



Press release

## **FDA approves Extended Dosing Interval for Somatuline<sup>®</sup> Depot (lanreotide) Injection in the United States**

- **Significant product enhancement for patients with acromegaly**
  - **Fewer injections for medically appropriate patients**
- **Demonstrates Ipsen's ongoing commitment to advancing patient care**

**Brisbane (CA, United States)**, 10 March 2011 – Tercica, Inc. a subsidiary of the Ipsen Group (Euronext: IPN, ADR: IPSEY), a global biopharmaceutical group, announced today that the Food and Drug Administration (FDA) has approved an Extended Dosing Interval of Somatuline<sup>®</sup> Depot for patients with acromegaly.

The updated US prescribing information allows patients who have been controlled on Somatuline<sup>®</sup> Depot 60 mg or 90 mg injections every 4 weeks to be considered for an extended dosing interval of Somatuline<sup>®</sup> Depot 120 mg every 6 or 8 weeks. Physicians should obtain growth hormone (GH) and insulin-like growth factor-1 (IGF-1) levels 6 weeks after this change in dosing regimen to evaluate if patient response is maintained. These patients can benefit from a reduction in the number of injections required per year.

### **About Acromegaly**

Acromegaly is a rare hormonal disorder that results from an excess production of growth hormone (GH) usually caused by a pituitary tumor. Disease-related symptoms include abnormal growth of the hands and feet, and changes in facial features. Acromegaly, if ignored, can lead to serious health complications.

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

Somatuline<sup>®</sup> Depot (lanreotide) Injection is indicated in the US for the long-term treatment of patients with acromegaly who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. In well-controlled clinical studies, Somatuline Depot has been shown to be an effective treatment that reduces IGF-1 and GH levels in some patients with acromegaly. The most commonly reported side effects include stomach and intestinal problems, gallstones, skin reactions, headaches and joint pain.

In August 2007, the U.S. Food and Drug Administration (FDA) approved Somatuline<sup>®</sup> Depot for marketing in the United States. At the end of 2010, Ipsen marketed the product under the names Somatuline<sup>®</sup> and Somatuline<sup>®</sup> Autogel<sup>®</sup> in more than 54 countries for various uses.

## **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).

### **For further information:**

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