

Press release

## **Adenuric<sup>®</sup> (febuxostat) receives marketing authorisation in the European Union**

### **Adenuric<sup>®</sup> represents the first major treatment of chronic hyperuricemia in gout for more than forty years**

**Paris (France), 5 May 2008** – Ipsen (Euronext: FR0010259150; IPN) today announced that the European Commission granted marketing authorisation for Adenuric<sup>®</sup> (febuxostat) for the treatment of chronic hyperuricaemia in gout. Adenuric<sup>®</sup> thus pioneers the first major treatment alternative for gout, a severe debilitating disease, for more than 40 years.

*"Recent surveys confirm that management of gout is often suboptimal, with less than half of patients receiving appropriate lifestyle advice or urate lowering treatment" said Michael Doherty, Professor of Rheumatology at the University of Nottingham (UK) and Co-chair of the 2006 EULAR Task Force for the Recommendations on Diagnosis and Management of Gout. "Recent European (EULAR) Recommendations emphasise the aim of "cure" by lowering serum urate levels below the saturation point for crystal formation. For some patients, the existing urate lowering therapies have limitations in terms of suitability or side effects. The availability of a new effective therapy that allows the therapeutic target to be achieved will improve the physicians armamentarium and ultimately benefit the population of patients with gout."*

Adenuric<sup>®</sup> (febuxostat) 80 mg and 120 mg tablets are indicated for the treatment of chronic hyperuricaemia for conditions in which urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis).

Adenuric<sup>®</sup> will be marketed by Ipsen in France. Outside France, the commercialisation of the product will be partnered.

#### **About the marketing authorisation**

(The European Public Assessment Report (EPAR) summary will be accessible at <http://www.emea.europa.eu>). This decision follows the filing by Ipsen, of an application for marketing authorisation for Adenuric<sup>®</sup> in the European Union in 2006. A positive opinion, recommending to grant a marketing authorisation was adopted by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on 21 February 2008.

The EU submission, included two of the largest industry sponsored studies to date studying treatment of chronic gout patients. The goal of chronic gout treatment is per EULAR guidelines (European League Against Rheumatism) to reduce and maintain sUA levels below 6 mg/dL. Febuxostat demonstrated superior ability to lower and maintain in patients, serum uric acid at a level inferior to 6 mg/dl compared to conventionally used doses of allopurinol (febuxostat 80 and 120 mg: 51 & 63 % resp. vs. allopurinol: 22%). In addition, one phase III study showed that gout patients with mild to moderate renal impairment (serum creatinine >1.5 - ≤2.0 mg/dl) had response rate of 44 and 45 % respectively with febuxostat 80 and 120 mg.

#### **About Adenuric<sup>®</sup> (febuxostat)**

Gout, a particularly painful type of arthritis, is the most frequent arthritis in men. It is caused by elevated levels of uric acid in the body: hyperuricaemia. Febuxostat, an oral, once-daily medication, is a novel non-purine, selective inhibitor of xanthine oxidase studied for its effects on lowering levels of serum uric acid (sUA) in patients with gout.

The recommended oral dose of Adenuric<sup>®</sup> is 80 mg once daily without regard to food. If serum uric acid is > 6 mg/dl (357 µmol/l) after 2-4 weeks, Adenuric<sup>®</sup> 120 mg once daily may be considered. Adenuric<sup>®</sup> works sufficiently quickly to allow retesting of the serum uric acid after 2 weeks. The therapeutic target is to decrease and maintain serum uric acid below 6 mg/dl (357µmol/l). Gout flare prophylaxis of at least 6 months is recommended at initiation of treatment with Adenuric<sup>®</sup>.

Febuxostat is licensed to Ipsen for Europe from Teijin Pharma Limited, Tokyo. In 2003, Ipsen entered into a Research and Development partnership with Teijin Pharma Limited, the core company of Teijin Group's pharmaceutical and home healthcare business. The Teijin group is a Japanese industrial conglomerate specialising in the businesses of fibres, films, plastics and information technology (IT) as well as pharmaceuticals and home healthcare. This partnership covers the development and subsequent commercialisation of four of Ipsen's products by Teijin Pharma in Japan and the development and marketing by Ipsen in Europe (i.e. European Union and Russia) of febuxostat, a product owned by Teijin Pharma and known as TMX-67.

### **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. Its development strategy is based on a combination of specialty products, which are growth drivers, in targeted therapeutic areas (oncology, endocrinology and neuromuscular disorders), 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 700 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 2007, Research and Development expenditure was about €185 million, in excess of 20% of consolidated sales, which amounted to €920.5 million while total revenues amounted to €993.8 million. Ipsen's shares are traded on Segment A of Eurolist by Euronext<sup>TM</sup> (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.ipсен.com](http://www.ipсен.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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