

Ipsen announces a step forward in the resupply of Increlex[®] in the U.S.

- *In collaboration with the FDA, Ipsen will release one batch of Increlex[®] on June 2, 2014*
- *Ipsen anticipates release of additional lots in the coming months*

Paris (France), 13 May 2014 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that a supply of Increlex[®] will be available in the U.S. starting June 2, 2014. In collaboration with the FDA (Food and Drug Administration), Ipsen is releasing one batch of Increlex[®]'s active ingredient. Ipsen anticipates that additional lots will be released in the coming months, as the company continues to work closely with the FDA to make additional Increlex[®] lots available as soon as possible.

Increlex[®] is used to treat children with a form of growth failure called severe primary IGF-1 deficiency (IGFD), which can cause permanent short stature. The supply interruption of Increlex[®] occurred in mid-June 2013.

“We are very pleased that the resupply of Increlex[®] will be taking place in the US, as we have been working in very close collaboration with the FDA and the manufacturer Lonza to make this happen,” said **Marc De Garidel, Chairman and Chief Executive Officer of Ipsen**. He added: *“While the manufacturing of a product like Increlex[®] remains challenging, Ipsen is committed to the children across the world who need this treatment.”*

About Increlex[®]

The active substance in Increlex[®] is a recombinant insulin-like growth factor of human origin (IGF-1). IGF-1 is the direct hormonal mediator of stature and bone growth and must be present for normal growth of bones and cartilage in children. In severe primary IGF-1 deficiency, children's serum IGF-1 levels are low despite the presence of normal or elevated GH levels. If the IGF-1 is not present in sufficient quantities, the child will not reach a normal stature.

Ipsen markets the orphan drug, which is considered to be a drug of medical necessity, in the United States and most European countries. On 25 April 2013, Ipsen announced that the supplier of Increlex[®]'s active ingredient, Lonza Biologics Inc, was facing manufacturing issues



with Increlex[®] at its Hopkinton, MA site. Lonza has been working closely with the U. S. Food and Drug Administration (FDA) to address these issues. The supply interruption occurred in mid-June 2013 in the US and in Q3 2013 in Europe and the rest of the world. Resupply in EU and other markets has been effective since December 2013.

Safety use of Increlex[®]

The product information should be consulted for further details of undesirable effects that may occur following treatment with Increlex[®] and for recommendations for dosing adjustments that may be needed depending on patient's response. There are limited data on re-starting Increlex[®] in patients whose treatment has been interrupted. These patients should therefore be given Increlex[®] in line with approved dosing instructions for starting treatment in the Summary of Product Characteristics, taking into account patients' previous clinical history with Increlex[®] treatment. Patient safety is a primary concern at Ipsen and we continue to encourage the reporting of any adverse event experienced by patients treated with INCRELEX that are considered related to treatment.

Warnings and precautions

The product information should be consulted regarding details of undesirable effects that may occur following treatment with Increlex[®]. Increlex[®] treatment should be directed by physicians experienced in the diagnosis and management of patients with growth disorders. Increlex[®] contains benzyl alcohol and should therefore not be administered to premature babies or newborns. Thyroid and nutritional deficiencies should be corrected before commencement of therapy. Increlex[®] should not be used for growth promotion in patients with closed epiphyses. Increlex[®] is not a substitute for therapy with growth hormone. Increlex[®] should be given shortly before or after a meal or snack because it has hypoglycaemic effects. Increlex[®] should not be administered if a meal or snack is omitted. At the time of initial prescription, physicians should educate parents on the signs, symptoms and treatments of hypoglycaemia, including injection of glucagon. Doses of insulin and / or other hypoglycaemic agents may need to be reduced for diabetic patients using Increlex[®]. Increlex[®] has not been studied in children less than 2 years of age or in adults. Lymphoid tissue (eg tonsillar) hypertrophy and chronic middle-ear obstructions have been reported with the use of Increlex[®]. Intracranial hypertension with papilledema, visual changes, headaches nausea and / or vomiting have been reported in patients treated with Increlex[®]. Signs and symptoms resolve after interruption of dosing. Slipped capital femoral epiphyses and progression of scoliosis can occur in patients who experience rapid growth.

Contraindications

Increlex[®] is contraindicated in the presence of active or suspected neoplasia. And therapy should be discontinued if evidence of neoplasia develops. Increlex[®] should not be used in patients who have experienced hypersensitivity to the product. Increlex[®] must not be administered by intravenous administration.

About Ipsen

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.2 billion in 2013. 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 uro-oncology. 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. In 2013, R&D expenditure totaled close to €260 million, representing more than 21% of Group sales. Moreover, Ipsen also has a



significant presence in primary care. The Group has close to 4,600 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, visit www.ipsen.com.

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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