

# Press release

# **Ipsen closes its BIM 23A760 trials**

 Preliminary phase II acromegaly data does not meet expected inhibition of GH and IGF-1 levels after repeat dosing

# Ipsen remains committed to improving the treatment of acromegaly and neuroendocrine tumours (NET)

Paris (France), 15 December 2010 – Ipsen (Euronext: IPN, ADR: IPSEY) announced today that the preliminary data from the ongoing phase IIb study in patients with acromegaly for its chimeric compound BIM 23A760 does not meet the expected inhibition of growth hormone (GH) and IGF-1 levels after repeat dosing. Preliminary phase IIb data showed a strong dopaminergic activity but only weak evidence of somatostatinergic activity. No safety concerns have been observed throughout the trial. Consequently, Ipsen has decided to discontinue the development of BIM 23A760. Patients will be switched to appropriate approved treatment at the end of their respective monitoring period.

Claude Bertrand, Ipsen's Executive Vice-President, Chief Scientific Officer said: "We are confident in the scientific rational of chimeric molecules as they can show enhanced biological activity compared to co-administered independent compounds. Chimeric molecules represent a powerful avenue for Ipsen on which we will continue to actively progress some of our R&D programs in several disease areas."

In order to grow its leading pituitary disorders franchise, Ipsen will continue to focus its development programmes on Somatuline $^{@}$ .

Somatuline<sup>®</sup> benefits from a longstanding and well-established global commercial footprint. It is now available in more than 45 countries for the treatment of acromegaly and to a lesser extent NET. In 2009, worldwide sales of Somatuline<sup>®</sup> amounted to almost €140 million delivering an annual growth rate exceeding 14% since 2004. Current development activity on Somatuline<sup>®</sup> includes:

- On-going phase III of Somatuline<sup>®</sup> in functioning NET in the USA;
- On-going phase III of Somatuline<sup>®</sup> in non-functioning NET giving the opportunity to become first somatostatin analogue to be registered in this indication on a worldwide basis:
- On-going phase III in acromegaly in Japan by Ipsen's partner Teijin;
- Improved device providing both safety and certainty of full dose administration;
- Some innovative formulation programs.

Stéphane Thiroloix, Ipsen's Executive Vice-President, Corporate Development added: "Despite the discontinuation of BIM 23A760 development, Ipsen remains fully committed to bringing value-added therapies to patients and clinicians in endocrinology, especially in the treatment of statural and pituitary disorders. Patients suffering from acromegaly and, in some countries, neuroendocrine tumours, already benefit from Somatuline<sup>®</sup>. We are actively engaged in improving the availability of Somatuline<sup>®</sup> for patients in need, in exploring its full potential for use in additional indications, and in further improving the medical value and patient-friendliness of therapy in those indications."



#### About BIM 23A760

BIM 23A760 was designed and developed by Ipsen's research team using its validated peptide engineering platform, with a view to improving the treatment of acromegaly and neuroendocrine tumors. This innovative chimeric compound bears within a single molecule two pharmacological moieties, i.e. a somatostatin analog and a dopamine agonist and acts synergistically by inducing an interaction between these receptors. The design of BIM 23A760 was based on a novel concept in molecular biology regarding the amplification of intracellular signalling when engaging simultaneously two receptors with their respective ligands.

## **About Ipsen**

Ipsen is a global biopharmaceutical group, with sales exceeding 1 billion euros in 2009. The Group has total worldwide staff of more than 4,400 employees, of which nearly 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 2009, R&D expenditure totaled close to €200 million, representing nearly 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.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. 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. Notably, future currency fluctuations may negatively impact the profitability of the Group and its ability to reach its objectives. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties. The Group does not commit nor gives any guarantee that it will meet the targets mentioned above. Furthermore, the Research and Development process involves several stages each of which involve 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 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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