PRESS RELEASE

New patient-reported data demonstrated high satisfaction levels and fewer patients reporting injection-site pain with Somatuline® Autogel®/Somatuline® Depot (lanreotide)

- New data presented at ENETS 2022 showed patients treated with Somatuline® Autogel®/Somatline® Depot (lanreotide) pre-filled syringe reported less frequent injection-site pain lasting more than two days than those treated with octreotide long-acting release syringe
- People living with gastroenteropancreatic neuroendocrine tumors enrolled on Somatuline® Autogel® patient support programs reported feeling in control and satisfied when administering at-home injections

PARIS, France, 8 March 2022 – Ipsen (Euronext: IPN; ADR: IPSEY) published today new data from seven abstracts to be presented at the hybrid-setting 19th Annual European Neuroendocrine Tumor Society (ENETS) Conference, 10-11 March 2022, in Barcelona, Spain. Presentations include data from the PRESTO 2 and HomeLAN surveys which demonstrated patient-reported benefits when administering Somatuline® Autogel®/Somatuline® Depot (lanreotide). These include fewer patients reporting experiencing injection-site pain and high levels of injection experience satisfaction when participating in patient support programs (PSP), respectively.

Data from PRESTO 2, an e-survey which evaluated injection site pain in people living with gastroenteropancreatic neuroendocrine tumors (GEP-NETs) or acromegaly (n=219 and n=85), demonstrated that significantly fewer patients receiving Somatuline Autogel/Somatuline Depot pre-filled syringe had reported injection-site pain lasting more than two days after their last dose compared with the octreotide long acting release syringe (OCT) (6.0% vs 22.8% [primary endpoint]; odds ratio, adjusted for disease group and occurrence of injection-site reaction: 0.13 [95% confidence interval (CI) 0.06, 0.30]; p<0.0001).[1] Furthermore, compared with OCT, fewer patients treated with Somatuline Autogel/Somatuline Depot, reported interference with daily life as a result of injection-site pain (41% vs 60%).[1]

Professor Dermot O'Toole, Consultant Gastroenterologist (Dublin at St. Vincent's and St James's Hospitals & Trinity College) and Neuroendocrine Tumor Specialist in the ENETS accredited European Centre of Excellence in St Vincent's Hospital Dublin said, "These new data from PRESTO 2 reinforce the importance of gathering feedback directly from patients to understand the impact of their treatment on their wellbeing. Injection-site pain can be a real concern for patients, especially for those who are on long-term treatment regimens, so it is interesting to see that significantly fewer patients receiving Somatuline Autogel/Somatuline Depot reported injection-site pain compared with the octreotide long-acting release syringe. These data will help healthcare professionals better understand the impact of injection-site pain, an important consideration to discuss with patients when making treatment decisions."

Ipsen is also presenting new data from its HomeLAN survey, evaluating the injection experience satisfaction of people living with GEP-NETs who participate in PSPs. Somatuline Autogel PSPs aim to assist patients receiving their treatment at home, reducing both travel burden and the current risk of COVID-19 exposure. Furthermore, after training, patients on stable dose can administer Somatuline Autogel independently (self or partner), where approved. This study evaluated patients' reported injection experience and the impact of administration in the home setting. Overall, 95.5% (95% CI 89.89–98.06) of patients were satisfied with their most recent at-home injection experience by a HCP, with around 70% reporting that it made them feel 'a great deal' or 'quite a bit' in control of their lives. The majority of participants (85%) strongly agreed that the PSP met their medical needs.[2]

Professor Steven Hildemann, Executive Vice President, Chief Medical Officer, Head of Global Medical Affairs and Patient Safety, Ipsen said, “Ipsen has a longstanding heritage in neuroendocrine tumors and our data presented at the ENETS Conference showcase our ongoing commitment to the patient community. We continue to listen and learn from patients, with the goal of finding new opportunities throughout their treatment journey. By gathering direct feedback, data and insights from patients and healthcare professionals, we can continually evaluate our delivery systems and patient support resources to drive the best possible patient outcomes.”

Please see below for details of all Ipsen data at ENETS Conference 2022:

Abstract	Authors	Presentation details
PRESTO 2: an international patient survey to evaluate impact of injection and delivery system on local pain when administering somatostatin analogue (SSA) therapy	O’Toole et al.	Poster and poster discussion Thu 10 March 17:29 within Poster discussion session – Clinical science 17:05–17:35 CET
HomeLAN: an international online survey to assess satisfaction with injection experience of patients with neuroendocrine tumours (NETs) enrolled in lanreotide autogel (LAN) Patient Support Programmes	Hernando et al.	Poster
Prognostic factors for progression-free survival (PFS) in patients with metastatic bronchopulmonary neuroendocrine tumors (BP-NETs): exploratory data from the phase 3 SPINET study	Baudin et al.	Oral and poster Thu 10th March at 11:24 within Session 2B: Best abstracts Clinical Science 11:00–12:15
Effect of lanreotide autogel/depot (LAN) on tumor growth rate (TGR) in patients with metastatic bronchopulmonary neuroendocrine tumors (BP-NETs): exploratory data from the phase 3 SPINET study	Capdevila et al.	Oral and poster Thu 10 March at 11:36 within Session 2B: Best abstracts Clinical Science 11:00–12:15
Impact of a reduced dosing interval of lanreotide autogel (LAN) on tumor growth rate (TGR) in patients with progressive neuroendocrine tumors (NETs) in the prospective, single-arm, phase 2 CLARINET FORTE trial	Dromain et al.	Poster
Lanreotide 120 mg every 28 days (LAN) in patients with locally advanced or metastatic pancreatic neuroendocrine tumors (panNET) in routine clinical practice in Iberia	Alonso et al.	Poster
Factors at Time of Diagnosis Associated with Progressive or Stable Disease in Patients with Small Intestinal Neuroendocrine Tumors (SI-NETs)	Schalin-Jäntti et al	Poster

