

## **Ipsen to Present New Data on Enhancement of Patient Care at the 16<sup>th</sup> European Neuroendocrine Tumor Society (ENETS) Annual Conference**

### **Studies Demonstrate Ipsen's Ongoing Commitment to Innovation and Improving Patient Care in Neuroendocrine Tumors (NETs)**

**Paris (France), 28 February 2019** – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that they are looking forward to revealing 17 presentations that detail their research into neuroendocrine tumors (NETs) at the 16<sup>th</sup> European Neuroendocrine Tumor Society (ENETS) Annual Conference, which is taking place in Barcelona, Spain between 6<sup>th</sup>-8<sup>th</sup> March 2019.

One of the key presentations, titled (Abstract #H14) **'Development of a new and improved delivery system for lanreotide autogel/depot to further enhance care for patients with NETs and acromegaly'**, reports results from five separate, but complementary studies designed to inform and test enhancements to the existing Somatuline<sup>®</sup> Autogel<sup>®</sup> (lanreotide) pre-filled syringe.<sup>1</sup>

Input from patients and their caregivers, as well as nurses and other healthcare professionals, was used to design a new pre-filled syringe<sup>1</sup> that was submitted to the European Union as a type II variation via a work-sharing procedure with HPRA (Ireland) as the reference country. Following a positive outcome of the work-sharing procedure, each member state would consider a national approval. 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>

*"It is our mission to ensure patients continue to receive optimized care as they navigate the challenges of living with NETs and acromegaly,"* said Sotirios Stergiopoulos, Chief Medical Officer at Ipsen. *"The data we are sharing at this year's ENETS conference underscores our commitment to understanding the patient experience and to supporting a multidisciplinary treatment approach to make treatment administration as simple as possible whether in hospital or at home."*

*"For nurses and other healthcare practitioners treating patients with NETs or acromegaly, the value of innovation across the entire treatment landscape supports our ability to provide the best care for our patients,"* said Daphne T Adelman, Clinical Nurse Specialist from Northwestern University in Chicago, U.S. and one of the authors of the study. *"As a nurse who administers treatments to patients often, efficient pre-filled syringes allow me to save time and focus on patients and their needs."*

Also, being highlighted are results from:

**(Abstract #H18) Tumour growth rate (TGR) to monitor growth/predict response to lanreotide autogel (LAN) use before, during and after peptide receptor radionuclide therapy (PRRT) in advanced gastroenteropancreatic neuroendocrine tumors (GEP-NETs): data from PRELUDE**

This abstract has been selected for a poster walk during ENETS' scientific program and will report effectiveness data and post-hoc analyses of tumor growth rate (TGR) as a measure of response to LAN-PRRT (lanreotide autogel – peptide receptor radionuclide therapy).

**(Abstract #M03) ATLANT, phase 2 study combination trial between long acting somatostatin analogue (SSA) lanreotide (LAN) and temozolomide (TMZ) in progressive thoracic (lung / thymus)**

**well differentiated NET (carcinoid) (TNETS).**

**(Abstract #F22) Exploratory assessment of the clinical value of baseline (BL) circulating tumour cells (CTC) to predict symptomatic response in pts with functioning midgut neuroendocrine tumours (NETs) receiving lanreotide autogel (LAN): CALM-NET study results**

In addition to these posters, Ipsen will share data from the following 13 company sponsored or supported studies and literature reviews:

**(Abstract #H17) Safety and Efficacy of 14-Day Dosing Interval of Lanreotide Autogel/Depot (LAN) For Patients With Pancreatic or Midgut Neuroendocrine Tumours (NETs) Progressing on LAN Every 28 Days: The Prospective, Open-label, International, Phase 2 CLARINET FORTE Study**

**(Abstract #P04) Lanreotide autogel 120mg (LAN) in patients (pts) with locally advanced or metastatic gastroenteropancreatic neuroendocrine tumours (GEP-NETs): prospective observational NETways study**

**(Abstract #D13) Satisfaction Survey of Administration Modes for Long-Acting (LA) Somatostatin Analog (SSA) Therapy in Patients (pts) with Neuroendocrine Tumours (NETs): Results of Cognitive Interviews With Patients and Nurses**

**(Abstract #J15) The Effect of Carcinoid Syndrome Diarrhea (CSD) Interventions on Patient Experience Outcomes: a Systematic Literature Review (SLR)**

**(Abstract #J08) Differential Diagnosis (DDx) of Carcinoid Syndrome Diarrhea (CSD): a Systematic Literature Review (SLR)**

**(Abstract #H25) Evaluation of the use of resources and costs associated with Uncontrolled or Controlled Carcinoid Syndrome (CS) in patients (pts) with Neuroendocrine Tumours (NETs) in Spain: RECOSY study**

**(Abstract #F10) Relationship between biomarkers and number of liver metastases at the time of diagnosis of small intestinal neuroendocrine tumors**

**(Abstract #A11) Evaluation of gene expression changes associated with response to somatostatin analogues (SSAs) in gastrointestinal (GI) neuroendocrine tumors (NETs)**

**(Abstract #J07) Long-term Treatment with Telotristat Ethyl (TE) in Patients with Carcinoid Syndrome (CS) Symptoms: Results from TELEPATH Study**

**(Abstract #P05) TELEFIRST: A randomized phase III clinical trial of Lanreotide (LAN) combined with Telotristat ethyl (TE) or placebo (PBO) for the First-line treatment in patients (pts) with advanced well-differentiated (wd) small intestinal neuroendocrine tumours (siNET) with highly-functioning carcinoid syndrome (CS)**

**(Abstract #K30) OPS-C-001: A Phase I/II Study To Investigate Safety, Tolerability, Biodistribution, Dosimetry and Preliminary Efficacy of 177Lu-OPS201 for the Therapy of Somatostatin Receptor (SSTR)-Positive Neuroendocrine Tumours (NETs)**

**(Abstract #P08) Study to evaluate the optimal dose of 68Ga-OPS202 as a PET imaging agent in patients with GEP-NETs**

**(Abstract #D33) Establishment of a NET data base in a German tertiary referral center; preliminary results**

### **About SOMATULINE<sup>®2</sup>**

Somatuline<sup>®</sup> Autogel<sup>®</sup> is made of the active substance lanreotide, which is a long-acting somatostatin analogue that inhibits the secretion of growth hormone and certain hormones secreted by the digestive system. The main indications of Somatuline<sup>®</sup> and Somatuline<sup>®</sup> Autogel<sup>®</sup> 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](#).

### **About XERMELO<sup>®3</sup>**

Xermelo<sup>®</sup> is a novel, orally administered, inhibitor of the enzyme tryptophan hydroxylase (TPH). Through inhibition of TPH, the rate-limiting step in the synthesis of serotonin, Xermelo<sup>®</sup> was designed to reduce the production of serotonin within neuroendocrine tumors.

Xermelo<sup>®</sup> (telotristat ethyl) is commercialized by Ipsen in all territories excluding the United States and Japan, where Lexicon retains the rights. Lexicon has approval for Xermelo<sup>®</sup> in the U.S. as a first and only orally administered therapy for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.

Xermelo<sup>®</sup> is approved in Europe for the treatment of carcinoid syndrome diarrhea in patients inadequately controlled by somatostatin analogue therapy.

#### **Important Safety Information**

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

### **References**

<sup>1</sup> Data on File. ENETS '19

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

<sup>3</sup> Xermelo SmPC. January 2019

### **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 Depository 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 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. 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 2017 Registration Document available on its website ([www.ipsen.com](http://www.ipsen.com)).

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