

Press release

## **Launch by Menarini and Ipsen of ADENURIC<sup>®</sup> (febuxostat) in France for the treatment of chronic hyperuricemia in gout**

- **First therapeutic alternative in gout for decades**
- **France is the first country to launch ADENURIC<sup>®</sup> in Europe**

**Paris (France), 5 March 2010** - Ipsen (Euronext: FR0010259150; IPN), a global biotechnology specialty care group and Menarini, the first Italian pharmaceutical Group in the world with a significant pan-European presence, today announced the launch of ADENURIC<sup>®</sup> (febuxostat) in France where they will co-promote the drug. Other launches by Menarini are planned shortly, notably in United Kingdom, Germany and Ireland.

**Thierry Poiraud, MD, General Manager, Menarini France** said: *"We are proud to be the first country in Europe to launch this very promising drug with Ipsen. In collaboration with rheumatologists and general practitioners I hope we can significantly improve the chronic management of this painful and frequent disease, which may lead to serious complications with a major impact on quality of life. "*

**Etienne de Blois, Deputy General Manager, Ipsen France Operations**, Ipsen said: *"The launch of ADENURIC<sup>®</sup> will provide patients and physicians with a new treatment alternative in a condition with high unmet medical needs. It also strengthens Ipsen's primary care franchise in France, the first country to launch the drug in Europe. Ipsen is proud to work with Menarini to make that achievement possible."*

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

ADENURIC<sup>®</sup> (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.

ADENURIC<sup>®</sup> received marketing authorisation in the European Union on 21<sup>st</sup> April 2008. Its 80 mg and 120 mg tablets are indicated for the treatment of chronic hyperuricemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis). In its evaluation<sup>1</sup>, the French *Haute Autorité de Santé* indicates that ADENURIC<sup>®</sup> has demonstrated superiority over allopurinol in decreasing and maintaining uricaemia below the therapeutic objective of 360 µmol/l (6 mg/dl) as defined, in 2006, by EULAR guidelines in the chronic management of gout. Additionally, ADENURIC<sup>®</sup> can be prescribed without dose adjustment to patients suffering from mild to moderate renal impairment and might be an alternative option for patients that are intolerant to allopurinol. Treatment with febuxostat in patients with ischaemic heart disease or congestive heart failure is not recommended.

In 2003, Teijin Pharma Limited, Tokyo, the core company of Teijin Group's pharmaceutical and home healthcare business, who discovered febuxostat, had granted Ipsen the exclusive

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<sup>1</sup> Avis de la commission de transparence M04AA03 - ADENURIC - CT-6315  
Adenuric<sup>®</sup> is a registered trademark of Teijin Pharma Limited, Tokyo, Japan.

development and marketing rights to ADENURIC<sup>®</sup> (febuxostat) in Europe. On 20 October 2009, Ipsen has granted Menarini exclusive licence rights to ADENURIC<sup>®</sup> in the European Union, Russia and countries west of Russia for a total of 41 countries.

### **About gout**

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 : hyperuricemia. In this condition, crystals of monosodium urate (MSU) are deposited on the articular cartilage of joints, tendons, and surrounding tissues. It is marked by transient painful attacks of acute arthritis initiated by crystallization of urates within and about the joints and can eventually lead to chronic gouty arthritis and the deposition of masses of urates in joints and other sites, sometimes creating tophi. In the absence of treatment, symptomatic chronic hyperuricemia may lead to a handicap and / or a noticeable degradation of quality of life, linked to articular and/or renal (lithiasis, nephropathy) impairment<sup>1</sup>.

In 2006, European League Against Rheumatism (EULAR)<sup>2</sup> established the following principles:

- Optimal management requires both non-pharmacological and pharmacological treatment and needs to be tailored to the individual.
- Urate lowering therapy to promote crystal dissolution and prevent crystal formation is achieved by maintaining the serum uric acid below the saturation point for monosodium urate (360 µmol/l or 6 mg/dl).

