

## **Ipsen announces new data from the Phase II CLARINET FORTE study which demonstrated preservation of quality of life when increasing dose frequencies of Somatuline® Autogel® (lanreotide)**

- A total of 9 abstracts presented at the 18th Annual European Neuroendocrine Tumor Society (ENETS) Conference showcasing new data across the patient pathway in neuroendocrine tumors
- Latest data from the Phase II CLARINET FORTE study are the subject of an oral presentation showing quality of life is maintained when doubling the dose regimen of lanreotide autogel with no new safety signals
- These new analyses suggested no deterioration in quality of life from baseline in patients living with pancreatic neuroendocrine tumors (panNETs) and midgut neuroendocrine tumors (NETs) who received lanreotide autogel (120 mg every 14 days) following progression on the standard dose regimen
- Moreover, new data on independent injection of lanreotide autogel highlighted the substantial impact on cost and hospital visit reductions in the UK

**PARIS, France, 22 February 2021** – Ipsen (Euronext: IPN; ADR: IPSEY) announced today a total of 9 abstracts presenting new data with a focus in NETs.<sup>1-10</sup> These include data from the Phase II CLARINET FORTE study and data on the use of independent administration of lanreotide autogel to be presented at the ENETS Conference, taking place virtually 25-27 February 2021.<sup>1-3</sup>

Updated data from the CLARINET FORTE study were presented including additional quality of life (QoL) data showcasing assessments of patients' perceived QoL during the treatment period of the study.<sup>1</sup> QoL was assessed using three validated questionnaires covering the severity of problems associated with mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (EQ-5D-5L), as well as questionnaires specific to patients with cancer (EORTC QLQ-C30) and NETs (QLQ-GINET.21).<sup>1</sup> Results from these measurements suggest no deterioration of QoL with no substantial deviation from baseline prior to treatment.<sup>1</sup> Additional pharmacokinetic (PK) analyses of the increased dosing regimen showed that PK increased in a proportional manner and no increase in rates of glycoregulation, cholelithiasis or hypertension in patients with increased lanreotide autogel exposure was observed.<sup>2</sup> With confirmation of the PK data together with the substantial period of QoL preservation, data from the CLARINET FORTE study could represent a potentially meaningful treatment option for a population of patients with high unmet needs.<sup>1-2</sup>

"The new findings from the CLARINET FORTE trial highlighted that QoL remained stable throughout the study in patients who were enrolled with progressive disease and who were receiving twice the frequency of injections compared with their pre-study regimen", said Professor Marianne Pavel, Friedrich-Alexander University of Erlangen, Germany, Senior Physician and Chair of Endocrinology, and principal investigator of the study. "This is an important new measure as it reflects the patients' perceptions of their own current overall health and means that patients with progressive NETs may be able to remain on a more tolerable first-line standard of care for longer with no new safety signals or quality of life deterioration."

Among the Ipsen data presented at ENETS 2021 is the presentation of findings from a study into the potential cost savings associated with increased uptake of independent administration of long-acting somatostatin analogues (SSAs) for the treatment of gastroenteropancreatic NETs (GEP-NETs) within the UK's National Healthcare Service (NHS).<sup>3</sup> In the UK, lanreotide autogel is approved for independent injection at home by the patient or a partner\*.<sup>11</sup> Health-economic modeling suggests that when a patient with GEP-NETs treated with octreotide long-acting release (LAR) transition to lanreotide autogel administered via independent injection, an average of 14.5 nurse contacts, including four hospital visits,

could potentially be avoided every year as well as potential overall expenses per patient being lowered by 16.4% equating to £2,458 saved per year. At a population level, the increase in patients independently injecting SSAs, from 12.6% (pre-COVID) to 24.5% (during COVID), may have reduced the annual overall healthcare expenditure for the NHS from £53.4M to £52.9M.<sup>3</sup>

“The effective remote management of patients has never been more critical. As a chronic condition, patients living with NETs require long-term solutions which provide continuity of treatment and flexibility. Home administration of lanreotide autogel provides patients living with NETs the independence to manage their own treatment and can ease the pressure on frontline healthcare professionals, reducing hospital visits and potentially the risk of COVID-19 for patients,” said Lilian Cortez, author and GI specialist pharmacist at the The Royal Marsden NHS Foundation Trust, UK. “The potential benefits identified in this study should be considered alongside patient experience in evaluating pandemic-enforced practices that may be beneficial to adopt long-term.”

