

**Ipsen’s partner, Lexicon Pharmaceuticals, announces positive results from TELESTAR phase 3 study showing that telotristat etiprate is effective in the treatment of carcinoid syndrome caused by neuroendocrine tumors not adequately controlled by somatostatin analogs**

- **Telotristat etiprate met the primary endpoint, i.e. reduction from baseline compared to placebo in the average number of daily bowel movements over the 12-week study period**
- **Ipsen owns global commercial rights to telotristat etiprate (excluding the US and Japan)**

**Paris (France), 03 August 2015** – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that its partner, Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), disclosed positive results from the pivotal Phase 3 TELESTAR study. TELESTAR evaluated the efficacy and safety of telotristat etiprate for carcinoid syndrome patients with metastatic neuroendocrine tumor (NET) inadequately controlled by somatostatin analog (SSAs), the current standard of care.

Top-line results from the Phase 3 study show that patients who added telotristat etiprate to the standard of care at both the 250 mg and 500 mg doses experienced a statistically significant reduction from baseline compared to placebo in the average number of daily bowel movements over the 12-week study period ( $p < 0.001$ ), meeting the study’s primary endpoint.

Complete results from the Phase 3 TELESTAR study will be presented at an upcoming scientific conference.

**Claude Bertrand, Executive Vice President R&D and Chief Scientific Officer, Ipsen** stated: *“We are pleased with the positive top-line Phase 3 results for telotristat etiprate. Should telotristat etiprate be approved, its oral formulation would satisfy an unmet medical need for patients with carcinoid syndrome not adequately controlled with SSAs therapy. After the approval of Somatuline® Autogel® as the first and only SSA for tumor control of gastro-intestinal and pancreatic neuroendocrine tumors (NETs) in the US and Europe, and the more recent acquisition of Octreopharm’s nuclear medicine platform, these results are an important milestone in our strategy to become a global leader in NETs.”*



**Professor Marianne Pavel, Charité-Universitätsmedizin Berlin, Principal Investigator, study lead in Germany** stated: *“There is a need for effective treatment to improve the health and comorbidities of patients whose carcinoid syndrome is not adequately controlled with somatostatin analogue therapy. Results of this positive phase 3 study with telotristat etiprate are promising in improving symptom management, and outcome of patients with carcinoid syndrome not adequately controlled with SSA therapy”.*

In October 2014, Ipsen and Lexicon announced that they had entered into an exclusive licensing agreement for Ipsen to commercialize telotristat etiprate, excluding the US and Japan, with a focus on the symptomatic treatment of carcinoid syndrome inadequately controlled with SSAs. Lexicon retains sole rights to commercialize telotristat etiprate in the United States and Japan.

#### **About the study**

The double-blind Phase 3 study known as TELESTAR (Telotristat Etiprate for Somatostatin Analogue Not Adequately Controlled Carcinoid Syndrome) enrolled 135 patients with carcinoid syndrome who were not adequately controlled on SSA therapy, the current standard of care. The three-arm study evaluated two doses of oral telotristat etiprate – 250 mg and 500 mg, each taken three times daily – against placebo over a 12-week period and measured the reduction from baseline in the average number of daily bowel movements. Patients in both the treatment and placebo arms continued their SSA therapy throughout the study.

Top-line results from TELESTAR show that patients who added telotristat etiprate to SSA therapy at both the 250 mg and 500 mg doses experienced a statistically significant reduction from baseline compared to placebo in the average number of daily bowel movements over the 12-week study period ( $p < 0.001$ ), meeting the study's primary endpoint.

In another key finding, a substantially greater proportion of patients on telotristat etiprate achieved a durable response (44 percent and 42 percent in the 250 mg and 500 mg arms, respectively), defined as at least a 30 percent reduction in daily bowel movements over at least half the days of the study period, as compared to 20 percent response on placebo ( $p < 0.040$ ).

Patients who received 250 mg of telotristat etiprate experienced a 29 percent reduction in the average number of daily bowel movements during the final week (week 12) of the study period compared to baseline, and those in the 500 mg arm had a 35 percent reduction, while the placebo group showed a 17 percent reduction. These results are consistent with those seen in the 12-week Phase 2 study of telotristat etiprate.

The proportion of patients with treatment-emergent adverse events (AEs), serious AEs and discontinuation due to AEs were generally similar in all three treatment arms. The tolerability profile of telotristat etiprate 250 mg tid appeared similar to placebo and somewhat better than 500 mg tid with respect to gastrointestinal discomfort and mood. Further in depth analysis of safety and tolerability data will be conducted.



The 12-week double-blind study period is being followed by a 36-week open-label extension where all patients receive telotristat etiprate 500 mg three times daily.

### **About Ipsen**

Ipsen is a global specialty-driven biotechnological group with total sales exceeding €1.2 billion in 2014. Ipsen sells more than 20 drugs in more than 115 countries, with a direct commercial presence in 30 countries. Ipsen's ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its development strategy is supported by 3 franchises: neurology, endocrinology and urology-oncology. Ipsen's commitment to oncology is exemplified through its growing portfolio of key therapies improving the care of patients suffering from prostate cancer, bladder cancer or neuroendocrine tumors. Ipsen also has a significant presence in primary care. Moreover, the Group has an active policy of partnerships. Ipsen's R&D is focused on its innovative and differentiated technological platforms, peptides and toxins, located in the heart of the leading biotechnological and life sciences hubs (Les Ulis, France; Slough/Oxford, UK; Cambridge, US). In 2014, R&D expenditure totaled close to €187 million, representing about 15% of Group sales. The Group has more than 4,500 employees worldwide. Ipsen's shares are traded on segment A of Euronext Paris (stock code: IPN, ISIN code: FR0010259150) and eligible to the "Service de Règlement Différé" ("SRD"). The Group is part of the SBF 120 index. Ipsen has implemented a Sponsored Level I American Depositary Receipt (ADR) program, which trade on the over-the-counter market in the United States under the symbol IPSEY. For more information on Ipsen, visit [www.ipсен.com](http://www.ipсен.com).

### **Ipsen Forward Looking Statements**

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.

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