

Press release

## **AZZALURE<sup>®</sup> approved in Germany for Aesthetic Use in the Treatment of Glabellar Lines**

- **This market authorisation is part of a process including 15 countries in Europe**
  - **Azzalure<sup>®</sup> will be commercialised in Germany by Galderma**

**Lausanne (Switzerland) and Paris (France), 26 June 2009** – Galderma, the leading pharmaceutical company in dermatology, and Ipsen (Euronext: IPN), an international innovation-driven specialty pharmaceutical group, today announced that Azzalure<sup>®</sup> (botulinum toxin Type A manufactured by Ipsen), a muscle relaxant specifically developed for aesthetic use, has received a marketing authorization in Germany from the regulatory authorities (Bundesinstitut für Arzneimittel und Medizinprodukte) for the temporary improvement in the appearance of moderate to severe glabellar lines seen at the frown (vertical lines between the eyebrows), in adult men and women aged 65 years and under, when the severity of these lines has an important psychological impact on the patient.

The approval was based on several clinical trials involving more than 2,600 patients, which confirmed the safety and efficacy of Azzalure<sup>®</sup>. Azzalure is adapted from Dysport<sup>®</sup> (botulinum toxin type-A), which is already marketed by Ipsen for a variety of indications and has a 20-year long history of product consistency and safety. Azzalure<sup>®</sup> will come in a very easy to use customized dosage that is specifically designed to better meet the patient and physician need.

This marketing authorisation for Azzalure<sup>®</sup> follows the collective green light from 15 European countries' Health Authorities and is one of the several licenses Galderma and Ipsen anticipate in Europe this year. Azzalure will be commercially available in Germany by the beginning of the 3<sup>rd</sup> quarter 2009.

*"Azzalure<sup>®</sup>'s marketing authorisation is an important event for patients who need corrective and aesthetic procedures. Patients can look forward to benefiting from Galderma's years of experience in dermatology, and our commitment to providing the highest standards of medical education and training to healthcare professionals. Azzalure<sup>®</sup> is the latest product in our expanding range of dermatology treatments and emphasizes our commitment to the future of dermatology",* said **Marc Wannhoff**, General Manager of Galderma Germany.

The world Corrective and Aesthetic marketplace was estimated in 2008 to 5 billion euros by Medical Insight (report published last year). Its growth could reach up to 10% in 2009. In Europe, the average annual growth expected between 2009 and 2012 is 13.2%, driven by dramatic rise in the popularity of easy to use and non invasive treatments, such as botulinum toxin procedures, that already represent 60% of specialist procedures in Europe.

### **About the agreement**

This announcement represents the latest developments in a partnership established in 2007 between Galderma and Ipsen. Under the terms of this agreement, Galderma has been granted by Ipsen exclusive rights to develop, promote and distribute Azzalure<sup>®</sup>, a customized dosage of its botulinum toxin type A product Dysport<sup>®</sup>, for aesthetic indications. This agreement includes the European Union and certain territories of the Middle East and Eastern Europe. In addition, Galderma has also been granted first rights of negotiation for aesthetic indications in the rest of the world, excluding the United States, Canada and Japan. 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 Galderma**

Galderma, created in 1981 as a joint venture between Nestlé and L'Oréal, is a global leading pharmaceutical company dedicated to the research, development and marketing of innovative 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 dermatosis, onychomycosis, pigmentary disorders, skin cancer and medical solutions for skin senescence. The Company is present in 65 countries with more than 2900 employees (including 1000 medical sales representatives). In 2008, Galderma had global revenues of 854 million euros. 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 major brands 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).

### **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.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.

#### **For more information**

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