



Press release

Encouraging preliminary new data available for the treatment of short stature children with low IGF-1 levels

Preliminary results from a phase II study of a co-administration of rhGH/rhIGF-1 therapy and other studies presented at a major pediatric endocrinology congress (8th Joint LWPES/ESPE Meeting, New York, USA)

Paris (France), 15 September 2009 - Ipsen (Euronext: FR0010259150; IPN) today announced preliminary results from a Phase II open-label clinical trial (MS316 study) that evaluates the co-administration of recombinant human growth hormone (rhGH) and recombinant human insulin-like growth factor-1 (rhIGF-1) in two separate daily injections as a potential treatment for children with otherwise unexplained short stature associated with low IGF-1 levels. Ipsen also announced results from a long-term study of rhIGF-1 (study 1419) in patients with severe primary insulin-like growth factor deficiency (sPIGFD) that demonstrated that long-term twice-daily therapy with rhIGF-1 improved the adult and near adult heights of extremely short patients with sPIGFD. The data from these two studies were presented along with posters on rhIGF-1 (Increlex[®], mecasermin [rDNA origin] injection) at the 8th Joint Meeting of the Lawson Wilkins Pediatric Endocrine Society / European Society for Pediatric Endocrinology (LWPES/ESPE) in New York, NY.

These studies were performed under INDs (investigational new drug application protocols) and the co-administration of rhGH and rhIGF-1 is not an approved administration regimen for Increlex[®]. At this point in time, Increlex[®] is marketed in the U.S. and other countries throughout the world for the treatment of growth failure in children with severe Primary IGFD using twice-daily injections.

“The structuring of its US platform in 2008 enabled Ipsen to build a fully fledged commercial presence in the US but also to gain access to a promising pipeline. The Group intends to capitalize on its unique growth disorders and endocrinology franchise. The interim data presented at the LWPES/ ESPE meeting validate ongoing investigations and we look forward to continuing our research progress with our partners on this effort,” said **Jean-Luc Bélingard**, Chairman and Chief Executive Officer, Ipsen. *“Ipsen Group remains fully committed to furthering its endocrinology research and product development in support to its fastest growing franchise in this highly-specialized therapeutic area.”*

The MS316 study is an ongoing Phase II, randomized, open-label, active-treatment controlled trial evaluating the efficacy and safety of the co-administration of rhGH and rhIGF-1 therapy versus rhGH alone in 106 children with short stature associated with low levels of IGF-1. All participants received morning injections of either rhGH alone (45 µg/kg once-daily) or co-administered with rhIGF-1 (45 µg/kg rhGH and 50, 100 or 150 µg/kg rhIGF-1 also once daily as two injections). Subjects had a baseline mean height standard deviation score (SDS) of – 2.5. Thirty-six of the children enrolled in the study have completed one year of treatment. First-year height velocities were 9.2 cm for the patients receiving rhGH alone and 10.4, 10.7, and 12.1cm for the three rhGH/rhIGF-1 groups. At the end of one year, changes in mean height SDS were 0.72 for the patients receiving rhGH alone and 0.88, 0.91, and 1.11 for the three rhGH/rhIGF-1 groups. Among all patients, the most common adverse events (> 15%) were headache, upper



respiratory infection, injection site reactions and fever. Other noteworthy but less frequent adverse events included vomiting, hypoglycemia and gynecomastia. In addition, 2 transient cases of papilledema (probable intracranial hypertension) occurred with co-administration. In both cases, treatment was discontinued and restarted without recurrence.

"The preliminary results for the MS316 study of a co-administration treatment of recombinant IGF-1 and recombinant growth hormone in children with short stature associated with low IGF-1 are encouraging," said L. Kurt Midyett, MD, Medical Director, Children's Mercy Hospital and Clinics, Kansas City, Missouri. "While there is a compelling scientific rationale for co-administration therapy, this remains a research endeavor at this point and I look forward to seeing the completed data compiled and analyzed for this potential co-administration treatment option."

