

Joint Press Release

**FDA approves  
Dysport™ for therapeutic and aesthetic uses**

- **Ipsen's abobotulinumtoxinA approved simultaneously for the treatment of cervical dystonia and glabellar lines under a single trade name, DYSPORE™**
  - **Major strategic milestone achieved for both Medicis and Ipsen**
  - **Medicis to launch DYSPORE™ (abobotulinumtoxinA) for glabellar lines within the next 30 to 60 days**
  - **Ipsen to launch DYSPORE™ (abobotulinumtoxinA) for cervical dystonia during the second half of 2009**

**SCOTTSDALE, Arizona and PARIS, France— April 30, 2009—** Medicis (NYSE:MRX) and Ipsen (Euronext:IPN) today announced the U.S. Food and Drug Administration's (FDA) approval of the Biologics License Application (BLA) for DYSPORE™ (abobotulinumtoxinA), an acetylcholine release inhibitor and a neuromuscular blocking agent. The approval includes two separate indications, the treatment of cervical dystonia in adults to reduce the severity of abnormal head position and neck pain, and the temporary improvement in the appearance of moderate to severe glabellar lines in adults younger than 65 years of age. Reloxin®, which was the proposed U.S. name for Ipsen's botulinum toxin product for aesthetic use, will be marketed under the name of DYSPORE™. Ipsen will market DYSPORE™ in the United States for the therapeutic indication (cervical dystonia), while Medicis will market DYSPORE™ in the U.S. for the aesthetic indication (glabellar lines). Additionally, DYSPORE™ is differentiated from other marketed botulinum toxin products with the unique established name abobotulinumtoxinA.

*"We are extremely pleased to announce FDA's approval of DYSPORE™," said **Jonah Shacknai, Chairman and Chief Executive Officer of Medicis**. "Medicis and Ipsen have been diligent in efforts with FDA to achieve this goal. DYSPORE™ was evaluated for the treatment of glabellar lines in robust clinical studies, which included approximately 2,900 patients at more than 80 clinical study sites.<sup>1</sup> We are excited to be entering the market for the most popular nonsurgical aesthetic procedure in the U.S.<sup>2</sup>, and anticipate being highly competitive. We believe physicians and their patients will appreciate the benefits of this new product offering. Additionally, we are grateful to our colleagues at Ipsen, who have worked tirelessly alongside the Medicis team to make this approval possible, and to our shareholders, who have supported our efforts with eagerness and patience. We look forward to continuing our strong partnership as we endeavor to maximize the commercial success of DYSPORE™."*

**Jean-Luc Bélingard, Chairman and Chief Executive Officer of Ipsen**, said: *"The approval of our DYSPORE™ BLA by the FDA for both therapeutic and aesthetic indications is the fruit of hard work and efficient organization of both the Ipsen and Medicis teams. We are proud to have closely collaborated with the FDA on the labeling and Risk Evaluation and Mitigation Strategy (REMS) for increased patient safety awareness in the use of DYSPORE™. DYSPORE™ represents an important new treatment option for patients suffering from cervical dystonia, and we hope to capitalize on our successful therapeutic focus worldwide to build as strong a position in the U.S."* Jean-Luc Bélingard concluded, *"Today marks a major strategic milestone in our history, being now in a position to effectively market four products in the U.S., whilst benefiting from Medicis' presence in the fast-growing aesthetic market."*



The REMS for DYSPO<sup>TM</sup> is designed to help prevent medication errors related to the lack of interchangeability of DYSPO<sup>TM</sup> with other marketed botulinum toxin products, and ensure that the potential benefits of treatment with DYSPO<sup>TM</sup> outweigh any potential risk of the spread of toxin effect beyond the injection site. The labeling for DYSPO<sup>TM</sup> also contains a boxed warning about the potential distant spread of all botulinum toxin products, including DYSPO<sup>TM</sup>.

Ipsen anticipates launching DYSPO<sup>TM</sup> for the treatment of cervical dystonia in the U.S. during the second half of 2009. Furthermore, in terms of post-marketing commitments for DYSPO<sup>TM</sup>, Ipsen is notably committed to perform clinical studies in children and adults with spasticity.

