



Press release

## **Initiation of two phase II studies with Ipsen's proprietary BIM 23A760 first-in-class chimeric compound in the treatment of acromegaly and carcinoid syndrome due to neuroendocrine tumors**

**Paris (France), 15 March 2010** - Ipsen (Euronext: FR0010259150; IPN) announced today the initiation of dosing in two phase II clinical studies to evaluate efficacy and safety of BIM 23A760 in two groups of patients, one suffering from carcinoid syndrome due to neuroendocrine tumors, the other from acromegaly.

*"After the encouraging signs of efficacy observed in the first clinical studies in healthy as well as acromegalic volunteers, we look forward to further investigating BIM 23A760 efficacy and safety in patients with neuroendocrine tumors or acromegaly. This very promising compound is core to Ipsen's strategy to enhance its fast-growing and competitive endocrinology franchise, featuring among other drugs Somatuline<sup>®</sup>, a somatostatin analogue developed and marketed on a global scale"* said **Stéphane Thiroloix, Executive Vice-President, Corporate Development, Ipsen.**

### **About BIM 23A760**

BIM 23A760 has been designed and developed by Ipsen's research team using its validated peptide engineering platform. This first-in-class innovative chimeric compound bears within a single molecule two pharmacological moieties, i.e. a somatostatin analog and a dopamine agonist which act synergistically following activation of those receptors in disorders such as acromegaly and neuroendocrine tumors. The design of BIM 23A760 is based on a novel concept in molecular biology regarding the amplification of intracellular signalling when engaging simultaneously two receptors with their respective ligands. The molecule targets two patho-physiological pathways among the most commonly associated with pituitary tumors: Growth hormone and prolactin. Aside from the symptomatic treatment of acromegaly and carcinoid syndrome due to neuroendocrine tumors, BIM 23A760 might potentially also reduce the tumor size, thereby eliminating some of the shortcomings of the treatments currently available. Ipsen is currently studying this molecule whose spectrum of activity is wider than that of currently marketed somatostatin analogues.

### **About the phase II trial in acromegaly**

The clinical trial is a phase II open, randomized, parallel group, non comparative multicenter study to assess the efficacy and safety of repeated subcutaneous (s.c.) administration of different doses of BIM 23A760 on growth hormone (GH) and insulin-like growth factor-1 (IGF-1) levels in patients with acromegaly after 6 months of treatment.

This clinical trial follows phase I and IIa trials. In the phase I, BIM 23A760 administration in healthy volunteers potently suppressed prolactin levels and statistically significant reductions in IGF-1 levels were observed. In the phase IIa study, the exposure to BIM 23A760 in acromegalic patients, exhibited a 66–74% mean maximum reduction in growth hormone (GH) levels. A dose dependent tendency for a more pronounced and longer GH inhibition was also observed. Additionally, a reduction in IGF-1 levels was seen in both dosage (1 mg and 4 mg). BIM 23A760 was well tolerated at both dosages.



### About acromegaly

Acromegaly is a disorder caused by the over production of growth hormone due to a benign tumor of the anterior pituitary gland. This relatively rare disorder occurs in approximately 90 out of every one million people (90/1,000,000). Both men and women are affected. Approximately 50% of the diagnosed patients receive a drug therapy.

### **About the phase II trial in neuroendocrine tumors**

The clinical trial is a phase II, open, adaptive, dose escalating, multicentre titration study to assess the efficacy and safety of repeated s.c. administration of different doses of BIM 23A760 for the treatment of carcinoid syndrome in patients affected with neuroendocrine tumors on patient's overall satisfaction in terms of symptom relief after 6 months of treatment.

### About Carcinoid tumors

Carcinoid tumors are rare diseases affecting about 2.5 to 5 out of 100 000 people. Most of them develop in the gastrointestinal tract. The hypersecretion of substances by the tumor, in particular serotonin, results in symptoms, mainly diarrhea and flushing. The treatment includes symptomatic control as well as tumor reduction.

### **About Ipsen**

Ipsen is a global biotechnology specialty care company with total sales in excess of 1 billion euros in 2009, and total worldwide staff of more than 4,400. Its strategy is based on fast growing specialty care drugs in oncology, endocrinology, neurology and hematology, and primary care drugs, significantly contributing to research financing. This strategy is also supported by an active policy of partnerships. Ipsen's specific Research & Development (R&D) centers and peptide & protein engineering platform give the Group a competitive edge. More than 800 people are dedicated to the discovery and development of innovative drugs for patient care. In 2009, R&D spend reached close to €200 million, representing more than 19% of total Group sales. Ipsen's shares are traded on *Segment A* of Euronext Paris (stock code: IPN, ISIN code: FR0010259150). Ipsen's shares are eligible to the "Service de Règlement Différé" ("SRD") and the Group is part of the SBF 120 index. For more information on Ipsen, visit our website at [www.ipsen.com](http://www.ipsen.com).

### **Ipsen 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 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 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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