

## **Ipsen maintains Increlex<sup>®</sup> (mecasermin [rDNA origin] injection) supply in the US**

**Paris (France), September 10, 2012** – Ipsen (Euronext: IPN; ADR: IPSEY) announced today that it has avoided an interruption in US supply of Increlex<sup>®</sup> (IGF-1) for the treatment of Severe Primary IGF-1 Deficiency due to delays in manufacturing site approval.

Increlex<sup>®</sup> is an important drug used to treat patients with Severe Primary IGF-1 Deficiency (Primary IGFD) and is considered to be a drug of medical necessity. As a result, Ipsen has worked closely with the US Food and Drug Administration to maintain product supply.

Increlex<sup>®</sup>'s active principle (IGF-1) for the treatment of Severe Primary IGF-1 Deficiency (Primary IGFD) is manufactured by Lonza Biologics Inc. at its Hopkinton, MA facility.

Ipsen and Lonza will continue to work with FDA in the supply of US patients with this important drug.

### **Indication and Important Safety Information About Increlex<sup>®</sup> in the U.S.**

#### **Who should use Increlex<sup>®</sup>?**

Increlex<sup>®</sup> is used to treat children who are very short for their age because their bodies do not make enough IGF-1. This condition is called severe primary IGF-1 deficiency. Increlex<sup>®</sup> should not be used instead of growth hormone.

#### **Who should not use Increlex<sup>®</sup>?**

Your child should not take Increlex<sup>®</sup> if your child: has finished growing (the growth plates at the end of the bones are closed); has cancer; has other causes of growth failure; OR is allergic to mecasermin or any of the inactive ingredients in Increlex<sup>®</sup>. Increlex<sup>®</sup> has not been studied in children under 2 years of age and should never be used in newborns. Your child should never receive Increlex<sup>®</sup> through a vein.

#### **Before your child takes Increlex<sup>®</sup>, you should tell your child's doctor about:**

All of your child's health conditions, including: diabetes, kidney problems, liver problems, allergies, scoliosis (curved spine), pregnancy, or breast-feeding.

**All the medicines (prescription and nonprescription), vitamins, and herbal supplements your child takes, especially insulin or other anti-diabetes medicines, which may require dose adjustment of these medicines.**

#### **What are possible side effects of increlex<sup>®</sup> (some of which can be serious)?**

**Low blood sugar (hypoglycemia).** Only give your child Increlex<sup>®</sup> right before or right after (20 minutes on either side of) a snack or meal to reduce the chances of hypoglycemia. Signs include dizziness, tiredness, restlessness, hunger, irritability, trouble concentrating, sweating, nausea, and fast or irregular heartbeat. Do not give your child Increlex<sup>®</sup> if your child is sick or cannot eat.

**Severe hypoglycemia may cause unconsciousness, seizures, or death.** People taking Increlex<sup>®</sup> should avoid participating in high risk activities (such as driving) within 2 to 3 hours after an Increlex<sup>®</sup> injection.

**Increased pressure in the brain (intracranial hypertension).** Increlex<sup>®</sup>, like growth hormone, can sometimes cause a temporary increase in pressure within the brain. Symptoms include persistent headache, blurred vision, and nausea with vomiting.

**Allergic reactions.** Your child may have a mild or serious allergic reaction with Increlex<sup>®</sup>. Call your child's doctor right away if your child gets a rash or hives. Hives, also known as urticaria, appear as a raised, itchy skin reaction. Hives appear pale in the middle with a red rim around them. Hives generally appear minutes to hours after the injection and may sometimes occur at numerous places on the skin. Get medical help immediately if your child has trouble breathing or goes into shock, with symptoms like dizziness, pale, clammy skin, and/or passing out.

**Enlarged tonsils.** Signs include: snoring, difficulty breathing or swallowing, sleep apnea (a condition where breathing stops briefly during sleep), or fluid in the middle ear.

**A bone problem called slipped capital femoral epiphysis.** This happens when the top of the upper leg (femur) slips apart from the rest of the bone. Seek immediate medical attention if your child develops a limp or has hip or knee pain.

**Worsened scoliosis** (caused by rapid growth).

**Injection site reactions including:** swelling, loss of fat, increase of fat, pain, redness, or bruising. This can be avoided by changing/rotating the injection site at each injection.

Please see the full Prescribing Information for Increlex<sup>®</sup> at [http://www.increlex.com/pdf/Full\\_Prescribing\\_Information.pdf](http://www.increlex.com/pdf/Full_Prescribing_Information.pdf)

and the Patient Product Information available at [http://www.increlex.com/pdf/Patient\\_Product\\_Information.pdf](http://www.increlex.com/pdf/Patient_Product_Information.pdf).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

### **About Increlex<sup>®</sup> (mecasermin [rDNA origin] injection)**

The active substance in Increlex<sup>®</sup> 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. In October 2006, Tercica Inc. granted Ipsen the rights to develop and market Increlex<sup>®</sup> worldwide, with the exception of the United States, Japan, Canada, the Middle East and Taiwan. Ipsen's acquisition of Tercica in 2008 gave it full access to this molecule (IGF-1). The only indication filed for Increlex<sup>®</sup> is the treatment of severe primary IGF-1 deficiency in children and adolescents. Increlex<sup>®</sup> has been marketed in the United States since the beginning of 2006. It was granted orphan drug status by the EMEA

on 5 April 2006 and marketing authorization in the European Union on 9 August 2007. Increlex<sup>®</sup> is currently marketed by Ipsen in most European countries. Increlex<sup>®</sup> sales in 2011 were close to €25.2 million.

### **About Ipsen**

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.1 billion in 2011. Ipsen's ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its development strategy is supported by four franchises: neurology /, endocrinology /, uro-oncology / and hemophilia. Moreover, the Group has an active policy of partnerships. R&D is focused on innovative and differentiated technological patient driven platforms, peptides and toxins. In 2011, R&D expenditure totaled more than €250 million, above 21% of Group sales. The Group has total worldwide staff of close to 4,500 employees. 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).

### **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.

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 Generics that might translate into loss of market share.

Furthermore, the Research and Development process involves several stages each of which involve 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. 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 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.

### **Forward Looking Statement (US)**

This press release contains forward-looking statements that reflect our current views about future events. The words "anticipate," "assume," "believe," "estimate," "expect," "intend," "may," "plan," "project," "should" and similar expressions are used to identify forward-looking statements. These statements are subject to many risks and uncertainties.

The forward-looking statements contained herein are based on current expectations and assumptions that are subject to risks and uncertainties, many of which are outside of our control, and could cause our actual results to materially differ from our expectations. Such risks and uncertainties, include, but are not limited to:

a decline of consumer demand and investment activity in Western Europe or the United States, or a downturn in major economies; deterioration of the situation in the global credit and financial markets; changes in currency exchange rates or interest rates; our inability to take to market a product that is promising in the early phases of development or pre-clinical trials due to, among other reasons, such product's failure to obtain regulatory approval or failure in clinical trials; a loss of market share due to increased competition from generic products; at any stage of the development process, our abandoning a potential product that fails to produce desired objectives and our subsequent failure to recoup significant up front research and development costs for such product; and acts by third-parties beyond our control that could damage the Group, the Group's brand or the Group's financial results.

For further information regarding risks and uncertainties associated with our businesses, please refer to our registration documents filed with the French Autorité des Marchés Financiers.

Ipsen undertakes no duty to update or revise any forward-looking statement whether to conform this statement to actual results or changes in the company's expectations or otherwise, except as required by law.

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