

Press release

## **The Health Authorities of 15 European countries give a collective green light to Azzalure® for the treatment of glabellar lines, paving the way for national marketing authorizations**

**Paris (France) and Lausanne (Switzerland), 2 February 2009** – Ipsen (Euronext: IPN), an international innovation-driven specialty pharmaceutical Group, and Galderma, the leading pharmaceutical company in dermatology, today announced that Azzalure®, a muscle relaxant specifically developed for aesthetic use, has received the collective green light from 15 European countries' Health Authorities for the granting of national marketing authorizations. The assessment was based on clinical trials involving more than 2,600 patients, which confirmed the safety and efficacy of Azzalure®.

**Stéphane Thiroloix**, Ipsen's Executive Vice-President in charge of Corporate Development said: *"The collective green light from Health Authorities for Azzalure® confirms the quality of our botulinum toxin, backed by solid clinical data. In addition, this decision rewards the great work accomplished by the Ipsen and Galderma teams".* Stéphane Thiroloix added: *"Once the local marketing authorizations are granted, we are convinced that Galderma's expertise and sales force, combined with a product such as Azzalure® will efficiently bring a new treatment alternative and advancement for patients and the medical community".*

*"This green light for Azzalure® is a great milestone for Galderma and confirms our company's entry in the corrective and aesthetic dermatology market. With Azzalure®, we have devoted Galderma's expertise to helping doctors better address the needs of their patients who want safe and effective results. Once the local marketing authorizations are granted, we will be able to meet these growing expectations rapidly",* said **François Fournier**, Galderma's Vice-President of the EURMEAAS Area (Europe, Middle East, Africa, Australia and Asia).

This announcement is part of the partnership established in 2007 between Galderma and Ipsen. Under the terms of this agreement, Ipsen granted Galderma exclusive rights to develop, promote and distribute a specific formulation of its botulinum toxin type A product Dysport®, for aesthetic indications. This agreement includes the European Union and certain territories of the Middle East and Eastern Europe. In addition, Ipsen also granted Galderma first rights of negotiation for aesthetic indications in the rest of the world, excluding the United States, Canada and Japan. Besides, last December 2007 Ipsen and Galderma entered into another partnership for the exclusive promotion and distribution of Ipsen's botulinum toxin type A product, for use in aesthetic medicine and dermatological indications in Brazil, Argentina and Paraguay.

Galderma will pay up to €20 million to Ipsen upon the achievement of certain milestones, including local market approvals and product launches in certain territories. Ipsen will manufacture and supply Galderma's finished product at a fixed supply price. In addition, Galderma will pay royalties on net sales to Ipsen.

### **About the Azzalure<sup>®</sup> indication**

Azzalure<sup>®</sup> is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines (vertical lines between the eyebrows) seen at the frown, in adult patients under 65 years, when the severity of these lines has an important psychological impact on the patient.

### **About Ipsen's botulinum toxin**

Ipsen's botulinum toxin which acts to block acetylcholine release, hence reducing muscular spasm was initially developed for medical indications such as 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.

Launched in 1991 in the UK, Ipsen's botulinum toxin has marketing authorizations in 73 countries and is marketed under the brand name Dysport<sup>®</sup>.

In February 2007, Ipsen granted Galderma the rights to develop, promote and distribute its botulinum toxin type A for aesthetic use in Europe and certain other territories. Galderma will market the product notably under its own brand name, Azzalure<sup>®</sup>.

Moreover, in March 2006 Ipsen granted Medicis the rights to develop, promote and distribute its botulinum toxin for aesthetic use in the United States, Canada and Japan under a brand other than Dysport<sup>®</sup>, which could be Reloxin<sup>®</sup>.

### **About Ipsen**

Ipsen is an international innovation-driven 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 significantly contribute 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 for 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 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 account external growth assumptions, as announced on June 5, 2008 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. 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 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*.

### **About Galderma**

Galderma, created in 1981 as a joint venture between Nestlé and L'Oréal, is an international pharmaceutical company dedicated to the research, development and marketing of therapeutic, corrective and aesthetic solutions for dermatology patients. Galderma's expertise covers a broad spectrum of skin, hair and nail diseases, with a focus on acne, rosacea, psoriasis and steroid-responsive dermatoses, onychomycosis, pigmentary disorders, skin cancers and medical solutions for skin senescence.

The Company is present in 65 countries with 2900 employees (including 1000 medical sales representatives). In 2007, Galderma had global revenues of 735 million euros and committed 14.1% of its revenues to R&D.

With a main research and development center in Sophia Antipolis, France, Galderma has one of the largest R&D facilities devoted exclusively to dermatology.

Galderma's key brands, the drivers of the portfolio, are: Differin<sup>®</sup> (adapalene), the company's first home-grown product indicated for topical treatment of acne, Epiduo<sup>®</sup> (adapalene and benzoyl peroxide, acne), Rozex<sup>®</sup>/MetroGel<sup>®</sup> 1% (metronidazole, rosacea), Oracea<sup>®</sup> (doxycycline, rosacea), Clobex<sup>®</sup> (clobetasol propionate, psoriasis), Tri-Luma<sup>®</sup> (hydroquinone, tretinoin, fluocinolone acetonide, pigmentary disorders), Loceryl<sup>®</sup> (amorolfine, onychomycosis), Azzalure<sup>®</sup> / Dysport<sup>®</sup> (botulinum toxin type A, glabellar lines) and Cetaphil<sup>®</sup> (therapeutic skin care line). The Company's international website is [www.galderma.com](http://www.galderma.com).

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