

Press release

**FDA's first-cycle review of Dysport® to be completed by year-end:  
US launch of Dysport® on track**

**Paris (France), 30 September 2008** - Ipsen (Euronext; IPN) today announced that the U.S. Food and Drug Administration (FDA) provided notification that the Prescription Drug User Fee Act (PDUFA) action date for Dysport® (botulinum toxin of type A) Biologics License Application (BLA) for the treatment of patients with cervical dystonia has been extended to no later than 28 December 2008. This regulatory decision will not impact the anticipated company launch plan timing.

The FDA has not requested additional safety or clinical studies for review.

In accordance with first-cycle review of new therapies, the FDA requested a Risk Communication Plan in order to ensure safe use of the product in treating patients. The Agency has therefore extended the PDUFA action date to no later than December 28, 2008, in order to finalize the review of those items.

*"We are assembling the requested information from the dossier, in close coordination with the FDA," said Stéphane Thiroloix, Executive Vice-President, Corporate Development of the Ipsen Group. "We strongly believe that appropriate recommendations through vehicles like patient medication guide and appropriate direct communications to attending physicians are the way forward to enhance and further define information already available in the package inserts. In meeting the Agency's information need, Ipsen also addresses a patient-care imperative."*

Dysport® has been granted orphan product status by the FDA as a treatment for cervical dystonia, an orphan disease in the United States. The BLA submission relies on data from two pivotal Phase III studies performed in the United States and abroad totalling 252 patients followed-up for up to 12 treatment cycles, in addition to substantial patient exposure in other clinical studies in cervical dystonia.

The timeline for the US commercialisation of Dysport® is unchanged from original plans, and the US neurology team is preparing diligently for the launch.

Used in patient care in the United Kingdom since 1991, Dysport® has marketing authorizations in more than 70 countries. Patient exposure is estimated to be above two million single treatment cycles representing more than 600 000 patients/year of treatment. Dysport® is approved outside the US for eight indications including cervical dystonia (involuntary distortions of the neck).

**About Dysport®**

The active substance in Dysport® is a botulinum neurotoxin type A complex, which acts at the level of the neuromuscular junction in the targeted muscle. Dysport® is a neuromuscular blocking toxin which acts to block acetylcholine release at motor nerve ends and reduces muscular spasm. It was initially developed for the treatment of movement disorders such as cervical dystonia (a chronic condition in which the neck is twisted or deviated), blepharospasm (involuntary eye closure), hemifacial spasm

and various forms of muscle spasticity, including post-stroke arm spasticity, spasticity of the lower limbs (calf) in adults and children with cerebral palsy.

### **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 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)

### **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. Moreover, the targets described in this document were prepared without taking into account external growth assumptions, as announced on June 5, 2008 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. 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 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. 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:**

#### **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@ipсен.com](mailto:didier.veron@ipсен.com)

#### **David Schilansky**

Investor Relations Officer  
Tel.: +33 (0)1 58 33 51 30  
Fax: +33 (0)1 58 33 50 63  
E-mail: [david.schilansky@ipсен.com](mailto:david.schilansky@ipсен.com)