

## **Ipsen to Present Improvements to Somatuline® Autogel® Pre-filled Syringe at the 16<sup>th</sup> European Neuroendocrine Tumor Society (ENETS) Annual Conference**

### **ENETS abstract coincides with first European launch**

**Paris (France), 6 March 2019** – Ipsen (Euronext: IPN; ADR: IPSEY) today simultaneously announced the EU launch of a new pre-filled syringe for Somatuline® Autogel® (lanreotide) for patients with neuroendocrine tumors (NETs), acromegaly or symptoms associated with carcinoid syndrome, and released findings from the human factor studies that underpinned its development as a poster presentation (Abstract #H14) at ENETS 2019.<sup>1,2</sup> As of April 2019, patients in Ireland will be the first to benefit from the new ready-to-use, pre-filled syringe. Ipsen has confirmed they are committed to making this new pre-filled syringe available to patients and healthcare professionals throughout Europe, the U.S., Canada, Australia and New Zealand during 2019 following necessary regulatory approvals.

The new pre-filled syringe for Somatuline® Autogel® was the result of several studies, involving patients, their caregivers, nurses and other healthcare professionals, to inform and test enhancements to the existing pre-filled syringe.<sup>1</sup> Notable new features are modified ergonomics and handling, a needle shield removal system, an injection process with plunger support and heightened ease of use.<sup>1</sup> The automatic, built-in safety system, which helps to prevent needle stick injury by locking in place following the administration, has not been changed.

*“Today’s announcement around the EU launch of a new pre-filled syringe for Somatuline® Autogel® is not only an important new option for patients living with acromegaly and NETs but represents a significant milestone in our commitment to patient-centric innovation,”* said Bartek Bednarz, Senior Vice President, Global Oncology Franchise at Ipsen. *“We are also proud to be sharing as a poster presentation at ENETS 2019 the results of several studies, where we tested, evolved and validated changes for every stage of the Somatuline® Autogel® injection experience”*, added Sotirios Stergiopoulos, Chief Medical Officer at Ipsen.

*“NETs and acromegaly can be associated with a number of uncomfortable and unpleasant symptoms, so any innovation that eases the physical challenges of treatment for the patient and their healthcare team is a step forward,”* said Daphne T Adelman, Clinical Nurse Specialist from Northwestern University in Chicago, U.S. and one of the authors of the study.

## About SOMATULINE®<sup>2</sup>

Somatuline® Autogel® is made of the active substance lanreotide, which is a somatostatin analogue that inhibits the secretion of growth hormone and certain hormones secreted by the digestive system. The main indications of Somatuline® and Somatuline® Autogel® are:<sup>2</sup>

- The treatment of individuals with acromegaly when the circulating levels of Growth Hormone (GH) and/or Insulin-like Growth Factor-1 (IGF-1) remain abnormal after surgery and/or radiotherapy, or in patients who otherwise require medical treatment.
- The treatment of grade 1 and a subset of grade 2 (Ki-67 index up to 10%) gastroenteropancreatic neuroendocrine tumors (GEP-NETs) of midgut, pancreatic or unknown origin where hindgut sites of origin have been excluded, in adult patients with unresectable locally advanced or metastatic disease.
- The treatment of symptoms associated with neuroendocrine (particularly carcinoid) tumors.

## Important Safety Information

- The detailed recommendations for the use of Somatuline® Autogel® are described in the Summary of Product Characteristics (SmPC), available [here](#).

## References

<sup>1</sup> Data on file. ENETS 2019

<sup>2</sup> Somatuline® Autogel® SmPC. November 2018

## 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, Neuroscience 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 over €2.2 billion in 2018, 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 5,700 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](http://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 guarantee 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 2017 Registration Document available on its website ([www.ipсен.com](http://www.ipсен.com)).

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