



Press release

Launch of Ipsen's Decapeptyl® 6-month formulation (LP 22.5 mg) in France for the treatment of locally advanced or metastatic hormone-dependent prostate cancer

Paris (France) and Lausanne (Switzerland), 4 February 2010 - Ipsen (Euronext: FR0010259150; IPN), an innovation-driven global specialty pharmaceutical group and Debiopharm Group (Debiopharm), a Swiss-based global biopharmaceutical group of companies with a focus on the development of prescription drugs that target unmet medical needs, announce the launch by Ipsen in France of Decapeptyl® LP 22.5 mg 6-month sustained-release formulation for the treatment of locally advanced or metastatic hormone-dependent prostate cancer. Other launches are planned shortly, notably in Germany and Portugal.

The marketing authorization (MA) to this 6-month sustained-release formulation of Decapeptyl® (triptorelin embonate¹ 22.5 mg) was granted on 10 November 2009 by the French regulatory authorities (Agence Française de Sécurité Sanitaire des Produits de Santé, AFSSAPS) for the treatment of locally advanced and metastatic hormone-dependent prostate cancer. France was the first country to approve Decapeptyl® LP 22.5 mg in the context of a Decentralized Procedure in Europe. The reimbursement rate by Social Security and price setting decision have been published in the *Journal Officiel* of 3 February 2010, i.e. less than three months after MA was granted.

Decapeptyl® LP 22.5 mg is the new sustained-release 6-month formulation of a gonatropin-releasing hormone (GnRH) agonist analogue developed by Debiopharm Group. Debiopharm has licensed the marketing rights to Ipsen for all territories where Ipsen currently commercializes triptorelin.

On 13 October 2009, Ipsen and Debiopharm Group announced the successful completion of the European decentralised registration procedure involving nine countries: Germany (reference member state), France, Austria, Finland, Norway, Belgium, Denmark, Spain and The Netherlands while for other European countries (Portugal, United Kingdom, Ireland, Italy, Romania and Lithuania), the marketing authorisation applications were filed as national line extensions to the existing Decapeptyl[®] s ones.

About Decapeptyl®

Debiopharm licensed-in triptorelin from Tulane University in 1982.

Decapeptyl® is available in 1- and 3-month sustained-release formulations, as well as a daily formulation. Debiopharm developed and registered the 1- and 3-month sustained release formulations of triptorelin embonate in Europe and the U.S. The active substance in Decapeptyl® is triptorelin, a decapeptide analogue of GnRH (Gonadotropin Releasing Hormone), a hormone secreted by the hypothalamus, which initially stimulates the release of pituitary gonadotropins (hormones produced by the pituitary gland), which in turn control hormonal secretions by the testes and ovaries.

¹ triptorelin embonate (INN) = triptorelin pamoate (USAN)





The product is now marketed worldwide for the treatment of advanced prostate cancer, endometriosis, uterine fibroids, precocious puberty, and female infertility as part of in-vitro fertilisation programs.

The marketing authorisation application for the 6-month-formulation was submitted to the registration authorities of nine European countries in September 2008, in accordance with the Decentralised Procedure. It was supported by data from a phase III study on the efficacy, pharmacokinetics and safety of two consecutive injections of triptorelin 6-month-formulation in 120 patients with advanced prostate cancer. The results showed that 97.5% of patients achieved castrate levels of serum testosterone (defined as ≤ 1.735 nmol/L or 50 ng/dL) 28 days after the first injection, and 93.0% of the patients maintained castrate levels of testosterone from week 8 to 48. Furthermore, at months 6 and 12, 98.3% of the patients were castrated. Overall the phase III data demonstrated that the treatment was well tolerated. The local tolerance of the product was very good with few patients (6.7%) experiencing local side effects, the majority of them being mild. These efficacy and safety results are similar to those obtained previously with repeated administrations of the 1- and 3-month-formulations of triptorelin.

Debiopharm will manufacture the 6-month formulation at Debio R.P., its FDA-inspected production facility in Switzerland.

About Ipsen

Ipsen is an innovation-driven global specialty pharmaceutical group with over 20 products on the market and a total worldwide staff of nearly 4,200. Its development strategy is based on a combination of specialty medicine, which is Ipsen's growth driver, in targeted therapeutic areas (oncology, endocrinology, neurology and haematology), 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 800 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 2008, Research and Development expenditure was about €183 million, close to 19% of consolidated sales, which amounted to €971 million while total revenues exceeded €1 billion. 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.

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.

About Debiopharm Group

Debiopharm Group is a Swiss-based global biopharmaceutical group of companies with a focus on the development of prescription drugs that target unmet medical needs. The group in-licenses promising biological and small molecule drug candidates. It develops its products for global registration and maximum commercial potential. Once registered, the products are out-licensed to pharmaceutical partners for sales and marketing.

Debiopharm independently funds the worldwide development of all of its products while providing expertise in pre-clinical and clinical trials, manufacturing, drug delivery and formulation, and regulatory affairs.

For more information on Debiopharm Group, please visit: www.debiopharm.com

For further information:

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