

Press release

## **Ipsen announces the filing of Decapeptyl<sup>®</sup> 6-month formulation for the treatment of locally advanced or metastatic prostate cancer in Europe**

**The filing of the new Decapeptyl<sup>®</sup> 6-month formulation  
is in accordance with Ipsen's regulatory timeline**

**Paris (France), 25 September 2008** - Ipsen (Euronext: FR0010259150; IPN) today announced the start of the filing process in Europe of the 6-month sustained release formulation of Decapeptyl<sup>®</sup>, a luteinizing hormone releasing hormone agonist (LHRHa) developed by Debiopharm for the treatment of locally advanced or metastatic hormone-dependent prostate cancer.

On 31 October 2007, Ipsen exclusively in-licensed from Debiopharm know-how and new patent applications for the commercialization rights of the new 6-month formulation 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 Group and continues to be used mainly in the treatment of locally advanced or 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> is mainly indicated in the treatment of locally advanced or metastatic prostate cancer. In this indication, Decapeptyl<sup>®</sup> temporarily increases the concentration of testosterone and dihydro testosterone, but continuous administration paradoxically leads to a reduction in plasmatic testosterone concentration. After two to three weeks of treatment, testosterone is reduced to levels below the castration threshold, thereby depriving prostate tumours of one of the main hormones promoting tumour development. 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, 60.9% of Decapeptyl<sup>®</sup> sales were generated in the 5 major European Countries. Debiopharm, which holds the patent to pamoate formulations of Decapeptyl<sup>®</sup> has granted the Group an exclusive license to commercialise Decapeptyl<sup>®</sup> within the European Union (outside Sweden) and in certain other countries. Debiopharm has also granted the Group a non-exclusive license 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. Its development strategy is based on a combination of specialty products, which are growth drivers, in targeted therapeutic areas (oncology,

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<sup>1</sup>depending on the countries, Ipsen commercialises Decapeptyl<sup>®</sup> under different brand names (Diphereline<sup>®</sup>, Pamorelin<sup>®</sup>, Arvekap<sup>®</sup>)

endocrinology and neuromuscular disorders), and primary care products which contribute significantly to its research financing. The location of its four Research & Development centres (Paris, Boston, Barcelona, London) and its peptide and protein engineering platform give the Group a competitive edge in gaining access to leading university research teams and highly qualified personnel. More than 700 people in R&D are dedicated to the discovery and development of innovative drugs for patient care. This strategy is also supported by an active policy of partnerships. In 2007, Research and Development expenditure was about €185 million, in excess of 20% of consolidated sales, which amounted to €920.5 million while total revenues amounted to €993.8 million. 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)

#### **Forward-looking statements**

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, as announced on June 5, 2008 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. 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 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. 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.

#### **For further information:**

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