

## **Ipsen announces that the International Breast Cancer Study Group (IBCSG) presented phase 3 results evaluating the use of ovarian suppression to adjuvant treatment with tamoxifen**

- **22% risk reduction of developing invasive breast cancer with tamoxifen plus ovarian suppression, versus tamoxifen alone**
- **Ovarian suppression was obtained entirely by monthly injections of triptorelin over 5 years for 81% of patients**

**Paris (France), 12 December 2014** – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that the International Breast Cancer Study Group (IBCSG) presented results of the randomized phase III SOFT clinical trial at the 2014 San Antonio Breast Cancer Symposium.

Suppression of Ovarian Function Trial (SOFT) assessed the value of ovarian suppression in reducing breast cancer recurrence in young women receiving tamoxifen, and evaluated the role of the aromatase inhibitor exemestane plus ovarian suppression in this population. Ovarian suppression was obtained entirely by monthly injections of triptorelin (active ingredient of Ipsen's Decapeptyl®) over 5 years for 81% of patients.

Treatment combining tamoxifen plus ovarian suppression reduced the relative risk of developing invasive breast cancer recurrence by 22% in women who did not transition into menopause after receiving chemotherapy, when compared to treatment with tamoxifen alone. On average, these women were 40 years old when starting hormonal therapy after chemotherapy. A secondary analysis revealed that further benefit could be gained by treating these women with exemestane plus ovarian suppression, which reduced their relative risk of breast cancer recurrence by 35%, compared to tamoxifen alone, resulting in 7 or 8 fewer women out of 100 having a breast cancer recurrence within 5 years.

**Prudence Francis, M.D., Head of Breast Medical Oncology, Peter MacCallum Cancer Centre, Australia** stated: *“For the youngest women with hormone-sensitive breast cancer, ovarian suppression will increasingly be recommended. For women who have not reached menopause and have hormone-sensitive breast cancer that carries sufficient risk of recurrence to warrant chemotherapy, doctors are likely to discuss the option of treatment with ovarian suppression plus an aromatase inhibitor as an alternative to tamoxifen.”*



**Gini Fleming, M.D., Clinical Medical Oncology Breast Program Director, University of Chicago, USA** added: *“While ovarian suppression is not recommended for everyone, adding it to tamoxifen can reduce breast cancer recurrence in higher-risk patients who remain premenopausal after chemotherapy, particularly in women under the age of 35.”*

**Claude Bertrand, Executive Vice-President, Research & Development and Chief Scientific Officer of Ipsen** stated: *“Ipsen is very pleased to have participated in this landmark study, which could change clinical practice in breast cancer treatment. In addition to solid efficacy results, the SOFT study provides the largest clinical trial safety database for the long term use of triptorelin in women.”*

More information can be found in SABCS Abstract S3-08 (SOFT Efficacy) and SABCS Abstract S3-09 (SOFT Quality of Life).

#### **About the study**

SOFT (Suppression of Ovarian Function Trial) enrolled more than 3,000 premenopausal women with hormone receptor-positive early-stage breast cancer and estradiol levels in the premenopausal range between December 2003 and April 2011. Trial treatment lasted 5 years and women continue to be followed for life to assess long-term prognosis and side effects. The trial is led by the International Breast Cancer Study Group (IBCSG), in partnership with the Breast International Group (BIG) and the North American Breast Cancer Group (NABCG), and supported by IBSCG, Pfizer, Ipsen and the U.S. National Cancer Institute (NCI).

SOFT was designed to assess the value of ovarian suppression in reducing breast cancer recurrence in young women receiving tamoxifen, and to assess the role of the aromatase inhibitor exemestane plus ovarian suppression in treating young women. Premenopausal women with estrogen and/or progesterone receptor-positive, breast cancer were randomly assigned to treatment with tamoxifen alone for 5 years, tamoxifen plus ovarian suppression for 5 years, or exemestane plus ovarian suppression for 5 years.

#### **About triptorelin (active substance of Decapeptyl®)**

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 or acetate, 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 menopause in women and hormonal castration in men. The formulations of Decapeptyl® marketed by the Ipsen Group include a daily formulation, one-month, three-month and six-month formulations.



## **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 €260 million, representing more than 21% 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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