

Ipsen presents additional results from a Phase III clinical trial of the investigational use of Dysport® in children with spastic equinus foot deformity due to cerebral palsy

- **At Week 4, Dysport® (10U/kg/leg and 15U/kg/leg) showed significant reductions in muscle tone versus placebo as measured by the Modified Ashworth Scale (MAS) and improved Goal Attainment Scale (GAS) score**
- **Safety profile of both doses 10U/kg/leg and 15U/kg/leg consistent with previously reported data on Dysport® in pediatric lower limb spasticity**

Paris (France), 22 October 2015 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced additional results from a Phase III study evaluating the investigational use of Dysport® for the treatment of spastic equinus foot, a condition associated with cerebral palsy (CP) in children aged 2-17 (NCT01249417).

The data will be presented during an oral session on Thursday, October 22 at the “Free Paper Session B: Tone Management Strategies and Pain Control” between 10:50 AM –10:57 AM CT at the 69th Annual Meeting of the American Academy for Cerebral Palsy and Developmental Medicine (AACPD) in Austin, Texas. The title of Dr Delgado’s presentation will be “Effect of Abobotulinum toxin A (Dysport®) injections on functioning in children with dynamic equinus foot deformity due to cerebral palsy: analysis of treatment goals, gait and quality of life from a phase 3 study”.

Claude Bertrand, Executive Vice-President Research & Development and Chief Scientific Officer of Ipsen commented: *“These results evaluate the efficacy of Dysport® on both spasticity and function after a single injection in children with lower limb spasticity due to cerebral palsy. Ipsen is committed to developing new alternatives for the treatment of spasticity in children.”*

“We are encouraged by the most recent study results evaluating the efficacy and safety of Dysport® in children with spastic equinus foot deformity due to cerebral palsy” said **Mauricio Delgado, MD, FAAN, FRCPC, Director of Pediatric Neurology, Texas Scottish Rite Hospital for Children, Professor at University of Texas Southwestern Medical Center at Dallas**. *“To date, this is the largest enrolled and completed clinical trial of a botulinum toxin for a population of children with cerebral palsy.”*



About the study

This global, multicenter, double-blind, randomized, placebo-controlled study evaluated the efficacy and safety of Dysport® versus placebo on the mean change from baseline in ankle joint hypertonicity in 241 children with cerebral palsy. Eligible patients were randomized (1:1:1) to injections of Dysport® 10U/kg/leg, Dysport® 15U/kg/leg or placebo into the gastrocnemius and soleus muscles (one or both legs injected). The primary endpoint was the change in Modified Ashworth Scale (MAS) from baseline to Week 4. Selected secondary endpoints presented were the mean Goal Attainment Scale (GAS) score at Week 4.

At Week 4, muscle tone was improved with Dysport® as measured by the primary endpoint, the Modified Ashworth Scale (MAS). In the intention to treat (ITT) population, the adjusted least squares (LS) mean changes in the MAS score from baseline to Week 4 showed statistically significant differences in favor of the Dysport® 10U/kg/leg treatment group (p=0.0029) and the Dysport® 15U/kg/leg treatment group (p=0.0002) as compared to placebo.

Data presented also included the secondary endpoint of Goal Attainment Scale (GAS). In this study, the most frequently chosen goals were improved walking pattern (70.2% of patients), improved balance (32.3%), and decreased falling (31.1%). As measured by the GAS, where a score of 50 represents goal achieved as expected, patients with Dysport® showed higher goal achievement than the expected score of 50 (GAS of 51.5 for 10U/kg and 50.9 for 15U/kg), whereas patients on placebo did not reach the expected level (GAS score of 46.2). Treatment effects for GAS were significant for both Dysport® groups versus placebo (p=0.0006 and p=0.0031 respectively).

The safety profile of both 10U/kg/leg and 15U/kg/leg doses is consistent with previously reported data on Dysport® in pediatric lower limb spasticity.

Treatment related adverse events occurred in 8.9% of the placebo group, 7.5% in the Dysport® 10U/kg/leg group, and 6.3% in the Dysport® 15U/kg/leg treatment. The most common treatment related AE was localized muscular weakness (Dysport® 10U/Kg/leg=2; placebo=1).

About Cerebral Palsy

Cerebral Palsy is the most common motor disability in children, affecting the ability to move and to maintain balance and posture. While the specific cause is unknown, CP occurs due to abnormal development of the brain or damage to the developing brain.¹ Signs and symptoms can vary; in addition to movement and coordination problems, CP can cause difficulty swallowing or speaking as well as other neurological issues such as seizures or intellectual disabilities.² Most

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1. Centers for Disease Control and Prevention: Cerebral Palsy (CP). Retrieved from: <http://www.cdc.gov/ncbddd/cp/index.html> on September 28, 2015.
 2. Mayo Clinic: Cerebral Palsy. Retrieved from: <http://www.mayoclinic.org/diseases-conditions/cerebral-palsy/basics/symptoms/con-20030502> on September 28, 2015.



(80%) of the children identified with CP have spastic CP, meaning their muscles are stiff and, as a result, their movements can appear irregular.¹ Many with CP experience foot disorders, with the most common being equinus, in which the foot points downward.³

About Dysport®

Dysport® is an injectable form of botulinum toxin type A (BTX-A), which is isolated and purified from Clostridium BTX-A bacteria. It is supplied as a lyophilized powder.

Dysport® was first registered for the treatment of blepharospasm and hemifacial spasm in the United Kingdom in 1990, and is licensed in 82 countries for various indications including: blepharospasm, adult upper and lower limb spasticity, hemifacial spasm, spasmodic torticollis (ST) (previously referred to as cervical dystonia), pediatric lower limb spasticity due to cerebral palsy (CP), axillary hyperhidrosis, and glabellar lines.

Dysport® is approved for the treatment of pediatric lower limb spasticity in many European and international markets, but not in the United States (USA). As such, data from studies in children with lower limb spasticity are of an investigational use of Dysport® in the USA.

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.ipsen.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. 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

³ The Children's Hospital at Philadelphia. Cerebral Palsy Foot Disorders. Retrieved from: <http://www.chop.edu/conditions-diseases/cerebral-palsy-foot-disorders#.ViVOYH6rRxA> on October 19, 2015.



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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