

Somatuline® Autogel® 120 mg receives Japanese approval for a new indication for the treatment of gastro-entero-pancreatic neuroendocrine tumors

Paris (France) and Tokyo (Japan), July 3, 2017 - Ipsen (Euronext: IPN; ADR: IPSEY) and Teijin Pharma Limited, the core company of the Teijin Group's healthcare business, today announced that Teijin Pharma has received approval from the Japanese Ministry of Health, Labour and Welfare for Ipsen's subcutaneous drug Somatuline® (lanreotide) for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP NET). The drug is approved in Japan for the treatment of acromegaly and pituitary gigantism since 2012.

The request for the additional approval was filed in July 2016, based on Ipsen's investigational, pivotal phase III randomised placebo-controlled trial (CLARINET) in 204 patients with GEP NET conducted in 14 countries, and an open-label single group multicenter Phase II trial (J-001) in 32 patients with NET that Teijin Pharma conducted in Japan. This approval establishes Somatuline® as the first drug available in Japan for the treatment of pancreatic NET.

Harout Semerjian, Executive Vice-President & President, Specialty Care International & Global Franchises said: *"We are pleased that Somatuline® is now also available for Japanese patients suffering from gastrointestinal and pancreatic neuroendocrine tumors. In line with our commitment to serve NET patients worldwide, this is a significant step after our partner Teijin launched Somatuline® for the treatment of acromegaly and pituitary gigantism in Japan in January 2013."*

Akihisa Nabeshima, President of Teijin Pharma said: *"It is our great pleasure to now have the capacity to provide a new therapeutic option to NET patients in Japan. We will continue to focus on drug discovery and improve the quality of life of patients by offering them new treatment options to fulfill unmet medical needs."*

About Neuroendocrine Tumors

NETs are malignant tumors arising from neuroendocrine cells. Most of the NET tumors present with metastasis and are discovered fortuitously. In some patients, excess hormones secreted from a NET can lead to severe diarrhea, peptic ulcers or hypoglycemia. While incidence rates are relatively rare, at about 3.5 gastrointestinal NET patients and 1.3 pancreatic NET patients per 100,000 people in Japan, the number of patients has been increasing year by year due to disease awareness and better diagnosis¹.

¹ Tetsuhide Ito et al J Gastroenterol (2015) 50:58-64

The primary treatment for NETs is removal by surgery, but if this is not possible as the disease is usually disseminated, or if a tumor relapses following surgery, another option is a medical treatment.

About Somatuline®

The active substance in Somatuline® is lanreotide acetate, a somatostatin analogue that inhibits the secretion of several endocrine, exocrine and paracrine functions. It has been shown to be effective in inhibiting the secretion of GH and certain hormones secreted by the digestive system. Somatuline® is marketed as Somatuline® Depot® within the United States and as Somatuline® Autogel® in other countries where it has marketing authorization. Somatuline® is indicated for the treatment of acromegaly and neuroendocrine tumors in 70 countries.

< Product Summary >

BRAND NAME	SOMATULINE® 60 mg for s.c. Injection; SOMATULINE® 90 mg for s.c. Injection; SOMATULINE® 120 mg for s.c. Injection	
GENERIC NAME	lanreotide acetate	
DOSAGE FORM	Sustained -release Injection (pre-filled syringe with needle)	
INDICATIONS	To ameliorate oversecretion of growth hormone and/or IGF-I (Somatomedin-C) as well as improvement of symptoms associate with the following diseases: Acromegaly, Pituitary gigantism (when response to surgical therapies has not been satisfactory or surgery is difficult to be performed)	<u>Gastroentero-pancreatic neuroendocrine tumors</u>

DOSAGE AND ADMINISTRATION	In adults, 90 mg of lanreotide is usually administered by deep subcutaneous injection at 4-week intervals for 3 months, followed by 60, 90 or 120 mg every 4 weeks. The dosage may be adjusted according to the patients' clinical condition.	<u>In adults, 120 mg of lanreotide is usually administered by deep subcutaneous injection at 4-week intervals</u>
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※The additional indication is described in the underlined part.

The indication for Gastroentero-pancreatic NETs is approved for SOMATULINE® 120 mg for s.c. Injection alone.

About the Teijin Group

Teijin (TSE: 3401) is a technology-driven global group offering advanced solutions in the areas of environmental value; safety, security and disaster mitigation; and demographic change and increased health consciousness. 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 170 companies and around 19,000 employees spread out over 20 countries worldwide. It posted consolidated sales of JPY741.3 billion (USD 6.5 billion) and total assets of JPY 964.1 billion (USD 8.5 billion) in the fiscal year ending March 31, 2017. Please visit www.teijin.com

About Ipsen

Ipsen is a global specialty-driven biopharmaceutical group focused on innovation and specialty care. The group develops and commercializes innovative medicines in three key therapeutic areas - Oncology, Neurosciences and Rare Diseases. Its commitment to oncology is exemplified through its growing portfolio of key therapies for prostate cancer, neuroendocrine tumors, renal cell carcinoma and pancreatic cancer. Ipsen also has a well-established Consumer Healthcare business. With total sales close to €1.6 billion in 2016, Ipsen sells more than 20 drugs in over 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's R&D is focused on its innovative and differentiated technological platforms located in the heart of the leading biotechnological and life sciences hubs (Paris-Saclay, France; Oxford, UK; Cambridge, US). The Group has about 5,100 employees worldwide. Ipsen is listed in Paris (Euronext: IPN) and in the United States through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information on Ipsen, visit www.ipсен.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. Use of the words "believes," "anticipates" and "expects" and similar expressions are intended to identify forward-looking statements, including the Group's expectations regarding future events, including regulatory filings and determinations. 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 generic products 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. There can be no guarantees a product will receive the necessary regulatory approvals or that the product will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Group's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the Group's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. 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 fulfil 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.

The risks and uncertainties set out are not exhaustive and the reader is advised to refer to the Group's 2016 Registration Document available on its website (www.ipsen.com).

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