



Press release

## **Ipsen announces the launch of Dysport® (abobotulinumtoxinA) in the United States for the treatment of cervical dystonia**

**Dysport® represents the first new botulinum toxin type A treatment option in eight years to reach the U.S. market place**

**Paris (France), 29 October 2009** - Ipsen (Euronext: FR0010259150; IPN), an innovation-driven global specialty pharmaceutical group, today announced that Dysport® is now available in the United States for the treatment of cervical dystonia in adults.

Dysport® is the latest addition to the growing range of Ipsen's drugs already available in North America, both in endocrinology with Somatuline® Depot and Increlex®, and in neurology, with Apokyn®.

**Christophe Jean**, Executive Vice President, Operations of the Ipsen Group said: *"The launch of Dysport® in its therapeutic indication for the treatment of cervical dystonia in the United States is undoubtedly a significant milestone to strengthen Ipsen's presence in North America. We are very pleased to be able to offer physicians a new and important treatment option for their patients suffering from cervical dystonia. Dysport®, together with Somatuline® and Increlex®, becomes Ipsen's third product to be available globally. With the achievement of this key milestone, I wish to congratulate and thank the teams that are making this launch a reality thanks to their hard work and dedication reflective of an efficient organization."*

### **About Dysport® (abobotulinumtoxinA)**

Dysport® (abobotulinumtoxinA) inhibits release of the neurotransmitter acetylcholine from peripheral cholinergic nerve endings, which reduces muscular spasm. The active ingredient in Dysport® is a botulinum toxin type A, which acts at the level of the neuromuscular junction in the targeted muscle. Used in patient care in the United Kingdom since 1991, Dysport® has marketing authorizations in 75 countries (as of 31 December 2008) for multiple therapeutic uses. Patient exposure is estimated to be above two million single treatment cycles, representing more than 840,000 patient years of treatment.

Dysport® was approved by the Food and Drug Administration on 29 April 2009 for two separate indications, the treatment of cervical dystonia to reduce the severity of abnormal head position and neck pain in both toxin-naïve and previously treated patients, and the temporary improvement in the appearance of moderate to severe glabellar lines in adults younger than 65 years of age. Ipsen will market Dysport® in the United States for the therapeutic indication (cervical dystonia), while Medicis already markets Dysport® in the U.S. for the aesthetic indication (glabellar lines).

To help streamline access to Dysport®, Ipsen has developed a comprehensive reimbursement program that provides comprehensive access and support for U.S. patients and healthcare providers. The program, called PACE™ (Patient Access, Care and Education), offers a customer service call center (888-525-2423) to assist people seeking information about Dysport®.



### **Boxed Warning for All Botulinum Toxin Products**

On 30 April 2009, the U.S. Food and Drug Administration announced that safety label changes, including a boxed warning, and a Risk Evaluation and Mitigation Strategy (REMS), are necessary for all botulinum toxin products.

### **About the Risk Evaluation and Mitigation Strategy (REMS) for Dysport®**

DYSPO<sup>®</sup>RT is differentiated from other marketed botulinum toxin products with the unique name abobotulinumtoxinA.

Ipsen has implemented a REMS in order to ensure that the potential benefits of treating cervical dystonia with Dyspo<sup>®</sup>RT outweigh the potential risks of:

- Medication errors related to the lack of interchangeability of Dyspo<sup>®</sup>RT Units with those of toxins of other manufacturers; and
- The potential for the occurrence of spread of toxin effect beyond the injection site.

A key element of the Dyspo<sup>®</sup>RT REMS is an FDA-approved patient Medication Guide, which will be provided with each carton of Dyspo<sup>®</sup>RT. The physician should provide a copy of the Medication Guide to each patient and review the contents with the patient. By promoting an informed discussion between the physician and patient, the Medication Guide will help ensure that patients are fully aware of and understand the risks of Dyspo<sup>®</sup>RT treatment in relation to the potential benefits.

### **Important Safety Information About Dysport®**

Dyspo<sup>®</sup>RT should not be used in children or pregnant women.

The effects of Dyspo<sup>®</sup>RT and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening, and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults, particularly in those patients who have underlying conditions that would predispose them to these symptoms. Immediate medical attention may be required in cases of respiratory, speech or swallowing difficulties.

Dyspo<sup>®</sup>RT is contraindicated in patients with hypersensitivity to any botulinum toxin product or excipients, allergy to cow's-milk protein, or infection at the proposed injection site.

The potency units of Dyspo<sup>®</sup>RT are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of Dyspo<sup>®</sup>RT cannot be compared to or converted into units of any other botulinum toxin products assessed with any other specific assay method.

Dyspo<sup>®</sup>RT should be administered in accordance with the labelling instructions, and the recommended dosage and frequency of administration should not be exceeded.

Patients with a neuromuscular disorder of the nerve-muscle junction may be at increased risk of side effects.

Concomitant neuromuscular disorder may exacerbate clinical effects of treatment.

Patients receiving concomitant treatment of Dyspo<sup>®</sup>RT and aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents), or muscle relaxants, should be observed closely because the effect of botulinum toxin may be potentiated.

The most commonly reported adverse reactions (>5% of patients) observed with Dyspo<sup>®</sup>RT for the treatment of cervical dystonia are muscular weakness, dysphagia, dysphonia, dry mouth, injection site discomfort or pain, fatigue, headache, neck pain, musculoskeletal pain, and eye disorders.

Visit [www.Dysport.com](http://www.Dysport.com) to see the full Prescribing Information, including Boxed Warning and Medication Guide, as well as the PACE™ program.



## About Cervical Dystonia

Cervical dystonia is an orphan condition in the U.S. affecting approximately 125,000 people.<sup>1</sup> It is a chronic and painful condition characterized by neck muscles contracting involuntarily, which causes abnormal movements and awkward posture of the head and neck. Symptoms usually begin in people age 40 years or older, and women are more commonly affected by the condition than men.<sup>2</sup>

## About Ipsen

Ipsen is an innovation-driven global specialty pharmaceutical group with over 20 products on the market and a total worldwide staff of nearly 4,200. Its development strategy is based on a combination of specialty medicine, which is Ipsen's growth driver, in targeted therapeutic areas (oncology, endocrinology, neurology and haematology), 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 800 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 2008, Research and Development expenditure was about €183 million, close to 19% of consolidated sales, which amounted to €971 million while total revenues exceeded €1 billion. 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.

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<sup>1</sup> Saunders-Pullman R *et al.* (2005) A new screening tool for cervical dystonia. *Neurology* **64**: 2046–2049

<sup>2</sup> Dystonia Medical Research Foundation: [www.dystonia-foundation.org](http://www.dystonia-foundation.org)



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