

## **Ipsen announces positive results from phase III clinical study of Decapeptyl<sup>®</sup> (triptorelin pamoate) 11.25 mg administered by subcutaneous route to prostate cancer patients**

- **At week 4, testosterone level controlled in 97.6% of men and PSA level reduced by 64.2%**
- **At week 26, testosterone level maintained under control in 96.6% of men and PSA level reduced by 96.0%**
- **Efficacy results and safety profile consistent with those of Decapeptyl<sup>®</sup> administered by intramuscular route**

**Paris (France), 10 October 2014** – Ipsen (Euronext: IPN; ADR: IPSEY) today announced positive results from the phase III study of triptorelin pamoate 11.25 mg (Decapeptyl<sup>®</sup> 3 months) administered subcutaneously in patients with locally advanced or metastatic prostate cancer at the European Association of Urology (EAU) 14<sup>th</sup> Central European Meeting in Cracow, Poland (10-12 October 2014).

The primary objective of the study was to assess the efficacy and safety profile of the sustained-release triptorelin pamoate 11.25 mg (Decapeptyl<sup>®</sup> 3 months) formulation when administered by the subcutaneous route in men with locally advanced or metastatic prostate cancer. This objective was met with castration levels of testosterone achieved in 97.6% [95% CI: 93.2-99.5] of men at week 4 and castration maintained in 96.6% of these men [95% CI: 91.6-99.1] at week 26.

Mean testosterone levels decreased to 18.4 ng/dl and 10.2 ng/dl at week 4 and week 8, respectively, and remained within this range until the end of the study. Median time to achieve castration was 22 days. For more than 90% of the patients, the level of testosterone was maintained below 20 ng/dl from week 8 up to the end of the trial.

Median Prostate Specific Antigen (PSA) levels were reduced by 64.2% and 96.0% at week 4 and week 26, respectively. PSA levels remained within the normal range (0–4 ng/ml) from week 8 until the end of the study.



The efficacy results and safety profile of triptorelin pamoate 11.25 mg administered by the subcutaneous route are consistent with the known efficacy and safety profile of triptorelin administered by the intramuscular route.

Based on these results, Ipsen has applied for the addition of the subcutaneous route, alongside the intramuscular route, to the label of triptorelin pamoate 11.25 mg.

**Claude Bertrand, Executive Vice-President, Research & Development and Chief Scientific Officer of Ipsen** stated: *“These results provide further evidence to the efficacy and safety of Decapeptyl® in the treatment of patients with prostate cancer. The subcutaneous route widens the options for the administration of Decapeptyl® and may be offered to patients for whom intramuscular administration is not recommended. Ipsen is pleased to reaffirm its positioning as a patient-centric organization.”*

#### **About the study**

This study is a multicentre, open-label, single-arm study of triptorelin pamoate 11.25 mg given by the subcutaneous route twice (at baseline and 13 weeks later), in which patients from 14 centres were monitored for 26 weeks between October 2012 and October 2013. The co-primary endpoints were the proportion of patients with a castration level of serum testosterone (<50 ng/dl) at 4 weeks (target >80% achieving castration), and of these, those still castrated at 26 weeks (target >85% maintaining castration). Key secondary endpoints notably comprised: time to achieve castration; probability of testosterone levels remaining <50 ng/dl between week 4 and week 26; change in prostate-specific antigen (PSA) levels from baseline; proportion of patients with normal PSA levels at 26 weeks compared with baseline.

#### **About Decapeptyl® (triptorelin pamoate)**

Decapeptyl® is a peptide formulation for injection 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) after surgery or when surgery is not deemed appropriate, as well as early onset puberty and female infertility (in vitro fertilisation).

The active substance in Decapeptyl® is triptorelin pamoate, 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 testicles and ovaries. Administration of triptorelin results in the suppression of the GnRH activity leading to hormonal castration in men and menopausal phase in women.

The formulations of Decapeptyl® marketed by the Group include a daily formulation, one-month, three-month and six-month formulations. Ipsen is the first pharmaceutical company to have launched the three-month formulation in China.



## **About Ipsen**

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.2 billion in 2013. Ipsen's ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its development strategy is supported by 3 franchises: neurology, endocrinology and uro-oncology. Moreover, the Group has an active policy of partnerships. Ipsen's R&D is focused on its innovative and differentiated technological platforms, peptides and toxins. In 2013, R&D expenditure totaled close to €250 million, representing more than 20% of Group sales. Moreover, Ipsen also has a significant presence in primary care. The Group has close to 4,600 employees worldwide. Ipsen's shares are traded on segment A of Euronext Paris (stock code: IPN, ISIN code: FR0010259150) and eligible to the "Service de Règlement Différé" ("SRD"). The Group is part of the SBF 120 index. Ipsen has implemented a Sponsored Level I American Depositary Receipt (ADR) program, which trade on the over-the-counter market in the United States under the symbol IPSEY. For more information on Ipsen, visit [www.ipсен.com](http://www.ipсен.com).

## **Ipsen 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. All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words "believes," "anticipates" and "expects" and similar expressions are intended to identify forward-looking statements, including the Group's expectations regarding future events, including regulatory filings and determinations. 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. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising product in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. The Group must face or might face competition from generic products that might translate into a loss of market share. Furthermore, the Research and Development process involves several stages each of which involves 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. There can be no guarantees a product will receive the necessary regulatory approvals or that the product will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Group's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of



international economies and sovereign risk; dependence on the effectiveness of the Group's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. 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 cannot be certain that its partners will fulfil their obligations. It might be unable to obtain any benefit from those agreements. A default by any of the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial position or performance. 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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