



Press release

## **The FDA approves Somatuline<sup>®</sup> Depot (lanreotide) Injection Extended Dosing Interval as part of Ipsen's Prior Approval Supplement application**

- **Further differentiation of Somatuline<sup>®</sup> Depot (lanreotide) Injection as a formula for control in acromegaly**
  - **Fewer injections and a decreased cost for eligible patients**
- **Confirmation of Somatuline<sup>®</sup> Depot as a key growth driver for Ipsen**

**Paris (France), 9 March 2011** – Ipsen (Euronext: IPN; ADR: IPSEY) announced today that the Food and Drug Administration (FDA) has approved Ipsen's Prior Approval Supplement application for the Extended Dosing Interval of Somatuline<sup>®</sup> Depot for patients suffering from acromegaly.

The approval revises the US Package Insert to allow acromegalic patient to be treated on an extended dosing interval for up to 8 weeks, through the addition of the following sentence in the labelling: "Patients who are controlled on Somatuline<sup>®</sup> Depot 60 mg or 90 mg may be considered for an extended dosing interval of Somatuline<sup>®</sup> Depot 120 mg every 6 or 8 weeks. GH and IGF-1 levels should be obtained 6 weeks after this change in dosing regimen to evaluate persistence of patient response". The extended dosing interval has already been approved in all European countries where Somatuline<sup>®</sup> Autogel is registered.

The Extended Dose Interval of Somatuline<sup>®</sup> Depot 120mg of 6 to 8 weeks will provide patients with acromegaly who are currently controlled on Somatuline<sup>®</sup> Depot 60mg or 90mg every 4 weeks, a possibility to reduce the number of injections per year.

**Stéphane Thiroloix, Executive Vice-President, Corporate Development at Ipsen**, said: "*This new approval confirms Ipsen's positioning as a patient-centric organization and reaffirms the Group's commitment to innovation for patient care. Ipsen is proud to provide physicians and acromegaly patients with an effective and convenient treatment option specifically developed to meet their medical needs. The Group will aggressively pursue its life cycle management strategy to maximize the potential of Somatuline<sup>®</sup> Depot and to reinforce its status of key growth driver in the coming years*".

### **About Somatuline<sup>®</sup> Autogel<sup>®</sup>**

The active substance in Somatuline<sup>®</sup> and Somatuline<sup>®</sup> Autogel<sup>®</sup> (Somatuline<sup>®</sup> Depot in the US) is lanreotide, a somatostatin analog that inhibits the secretion of several endocrine, autocrine and paracrine functions. It is highly effective in inhibiting the secretion of growth hormones and certain hormones secreted by the digestive system.



Somatuline<sup>®</sup> Autogel<sup>®</sup> represents a major technological advance as it is the only formulation of a somatostatin analogue that enables rapid therapeutic response and a longer treatment interval in a pre-filled syringe for easier administration. Somatuline<sup>®</sup> was developed and is registered for the treatment of acromegaly. It was subsequently developed for the treatment of certain syndromes associated with neuroendocrine tumors (carcinoid syndrome) and registered as such in some countries (treatment of acromegaly remains the only indication of Somatuline<sup>®</sup> Depot in the United States). At the end of 2010, Somatuline<sup>®</sup> and Somatuline<sup>®</sup> Autogel<sup>®</sup> were marketed in more than 54 countries.

Ipsen is pursuing the following developments on Somatuline<sup>®</sup> Autogel<sup>®</sup> and Somatuline<sup>®</sup> Depot:

- a phase III clinical trial of Somatuline<sup>®</sup> Autogel for the treatment of non functioning neuroendocrine tumors is in progress in Europe and in the US so as to support future marketing authorization applications.
- Additional phase III clinical trials for the treatment of functioning neuroendocrine tumor symptoms were launched in 2009 so as to support a future marketing authorization application in the US
- In Japan, Ipsen's partner Teijin entered phase III with Somatuline<sup>®</sup> Autogel<sup>®</sup> for the treatment of acromegaly in January 2010 to support a future marketing authorization application in Japan.

## **About Ipsen**

Ipsen is a global biopharmaceutical group, with sales exceeding 1.1 billion euros in 2010. The Group has total worldwide staff of more than 4,400 employees, of which more than 900 contribute to the discovery and development of innovative drugs for patient care. Ipsen's development strategy is based on fast growing specialty care drugs in oncology, endocrinology, neurology and hematology and on primary care drugs. This strategy is supported by an active policy of partnerships. Ipsen's research & development (R&D) centers and its peptide & protein engineering platform give the Group a strong competitive edge. In 2010, R&D expenditure totaled more than €220 million, above 20% of Group sales. 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 on Ipsen, visit our website at [www.ipсен.com](http://www.ipсен.com).

## **Forward Looking Statement**

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. 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. Notably, future currency fluctuations may negatively impact the profitability of the Group and its ability to reach its objectives. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties. The Group does not commit nor gives any guarantee that it will meet the targets mentioned above. Furthermore, the Research and Development process involves several stages each of which involve 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. 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 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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