Ipsen also unveiled details from multiple studies highlighting a data-driven vision of patient-centricity, which show how mining the wealth of data generated from a drug’s discovery to real-world use after regulatory approval can unlock insights into the epidemiology and clinical features of NETs. These include a retrospective study leveraging data from five years of electronic health records to increase understanding of NETs and help to identify new therapeutic strategies; and results from the Phase III RAISE study investigating the use of deep learning models and dissociated response to predict early treatment efficacy in patients with NETs.<sup>4,5</sup>

“True patient-centricity requires an analytical, insights-driven mindset and at Ipsen we are pushing the boundaries to bring new data to best serve patients and their families, and generate pharmacoeconomic measures of Health Systems,” said Prof. Dr. Steven Hildemann, Executive Vice President, Chief Medical Officer, Head of Global Medical Affairs and Patient Safety, Ipsen. “Ipsen remains a committed partner and leader in the NET landscape and our presence at ENETS showcases how we are taking strides in making tangible differences for patients living with NETs. As a company, we continue to champion the empowerment of patients across the treatment pathway.”

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## **Notes to editors**

### **About NETs**

Neuroendocrine tumors, or NETs, are a group of uncommon tumors that develop in the cells of the neuroendocrine system, throughout the body.<sup>12,13</sup> NETs occur in both men and women, in general aged 50 to 60 years old, although they can affect anyone of any age.<sup>14</sup>

The three licensed areas where NETs are found in the body are the gastrointestinal tract, the pancreas and the lungs.<sup>15</sup>

- Gastrointestinal NETs (GI-NETs) are found in the gastrointestinal tract or digestive system and are the most common type of NETs.<sup>15</sup>
- Pancreatic NETs (panNETs) are formed in the islet cells of the pancreas and include several uncommon types of NETs.<sup>15</sup>
- Lung NETs are less common than other types, accounting for about one quarter of NETs.<sup>15</sup>

The symptoms of NETs are often not distinct and difficult to identify, and can sometimes take between five to seven years to fully diagnose.<sup>16</sup> The number of people being newly diagnosed with NETs overall is believed to be rising.<sup>17</sup> This is mainly due to increased awareness of the condition and diagnostic testing.<sup>17</sup> NETs are now the fastest growing class of cancers worldwide, accounting for around 2% of all cancers at any time.<sup>17</sup>

### **About CLARINET FORTE**

CLARINET FORTE was a prospective single-arm, open-label, exploratory, international Phase II study

to explore the efficacy and safety of an increased lanreotide autogel dosing frequency (120 mg every 14 days) in patients with metastatic or locally advanced unresectable pancreatic NETs or midgut NETs, with centrally-accessed progression within the last two years while on a standard lanreotide autogel regimen (120 mg every 28 days) for 24 weeks or more.<sup>18</sup> Initial efficacy and safety data from the CLARINET FORTE study were presented at the 2020 European Society for Medical Oncology (ESMO) Congress, which took place on 19-21 September 2020.

### **About Somatuline® Autogel® (lanreotide)**

Somatuline® Autogel®/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:<sup>11</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. The recommended starting dose is one injection of Somatuline Autogel® 120 mg administered every 28 days.

The detailed recommendations for the use of Somatuline® Autogel® are described in the [Summary of Product Characteristics](#) (SmPC) in the UK.<sup>11</sup>

\* The decision regarding administration by the patient or a trained person should be taken by a healthcare professional.

### **About Ipsen**

Ipsen is a global mid-size biopharmaceutical company with a focus on transformative medicines in Oncology, Rare Disease and Neuroscience. Ipsen also has a well-established Consumer Healthcare business. With total sales over €2.5 billion in 2020, 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; Shanghai, China). 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.ipsen.com.fr](http://www.ipsen.com.fr)

### **Ipsen's 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, and the outcome of this study or other studies. 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 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

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industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of 6 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 2019 Universal Registration Document available on its website ([www.ipsen.com](http://www.ipsen.com)).

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