PRESS RELEASE

Ipsen announces the FDA Approval of Somatuline® Depot® (lanreotide) Injection for the treatment of gastroenteropancreatic neuroendocrine tumors

Somatuline® is the first and only antitumor therapy demonstrating a statistically significant progression-free survival benefit in a combined population of patients with gastrointestinal and pancreatic tumors

BASKING RIDGE, N.J. December 16 , 2014 – Ipsen Biopharmaceuticals, Inc., an affiliate of Ipsen (Euronext: IPN; ADR: IPSEY), today announced that Somatuline® Depot® (lanreotide) Injection 120 mg (referred to as Somatuline®) was approved by the U.S. Food and Drug Administration (FDA) for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs) in adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic disease to improve progression-free survival (PFS).

"The approval of Somatuline® for the treatment of patients living with gastrointestinal and pancreatic tumors is a major achievement for Ipsen that will provide a new therapeutic option with the potential to help many of the thousands of patients in the United States suffering from this devastating disease," said **Cynthia Schwalm, President and CEO of Ipsen Biopharmaceuticals, Inc.** "Somatuline® is the first and only treatment with a statistically significant progression-free survival benefit approved by the FDA for patients as an antitumor therapy in the treatment of gastrointestinal and pancreatic neuroendocrine tumors. This is a significant step forward in our mission to develop and deliver innovative therapies to treat serious illnesses."

The approval of Somatuline® was based on a 96-week landmark registrational Phase III, double-blind, placebo-controlled study (CLARINET®) of 204 patients enrolled in 48 centers across 14 countries. The trial showed that Somatuline® reduced the risk of disease progression or death by 53% versus placebo in patients with advanced gastrointestinal and pancreatic neuroendocrine tumors ($p<0.001$). Safety data generated from the Phase III study were consistent with the known safety profile of Somatuline®. The rates of discontinuation due to treatment-emergent adverse reactions were 5% (5/101 patients) in the Somatuline® arm and 3% (3/103 patients) in the placebo arm.

Gastrointestinal and pancreatic neuroendocrine tumors are rare, but serious cancers. There are an estimated 112,000 individuals currently living with neuroendocrine tumors in the U.S., and the incidence and prevalence of this type of cancer have risen 4-to-6 fold in the last 30 years. Furthermore, up to ninety percent of patients are incorrectly diagnosed, many for more than 5 years, meaning that they are often diagnosed at a late stage. During this process, patients may be misdiagnosed with other gastrointestinal diseases, such as irritable bowel syndrome or Crohn's disease.

"Somatuline® is the first somatostatin analog to demonstrate a statistically significant improvement in progression-free survival, a clinically significant endpoint in oncology which measures how long the patient continues to live with the disease without it getting any worse," said **Dr. Alexandria Phan, Director of GI Medical Oncology at Houston Methodist**. "Somatuline® offers a new weapon in our fight against this deadly disease."

Maryann Wahmann, President of the Neuroendocrine Cancer Awareness Network and a Carcinoid Cancer Patient added, "As a patient who also started an advocacy group for this community, I know first-hand how important it is to have a new treatment option with anticancer benefits for neuroendocrine tumors."

Somatuline® will be delivered via a newly approved, ready-to-use, prefilled syringe which incorporates Safe'n'Sound® technology, including a retractable needle guard to help avoid needle sticks, and it is manufactured without latex or natural dry rubber. The new delivery device does not require reconstitution and is a low volume (0.5 mL) deep subcutaneous injection offering a streamlined process that supports full dose delivery.

About Gastrointestinal and Pancreatic Neuroendocrine Tumors
Gastrointestinal and pancreatic neuroendocrine tumors, also known as gastroenteropancreatic neuroendocrine tumors, are a rare type of cancer. It is diagnosed in approximately 5 out of every 100,000 people in the U.S. The average time until a GEP-NET patient is accurately diagnosed is at least 5 years; with more than 80% of patients seeing at least three doctors prior to their diagnosis. Because of this, most patients are diagnosed while in the advanced stages of the disease, which often leads to a poor prognosis. Additionally, the symptoms of GEP-NETs are gastrointestinal in nature, thus they can be misdiagnosed as Crohn's disease or irritable bowel syndrome (IBS).

About the Phase III Study
The approval of Somatuline® Depot® in gastrointestinal and pancreatic neuroendocrine tumors is based on a Phase III, randomized, double-blind, placebo-controlled study (CLARINET®) of lanreotide's antiproliferative response in patients with enteropancreatic neuroendocrine tumors (ClinicalTrials.gov NCT00353496). This 96-week multinational study was conducted in collaboration with the UK & Ireland Neuroendocrine Tumour Society (UKI NETS) and the European Neuroendocrine Tumour Society (ENETS).

