP-NETs and for the treatment of carcinoid syndrome," said **Cynthia Schwalm, Executive Vice-President, and President, North American Commercial Operations, Ipsen**. *"The additional approval also confirms Ipsen's commitment to developing research-driven treatments intended to help provide patients battling cancer with new therapy options."*

The additional Somatuline[®] Depot approval for carcinoid syndrome was based on "Evaluation of Lanreotide Depot/Autogel Efficacy and Safety as a Carcinoid Syndrome Treatment (ELECT): A Randomized, Double-Blind, Placebo-Controlled Trial," published in *Endocrine Practice*.^{1,2}

IMPORTANT SAFETY INFORMATION

Contraindications

- Somatuline[®] Depot is contraindicated in patients with hypersensitivity to lanreotide. Allergic reactions (including angioedema and anaphylaxis) have been reported following administration of lanreotide.

Warnings and Precautions

- **Cholelithiasis and Gallbladder Sludge**
 - Somatuline[®] Depot may reduce gallbladder motility and lead to gallstone formation.
 - Periodic monitoring may be needed.

¹ Somatuline Depot (lanreotide) Injection Prescribing Information. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.

² *Endocrine Practice*, September 2016, Vol. 22, No. 9, pp. 1068-1080

- **Hypoglycemia or Hyperglycemia**
 - Pharmacological studies show that Somatuline[®] Depot, like somatostatin and other somatostatin analogs, inhibits the secretion of insulin and glucagon. Patients treated with Somatuline[®] Depot may experience hypoglycemia or hyperglycemia.
 - Blood glucose levels should be monitored when Somatuline[®] Depot treatment is initiated, or when the dose is altered, and antidiabetic treatment should be adjusted accordingly.
- **Cardiovascular Abnormalities**
 - Somatuline[®] Depot may decrease heart rate.
 - In patients in the GEP-NET pivotal trial, 23% of Somatuline[®] Depot-treated patients had a heart rate of less than 60 bpm compared to 16% of placebo-treated patients. The incidence of bradycardia was similar in the treatment groups. Initiate appropriate medical management in patients with symptomatic bradycardia.
 - In patients without underlying cardiac disease, Somatuline[®] Depot may lead to a decrease in heart rate without necessarily reaching the threshold of bradycardia. In patients suffering from cardiac disorders prior to treatment, sinus bradycardia may occur. Care should be taken when initiating treatment in patients with bradycardia.

Most Common Adverse Reactions

- **GEP-NETs:** Adverse reactions occurring in greater than 10% of patients who received Somatuline[®] Depot in the GEP-NET trial were abdominal pain (34%), musculoskeletal pain (19%), vomiting (19%), headache (16%), injection site reaction (15%), hyperglycemia (14%), hypertension (14%), and cholelithiasis (14%).
- **Carcinoid Syndrome:** Adverse reactions occurring in the carcinoid syndrome trial were generally similar to those in the GEP-NET trial. Adverse reactions occurring in greater than 5% of patients who received Somatuline[®] Depot in the carcinoid syndrome trial and occurring at least 5% greater than placebo were headache (12%), dizziness (7%) and muscle spasm (5%).

Drug Interactions: Somatuline[®] Depot may decrease the absorption of cyclosporine (dosage adjustment may be needed); increase the absorption of bromocriptine; and require dosage adjustment for bradycardia-inducing drugs (e.g., beta-blockers).

Special Populations

- **Lactation:** Advise women not to breastfeed during treatment and for 6 months after the last dose.

To report SUSPECTED ADVERSE REACTIONS, contact Ipsen Biopharmaceuticals, Inc. at +1-855-463-5127 or FDA at +1-800-FDA-1088 or www.fda.gov/medwatch.

Please click here for the full [Prescribing Information](#) including [Patient Information](#).

About Ipsen in North America

Ipsen Biopharmaceuticals, Inc. is the US affiliate of Ipsen, a global specialty-driven biopharmaceutical group. The US head office is located in Basking Ridge, New Jersey. Ipsen Biopharmaceuticals Canada, Inc. is an integrated business unit within North America and has its head office located in Mississauga, Ontario. Ipsen

Bioscience, Inc., the Ipsen US research and development center focused on the discovery of potentially highly differentiated and competitive products in neurosciences, oncology and rare diseases, is located in Cambridge, Massachusetts. At Ipsen Bioscience, we focus on creating a highly cooperative and passionate R&D organization through partnerships, innovation, and continuous learning to effectively deliver new treatments for patients. At Ipsen, we focus our resources, investments, and energy on discovering, developing, and commercializing new therapeutic options for oncologic, neurologic, and endocrine diseases. For more information on Ipsen in North America, please visit www.ipsenus.com or 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 tumors, 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.

Forward-Looking Statements

The forward-looking statements, objectives and targets contained herein are based on the Group's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words "believes," "anticipates" and "expects" and similar expressions are intended to identify forward-looking statements, including the Group's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by the Group. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising product in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. The Group must face or might face competition from generic products that might translate into a loss of market share. Furthermore, the Research and Development process involves several stages each of which involves the substantial risk that the Group may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Group cannot be certain that favorable results obtained during pre-clinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the product concerned. There can be no guarantees a product will receive the necessary regulatory approvals or that the product will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking

statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Group's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the Group's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. The Group also depends on third parties to develop and market some of its products which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to the Group's activities and financial results. The Group cannot be certain that its partners will fulfil their obligations. It might be unable to obtain any benefit from those agreements. A default by any of the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial position or performance. The Group expressly disclaims any obligation or undertaking to update or revise any forward looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. The Group's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers. The risks and uncertainties set out are not exhaustive and the reader is advised to refer to the Group's 2016 Registration Document available on its website (www.ipsen.com).

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