



Press release

Ipsen's Decapeptyl[®] 6-month formulation receives marketing authorization in France for the treatment of locally advanced or metastatic prostate cancer

Paris (France), 13 November 2009 - Ipsen (Euronext: FR0010259150; IPN), an innovation-driven global specialty pharmaceutical Group announces that the French regulatory authorities (*Agence Française de Sécurité Sanitaire des Produits de Santé*, AFSSAPS) have today granted the marketing authorization to the 6-month sustained-release formulation of Decapeptyl[®] (triptorelin embonate¹ 22.5 mg) for the treatment of locally advanced and metastatic prostate cancer. The launch of the 6-month formulation of Decapeptyl[®] in France by Ipsen should take place during the first semester of 2010.

"Ipsen is pleased that the new 6-month formulation of Decapeptyl[®] will soon be available for patients in France suffering from prostate cancer. Its improved convenience comes with a consistent and similar efficacy and tolerance to the already established Decapeptyl[®]'s 1 and 3-month Decapeptyl[®] formulations," said **Etienne de Blois**, Deputy General Manager, France Operations, Ipsen.

Triptorelin embonate 22.5 mg is a new 6-month-formulation of a luteinizing hormone releasing hormone (LHRH) agonist for the treatment of locally advanced or metastatic, hormone-dependent prostate cancer, developed by Debiopharm Group. Debiopharm has licensed the marketing rights to Ipsen for all territories where Ipsen currently commercializes triptorelin.

Last 13 October, 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 a national line extension to the existing Decapeptyl[®]'s ones. France is the first country to approve Decapeptyl[®] 6-month in the context of the Decentralized procedure in Europe.

About Decapeptyl[®]

Debiopharm licensed-in triptorelin from Tulane University in 1982.

Decapeptyl[®] is available in monthly or quarterly sustained-release formulations, as well as a daily formulation. Debiopharm developed and submitted 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.

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

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

¹ triptorelin pamoate is similar to triptorelin embonate



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 28 days after the first injection, and 93.0% of the patients maintained castrate levels of testosterone (defined as $\leq 1.735\text{nmol/L}$ or 50 ng/dL) from week 8 to 48. Furthermore, at month 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 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.



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