



Press release

## **Clinical update for Decapeptyl<sup>®</sup> 6-month formulation in advanced prostate cancer**

**Presentation of efficacy and safety Phase III results by Ipsen's partner,  
Debiopharm, at the 9th International Symposium on GnRH in Berlin (Germany)**

**Paris (France), 12 February 2008** - Ipsen (Euronext: FR0010259150; IPN) announced that its partner Debiopharm presented today the results of a phase III study with its new 6-month formulation of Decapeptyl<sup>®</sup><sup>1</sup>, a luteinizing hormone releasing hormone agonist (LHRHa) for the treatment of advanced prostate cancer. The results presented show similar efficacy and safety to the already marketed 1- and 3-month formulations of triptorelin.

This multicenter, open, non-comparative, phase III study on the efficacy and safety of two consecutive injections at a six-month interval of triptorelin 6-month formulation in 120 patients with advanced prostate cancer, showed that 97.5% of patients achieved castrate levels of serum testosterone 28 days after the first injection and that 93% of the patients maintained serum testosterone levels below castrate level (defined as  $\leq 1.735$  nmol/L or 50 ng/dL) from week 8 to 48. These efficacy and safety results are similar to those obtained previously with repeated administrations of the 1- and 3-month formulations of triptorelin in previous studies. Furthermore, local tolerance is good with only 6.7% of the patients treated reporting spontaneously site injection adverse events.

On 31 October 2007, Ipsen exclusively in-licensed from Debiopharm know-how and new patent applications for the commercialization rights of Decapeptyl<sup>®</sup> (triptorelin pamoate) in the world excluding North America, and some other countries (Sweden, Israel, Iran and Japan).

### **About Decapeptyl<sup>®</sup>**

Decapeptyl<sup>®</sup> is a peptide formulation for injection that was initially developed by Debiopharm and continues to be used mainly in the treatment of advanced metastatic prostate cancer. Additional indications developed subsequently include the treatment of uterine fibroids (a benign tumour of muscle tissues in the uterus), endometriosis (proliferation of endometrial tissue, the mucous membrane that lines the uterine wall outside the reproductive tract) prior to surgery or when surgery is not deemed appropriate, as well as early onset puberty and female infertility (in vitro fertilisation). Decapeptyl<sup>®</sup> is available in monthly or quarterly sustained-release formulations, as well as a daily formulation. The active substance in Decapeptyl<sup>®</sup> is triptorelin, a decapeptide analogue of GnRH (Gonadotrophin Releasing Hormone), a hormone secreted by the hypothalamus, which initially stimulates the release of pituitary gonadotrophins (hormones produced by the pituitary gland), which in turn control hormonal secretions by the testes and ovaries. Decapeptyl<sup>®</sup> was initially launched in France during 1986. At 31 December 2007, Decapeptyl<sup>®</sup> had marketing authorizations in over 60 countries, including 25 in Europe. In 2007, 59.7% of Decapeptyl<sup>®</sup> sales were generated in the five major European Countries, and reached a total of 235.1M€.

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<sup>1</sup> Triptorelin formulations are mainly sold as Decapeptyl<sup>®</sup>, Diphereline<sup>®</sup> and Pamorelin<sup>®</sup>



Debiopharm, which holds the patent to pamoate formulations of Decapeptyl<sup>®</sup> has granted Ipsen an exclusive licence to Decapeptyl<sup>®</sup> within the European Union (outside Sweden) and in certain other countries. Debiopharm has also granted Ipsen a co-exclusive licence to manufacture Decapeptyl<sup>®</sup> within the European Union (outside Sweden) and in certain other countries (with Debiopharm nonetheless retaining the right to manufacture and supply Decapeptyl<sup>®</sup> for its own purposes and those of its other licensees in territories not licensed to the Group).

### **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 Eurolist by Euronext<sup>TM</sup> (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 120 index. For more information on Ipsen, visit our website at [www.ipsen.com](http://www.ipsen.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, or that the regulatory authorities will be satisfied with the data and information provided by the Company. 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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