

# Ipsen's Somatuline<sup>®</sup> receives marketing approval in Japan for the treatment of acromegaly and pituitary gigantism

- Somatuline<sup>®</sup> 60/90/120 mg for subcutaneous (s.c.) injection becomes the first Ipsen's drug available worldwide (Europe, USA, Japan)
  - Launch expected in Q1, 2013 by Teijin

Paris (France), 29 June 2012 - Ipsen (Euronext: IPN; ADR: IPSEY) announced today that its partner Teijin has received manufacturing and marketing approval from the Japan's Ministry of Health, Labour and Welfare (MHLW) for Somatuline<sup>®</sup> 60/90/120 mg for s.c. injection (lanreotide acetate). In Japan, Somatuline<sup>®</sup> is indicated for the treatment of growth hormone and IGF-I (somatomedin-C) hypersecretion and related symptoms in acromegaly and pituitary gigantism (when response to surgical therapies is not satisfactory or surgical therapies are difficult to perform). Somatuline<sup>®</sup> will be available in a new enhanced presentation with a pre-filled syringe that does not need reconstitution and with a retractable needle that enhances safety for caregivers.

Marc de Garidel, Chairman and Chief Executive Officer of Ipsen said: "We are delighted to announce that Somatuline® will soon be available in Japan. Somatuline® becomes the first Ipsen's global drug with sales in Europe, the USA and soon Japan. We are confident that our partner Teijin will successfully bring this effective and convenient treatment to the Japanese patients." Marc de Garidel concluded: "This approval further confirms our strategy of focus and international leverage."

# About the agreements with Teijin

In the framework of the successive agreements signed between Teijin and Ipsen, Teijin is entitled to develop and commercialize Somatuline<sup>®</sup> in Japan and Ipsen will manufacture and supply the finished product to Teijin. Ipsen will record the supply sale to Teijin in its sales line.

# **About acromegaly**

Acromegaly is a disorder caused by the over-production of growth hormone usually by a benign tumor of the anterior pituitary gland. Acromegaly occurs in approximately 60 people per million of population. The number of patients in Japan, including latent patients, is thought to be about 10,000.

In acromegaly patients, the pituitary gland releases too much growth hormone ("GH") into the bloodstream, the GH then triggers the liver to produce IGF-1, which in turn directly stimulates bone and tissue growth. The most common signs and symptoms of this serious condition include: enlarged hands, feet, and head, facial changes such as bulging forehead, enlarged lower jaw, tongue and lips, wider spacing between teeth, enlarged heart, liver, kidneys, spleen and other organs, joint pain and fatigue and multiple organs failure (cardiac, respiratory and diabetes). The



term pituitary gigantism is used when the condition occurs in children, since it results in excess height and growth of feet and hands.

# About Somatuline®

The active substance in Somatuline® and Somatuline® Autogel® is lanreotide, which inhibits the growth and secretion of several endocrine, exocrine and paracrine functions. It is particularly effective in inhibiting the secretion of growth hormone.

Somatuline® (also marketed as Somatuline® Autogel® outside the USA and Somatuline® Depot® in the USA) is a sustained release formulation for injection containing lanreotide, a somatostatin analogue (a hormone that inhibits the release of growth hormone). Somatuline® was initially developed and continues to be used mainly in the treatment of acromegaly, a disorder caused by the overproduction of growth hormone or prolactin due to a benign tumour of the anterior pituitary gland. This product subsequently underwent further development in Europe in the treatment of symptoms associated with neuroendocrine tumours (particularly of a carcinoid type). Ipsen believes that the Somatuline® Autogel® formulation, to which it holds the patent, represents a major technological advance. As far as the Group is aware, this represents the first semisolid formulation for injection without any excipient, since the active substance itself controls the sustained release. Somatuline<sup>®</sup> Autogel<sup>®</sup> releases the active substance with no excipient other than water over a period of at least 28 days, thus requiring just one injection per month compared with the two or three injections previously necessary. This product is presented in a pre-filled syringe for easy administration. At 31 December 2011, Somatuline® and Somatuline® Autogel® were marketed in over 54 countries (including 25 in Europe and the USA) for the treatment of acromegaly and neuroendocrine tumors.

#### **About the Teijin Group**

Teijin (TSE 3401) is a technology-driven global group offering advanced solutions in the areas of sustainable transportation, information and electronics, safety and protection, environment and energy, and healthcare. Its main fields of operation are high-performance fibers such as aramid, carbon fibers & composites, healthcare, films, resin & plastic processing, polyester fibers, products converting and IT. The group has some 150 companies and around 17,000 employees spread out over 20 countries worldwide. It posted consolidated sales of JPY 854.4 billion (USD 10.7 billion) and total assets of JPY 762.1 billion (USD 9.5billion) in the fiscal year ending March 31, 2012. Please visit www.teijin.co.jp/english.

#### **About Ipsen**

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.1 billion in 2011. Ipsen's ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its development strategy is supported by four franchises: neurology / Dysport<sup>®</sup>, endocrinology / Somatuline<sup>®</sup>, uro-oncology / Decapeptyl<sup>®</sup> and hemophilia. Moreover, the Group has an active policy of partnerships. Ipsen's R&D is focused on its innovative and differentiated technological platforms, peptides and toxins. In 2011, R&D expenditure totaled more than €250 million, above 21% of Group sales. The Group has total worldwide staff of close to 4,500 employees. Ipsen's shares are traded on segment A of Euronext Paris (stock code: IPN, ISIN code: FR0010259150) and eligible to the "Service de Règlement Différé" ("SRD"). The Group is part of the SBF 120 index. Ipsen has implemented a Sponsored Level I American Depositary Receipt (ADR) program, which trade on the over-the-counter market in the United States under the symbol IPSEY. For more information on Ipsen, visit www.ipsen.com.



# **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. All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. 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. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising product in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. The Group must face or might face competition from Generics that might translate into loose of market shares.

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 favorable 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.

#### For further information:

## Media

#### **Didier Véron**

Vice President, Public Affairs and Corporate Communications

Tel.: +33 (0)1 58 33 51 16 Fax: +33 (0)1 58 33 50 58 E-mail: didier.veron@ipsen.com

# Financial Community Pierre Kemula

Vice President, Investor Relations

Tel.: +33 (0)1 58 33 60 08 Fax: +33 (0)1 58 33 50 63

E-mail: pierre.kemula@ipsen.com

### **Stéphane Durant des Aulnois**

Investor Relations Manager Tel.: +33 (0)1 58 33 60 09 Fax: +33 (0)1 58 33 50 63

E-mail:

stephane.durant.des.aulnois@ipsen.com