



Press release

## **EMA recommends marketing authorisation of Ipsen's Adenuric<sup>®</sup> (febuxostat) for the treatment of chronic hyperuricaemia in gout**

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

**Paris (France), 21 February 2008** - Ipsen (Euronext: FR0010259150; IPN) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) provided a positive opinion for Adenuric<sup>®</sup> (febuxostat) 80 mg and 120 mg tablets for the treatment of chronic hyperuricaemia in gout and recommended it for marketing authorisation. The CHMP recommendation will now be forwarded to the European Commission for final marketing approval, which typically occurs within 60 to 90 days. Following marketing approval, Adenuric<sup>®</sup> will become, since 1964, the first significant treatment alternative for chronic hyperuricaemia available to gout patients.

Adenuric<sup>®</sup> is to be 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). The detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC), to be made available after the medication receives marketing authorisation from the European Commission.

Once the product receives its marketing authorisation and its price is agreed, Febuxostat will be marketed by Ipsen in France under the brand name Adenuric<sup>®</sup>. Outside France, the commercialisation of the product will be partnered.

Jean-Luc Bélingard, Chairman and Chief Executive Officer of Ipsen, said, "*We are very proud to receive this positive opinion for Adenuric<sup>®</sup> from the EMA, and look forward to bringing this new molecule to market, pending European Commission approval. This innovative drug pioneers the first major treatment of gout for more than 40 years. It confirms Ipsen's ability to continue to bring to the market important new treatment options for severely debilitating diseases.*"

### **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. Febuxostat is licensed to Ipsen for Europe from Teijin Pharma Limited, Tokyo.

The EU submission includes 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.

CHMP press release can be accessed at <http://www.emea.europa.eu>.

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. 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 Euronext<sup>TM</sup> (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](http://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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