

Ipsen announces positive results from phase III CLARINET study of Somatuline[®] Autogel[®] 120mg in gastrointestinal and pancreatic neuroendocrine tumors (“GEP-NETs”)¹

- **Somatuline[®] Autogel[®] shows statistically significant improvement in progression free survival**
- **Major clinical results for the treatment of non-functioning GEP-NETs**

Paris (France), 11 July 2013 – Ipsen (Euronext: IPN; ADR: IPSEY) announced today results from the primary endpoint of the CLARINET study, assessing the effect of Somatuline[®] Autogel[®] 120 mg on tumor progression-free survival in patients with GEP-NETs. Treatment with Somatuline[®] Autogel[®] 120mg was found to be statistically significantly superior to placebo in extending time to either disease progression or death. The safety profile observed in the study is consistent with the known safety profile of Somatuline[®]. Comprehensive results from this study will be disclosed at the annual meeting of the European Society of Medical Oncology (ESMO) (Sept. 27 – Oct. 1, 2013).

CLARINET provides medically important results as it is the first large scale placebo-controlled randomized study to demonstrate the antitumoral activity of a somatostatin analog in non-functioning GEP-NETs.

Pr Martyn Caplin, Professor of Gastroenterology & Gastrointestinal Neuroendocrinology, Royal Free Hospital (London, UK) and Principal Investigator of CLARINET, commented: *“CLARINET is the first prospective large scale placebo-controlled study inclusive of gastrointestinal and pancreatic NETs which provides clear evidence that Somatuline[®] Autogel[®] 120mg delays tumor progression or death. These important results will help the medical community to confirm the place of Somatuline[®] Autogel[®] in the treatment algorithm of these patients.”*

Claude Bertrand, Executive Vice-President Research & Development and Chief Scientific Officer of Ipsen commented: *“Ipsen is very pleased with the top line results of the CLARINET study. We believe it should meet the expectations of physicians by potentially providing a new treatment option for patients with gastrointestinal and pancreatic neuroendocrine tumors.”*

¹GEP-NETs refer to gastro-entero-pancreatic neuroendocrine tumors



About gastroenteropancreatic neuroendocrine tumors

Gastrointestinal and pancreatic neuroendocrine tumors (GEP-NETs) are rare but their incidence is increasing. They constitute a heterogeneous group of tumors with location of the primary tumor in the gastric mucosa, pancreas, small and large intestine. GEP-NETs when they are functioning secrete hormones and neuroamines that cause distinct clinical symptoms, such as the carcinoid syndrome associating diarrhea and flushing. However, non-functioning GEP-NETs do not secrete hormones and can remain clinically silent, delaying the diagnosis until late presentation with symptoms related to mass effects such as abdominal pain or weight loss. Therapeutic strategies include somatostatin analogues that are the mainstay for the control of the symptoms of the carcinoid syndrome. Antineoplastic effects have been also reported with somatostatin analogues. Other therapeutic strategies are surgery, chemotherapy and metabolic radiotherapy.

About CLARINET

CLARINET (Controlled study of Lanreotide Antiproliferative Response in NET) is a 96-week, multinational study that was conducted in collaboration with UKI NETS and ENETS in patients (n=204) with well or moderately differentiated non-functioning GEP-NETs and a proliferation index (Ki67) of <10%. Patients were randomized to either Somatuline® Autogel® 120 mg or placebo. The primary endpoint of efficacy was time to either disease progression (using Response Evaluation Criteria In Solid Tumors, RECIST) or death. Two baseline computed tomography scans (≥12 weeks apart) were performed, followed by additional scans at intervals up to 96 weeks. Secondary endpoints included proportion of patients alive and without tumor progression at 48 and 96 weeks, time to progression, overall survival, safety, quality of life, plasma chromogranin A levels, tumor markers, and pharmacokinetic parameters. The trial is registered with ClinicalTrials.gov (NCT00353496).

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 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.

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 Generics 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. 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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