PRESS RELEASE

Ipsen announces FDA acceptance of filing for Dysport® in the treatment of upper limb spasticity in adult patients

Paris (France), 28 November 2014 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review its supplemental Biologics License Application (sBLA) for Dysport® (abobotulinumtoxinA) in the treatment of upper limb spasticity in adult patients.

The regulatory filing was based on a clinical Phase III study involving nearly 250 adult patients with upper limb spasticity. The international, multi-center, double-blind, randomized, placebo-controlled trial compared the efficacy of Dysport® versus placebo in hemiparetic patients following a stroke or brain trauma. The data showed that those treated with Dysport® demonstrated a statistically significant ($p<0.0001$) improvement in muscle tone and a higher clinical benefit, versus placebo. The safety profile observed in the study was consistent with the known safety profile of Dysport®.

Marc de Garidel, Chairman and Chief Executive Officer of Ipsen stated *"The filing of Dysport® in adult upper limb spasticity is an important step in the reinforcement of the US neurology franchise."* **Marc de Garidel** added: "*Upon FDA approval, Dysport® will become a new treatment option for adults who suffer from upper limb spasticity in the United States."*

Dysport® is approved for the treatment of upper limb spasticity in many international markets, but not in the United States (U.S.). Dysport®'s only approved therapeutic indication in the U.S. is for the treatment of adults with cervical dystonia (referred to as spasmodic torticollis in other markets). As such, data from the Phase III study in adults with upper limb spasticity are with respect to an investigational use of Dysport® in the U.S.

About the study

This phase III research study included 243 patients and was multicenter, prospective, double blind, randomised, and placebo-controlled. It was conducted in the USA, France, Italy, Belgium, Czech Republic, Poland, Slovakia, Russia and Hungary.

The purpose of this phase III study was to assess the efficacy of Dysport® compared to placebo in improving upper limb spasticity in hemiparetic patients following a stroke or a brain trauma. The study co-primary endpoints were the improvement of muscle tone in the treated upper limb measured by the Modified Ashworth Scale (MAS) and the clinical benefit for the patients assessed by the Physician Global Assessment (PGA). In addition, Dysport®'s efficacy was assessed on passive function as measured by the Disability Assessment Scale (DAS).

Patients were offered the option to continue in an open label long-term study where they would receive additional treatment with Dysport® for a total of 15 months.

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 75 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 upper limb spasticity in many international markets, but not in the United States (US). Dysport®'s only approved therapeutic indication in the United States (US) is for the treatment of adults with cervical dystonia (referred to spasmodic torticollis in other markets). As such, data from this study in adults with upper limb spasticity are with respect to an investigational use of Dysport® in the USA.

About Ipsen

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.2 billion in 2013. 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 uro-oncology. 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. In 2013, R&D expenditure totaled close to €260 million, representing more than 21% of Group sales. Moreover, Ipsen also has a significant presence in primary care. The Group has close to 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 Statements

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.

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