PRESS RELEASE

Ipsen Announces FDA Approval of Dysport® (abobotulinumtoxinA) for injection for the treatment of Lower Limb Spasticity in children aged two and older

- **First and only FDA-approved botulinum toxin for the treatment of pediatric lower limb spasticity**

Paris, France, 1st August, 2016 – Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven pharmaceutical group, today announced that the U.S. Food and Drug Administration (FDA) has approved Dysport® (abobotulinumtoxinA) for injection for the treatment of pediatric lower limb (PLL) spasticity in children two years of age and older.

"This approval in the US is a milestone in the treatment of pediatric lower limb spasticity, a condition that greatly impacts both children two years of age and older living with this form of spasticity and their caregivers. Dysport® is the first and only botulinum toxin approved by the FDA for this indication," said **Claude Bertrand, Executive Vice President, Research and Development, Chief Scientific Officer, Ipsen**. *"In our Phase 3 pivotal study, the majority of patients achieved a response lasting 16 to 22 weeks and sometimes longer. Dysport® is the only toxin to provide an FDA-approved dose range for the targeted muscles."*

Dysport® and all botulinum toxin products have a Boxed Warning which states that the effects of the botulinum toxin may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism. Those symptoms include swallowing and breathing difficulties that can be life-threatening.

"The approval of abobotulinumtoxinA means that, for the first time in the USA, physicians have an FDA-approved botulinum toxin and recommended dosing and administration guidance for the treatment of children from two years of age and older with lower limb spasticity," said **Mauricio R. Delgado M.D., Professor of Neurology and Neurotherapeutics, University of Texas Southwestern Medical Center and the U.S. principal investigator of the Phase III trial**. *"This approval is based on data coming from worldwide studies conducted on several continents. Results were published in the journal Pediatrics[1] confirming that we have conducted a pivotal study in this field. ."*

[1] Online at http://pediatrics.aappublications.org/content/early/2016/01/24/peds.2015-2830

About the Phase III Pivotal Study

The Phase III registrational study sponsored by Ipsen included 235 pediatric patients (158 received Dysport® and 77 received placebo; intent to treat population) and was multicenter, double-blind, prospective, randomized, and placebo-controlled. It was conducted in the U.S., Mexico, Poland, Turkey and France.

Patients were randomized (1:1:1) to Dysport® 10 Units/kg/leg, Dysport®15 Units/kg/leg or placebo injected into the gastrocnemius-soleus muscle complex located in the calf.[1] The trial included patients who were botulinum toxin naïve or previously treated with a botulinum toxin more than six months before study entry.

The study results showed a statistically significant improvement in mean change from baseline in MAS in ankle plantar flexor muscle tone at both doses of Dysport® versus placebo at Week 4 [LS mean treatment difference vs. placebo were: -0.5 for placebo, -0.9 for Dysport® 10 Units/kg/leg, and -1.0 for Dysport® 15 Units/kg/leg ($p<0.05$)]. Data at Week 12 as measured by the MAS was also statistically significant [LS mean treatment difference vs. placebo were: -0.5 for placebo, -0.8 for Dysport® 10 Units/kg/leg, and -1.0 for Dysport® 15 Units/kg/leg ($p<0.05$)]. The most common adverse reactions (≥10% of patients in any group and greater than placebo) in pediatric patients with lower limb spasticity for Dysport® 10 Units/kg, 15 Units/kg, 20 Units/kg, or 30 Units/kg; and placebo, respectively, were: upper respiratory tract infection (9%, 20%, 5%, 10%, 13%), nasopharyngitis (9%, 12%,16%, 10%, 5%), influenza (0%, 10%, 14%, 3%, 8%) and pharyngitis (5%, 0%,11%, 3%, 8%), cough (7%, 6%, 14%, 10%, 6%), and pyrexia (7%, 12%, 8%, 7%, 5%).

A statistically significant improvement was also observed on the mean PGA response to treatment score at Week 4 [LS mean treatment difference of 0.7 for placebo, 1.5 for Dysport® 10 Units/kg/leg, and 1.5 for Dysport® 15 Units/kg/leg ($p<0.05$)]. Data at Week 12 as measured by the mean PGA response to treatment score was also statistically significant [LS mean treatment difference vs. placebo were: 0.4 for placebo, 0.8 for Dysport® 10 Units/kg/leg, and 1.0 for Dysport® 15 Units/kg/leg ($p<0.05$)].

A majority of patients in the clinical study were eligible for retreatment between 16 and 22 weeks; however, some had a longer duration of response. The degree and pattern of muscle spasticity and overall clinical benefit at the time of re-injection may necessitate alterations in the dose of Dysport® and muscles to be injected.

About Dysport®

Dysport® is an injectable form of botulinum toxin type A (BoNT-A), which is isolated and purified from Clostridium bacteria producing BoNT-A. It is supplied as a lyophilized powder. Dysport® has approved therapeutic indications in the United States for the treatment of adults with Cervical Dystonia (CD), the treatment of Upper Limb Spasticity (ULS) in adult patients, and now in the treatment of lower limb spasticity in children to improve tone and spasticity. The medicine was first registered in the United Kingdom in 1990 for other uses and is licensed in more than 80 countries in eight different indications, with over 1,300 peer-reviewed publications.

Dysport® and all botulinum toxin products have a Boxed Warning which states that the effects of the botulinum toxin may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism. Those symptoms include swallowing and breathing difficulties that can be life-threatening.

About Pediatric Lower Limb Spasticity
Spasticity is a condition in which there is an abnormal increase in muscle tone or stiffness in one or more muscles, which might interfere with movement. Spasticity is usually caused by damage to nerve pathways in the brain or spinal cord that control muscle movement, and may occur in association with cerebral palsy, spinal cord injury, multiple sclerosis, stroke, and brain or head trauma.[2]

Lower limb spasticity commonly involves spasticity in the gastrocnemius and soleus muscle complex located in the calf.[1,3] These calf muscles are the chief extensors of the foot at the ankle-joint. In walking, they work to raise the heel from the ground.[1]

Symptoms of spasticity may include increased muscle tone, rapid muscle contractions, exaggerated deep tendon reflexes, and/or muscle spasms. The degree of spasticity can vary from mild muscle stiffness to severe, painful, and uncontrollable muscle spasms.[2]

About Ipsen
Ipsen is a global specialty-driven pharmaceutical group with total sales exceeding €1.4 billion in 2015. Ipsen sells more than 20 drugs in more than 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its fields of expertise cover oncology, neurosciences and endocrinology (adult & pediatric). 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 and neuro-endocrine 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/Paris-Saclay, France; Slough/Oxford, UK; Cambridge, US). In 2015, R&D expenditure totaled close to €193 million. The Group has more than 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 on Ipsen, visit www.ipsen.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. 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.

The risks and uncertainties set out are not exhaustive and the reader is advised to refer to the Group's 2015 Registration Document available on its website (www.ipsen.com).

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