

Ipsen announces positive top line results from phase III ELECT[®] study of Somatuline[®] in the control of symptoms in NET patients with a history of carcinoid syndrome

- **Treatment with Somatuline[®] resulted in statistically significantly fewer days of use of rescue medication needed to control symptoms in patients with carcinoid syndrome**

Paris (France), 17 September 2013 – Ipsen (Euronext: IPN; ADR: IPSEY) announced today positive top line results from the primary endpoint of the ELECT[®] study, assessing the effect of Somatuline[®] Autogel[®] / Somatuline Depot[®] (lanreotide) Injection 120 mg (referred to as Somatuline[®]) on the control of symptoms in patients with neuroendocrine tumors (NETs) associated with carcinoid syndrome. Treatment with Somatuline[®] was found to be statistically significantly superior to placebo in decreasing the number of days patients needed to use rescue medication (subcutaneous somatostatin analogues i.e., octreotide) to control symptoms associated with carcinoid syndrome. The safety profile observed in the study is consistent with the known safety profile of Somatuline[®]. Ipsen expects to present comprehensive results from this study at the 2014 Gastrointestinal Cancers Symposium (January 16-18, 2014 in San Francisco, CA).

Somatuline[®] is approved for the treatment of symptoms associated with carcinoid syndrome in neuroendocrine tumors in many international markets where it is marketed as Somatuline[®] Autogel[®], but not in the US, where it is marketed as Somatuline[®] Depot. As such, data arising from the ELECT[®] study can be considered as an investigational use of Somatuline Depot in the United States.

Claude Bertrand, Executive Vice-President Research & Development and Chief Scientific Officer of Ipsen stated: *“Ipsen is pleased with the top line results of the ELECT[®] study. We believe that the full package of data, once released, will provide important insights to the treatment of GEP-NET¹ patients.”*

About carcinoid syndrome

Neuroendocrine neoplasms are tumors arising from the diffuse neuroendocrine system most often along the gastrointestinal tract. They are rare but their incidence is increasing (approximately 2.5 to 4.5 new cases diagnosed per 100,000 persons per year). They constitute a heterogeneous group of tumors with location of the primary tumor in the gastric mucosa, pancreas, small and large intestine. As a result of their origin, they are capable of releasing a variety of hormones and neuroamines, most commonly serotonin, which, when released into the systemic circulation, can cause distinct clinical symptoms, such as the carcinoid syndrome associating diarrhea and flushing, with often abdominal pain. In some cases, digestive disorders and flushing are associated

¹ GEP-NETs: Gastrointestinal and pancreatic neuroendocrine tumors



with heart failure (wheezing, edema of the lower limbs, irregular heartbeats) indicator of carcinoid valvular heart disease.

About ELECT[®]

ELECT[®] (A double-blind, randomized placebo controlled Clinical Trial investigating the efficacy and safety of Somatuline[®] (lanreotide) injection in the treatment of carcinoid syndrome) is a 48-week Phase III trial in patients with a history of carcinoid syndrome. The study consisted of a 16-week, double-blind, randomized (to either Somatuline[®] or placebo), placebo-controlled phase followed by a 32-week open-label phase. Throughout the study the patients were allowed to use rescue medication in the form of subcutaneous somatostatin analogues (octreotide) as needed to control their symptoms related to carcinoid syndrome. The primary endpoint was the percentage of days subcutaneous octreotide was required to control symptoms associated with carcinoid syndrome, as rescue medication during the 16-week double-blind phase of the study. Secondary endpoints included frequency of diarrhea and flushing, usage of other rescue medication, Quality of Life, tumor markers and safety. The trial is registered in ClinicalTrials.gov (NCT00774930).

About Somatuline[®]

The active substance in Somatuline[®] is lanreotide acetate, a somatostatin analogue that inhibits the secretion of several endocrine, exocrine and paracrine functions. It has been shown effective in inhibiting the secretion of GH and certain hormones secreted by the digestive system. Somatuline[®] is marketed as Somatuline[®] Depot within the United States and as Somatuline[®] Autogel[®] in other countries where it has marketing authorization.

Somatuline[®] was initially developed and continues to be used for the treatment of acromegaly in many countries, including the United States, where it is 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. Somatuline[®] is not approved within the United States for the treatment of symptoms associated with neuroendocrine tumors, but is approved for this indication in other markets.

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.

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 fulfil 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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