

Ipsen announces positive results from phase IIa clinical study of Dysport® in the treatment of patients with Neurogenic Detrusor Overactivity (NDO)

Results show significant decrease in urinary incontinence episodes and improvement in patient quality of life

Paris (France), 18 March 2014 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced positive results from its phase IIa clinical trial assessing Dysport® in the treatment of Neurogenic Detrusor Overactivity (NDO) in patients with urinary incontinence not adequately managed by anticholinergics.

Results show that treatment with Dysport® was associated with a mean reduction from baseline of urinary incontinence episodes greater than 75%, 12 weeks after the injection, regardless of how the drug is administered. These results were achieved with a single dose of Dysport® 750 Units injected in either 15 or 30 sites in the detrusor muscle. Efficacy was confirmed by improvement in urodynamic parameters and quality of life. The safety profile observed in the study is consistent with the safety profile expected in this indication.

Claude Bertrand, Executive Vice-President R&D, Chief Scientific Officer of Ipsen said: *“These results are very encouraging for the Dysport® franchise, which has the opportunity of potentially expanding into urology, a core therapeutic area for Ipsen”*. **Claude Bertrand** added: *“We are excited about the potential benefits Dysport® could bring to patients suffering from NDO”*.

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 formulated as a complex of BTX-A with haemagglutinin, a large therapeutically inert protein used to stabilise the toxin. Dysport® is formulated with lactose (Ph Eur/NF) and human serum albumin (Ph Eur/USP) and is supplied as a lyophilised powder.

Dysport® was first registered for the treatment of blepharospasm and hemifacial spasm in the United Kingdom (UK) 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), paediatric spasticity due to cerebral palsy (CP), axillary hyperhidrosis, and glabellar lines. Dysport® is not currently approved in any country for the treatment of NDO.

About Neurogenic Detrusor Overactivity (NDO)

NDO is a chronic condition defined by abnormal bladder contractions related to an underlying neurological condition such as multiple sclerosis (MS) or spinal cord injury (SCI). Current standard of care includes self-catheterisation or oral anticholinergic medications that present frequent side-effects and insufficient efficacy on the long term. In case of inadequate treatment response to anticholinergics, a botulinum toxin-A is indicated, before considering rescue treatments such as neuromodulation or bladder augmentation surgery in refractory cases.



About the phase IIa clinical trial

This phase IIa, multinational, randomised, placebo-controlled study aimed to investigate the efficacy and safety of one cycle of a single dose of 750 U Dysport® in 47 patients with NDO secondary to Multiple Sclerosis (MS) or Spinal Cord Injury (SCI). Follow-up duration was of 96 days. The primary endpoint was the mean change from baseline in daily urinary incontinence episodes frequency 12 weeks after the injection for each administration mode, i. e. 15 or 30 injections points at a constant volume by injection site. Secondary endpoints included other clinical endpoints, urodynamic measurements, and safety.

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.ipсен.com.

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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