

**PRESS RELEASE**

**Ipsen and Debiopharm Group announce that Decapeptyl<sup>®</sup> (triptorelin embonate) 6-month successfully completes the European Decentralised Procedure for the treatment of locally advanced or metastatic prostate cancer**

**Developed by Debiopharm Group, triptorelin embonate 6-month will be commercialised by Ipsen in Europe**

**Lausanne (Switzerland) and Paris (France), 13 October 2009** - 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, and Ipsen (Euronext: FR0010259150; IPN), an innovation-driven global specialty pharmaceutical Group, announced that the 6-month sustained-release formulation of Decapeptyl<sup>®1</sup> (triptorelin embonate<sup>2</sup> 22.5 mg) successfully completed its European decentralised registration procedure involving nine countries: Germany (reference member state), France, Austria, Finland, Norway, Belgium, Denmark, Spain and The Netherlands.

Triptorelin embonate 22.5 mg is Debiopharm's new 6-month-formulation of a luteinizing hormone releasing hormone (LHRH) agonist for the treatment of locally advanced or metastatic, hormone-dependent prostate cancer. Debiopharm has licensed the European marketing rights to Ipsen. The first European countries to launch the 6-month formulation should be Germany, The Netherlands and Spain.

*"As expected, we are proud to offer patients suffering from prostate cancer a new 6-month formulation of Decapeptyl<sup>®</sup> with an improved convenience and a consistent and similar efficacy to the already established 1 and 3-month formulations,"* said **Jean-Luc Bélingard**, Ipsen's Chairman and Chief Executive Officer. *"The completion of this procedure represents a major step forward in the development of our uro-oncology franchise."*

*"It is great news that the completion of the European decentralised procedure for triptorelin embonate 6-month formulation was done in such a timely manner,"* added **Rolland-Yves Mauvernay**, President and Founder of Debiopharm Group. *"We view this achievement as further evidence of the efficacy and safety of this important product. LHRH-agonists will remain the mainstay of hormone-dependent prostate cancer in the years ahead, and patients can now look forward to receiving a more convenient treatment every six months instead of every three months."*

**About Decapeptyl<sup>®</sup>**

Debiopharm licensed-in triptorelin from Tulane University in 1982.

Decapeptyl<sup>®</sup> 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

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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>)

<sup>2</sup> triptorelin pamoate is similar to triptorelin embonate

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 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  $50\text{ ng/dL}$ ) 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.

### **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.

Founded in 1979 and headquartered in Lausanne, Switzerland, Debiopharm has developed four products with global combined sales of \$2.6 billion in 2008.

For more information on Debiopharm Group, please visit: [www.debiopharm.com](http://www.debiopharm.com)

### **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](http://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 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:**

#### **Ipsen**

##### *Media*

#### **Didier Véron**

Director, Public Affairs and Corporate  
Communications

Tel.: +33 (0)1 58 33 51 16

Fax: +33 (0)1 58 33 50 58

E-mail: [didier.veron@ipsen.com](mailto:didier.veron@ipsen.com)

##### *Financial Community*

#### **David Schilansky**

Investor Relations and Financial Officer

Tel.: +33 (0)1 58 33 51 30

Fax: +33 (0)1 58 33 50 63

E-mail: [david.schilansky@ipsen.com](mailto:david.schilansky@ipsen.com)

#### **Pierre Kemula**

Investor Relations Manager

Tel.: +33 (0)1 58 33 60 08

Fax: +33 (0)1 58 33 50 63

E-mail: [pierre.kemula@ipsen.com](mailto:pierre.kemula@ipsen.com)



**Debiopharm**

**Debiopharm S.A. Contact**

Maurice Wagner

Director Corporate Affairs & Communication

Tel.: +41 (0)21 321 01 11

Fax: +41 (0)21 321 01 69

[mwagner@debiopharm.com](mailto:mwagner@debiopharm.com)

**Additional Media Contacts**

**In London**

Maitland

Brian Hudspith

Tel: +44 (0)20 7379 5151

[bhudspith@maitland.co.uk](mailto:bhudspith@maitland.co.uk)

**In New York**

Russo Partners, LLC

Martina Schwarzkopf, Ph.D.

Account Executive

Tel: +1 212-845-4292

Fax: +1 212-845-4260

[martina.schwarzkopf@russopartnersllc.com](mailto:martina.schwarzkopf@russopartnersllc.com)