Epidemiology data on gout is scarce<sup>3</sup>. However, a 1999 study<sup>4</sup> estimated that prevalence of gout in the U.K. reached 1.4% with rates approaching 7% in men over the age of 65. This prevalence was confirmed by a another study<sup>5</sup> conducted from 2000 to 2005, in the U.K. and Germany. An observational study<sup>6</sup> took place in France in 1981 on 4,663 men employed by a Parisian public organisation, showed prevalence of 1.2% (0.4% in men aged 20-34; 1.1% on men aged 35-39; 2% on men aged 40-44).

### **About Menarini**

Menarini is the first Italian Pharmaceutical Group in the world. Menarini employs nearly 13,000 people, with a strong presence throughout Europe, CIS, Africa and in South and Central America. The company has expertise in successfully developing, registering and delivering medical information for drug products in a broad range of therapeutic areas. including drug products generated by its Research and Development activities located in Florence, Rome, Pisa, Barcelona and Berlin. The Group's total revenue exceeds euro 2.6 billion.

### **About Ipsen**

Ipsen is a global biotechnology specialty care group with total sales in excess of 1 billion euros in 2009, and total worldwide staff of more than 4,400. Its strategy is based on fast growing

<sup>1</sup> Avis de la commission de transparence M04AA03 - ADENURIC - CT-6315

<sup>2</sup> W. Zhang et al. EULAR evidence-based recommendations for gout. Part II: management. Report of a task force of the Euler Standing Committee for International Clinical Studies Including Therapeutics (ESCSIT). Ann of Rheum Dis 2006; 65:1312-1324

<sup>3</sup> Avis de la commission de transparence M04AA03 - ADENURIC - CT-6315

<sup>4</sup> Mikuls TR, Farrar JT, Bilker WB, et al. Gout epidemiology: results from the UK General Practice Research Database, 1990-1999. Ann Rheum Dis 2005;64:267-72.

<sup>5</sup> Annemans L et al. Gout in the UK and Germany: prevalence, comorbidities and management in clinical practice. Ann Rheum Dis 2008;67:960-966

<sup>6</sup> Zalokar J, Lellouch J, Claude JR. Goutte et uricémie dans une population de 4663 hommes jeunes actifs. Sem. Hôp. 1981 ;57 : 664-670

specialty care drugs in oncology, endocrinology, neurology and hematology, and primary care drugs, which significantly contribute to research financing. This strategy is also supported by an active policy of partnerships. Ipsen's specific Research & Development (R&D) centers and peptide & protein engineering platform give the Group a competitive edge. Almost 900 people are dedicated to the discovery and development of innovative drugs for patient care. In 2009, R&D spend reached close to €200 million, representing more than 19% of total Group sales. Ipsen's shares are traded on *Segment A* of Euronext Paris (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).

### **Ipsen Forward Looking Statement**

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. 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. Notably, future currency fluctuations may negatively impact the profitability of the Group and its ability to reach its objectives. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties. The Group does not commit nor gives any guarantee that it will meet the targets mentioned above. Furthermore, the Research and Development process involves several stages each of which involve 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. 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 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.

**For further information:**

**Ipsen**

*Media*

**Didier Véron**

Director, Public Affairs and Corporate Communications

Tel.: +33 (0)1 58 33 51 16

Fax: +33 (0)1 58 33 50 58

E-mail: [didier.veron@ipsen.com](mailto:didier.veron@ipsen.com)

*Financial Community*

**David Schilansky**

Investor Relations and Financial Officer

Tel.: +33 (0)1 58 33 51 30

Fax: +33 (0)1 58 33 50 63

E-mail: [david.schilansky@ipsen.com](mailto:david.schilansky@ipsen.com)

**Pierre Kemula**

Investor Relations Manager

Tel.: +33 (0)1 58 33 60 08

Fax: +33 (0)1 58 33 50 63

E-mail: [pierre.kemula@ipsen.com](mailto:pierre.kemula@ipsen.com)

**Menarini Group**

*Media*

**Valeria Speroni Cardì**

Public Relations and Corporate Communications

Tel.: +39 055 56 80 1

E-Mail : [pressoffice@menarini.com](mailto:pressoffice@menarini.com)

**Menarini France**

*Médias*

**Laurence Ducrot**

Public relations and France communications

Tél : + 33 1 45 60 64 33

E-mail : [lducrot@menarini.fr](mailto:lducrot@menarini.fr)