*Press release*

# FDA's first-cycle review of Reloxin® extended

**Paris (France), 7 January 2009 -** 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 Reloxin® (botulinum toxin of type A) Biologics License Application (BLA) in aesthetic indications (glabellar lines) has been extended to April 13, 2009. The FDA did not issue any specific request on the occasion of this extension. Furthermore, FDA has confirmed in its Establishment Inspection Report that the manufacturing process for Ipsen's botulinum toxin type A in its Wrexham (Wales) facility is in compliance with current Good Manufacturing Practices (CGMPs).

In March 2006, Ipsen granted Medicis (NYSE: MRX) the rights to develop, distribute and commercialize Ipsen's botulinum toxin product in the United States, Canada and Japan for aesthetic use by physicians.

**About Ipsen's botulinum toxin**

Ipsen's botulinum toxin (Dysport® / Reloxin® / Azzalure®) is a neuromuscular blocking toxin which acts to block acetylcholine release, hence reducing muscular spasm and was initially developed for the treatment of motor disorders and various forms of muscular spasticity, including cervical dystonia (spasmodic torticollis), spasticity of the lower limbs 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 and has marketing authorisations in 73 countries. As of April 2008, Ipsen's botulinum toxin type A, developed in the field of aesthetic medicine in the U.S., Canada and Japan under the trademark Reloxin®, is approved for aesthetic indications in 23 countries: Argentina, Australia, Belarus, Brazil, Columbia, Ecuador, Egypt, El Salvador, Germany, Honduras, Israel, Kazakhstan, Mexico, Moldova, New Zealand, Philippines, Slovak Republic, South Korea, Ukraine, Uruguay, Venezuela, Vietnam, and Russia (in Russia, it is the first botulinum toxin type A approved in this field). Ipsen is also pursuing regulatory approval for medical indications for the product in certain additional key international markets.

**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.ipsen.com

**Ipsen 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 any other 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, notably given that a new product can appear to be promising at a preparatory stage of development or after clinical trials but never be launched on the market or be launched on the market but fail to sell notably for regulatory or competitive reasons. The Group must deal with or may have to deal with competition from generic that may result in market share losses, which could affect its current level of growth in sales or profitability. 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:**

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