



Press release

## **Phase III clinical trial with 4-month long-acting formulation of triptorelin: Ipsen decides not to perform further administration**

**Paris (France), 11 June 2007** – Ipsen (Euronext: FR0010259150; IPN) announced today that the preliminary data from the ongoing phase III study for its investigational 4-month formulation of triptorelin do not support the expected sustainable blood levels of triptorelin for a duration of 4 months in all patients. Therefore, Ipsen has decided not to perform the second administration as planned in the protocol. No safety concerns have been observed throughout the trial. At the end of their respective monitoring period, patients will be switched to appropriate approved treatment.

The 4-month investigational product, one of Ipsen's new sustained release formulation candidates of triptorelin using one amongst several Ipsen proprietary technologies, has shown an adequate efficacy and safety profile in phase II allowing a move to phase III. Ipsen's goal remains to have a new formulation of triptorelin available when the current patents of the 3-month formulation of Decapeptyl<sup>®</sup> expire.

Jacques-Pierre Moreau, Executive Vice-President, Chief Scientific Officer of Ipsen said: *"We are taking all appropriate actions to solve the scale-up issues seen during this phase III, which are inherent to advanced formulations based on cutting edge technologies. From the onset, the introduction of an innovative subcutaneous presentation using a new retro-injection device was well received by patients and investigators. Thus, the teams are now focusing their energy and expertise in order to resume phase III as soon as possible. Our advanced drug delivery platform has already been validated through the success of Somatuline<sup>®</sup> Autogel<sup>®</sup>, and we are confident in Ipsen's ability to have a differentiated formulation of triptorelin."*

### **About triptorelin**

Triptorelin is a metabolically stabilized analogue of LHRH (Luteinizing Hormone Releasing Hormone) an hypothalamic hormone secreted in a pulsatile fashion. Upon binding to its pituitary receptor LHRH triggers the release of luteinizing hormone, a key factor for the regulation of reproductive function. Continuous administration of exogenous LHRH or its agonists such as triptorelin leads to a rapid desensitization of its pituitary receptor resulting in a paradoxical effect that translates into the suppression of gonadal steroids such as testosterone and estradiol. This chemically induced and reversible castration is of therapeutic benefit in the treatment of hormone sensitive tumours such as breast and prostate. Triptorelin is the active ingredient of Decapeptyl<sup>®</sup> and Diphereline<sup>®</sup> available as 1- and 3-month sustained release formulations registered for the treatment of advanced metastatic hormone-dependent prostate cancer.



## **About Ipsen**

Ipsen is an innovation driven international specialty pharmaceutical group with over 20 products on the market and a total worldwide staff of nearly 4,000. The company's development strategy is based on a combination of products in targeted therapeutic areas (oncology, endocrinology and neuromuscular disorders) which are growth drivers, and primary care products which contribute significantly to its research financing. This strategy is also supported by an active policy of partnerships. The location of its four Research and Development centres (Paris, Boston, Barcelona, London) gives the Group a competitive edge in gaining access to leading university research teams and highly qualified personnel. In 2006, R&D expenditure was €178.3 million, i.e. 20.7% of consolidated sales, which amounted to €861.7 million while total revenues amounted to €945.3 million (in IFRS). 700 people in R&D are dedicated to the discovery and development of innovative drugs for patient care. Ipsen's shares are traded on Segment A of Euronext by Euronext™ (stock code: IPN, ISIN code: FR0010259150). Ipsen's shares are eligible to the "Système à Règlement Différé" ("SRD") and the Group is part of the SBF 250 index. For more information on Ipsen, visit our website at [www.ipсен.com](http://www.ipсен.com).

## Forward-looking statements

The forward-looking statements and targets contained herein are based on Ipsen's management's 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 Research and Development process involves several stages at each of which there is a substantial risk that the Group will fail to achieve its objectives and be forced to abandon its efforts in respect of 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. Ipsen 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. Ipsen's business is subject to the risk factors outlined in its information documents filed with the French *Autorité des Marchés Financiers*.

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