In March 2006, Ipsen granted Medicis the rights to develop, distribute and commercialize Ipsen's botulinum toxin product for aesthetic use by physicians in the U.S., Canada and Japan. In accordance with the agreement, Medicis will now pay Ipsen approximately \$75 million as a result of the approval by FDA. Ipsen will receive a royalty based on sales and a supply price, the total of which is equivalent to approximately 30% of net sales as defined under the agreement.

Medicis anticipates shipping DYSPO<sup>TM</sup> for aesthetic use in the U.S. during the next 30 to 60 days. During that time, Medicis will complete the training of its aesthetic sales force. McKesson will serve as the U.S. distributor of DYSPO<sup>TM</sup> for aesthetic use. Ipsen will manufacture and provide the product to Medicis for the term of the agreement, which extends until December 2036.

DYSPO<sup>TM</sup> for the aesthetic indication will be available in the U.S. to patients through licensed practitioners. Physicians in the U.S. may place orders for DYSPO<sup>TM</sup> for the aesthetic indication by calling McKesson directly at 1-877-520-0500.

### **DYSPO<sup>TM</sup> Important Safety Information**

The effects of DYSPO<sup>TM</sup> 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.

The dosing units of DYSPO<sup>TM</sup> are not the same as other botulinum toxin products and therefore are not interchangeable with other preparations of botulinum toxin products.

DYSPO<sup>TM</sup> 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.

Caution should be exercised when administering DYSPO<sup>TM</sup> to patients who have surgical changes to their faces, drooping eyelid folds, deep facial scars, or thick oily skin.

Patients receiving treatment of Dyspo<sup>TM</sup> while already being treated with aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents or muscle relaxants) should be observed closely for symptoms consistent with botulinum toxin effects.



Patients should not have DYSPO<sup>TM</sup> treatment if the proposed injection site is infected or if they are allergic to any botulinum toxin preparation or to any of its ingredients.

DYSPO<sup>TM</sup> should not be used in children or pregnant women.

The most common side effects associated with the treatment of the glabellar lines are nose and throat irritation, headache, injection site pain, injection site skin reaction, upper respiratory tract infection, eyelid swelling, eyelid drooping, sinus inflammation, and nausea.

The most common side effects associated with the treatment of cervical dystonia are muscular weakness, difficulty in swallowing, dry mouth, injection site discomfort, fatigue, headache, neck pain, musculoskeletal pain, hoarseness, injection site pain, and eye disorders.

The Full Prescribing Information and Patient Medication Guide will be available at [www.fda.gov](http://www.fda.gov).

To report SUSPECTED ADVERSE REACTIONS, call 1-877-397-7671 or FDA at 1-800-FDA-1088 or visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### **About the Aesthetic Market**

According to the American Society for Aesthetic Plastic Surgery, over 10 million cosmetic procedures were performed in the U.S. in 2008, 83% of which represented nonsurgical procedures.<sup>2</sup> Injections of botulinum toxin type A have been the number one nonsurgical cosmetic procedure for the past five years, with over 2.4 million total procedures in 2008 alone.<sup>2</sup> The U.S. aesthetic market for botulinum toxin type A is estimated to be approximately \$300 million to \$400 million.<sup>3</sup>

### **About Cervical Dystonia**

Cervical dystonia is an orphan condition in the U.S. affecting approximately 125,000 people.<sup>4</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>5</sup>

### **About DYSPO<sup>TM</sup> (abobotulinumtoxinA)**

The active substance in DYSPO<sup>TM</sup> is a botulinum neurotoxin type A complex, which acts at the level of the neuromuscular junction in the targeted muscle. DYSPO<sup>TM</sup> is a neuromuscular blocking toxin which acts to block acetylcholine release at motor nerve ends and reduces muscular spasm.

Used in patient care in the United Kingdom since 1991, DYSPO<sup>TM</sup> has marketing authorizations in 76 countries for therapeutic use and in 27 countries for aesthetic use. Patient exposure is estimated to be above two million single treatment cycles, representing more than 600,000 patients year of treatment.

DYSPO<sup>TM</sup> was initially developed and subsequently approved in many markets around the world, outside the U.S., 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. It was later developed for the treatment of a wide variety of neuromuscular disorders and aesthetic medicine.