A total of 204 patients from 48 centers across 14 countries with well or moderately differentiated non-functioning enteropancreatic neuroendocrine tumors and a proliferation index (Ki67) of <10%, were randomized to treatment with Somatuline®Depot® 120 mg (n=101) or placebo (n=103). At enrollment, primary tumor locations were pancreas (45%), midgut (36%), hindgut (7%) and unknown (13%). Most patients had stable disease (96%) and were treatment-naïve (84%). Thirty percent of patients had a Ki67 of 3% to <=10% (WHO grade 2) and 33% had an hepatic tumor load >25%.

The primary efficacy endpoint was progression-free survivial (defined as time to either disease progression (centrally assessed using Response Evaluation Criteria In Solid Tumors, RECIST 1.0) or

death). Two baseline computed tomography or magnetic resonance imaging scans (12 to 24 weeks) were performed, followed by additional scans at 12- week intervals during the first year and 24-week intervals during the second year up to 96 weeks.

The data showed that placebo-treated patients had a median PFS of 16.6 months and 33.0% had not progressed or died at 96 weeks, whereas the median PFS for Somatuline® treated patients was not reached and will be greater than 22 months and 65.1% had not progressed or died at 96 weeks (stratified logrank test, p<0.001). This represented a 53% reduction in risk of disease progression or death with Somatuline® Depot compared to placebo, based on a hazard ratio of 0.47 (95% CI: 0.30-0.73). These statistically and clinically significant antiproliferative effects of Somatuline® Depot® were observed in a large population of patients with grade G1 or G2 (World Health Organization classification) GEP-NETs, and independent of hepatic tumor volume (<=25% or >25%). Overall survival and quality of life measures were not different between Somatuline® and placebo groups. Safety data generated from the study are consistent with the known safety profile of Somatuline®.

Indication:

Somatuline® Depot® (lanreotide) Injection 120 mg is indicated for the treatment of adult patients with unresectable, well- or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors to improve progression-free survival.

Important Safety Information

Contraindications:

Somatuline® is contraindicated in patients with hypersensitivity to lanreotide or related peptides.

Warnings and Precautions:

- Somatuline may reduce gallbladder motility and lead to gallstone formation. Periodic monitoring may be needed.
- Patients may experience hypoglycemia or hyperglycemia. Glucose level monitoring is recommended and antidiabetic treatment adjusted accordingly.
- Somatuline may decrease heart rate. In patients treated for GEP-NETs, the incidence of heart rate < 60 bpm was 23% with Somatuline vs 16% with placebo. Incidence of heart rate < 50 bpm or bradycardia was 1% in each group.
- Somatuline may decrease bioavailability of cyclosporine. Cyclosporine dose may need to be adjusted.

Adverse Reactions:

In the GEP-NET pivotal trial, the most common adverse reactions (incidence >10% and more

common than placebo) in patients treated with Somatuline® Depot® vs placebo were abdominal pain (34% vs 24%), musculoskeletal pain (19% vs 13%), vomiting (19% vs 9%), headache (16% vs 11%), injection site reaction (15% vs 7%), hyperglycemia (14% vs 5%), hypertension (14% vs 5%), and cholelithiasis (14% vs 7%).

You may report suspected adverse reactions to FDA at 1-800-FDA-1088 or to Ipsen Biopharmaceuticals, Inc. at 1-888-980-2889.

Please see the full Prescribing Information for Somatuline® Depot® by accessing the following link.

About Ipsen

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding EUR1.2 billion in 2013. One of the leading affiliates is Ipsen Biopharmaceuticals, Inc., the North American arm of Ipsen, headquartered in Basking Ridge, NJ. Ipsen's ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its development strategy is supported by 3 franchises: neurology, endocrinology and uro-oncology. Moreover, the Group has an active policy of partnerships. Ipsen's R&D is focused on its innovative and differentiated technological platforms, peptides and toxins. In 2013, R&D expenditure totaled close to EUR260 million, representing more than 21% of Group sales. Moreover, Ipsen also has a significant presence in primary care. The Group has close to 4,600 employees worldwide. Ipsen's shares are traded on segment A of Euronext Paris (stock code: IPN, ISIN code: FR0010259150) and eligible to the "Service de Règlement Différé" ("SRD"). The Group is part of the SBF 120 index. Ipsen has implemented a Sponsored Level I American Depositary Receipt (ADR) program, which trade on the over-the-counter market in the United States under the symbol IPSEY. For more information, 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 favourable 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 fulfill 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.

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