

Ipsen announces a step forward in the resupply of Increlex[®] (mecasermin [rDNA origin] injection) 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*

Basking Ridge, NJ (USA), May 13, 2014 – Ipsen Biopharmaceuticals, Inc., the U.S. affiliate of Ipsen (Euronext: IPN; ADR: IPSEY), today announced that a supply of Increlex[®] (mecasermin [rDNA origin] injection) will be available in the U.S. starting June 2, 2014. In collaboration with the U.S. Food and Drug Administration (FDA), 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 U.S., 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 growth hormone (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 April 25, 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 U.S. and in Q3 2013 in Europe and the rest of the world. Resupply in the EU and other markets has been effective since December 2013.

Indication

Increlex is indicated for the treatment of growth failure in children with severe primary IGF-1 deficiency (IGFD), or with growth hormone (GH) gene deletion, who have developed neutralizing antibodies to GH. Severe primary IGFD is defined by height standard deviation score ≤ -3.0 and basal IGF-1 standard deviation score ≤ -3.0 and normal or elevated growth hormone (GH).

Increlex is not intended for use in subjects with secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids. Thyroid and nutritional deficiencies should be corrected before initiating Increlex treatment. Increlex is not a substitute to GH for approved GH indications. Increlex has not been studied in children < 2 years of age.

Important Safety Information

Contraindications:

- Presence of active or suspected malignancy
- Hypersensitivity to mecasermin (rhIGF-1) or any of the inactive ingredients in Increlex
- Intravenous administration
- Closed epiphyses

Warnings and Precautions:

- Hypoglycemic effects: Increlex should be administered 20 minutes before or after a meal or snack, and should not be administered when the meal or snack is omitted.
- Hypersensitivity: Allergic reactions have been reported, including anaphylaxis requiring hospitalization.
- Intracranial hypertension: Funduscopic examination is recommended at the initiation of and periodically during the course of therapy.
- Tonsillar/adenoidal hypertrophy: Patients should have periodic examinations to rule out potential complications.
- Slipped capital femoral epiphysis: Evaluate any child with onset of limp or hip/knee pain.
- Progression of scoliosis: Monitor any child with scoliosis.

Common adverse reactions include: hypoglycemia, local and systemic hypersensitivity, and tonsillar hypertrophy.



Please see the full Prescribing Information for Increlex available at <http://increlex.com/pdf/hcp-full-prescribing-information.pdf>

Patient Information for Increlex available at <http://increlex.com/pdf/patient-full-prescribing-information.pdf>

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.ipсен.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 favorable 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 fulfill 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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