Press release

Toremifene citrate 80 mg meets primary and key secondary endpoints in phase III clinical trial in advanced prostate cancer patients on androgen deprivation therapy

Ipsen intends to submit toremifene citrate 80 mg in Europe before year-end 2008

Paris (France), 25 February 2008 - Ipsen (Euronext: IPN) announced today that GTx Inc. (NASDAQ: GTXI), from which it licensed the European rights for Acapodene® (toremifene citrate 80 mg) in September 2006, presented the results of the first phase III study evaluating the efficacy and safety of toremifene citrate 80mg daily, on multiple side effects of androgen deprivation therapy (ADT) in advanced prostate cancer patients. On the basis of these positive results, Ipsen intends to file toremifene citrate 80 mg for this indication in the European Union before year-end 2008. Androgen deprivation therapy using either luteinizing hormone releasing hormone or surgical castration is the most common treatment for advanced prostate cancer and have clearly demonstrated their efficacy. However, their impact on testosterone and oestrogen levels could result in a decrease of bone mineral density (BMD) potentially leading to osteoporotic fractures, and other adverse effects such as lipid changes, gynecomastia and hot flashes.

Stéphane Thiroloix, Executive Vice President, Corporate Development of Ipsen, said: "*We are very pleased with the results of this clinical trial, which confirm the efficacy and the good safety profile of toremifene citrate 80 mg. Subject to regulatory approval, this drug has the potential to address a significant unmet medical need by providing a new therapeutic approach to treat the side symptoms of androgen deprivation therapy. This product is an excellent fit with Ipsen's existing Decapeptyl® franchise, reinforcing our positioning in the treatment of hormone-dependent diseases and broadens the range of our prostate cancer related product portfolio.*"

About the study

In this large phase III study, 1389 ADT patients were randomized to evaluate the efficacy and safety of toremifene citrate 80 mg compared to placebo over two years in approximately 150 clinical sites in the United States and Mexico. All men enrolled were over 50 years or older with histologically documented prostate cancer, serum prostate specific antigen (PSA) 4 ng/ml or less and a history of orchiectomy, or treatment with GnRH agonist for at least 6 months or intermittent treatment with a GnRH agonist for at least 12 months. The primary endpoint of this study was reached with a significant reduction ($p<0.05$) in the incidence of morphometric vertebral fractures of at least 50% in the toremifene group as compared to the placebo group with a fracture rate of 2.5% vs 4.9% respectively (preliminary analysis). Furthermore, Bone Mineral Density (BMD) data have confirmed the anti-osteoporotic efficacy of toremifene citrate 80mg/day in significantly preventing bone loss ($p<0.0001$) at the spine as well as at the hip and femur level. Toremifene citrate 80 mg treatment compared to placebo also resulted in a decrease in total cholesterol ($p=0.011$), LDL ($p=0.018$), and triglycerides ($p<0.0001$), and an increase in HDL ($p=0.001$). In regard to the effect of toremifene citrate 80 mg on hot flashes, the evaluation of these data is still ongoing and will be reviewed with the final data set.

Tolerance of the treatment was good. Among the most common adverse events that occurred in over 2% of study subjects were arthralgia (treated 7.3%, placebo 11.8%), dizziness (treated 6.3%, placebo 5.0%), back pain (treated 5.9%, placebo 5.2%), and extremity pain (treated 5.0%, placebo 4.4%). There were 17 (2.4 %) venous thromboembolic events (VTE) in the toremifene citrate 80 mg treated group and 7 (1.02 %) in the placebo group. However the majority of VTE's occurred in men with an high risk for a thromboembolic event including: age >80 years, history of VTE, recent surgical procedure and immobilization.

About toremifene citrate 80 mg

Toremifene citrate 80 mg is a selective estrogen receptor modulator, or SERM, which GTx is developing as a daily tablet to treat the multiple estrogen related side effects of androgen deprivation therapy for advanced prostate cancer. Toremifene citrate was designed to bind to and selectively modulate estrogen receptors depending on the tissue type. GTx has rights to and plans to commercialize toremifene citrate 80 mg in the United States. GTx has licensed European rights to Ipsen Group, the leading marketer of ADT drugs in Europe.

About Ipsen

Ipsen is an innovation driven international specialty pharmaceutical group with over 20 products on the market and a total worldwide staff of nearly 4,000. The company's development strategy is based on a combination of products in targeted therapeutic areas (oncology, endocrinology and neuromuscular disorders) which are growth drivers, and primary care products which contribute significantly to its research financing. This strategy is also supported by an active policy of partnerships. The location of its four Research and Development centres (Paris, Boston, Barcelona, London) gives the Group a competitive edge in gaining access to leading university research teams and highly qualified personnel. In 2006, R&D expenditure was €178.3 million, i.e. 20.7% of consolidated sales, which amounted to €861.7 million while total revenues amounted to €945.3 million (in IFRS). 700 people in R&D are dedicated to the discovery and development of innovative drugs for patient care. Ipsen's shares are traded on Segment A of Eurolist by Euronext™ (stock code: IPN, ISIN code: FR0010259150). Ipsen' s shares are eligible to the "Système à 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.

Forward-looking statements

The forward-looking statements and targets contained herein are based on Ipsen's management's 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 Research and Development process involves several stages at each of which there is a substantial risk that the Group will fail to achieve its objectives and be forced to abandon its efforts in respect of 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, or that the regulatory authorities will be satisfied with the data and information provided by the Company. Ipsen 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. Ipsen's business is subject to the risk factors outlined in its information documents filed with the French *Autorité des Marchés Financiers*.

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