

Press release

## **Ipsen submits a Biologics License Application (BLA) in cervical dystonia to the FDA for Dysport®**

**Paris (France), 6 December 2007** - Ipsen (Euronext: FR0010259150; IPN) today announced that it has submitted a Biologics License Application (BLA) for Dysport® for Injection in cervical dystonia to the Food and Drug Administration (FDA) in the United States for the treatment of patients with cervical dystonia. In accordance with US regulations, the FDA will now be conducting a technical screening of the application to ensure that sufficient data and information have been submitted to justify the final review of the dossier by the Center for Drug Evaluation and Research.

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.

Jean-Luc Bélingard, Chairman and Chief Executive Officer of Ipsen stated: *“The submission of the Dysport® BLA to the FDA is a further sign of our strategic commitment to offer therapeutic responses for the care of patients with targeted medical conditions such as cervical dystonia. I am pleased that we were able to submit this application in the planned timeframe. Further to Somatuline® Depot’s approval by FDA in August, a new successful milestone has been achieved in Ipsen’s international development strategy in specialised care.”*

### **About Dysport®**

The product is currently referred to as Reloxin® in the United States aesthetic market and Dysport® for medical and aesthetic markets outside the U.S.

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, hence reducing muscular spasm was initially developed for the treatment of motor disorders and various forms of muscular spasticity, including cervical dystonia (a chronic condition in which the neck is twisted or deviated), spasticity of the lower limbs (heal) in children with cerebral palsy, blepharospasm (involuntary eye closure) and hemifacial spasm. It was later developed for the treatment of a wide variety of neuromuscular disorders and aesthetic medicine.

Dysport® was originally launched in the United Kingdom in 1991. At 31 December 2006, Dysport® had marketing authorisations in over 70 countries.

### **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 by Euronext™ (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 250 index. From 24 December 2007, the Group will be part of the SBF120 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. Thus, in order to develop a product which is viable from a commercial point of view, the Group must demonstrate, by means of pre-clinical and human clinical trials, that the molecules are effective and not dangerous to human beings. 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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