### **About Medicis**

Medicis is the leading independent specialty pharmaceutical company in the United States focusing primarily on the treatment of dermatological and aesthetic conditions. Medicis is dedicated to helping patients attain a healthy and youthful appearance and self-image. Medicis has leading branded prescription products in a number of therapeutic and aesthetic categories. Medicis' products have earned wide acceptance by both physicians and patients due to their clinical effectiveness, high quality and cosmetic elegance.

Medicis' products include the brands RESTYLANE<sup>®</sup> (hyaluronic acid), PERLANE<sup>®</sup> (hyaluronic acid), DYNACIN<sup>®</sup> (minocycline HCl), LOPROX<sup>®</sup> (ciclopirox), PLEXION<sup>®</sup> (sodium sulfacetamide 10% and sulfur 5%), SOLODYN<sup>®</sup> (minocycline HCl, USP) Extended Release Tablets, TRIAZ<sup>®</sup> (benzoyl peroxide), LIDEX<sup>®</sup> (fluocinonide) Cream 0.05%, VANOS<sup>®</sup> (fluocinonide) Cream 0.1%, ZIANA<sup>®</sup> (clindamycin phosphate 1.2% and tretinoin 0.025%) Gel, BUPHENYL<sup>®</sup> (sodium phenylbutyrate) Tablets and Powder, AMMONUL<sup>®</sup> (sodium phenylacetate and sodium benzoate) Injection 10%/10%, the LIPOSONIX<sup>®6</sup> system and the over-the-counter brand ESOTERICA<sup>®</sup>.

For more information about Medicis, please visit the Company's website at [www.Medicis.com](http://www.Medicis.com). Printed copies of Medicis' complete audited financial statements are available free of charge upon request.

NOTE: Full prescribing information for any of Medicis' prescription products is available by contacting Medicis. RESTYLANE<sup>®</sup> and PERLANE<sup>®</sup> are trademarks of HA North American Sales AB, a subsidiary of Medicis Pharmaceutical Corporation. All other trademarks are the property of their respective owners.

### **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 4,200. Its development strategy is based on a combination of specialty products, which are growth drivers, in targeted therapeutic areas (oncology, endocrinology and neurology), 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.Ipsen.com](http://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. These objectives or Forward-Looking Statements 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. 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*.

### **Medicis Forward-Looking Statements**

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act. All statements included in this press release that address activities, events or developments that Medicis expects, believes or anticipates will or may occur in the future are forward-

looking statements. Forward-looking statements can often be identified by words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "may," "will," "should," "would," "could," "potential," "continue," "ongoing," similar expressions, and variations or negatives of these words. Examples of such forward-looking statements include, but are not limited to, the anticipation of being highly competitive in the botulinum toxin market, the belief that physicians and their patients will appreciate the benefits of the new product offering and the anticipated launch date of DYSPO<sup>TM</sup>. These statements are based on certain assumptions made by Medicis based on its experience and perception of historical trends, current conditions, expected future developments and other factors it believes are appropriate in the circumstances. No assurances can be given, however, that these activities, events or developments will occur or that such results will be achieved. Such statements are subject to a number of assumptions, risks and uncertainties, many of which are beyond the control of Medicis. Several of these risks are outlined in Medicis' most recent annual report on Form 10-K for the year ended December 31, 2008, and other documents Medicis files with the Securities and Exchange Commission. Forward-looking statements represent the judgment of Medicis' management as of the date of this release, and Medicis disclaims any intent or obligation to update any forward-looking statements contained herein, which speak as of the date hereof.

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<sup>1</sup> Investigator and subject count specific to glabellar lines clinical studies only

<sup>2</sup> American Society for Aesthetic Plastic Surgery, Cosmetic Surgery National Data Bank Statistics, 2008

<sup>3</sup> Competitor company reports

<sup>4</sup> Saunders-Pullman R *et al.* (2005) A new screening tool for cervical dystonia. *Neurology* **64**: 2046–2049

<sup>5</sup> Dystonia Medical Research Foundation: [www.dystonia-foundation.org](http://www.dystonia-foundation.org)

<sup>6</sup> The LIPOSONIX<sup>®</sup> system is currently not approved for sale or use in the U.S.

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