

## **Ipsen Announces Eight Studies of Somatuline<sup>®</sup> Depot (lanreotide) in Gastroenteropancreatic Neuroendocrine Tumors Being Presented at the North American Neuroendocrine Tumor Society (NANETS) Symposium**

**Basking Ridge, N.J., October 15, 2015** – [Ipsen Biopharmaceuticals, Inc.](http://www.ipseyn.com), an affiliate of Ipsen (Euronext: IPN; ADR: IPSEY), today announced that eight studies about Somatuline<sup>®</sup> Depot (lanreotide), will be presented at the annual symposium of the North American Neuroendocrine Tumor Society (NANETS) being held in Austin, Texas, October 15-17, 2015.

Notable data presentations will include:

- **Multivariate Analysis of Progression-Free Survival in the CLARINET Study of Lanreotide Autogel/Depot vs Placebo Identifies Prognostic Factors in Neuroendocrine Tumors**  
This presentation is an analysis of the CLARINET study which affirmed the efficacy of lanreotide and identified the most important prognostic factors for progression-free survival in metastatic pancreatic and intestinal neuroendocrine tumors.
- **Efficacy and Safety of Lanreotide Depot vs Placebo in Patients With Neuroendocrine Tumor and a History of Carcinoid Syndrome and Prior Octreotide Therapy**  
This presentation is a subanalysis of the ELECT study which tested treatment with lanreotide depot for symptomatic control of carcinoid syndrome in patients with gastroenteropancreatic neuroendocrine tumors against a placebo treatment.

“The number of abstracts accepted for presentation at this year’s NANETS Symposium about gastroenteropancreatic neuroendocrine tumors demonstrates Ipsen’s commitment to continued research about lanreotide for this patient community,” said Cynthia Schwalm, President and CEO, Ipsen Biopharmaceuticals, Inc.

All eight posters will be presented on October 16 from 6:00pm to 7:30pm.

Other presentations include:

- **Treatment Patterns and Outcomes in Metastatic Neuroendocrine Tumors: Results From a Retrospective Community Oncology Database**
- **Patterns and Sequencing of Systemic Therapies in Patients with Advanced Neuroendocrine Tumors (NET)**
- **Design of a Phase 2, Prospective, Randomized, Double-Blind, Placebo-Controlled Study Assessing the Efficacy and Safety of Lanreotide Depot 120 mg in Patients with Well Differentiated, Advanced Lung, or Thymus Neuroendocrine Tumors (NETs)**
- **Relationship Between Lanreotide Autogel, Chromogranin A and Progression-Free Survival in Patients with Gastroenteropancreatic Neuroendocrine Tumors**

- **Lanreotide Depot/Autogel in Intestinal and Pancreatic Neuroendocrine Tumors According to Body Mass Index: Subgroup Analyses From the CLARINET Study**
- **Association of Progression-Free Survival with Overall Survival in Patients with Neuroendocrine Tumor Treated with Somatostatin Analogs**

## 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 (GEP-NETs) to improve progression-free survival.

## Important Safety Information

### Contraindications:

Somatuline 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 may reduce gallbladder motility and lead to gallstone formation. Periodic monitoring may be needed.
- **Hypoglycemia or Hyperglycemia:** Pharmacological studies show that Somatuline, like somatostatin and other somatostatin analogs, inhibits the secretion of insulin and glucagon. Blood glucose levels should be monitored when Somatuline treatment is initiated, or when the dose is altered, and antidiabetic treatment should be adjusted accordingly.
- **Cardiac Abnormalities:** Somatuline may decrease heart rate. In 81 patients with baseline heart rates of  $\geq 60$  beats per minute (bpm) treated with Somatuline DEPOT in the GEP-NETs clinical trial, the incidence of heart rate  $< 60$  bpm was 23% (19/81) with Somatuline vs 16% (15/94) with placebo; 10 patients (12%) had documented heart rates  $< 60$  bpm on more than one visit. The incidence of documented episodes of heart rate  $< 50$  bpm or bradycardia reported as an adverse event was 1% in each treatment group. Initiate appropriate medical management in patients who develop symptomatic bradycardia.  
In patients without underlying cardiac disease, Somatuline 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.
- **Drug Interactions:** The pharmacological gastrointestinal effects of Somatuline may reduce the intestinal absorption of concomitant drugs. Concomitant administration of Somatuline Depot may decrease the relative bioavailability of cyclosporine and may necessitate the adjustment of cyclosporine dose to maintain therapeutic levels.

## **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<sup>®</sup> Depot by accessing the following [link](#).

## **About Ipsen**

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding EUR1.2 billion in 2014. 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 2014, R&D expenditure totaled close to EUR187 million, representing about 15% 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](http://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.

Somatuline DEPOT is a registered trademark of IPSEN PHARMA S.A.S.

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