

Teijin Pharma to launch Ipsen's Somatuline® subcutaneous injection in the treatment of acromegaly and pituitary gigantism in Japan

Tokyo (Japan) and Paris (France), January 17, 2013, Teijin Pharma Limited, the core company of the Teijin Group's healthcare business, and Ipsen (Euronext: IPN; ADR: IPSEY), today announced the launch of Somatuline® 60/90/120 mg for subcutaneous injection in Japan for the treatment of acromegaly and pituitary gigantism (when response to surgical therapies is not satisfactory or surgical therapies are difficult to perform). In Japan, Teijin Pharma holds the rights to develop and market the drug.

Somatuline® is a synthetic somatostatin analog developed by Ipsen approved in more than 60 countries worldwide. In Japan, Somatuline® is available in a differentiated and enhanced presentation with a pre-filled syringe that does not need reconstitution and with a retractable needle that enhances safety for caregivers; Somatuline®'s long-lasting effects enable one administration every four weeks.

Kentaro Arao, President of Teijin Pharma said: “Somatuline®, used in more than 60 countries worldwide, is highly regarded by the medical profession and patients for its long-lasting effects and user-friendly dosing devices. We are pleased to launch Somatuline® in Japan, confident that it will offer patients a beneficial treatment option to control the symptoms of acromegaly, or pituitary gigantism, for improved quality of life.”

Christophe Jean, Ipsen's Executive Vice-President, Operations said: "We are privileged to have Teijin as our partner in Japan and pleased that Somatuline® is now also available to Japanese patients suffering from acromegaly and pituitary gigantism."

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® 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 metabolic disease in which pituitary gland tumors cause excess secretion of hormone responsible for growth of bone and muscle. This results in a variety of symptoms, including protrusion of the brow and jaw, enlargement of extremities such as nose, lips, hands and feet, headaches, and loss of outer field vision. The term pituitary gigantism is used when the condition occurs in children, since it results in excess height and growth of feet and hands.

Progression of acromegaly is so slow that the disease often goes unnoticed by the person afflicted as well as the people around them. Eventually it can lead to metabolic complications, such as diabetes, hypertension, angina, myocardial infarction or cerebrovascular disease. Acromegaly also increases the risk of malignant tumors, so patients are two to five times more likely to die early than healthy individuals, resulting in a shortened lifespan with a mean reduction of about 10 years.

In Japan, the number of patients with acromegaly is thought to be about 10,000 including subjects¹ that are not yet diagnosed for acromegaly. Acromegaly is designated as an intractable disease, so patients are eligible to receive publicly subsidized treatment. The most common treatment is surgical resection of the tumor, but drug therapy or radiation therapy is used when the tumor is too large to remove surgically, or when excess hormone secretion persists even after surgery. To date, drug therapy has consisted of somatostatin analogues (somatostatin is a hormone that inhibits secretion of growth hormone). However, at present there is only a single somatostatin agonist available in Japan, leaving unmet needs for additional treatment options.

About Somatuline®

The active substance in Somatuline® and Somatuline® Autogel® is lanreotide, which inhibits the growth and secretion of several endocrine, exocrine and paracrine hormones. 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 where the active substance itself controls the sustained release.

Somatuline® Autogel® releases the active substance over a period of at least 28 days, thus requiring just one injection per month. In some countries, for acromegaly patients well-controlled with 60mg or 90mg every four weeks, an extended dosing interval of Somatuline® 120mg given every 6 to 8 weeks, may be used, reducing the number of injections per year.

This product is presented in a pre-filled syringe for convenient administration. In some countries, Somatuline® is available in a differentiated and enhanced presentation with a pre-filled syringe that does not need reconstitution and with a retractable needle that enhances safety for caregivers. As of today, Somatuline® and Somatuline® Autogel® are marketed in more than 60 countries (including 25 in Europe, the USA, Canada and Japan) 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 9.9 billion) and total assets of JPY 762.1 billion (USD 8.8 billion) in the fiscal year ending March 31, 2012. Please visit www.teijin.co.jp/english.

¹ "The Japanese journal of endocrinology(2006)", "Pituitary(1999)"



Human Chemistry, Human Solutions



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®, endocrinology / Somatuline®, uro-oncology / Decapeptyl® 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 Depository 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.

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. 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 a loss of market share.

Furthermore, the Research and Development process involves several stages each of which involves 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 cannot be certain that its partners will fulfill their obligations. It might be unable to obtain any benefit from those agreements. A default by any of the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial position or performance.

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:



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