PRESS RELEASE

Ipsen announces FDA approval of Dysport® (abobotulinumtoxinA) for injection in the treatment of upper limb spasticity in adults in the United States

Paris (France), 16 July 2015 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that the U.S. Food and Drug Administration (FDA) has approved its supplemental Biologics License Application (sBLA) for Dysport® (abobotulinumtoxinA) for the treatment of upper limb spasticity in adult patients after the submission of the dossier in September 2014. Dysport® is now approved for the treatment of upper limb spasticity in adult patients, to decrease the severity of increased muscle tone in elbow flexors, wrist flexors and finger flexors. Clinical improvement may be expected one week after administration of Dysport®. A majority of patients in clinical studies were retreated between 12 and 16 weeks; some patients had a duration of response as long as 20 weeks. In Europe, regulatory procedures are in progress for strengthening the existing upper limb spasticity label indication of Dysport® to include key medical data such as muscle dose recommendations, treatment intervals, efficacy data and safety updates.

Marc de Garidel, Ipsen's Chairman and CEO, stated: *"We are pleased with the FDA approval of Dysport® in the treatment of upper limb spasticity in adults in the United States. This differentiated label is a testimony to the quality of the clinical data. Ipsen has reinforced its commercial capacity and is now prepared to start commercialization of Dysport® in this new indication in the US. This launch represents a major step forward in our ambition to become a global leader in treating patients with spasticity."*

"The FDA approval of Dysport® provides a new therapeutic option to help adults living with spasticity" **said Allison Brashear, M.D., Professor and Chair of Neurology, Wake Forest Baptist Medical Center and the U.S. principal investigator of the Phase III trial.** *"This approval is based on strong clinical data which showed that Dysport® improved muscle tone in the upper limb – essential for active use of the hand and arm. It is important to realize that early identification is critical for patients with upper limb spasticity, given that when left untreated, spasticity can result in increased muscle tone."*

About the Approval

The approval was based on a rigorous development program that included clinical trials conducted in over 600 patients. In the Phase III pivotal study, 238 adult patients with upper limb spasticity participated in the study for up to one year. The international, multi-center, double-blind, randomized, placebo-controlled study compared the efficacy of Dysport® (n=159) versus placebo (n=79) in hemiparetic patients following stroke or brain trauma. The trial also included patients who were botulinum toxin naïve or previously treated with a botulinum toxin, encompassing a broad patient population. The co-primary endpoints of the study were the improvement of muscle tone in the treated upper limb measured by the Modified Ashworth Scale (MAS) versus placebo and the clinical benefit for patients as assessed by the Physician Global Assessment (PGA) versus placebo at Week 4. The trial was followed by an open-label study wherein patients received Dysport® for up to five treatment cycles to assess the long term safety.

The Phase III pivotal data showed that those treated with Dysport® demonstrated statistically significant improvement in muscle tone measured by the MAS and a significantly higher physician-rated clinical benefit measured by the PGA versus placebo at Week 4 ($p \leq 0.05$). At Week 4, both doses of Dysport® (Dysport® 500 units and 1000 units) significantly reduced muscle tone as measured by MAS in all primary target muscle groups, which included elbow, wrist, and finger muscles, with approximately 3 out of 4 patients[1] responding to Dysport®. The most frequently reported adverse reactions (≥2%) are: urinary tract infection, nasopharyngitis, muscular weakness, musculoskeletal pain, dizziness, fall and depression. The safety profile observed in the study was consistent with the known safety profile of Dysport®, and there were no differences in the rate of serious adverse events between the treatment groups: placebo (3.7%), Dysport® 500 U (3.7%), Dysport® 1000 U (3.7%).

About Upper Limb Spasticity

It is estimated that 1.8 million adult Americans may suffer from spasticity[2] [3] [4] [5], which in the upper arm can cause muscle stiffness, flexing, spasms, twitching and pain. Upper limb spasticity (ULS) can make everyday tasks, such as washing your hands, difficult. The condition most commonly occurs after a stroke, but can also result from other injuries to the central nervous system, such as a spinal cord injury or traumatic brain injury (TBI), or occur in adults with multiple sclerosis (MS) or cerebral palsy (CP). Symptoms may not appear until months or even years after the stroke or injury but may include bent elbows or wrists, and hands clenched into fists.

About Dysport®

Dysport® is an injectable form of botulinum toxin type A (BoNT-A), which is isolated and purified from Clostridium BoNT-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 more than 80 countries for various indications including: blepharospasm, hemifacial spasm, spasmodic torticollis (ST) (previously referred to as cervical dystonia), axillary hyperhidrosis, and glabellar lines. Dysport® is approved in the United States for the treatment of adults with Cervical Dystonia, for the treatment of adults with moderate to severe glabellar lines, and now the treatment of upper limb spasticity in adults.

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 40 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

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[1] *MAS responders week 4: 74% to Dysport® 500 units, 79% to Dysport® 1000 units and 23% to placebo

[2] "Stroke Facts." Centers for Disease Control and Prevention. Web. 10 June 2015. http://www.cdc.gov/stroke/facts.htm 24 March 2015.

[3] Opheim A, et al. (2014). Upper-Limb Spasticity During the First Year After Stroke. Stroke Arm Longitudinal Study at the University of Gothenburg. *American Journal of Physical Medicine & Rehabilitation*, 93: 884:896.

[4] "Traumatic Brain Injury in the United States: Fact Sheet." Centers for Disease Control and Prevention. 6 June 2015. http://www.cdc.gov/traumaticbraininjury/get_the_facts.html, 24 February 2014.

[5] Ganish S, et al. (2013). Medical Comorbidities in Disorders of Consciousness Patients and Their Association with Functional Outcomes. *Archives of Physical Medicine and Rehabilitation,* 94: 1899-907.

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, 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.

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 2014 Registration Document available on its website (www.ipsen.com).

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