Ipsen also announced data on 16 patients with severe Primary IGFD treated with Increlex[®] until adult or near-adult height. These patients were part of the original registration trial for Increlex[®] (study 1419), which continues to collect long-term follow-up data on treatment until they reached adult height. The analysis was done with 9 male and 7 female patients. Patients received a mean dose of 112 µg/kg Increlex[®] twice-daily for a mean of 9.9 years. Five patients also received GnRH-analog. The mean estimated gain in height up to the time of near-adult height in patients taking Increlex[®] was 13.2 cm (range -0.4 to 23.4) and the mean estimated gain in adult height was conservatively estimated as 10.5 cm (range -2.9 to 22.3). While long-term Increlex[®] therapy improved adult height for extremely short patients with severe Primary IGFD, most patients did not experience enough catch-up growth to bring their heights into the normal adult range. The most common side effects associated with Increlex[®] include dizziness, headache, nausea and vomiting.

"The data supporting the efficacy and safety of recombinant human IGF-I (rhIGF-I) (Increlex[®]) continue to grow, and these results demonstrate that children with severe Primary IGF-I deficiency can improve their adult/near- adult height with long-term IGF-I therapy," said Philippe F. Backeljauw, MD, Professor of Pediatrics, Cincinnati Children's Hospital Medical Center. "These results provide increased confidence to treat patients with severe Primary IGFD with rhIGF-I (Increlex[®])."

Other Ipsen poster presentations included safety and efficacy data of Increlex[®] based on the IGFD Registry database, which now has over 700 patients enrolled since May 2006, and data on an 86-week, open-label trial of pharmacokinetic (PK)-based once-daily (QD) dosing of rhIGF-1 in 45 treatment-naïve prepubertal children with short stature associated with low IGF-1 levels.

About Increlex[®] (mecasermin (rDNA origin) injection)

The active ingredient of Increlex[®] is recombinant human insulin-like growth factor-1 (IGF-1). IGF-1 is the direct mediator of many of growth hormone's (GH) effects on statural growth, and must be present for normal growth of bones and cartilage in children. Without adequate IGF-1, children may not achieve normal height.

Increlex[®] has been marketed in the United States since early 2006 and in Europe since late 2007 for the treatment of growth failure in children with severe Primary IGFD. Severe Primary IGFD is defined by height at least three standard deviations below the mean and IGF-1 levels at least three standard deviations below the mean for age and sex, and presence of normal or elevated GH level in the US, and IGF-1 levels below the 2.5% percentile for age and sex, and GH sufficiency throughout Europe. In children with this disorder, low IGF-1 levels may be due to



growth-hormone resistance or insensitivity associated with mutations in GH receptors, post-GH receptor signaling pathways, or to defects in the IGF-1 gene.

About Ipsen

Ipsen is an innovation-driven international specialty pharmaceutical group with over 20 products on the market and a total worldwide staff of nearly 4,200. Its development strategy is based on a combination of specialty medicine, which is Ipsen's growth driver, in targeted therapeutic areas (oncology, endocrinology, neurology and haematology), and primary care products which contribute significantly to its research financing. The location of its four Research & Development centres (Paris, Boston, Barcelona, London) and its peptide and protein engineering platform give the Group a competitive edge in gaining access to leading university research teams and highly qualified personnel. More than 800 people in R&D are dedicated to the discovery and development of innovative drugs for patient care. This strategy is also supported by an active policy of partnerships. In 2008, Research and Development expenditure was about €183 million, close to 19% of consolidated sales, which amounted to €971 million while total revenues exceeded €1 billion. Ipsen's shares are traded on Segment A of Euronext Paris (stock code: IPN, ISIN code: FR0010259150). Ipsen's shares are eligible to the "Service de Règlement Différé" ("SRD") and the Group is part of the SBF 120 index. For more information on Ipsen, visit our website at www.ipсен.com.

Ipsen 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. 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. Notably, future currency fluctuations may negatively impact the profitability of the Group and its ability to reach its objectives. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties. The Group does not commit nor gives any guarantee that it will meet the targets mentioned above. 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 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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