

## Ipsen to set up its own US oncology team for Somatuline<sup>®</sup> Depot<sup>®</sup> (lanreotide) Injection in neuroendocrine tumors

- **“Go-it-alone” option favored to maximize long term value and reach critical mass in the US**

**Paris (France), 14 January 2014** – Ipsen (Euronext : IPN ; ADR : IPSEY) today announced its decision to set up its own oncology team to commercialize Somatuline<sup>®</sup> Depot<sup>®</sup> (lanreotide) 120 mg Injection (referred to as Somatuline<sup>®</sup>) in neuroendocrine tumors (NETs) in the US.

Over the past few months, the Group had been considering both a “go-it-alone” and a partnership strategy following the communication of the data from the investigational CLARINET<sup>®</sup> phase III clinical study evaluating the antiproliferative effect of Somatuline<sup>®</sup> in the treatment of non-functioning gastrointestinal & pancreatic NETs (GEP NETs). Ipsen expects that these encouraging results will support a key long-term opportunity for the Group to access an US addressable market in excess of 500 million dollars<sup>1</sup>.

Ipsen considers success in the US as a strategic priority. The “go-it-alone” option maximizes long term value creation and helps the US affiliate in reaching critical mass.

**Marc de Garidel, Chairman and CEO of Ipsen** said: *“With this strategic decision, the Group is strengthening its US platform. I’m convinced that we now have all the cards in hand to succeed. We will diligently work on setting up our own high quality, custom-built and experienced oncology team in the US to maximize potential for our differentiated Somatuline<sup>®</sup> product.”*

Ipsen anticipates filing a Supplemental New Drug Application seeking an indication for Somatuline<sup>®</sup> in NETs in the first half of 2014. Maximum incremental annual cost associated with the launch of Somatuline<sup>®</sup> in the NET indication in the US is expected to range from 30 million euros to 40 million euros. As a result, US breakeven<sup>2</sup>, initially expected in 2014, is postponed to 2017. Ipsen will continue to implement cost containment initiatives to minimize impact on overall Group profitability.

The data from CLARINET<sup>®</sup> is considered investigational, as Somatuline<sup>®</sup> is not approved for the treatment of GEP-NETs in the US. Somatuline<sup>®</sup>'s only approved US indication is for the treatment of acromegaly.

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<sup>1</sup> Ipsen 2013 estimates of US NET market

<sup>2</sup> Commercial contribution excluding Increlex<sup>®</sup> (mecasermin [rDNA origin]) Injection sales and revenues from U.S. collaboration with Valeant Pharmaceuticals Intl Inc. in aesthetic medicine



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

Somatuline<sup>®</sup> Depot<sup>®</sup> (lanreotide) Injection is a somatostatin analog indicated for the long-term treatment of patients with acromegaly who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.

### Select Important Safety Information about Somatuline<sup>®</sup> Depot<sup>®</sup>

- **Warnings and Precautions**

- Somatuline<sup>®</sup> 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<sup>®</sup> may decrease heart rate. In cardiac studies, the most common cardiac adverse reactions were sinus bradycardia, bradycardia, and hypertension. Dose adjustment of coadministered drugs that decrease heart rate may be necessary
- Somatuline<sup>®</sup> may decrease bioavailability of cyclosporine. Cyclosporine dose may need to be adjusted

- **Adverse Reactions**

The most common adverse reactions (incidence >5%) were diarrhea (37%), cholelithiasis (20%), abdominal pain (19%), nausea (11%), injection-site reaction (9%), constipation (8%), flatulence (7%), headache (7%), arthralgia (7%), vomiting (7%), and loose stools (6%).

- **Use in Special Populations**

Patients with moderate and severe renal impairment or moderate and severe hepatic impairment: Initial dose is 60 mg every 4 weeks.

## About Ipsen

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.2 billion in 2012. 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 2012, R&D expenditure totalled close to €250 million, representing more than 20% of Group sales. The Group has close to 4,900 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 on Ipsen, visit [www.ipsen.com](http://www.ipsen.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. 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 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.

**For further information:**

**Media**

**Didier Véron**

Senior Vice-Président, Public Affairs  
and Communication

Tel.: +33 (0)1 58 33 51 16

Fax: +33 (0)1 58 33 50 58

E-mail: [didier.veron@ipsen.com](mailto:didier.veron@ipsen.com)

**Brigitte Le Guennec**

Media and Public Relations Officer

Tel.: +33 (0)1 58 33 51 17

Fax: +33 (0)1 58 33 50 58

E-mail : [brigitte.le.guennec@ipsen.com](mailto:brigitte.le.guennec@ipsen.com)

**Financial Community**

**Pierre Kemula**

Vice President, Corporate Finance, Treasury and  
Financial Markets

Tel.: +33 (0)1 58 33 60 08

Fax: +33 (0)1 58 33 50 63

E-mail: [pierre.kemula@ipsen.com](mailto:pierre.kemula@ipsen.com)

**Stéphane Durant des Aulnois**

Investor Relations Officer

Tel.: +33 (0)1 58 33 60 09

Fax: +33 (0)1 58 33 50 63

E-mail: [stephane.durant.des.aulnois@ipsen.com](mailto:stephane.durant.des.aulnois@ipsen.com)

**Thomas Peny-Coblentz**

Investor Relations Manager

Tel.: +33 (0)1 58 33 56 36

Fax: +33 (0)1 58 33 50 63

E-mail: [thomas.peny-coblentz@ipsen.com](mailto:thomas.peny-coblentz@ipsen.com)