END

About neuroendocrine tumors
Neuroendocrine tumors, or NETs, are a group of uncommon tumors that develop in the cells of the neuroendocrine system, throughout the body.[3,4] NETs occur in both men and women, in general aged 50 to 60 years old, although they can affect anyone of any age.[6]

The three areas where NETs are mostly found in the body are the gastrointestinal tract, the pancreas and the lungs.[4]

- Gastrointestinal NETs (GI-NETs) are found in the gastrointestinal tract or digestive system and are the most common type of NETs.[4]
- Pancreatic NETs (panNETs) are formed in the islet cells of the pancreas and include several uncommon types of NETs.[4]
- Lung NETs account for about 20 – 30% of all NETs.[8]

The symptoms of NETs are often not distinct and difficult to identify, and can sometimes take up to seven years to diagnose.[5] The number of people being newly diagnosed with NETs overall is believed to be rising.[6] This is mainly due to increased awareness of the condition and diagnostic testing.[6]

About PRESTO 2[1]
PRESTO 2 is an international patient survey to evaluate impact of injection and delivery system on local pain when administrating somatostatin analogue (SSA) therapy. An e-survey of adults with NETs or acromegaly from Canada, the USA, UK and Ireland, who had received more than three months' of treatment with LAN or OCT (n=304), was used to investigate the proportion of patients with injection-site pain lasting more than two days after last injection (primary end point) as well as interference with daily life as a result of injection-site pain (among secondary end points).

About HomeLAN[2]
HomeLAN is a non-interventional, cross-sectional survey of adults with NETs, enrolled in PSPs in Belgium, Greece, Spain and The Netherlands for six or more months and receiving LAN at home. The target sample size was 120, based on the number of eligible patients and a 15% response rate. Endpoints included patient satisfaction with the most recent LAN injection (primary) and reasons for choosing their mode of administration (among secondary endpoints).

About Somatuline® Autogel®/Somatuline® Depot (lanreotide)[7]
Somatuline® Autogel®/Somatuline® Depot is made of the active substance lanreotide and is a long-acting somatostatin analogue that inhibits the secretion of growth hormone and certain hormones secreted by the digestive system. The licensed indications of Somatuline® Autogel® are[7]:

- The treatment of individuals with acromegaly when the circulating levels of Growth Hormone and/or Insulin-like Growth Factor-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. The recommended starting dose is one injection of Somatuline Autogel 60 to 120 mg administered every 28 days.

The decision regarding independent administration of Somatuline Autogel/Somatuline Depot is only applicable to countries where this option is approved in the Product Information/Summary of Product Characteristics and for patients on stable dose upon HCP decision and after appropriate training by HCP.

The detailed recommendations for the use of Somatuline® Autogel® are described in the Summary of Product Characteristics (SmPC) and US Prescribing Information (PI).

About Ipsen

Ipsen is a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Rare Disease and Neuroscience; it also has a well-established consumer healthcare business. With total sales of over €2.5bn in FY 2020, Ipsen sells more than 20 medicines in over 115 countries, with a direct commercial presence in more than 30 countries. The company's research and development efforts are focused on its innovative and differentiated technological platforms located in the heart of leading biotechnological and life-science hubs: Paris-Saclay, France; Oxford, U.K.; Cambridge, U.S.; Shanghai, China. Ipsen has c.5,700 colleagues worldwide and is listed in Paris (Euronext: IPN) and in the U.S. through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information, visit ipsen.com.

Ipsen's Forward Looking Statements

The forward-looking statements, objectives and targets contained herein are based on Ipsen'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 Ipsen'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 Ipsen'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 Ipsen. 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 and also taking into consideration assessment delays of certain clinical trials in light of the ongoing COVID-19 pandemic. Ipsen 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 Ipsen 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, Ipsen cannot be certain that favorable results obtained during preclinical 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; Ipsen'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 Ipsen's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. Ipsen 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 Ipsen's activities and financial results. Ipsen 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 Ipsen's partners could generate lower revenues than expected. Such situations could have a negative impact on Ipsen's business, financial position or performance. Ipsen 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. Ipsen'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 Ipsen's 2020 Universal Registration Document, available on ipsen.com.

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