

Press release

FDA issues Complete Response Letter to Ipsen for Dysport® Biologics License Application

- **No additional clinical data requested**
- **Manufacturing process for Dysport® in compliance with CGMPs¹
No Form 483 observation listed**
- **FDA requests finalization of the Risk Evaluation and Mitigation Strategy and
labelling**
- **Stepping-up to Dysport®'s full launch preparation phase**

Paris (France), 29 December 2008 - Ipsen (Euronext: IPN) today announced that the US Food and Drug Administration (FDA) issued a Complete Response Letter for its Biologics License Application (BLA) for its Botulinum toxin Type A, Dysport®. The application, submitted by the Group in late 2007, seeks approval to market Dysport® for the treatment of cervical dystonia. The Group is now actively preparing to launch the product, once approved by the FDA, and as soon as reimbursement coverage is adequate.

The FDA has not requested any new clinical studies evaluating the efficacy or safety of Dysport® prior to approval. The Complete Response Letter requests additional information, including the finalization of the Risk Evaluation and Mitigation Strategy (REMS) and of the draft labelling, as well as a Safety Update Report. Based on the information identified in the FDA's end of review complete response letter, Ipsen expects to submit the information to FDA during the first quarter of 2009.

Furthermore, FDA has confirmed in its Establishment Inspection Report that the manufacturing process for Dysport® in its Wrexham (Wales) facility is in compliance with CGMPs¹. The FDA issued no Form 483 observation. The Wrexham site gathers the manufacturing, product formulation, packaging and testing activities for the entire production of botulinum toxin type A currently marketed in 73 countries under the brand name Dysport®. *"We are confident that we can expeditiously respond to the questions set forth in the Complete Response Letter"* said **Stéphane Thiroloix**, Ipsen's Executive Vice President - Corporate Development. *"We anticipate answering to the FDA during the first quarter of 2009 and remain focused on bringing Dysport® to market as originally planned."*

About Dysport®

Dysport® has been approved as a treatment for cervical dystonia, an orphan disease in the United States.

Used in patient care in the United Kingdom since 1991, Dysport® has marketing authorizations in 73 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 U.S. for eight indications including cervical dystonia (involuntary distortions of the neck).

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

¹ current Good Manufacturing Practices

muscular spasm. It was initially developed and subsequently approved in many markets around the world for the treatment of movement disorders such as cervical dystonia (spasmodic torticollis), 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.

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.

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