

“PRIMARYS” study Investigators observed clinically relevant results in an investigational Phase III study with Somatuline[®] Autogel[®] 120 mg in patients with acromegaly

Statistical significance not met for the primary endpoint, but tumor volume reduction observed in a majority of acromegalic patients

Paris (France), June 17th, 2013. Ipsen (Euronext: IPN; ADR: IPSEY) today announced the results of an international phase IIIB study, PRIMARYS, assessing an investigational use of Somatuline[®] Autogel[®] (lanreotide) 120mg as first line therapy in newly diagnosed acromegaly patients with a macroadenoma. While PRIMARYS did not meet statistical significance with respect to its primary efficacy endpoint, investigators observed clinically relevant tumor volume reductions, in a majority of patients. Data from secondary biomarker endpoints of growth hormone (GH) and insulin-like growth factor-1 (IGF-1) levels were further supportive of these findings. Baseline GH level was the main factor identified as potential predictor for tumor response to primary therapy. Data were presented at the Endocrine Society¹ annual congress (ENDO Congress, San Francisco, USA) on June 16th, 2013.

PRIMARYS is the first study of a somatostatin analogue in such a large and homogeneous population (90 treatment-naïve acromegalic patients with macroadenoma) to evaluate tumor volume reduction as the primary endpoint using Magnetic Resonance Imaging (MRI) with a very robust and unique methodology for central assessment.

Pr John S. Bevan, co-Principal Investigator of the study, Head of Endocrinology at Aberdeen Royal Infirmary and Honorary Professor of Endocrinology at Aberdeen University (UK) said: *“The results not only show a clinically relevant effect on the volume of the macroadenoma but are also very convincing for GH and IGF-1 lowering and improvement in clinical symptoms. Interestingly, all these beneficial effects can be observed after only 3 injections of Somatuline[®] Autogel[®] 120mg. The overall safety profile observed during this one year study was consistent with the safety profile of Somatuline[®] in acromegalic patients – despite the high doses administered, no patient had to stop treatment due to gastro-intestinal adverse effects. This study*

¹ Oral presentation: OR27-3 High Dose Lanreotide Autogel Treatment Produces Early and Sustained Reductions in Tumor Volume and GH/IGF-1 Levels in Treatment-Naïve Acromegalic Patients with GH-Secreting Pituitary Macroadenoma: The PRIMARYS Study - Featured poster presentation: FP27-1 Potential Predictors of Macroadenoma Volume Reduction After Primary Therapy With Lanreotide Autogel in a Large Treatment-Naïve Acromegalic Population

reinforces the overall positive benefit/risk of Somatuline[®] Autogel[®] 120mg in acromegalic patients and provides new data to further explore its potential use as an alternative to frontline surgery for treatment-naïve patients with GH-secreting macroadenoma”.

Pr Philippe J. Caron, Investigator of PRIMARYS, Head of Endocrinology and Metabolic diseases Unit, Toulouse (France) added: *“We can be very proud of this unique and well-designed study. Although the primary endpoint was not statistically met, we observe clinically relevant results as Somatuline[®] Autogel[®] 120mg was associated with early and sustained reduction in pituitary adenoma volume. 63% of patients achieved 20% or more volume reduction as well as reduction in GH/IGF-1 levels and improvement in clinical symptoms”.*

Claude Bertrand, Executive Vice-President, Research & Development - Chief Scientific Officer, Ipsen (France) concluded: *“Not only does this study confirm efficacy and safety of Somatuline[®] Autogel[®] 120mg, but PRIMARYS also provides very interesting scientific information concerning an investigational use of Somatuline[®] Autogel[®] 120mg in a large cohort of newly diagnosed acromegalic patients. With this study, Ipsen demonstrates its commitment in endocrinology, exploring innovative solutions to treat newly diagnosed acromegalic patients. ”*

About PRIMARYS Phase IIIB study

PRIMARYS (PRIMARY treatment in macroadenoma acromegaly with Somatuline[®]) is a unique, open label, 1-year study, evaluating an investigational use of Somatuline[®] Autogel[®] 120mg (lanreotide) in 90 patients with newly diagnosed acromegaly. Spanning 9 countries worldwide, it is the only somatostatin analogue study assessing tumor volume reduction as a primary endpoint and with a rigorous central reading methodology involving 3 neuroradiologists.

Somatuline[®] Autogel[®] 120mg was initiated in patients with macroadenoma, with one injection every 4 weeks and patients tumor volume assessment every 12 weeks (using MRI), GH, IGF-1, clinical symptoms, biochemical parameters, quality of life and safety over a total period of 48 weeks. In the Intention To Treat (ITT) population, the proportion of patients achieving $\geq 20\%$ tumor volume reduction from baseline to week 48 was 63% (95% CI, 52%-73%), according to the neuroradiologist with the highest repeatability and lowest intra-variability (primary analysis), and from 72% (95% CI, 61-81%) to 75% (95% CI, 65-84%) according to two other readers for whom CIs for the proportion of patients with tumour response was above the protocol-predefined arbitrary 55% threshold.

Five patients prematurely discontinued the PRIMARYS study due to adverse events, among which three were considered as related to the study medication by the investigator (leakage of cerebral fluid, deterioration of hypertension and hair loss).

Most patients reported mild (57/90 [63%]) and/or moderate AEs (36/90 [40%]), but only 5/90 discontinued due to AEs (6%). In the absence of a control group, it is challenging to determine whether adverse events were related to the study drug. The safety profile observed in the study is consistent with the known safety profile of Somatuline[®]. The most frequent treatment emergent adverse events were gastrointestinal disorders, alopecia, cholelithiasis and fatigue.

About Somatuline[®]

The active substance in Somatuline[®] Depot / Somatuline[®] Autogel[®] is lanreotide acetate, a somatostatin analogue that inhibits the secretion of several endocrine, exocrine and paracrine functions. It is particularly effective in inhibiting the secretion of GH and certain hormones secreted by the digestive system.

Somatuline[®] is available in some countries in a differentiated and enhanced presentation with a pre-filled syringe that does not need reconstitution and with a retractable needle that enhances safety for caregivers. Somatuline[®] was initially developed and continues to be used for the treatment of acromegaly. It was subsequently developed and is now also used for the treatment of symptoms associated with

neuroendocrine tumors in many markets, but not in the US where it is still currently under development and yet to be approved for this indication.

As of 13th May 2013, Somatuline[®] (30mg) and Somatuline[®] Autogel[®] (60mg, 90mg, 120mg) were marketed in over 55 countries (including 29 in Europe) and registered in 70 countries (including 30 in Europe) for the treatment of acromegaly and/or neuroendocrine tumors.

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 totaled 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.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. 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 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 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.

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