

## Ipsen announces new clinical data to be presented at ISPRM 2018 demonstrating commitment to neurotoxin research

- **Clinical research reaffirms Ipsen's support for patients and the neuroscience community -**

**Paris (France), 04 July 2018** – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that its neurotoxin portfolio will be the subject of 13 abstracts at the 12th International Society of Physical and Rehabilitation Medicine World Congress. The meeting will be held in Paris, July 8-12, 2018.

The 13 abstracts will present neuroscience data that advances knowledge in physical and rehabilitation medicine including clinical outcomes linked to Ipsen's portfolio in adult spasticity (upper and lower limbs), pediatric spasticity, and in cervical dystonia. In addition, an international survey investigating the burden of spasticity on patients and their caregivers will be presented, as well as real-world data that supports better understanding of current clinical practices.

**Alexandre Lebeaut, MD, Executive Vice-President, R&D, Chief Scientific Officer, Ipsen** said:

*"Ipsen will have its strongest ever neuroscience presence at ISPRM 2018, demonstrating our strong focus on advancing the boundaries of neurotoxin research and our long-term commitment to patients and the neuroscience community, notably through medical education programs and symposia. We will also disclose new data from the first-ever recombinant botulinum neurotoxin to be administered to humans, an area where we have the ambition to advance and unlock the potential of this innovative technology platform."*

**Prof. Lynne Turner-Stokes, [Cicely Saunders Institute, King's College London, UK]** added:

*"The results of the large observational ULIS-III study, which aims to assess real-life clinical practice will be the subject of an oral presentation. This study demonstrated that pain reduction is an important and achievable primary treatment goal in some patients suffering with spasticity."*

### Oral presentations:

- **Abstract ISPR8-2524** – FP16 Neuro-Orthopedics and Spasticity - Part II, Amphitheatre Bleu Wednesday 11th July 17.40 – 17.50
  - Botulinum Toxin A in Upper Limb Spasticity Management: Baseline Data from the Upper Limb International Spasticity (ULIS)-III Study
  - Presenting author: Lynne Turner-Stokes
- **Abstract ISPR8-2530** – FP16 Neuro-Orthopedics and Spasticity - Part II, Amphitheatre Bleu Wednesday 11th July 17.50 – 18.00
  - Relief of Spasticity-Related Pain with Botulinum Neurotoxin-A (BoNT-A) in Real Life Practice. Post-Hoc Analysis from a Large International Cohort Series
  - Presenting author: Lynne Turner-Stokes

## Posters

- **Abstract ISPR8-1217** – A7.02 Rehabilitation Addressing to Specific Issues – Spasticity Management, Exhibition Area, 9th–12th July
  - Impact of Spasticity and Botulinum Toxin-A Injections on the Daily Life of Patients and their Caregivers: Results from an International Online Survey
  - Presenting author: Manuel Murie Fernandez
  
- **Abstract ISPR8-2146** – D3.03 Education and Training in Rehabilitation – Continuous Medical Education and Professional Development, Exhibition Area, 9th–12th July
  - Botulinum Neurotoxin-A Usage and Training in Cervical Dystonia & Spastic Paresis: First Results from the Ixcellence® Network Survey
  - Presenting author: Luis Jorge Jacinto
  
- **Abstract ISPR8-2147** – D3.03 Education and Training in Rehabilitation – Continuous Medical Education and Professional Development, Exhibition Area, 9th–12th July
  - Improving Management Practices of Cervical Dystonia and Spastic Paresis: 5 Years' Experience of Ixcellence® Network, an Innovative International Educational Program
  - Presenting author: Luis Jorge Jacinto
  
- **Abstract ISPR8-2514** – A7.02 Rehabilitation Addressing to Specific Issues – Spasticity Management, Exhibition Area, 9th–12th July
  - Simultaneous Upper and Lower Limb AbobotulinumtoxinA Injections and Guided Self-Rehabilitation Contracts in Spastic Hemiparesis: Baseline Data from the ENGAGE Study
  - Presenting author: Jean-Michel Gracies
  
- **Abstract ISPR8-2521** – A7.02 Rehabilitation Addressing to Specific Issues – Spasticity Management, Exhibition Area, 9th–12th July
  - Repeated AbobotulinumtoxinA Injections Benefit Walking Speed, Step Length and Cadence in Adults with Spastic Hemiparesis due to Stroke or Traumatic Brain Injury
  - Presenting author: Alberto Esquenazi
  
- **Abstract ISPR8-2529** – A7.02 Rehabilitation Addressing to Specific Issues – Spasticity Management, Exhibition Area, 9th–12th July
  - Efficacy and Safety of Early Use of AbobotulinumtoxinA in Adults with Post-Stroke Spasticity: Results from the ONTIME and ABCDE-S Studies
  - Presenting author: Raymond Rosales
  
- **Abstract ISPR8-2543** – A7.02 Rehabilitation Addressing to Specific Issues – Spasticity Management, Exhibition Area, 9th–12th July
  - Treatment Frequency for Long-Term Efficacy of AbobotulinumtoxinA Injections: a Phase 3 Study in Patients with Upper Limb Spasticity Following Stroke or Traumatic Brain Injury
  - Presenting author: Jean-Michel Gracies
  
- **Abstract ISPR8-2546** – A7.02 Rehabilitation Addressing to Specific Issues – Spasticity Management, Exhibition Area, 9th–12th July
  - When Can Maximal Efficacy be Expected with Repeated Botulinum Toxin Injections in Upper Limb Spastic Paresis? An Exploratory Statistical Analysis
  - Presenting author: Jean-Michel Gracies

- **Abstract ISPR8-2547** – A7.02 Rehabilitation Addressing to Specific Issues – Spasticity Management, Exhibition Area, 9th–12th July
  - AbobotulinumtoxinA Injections in Shoulder Muscles: Results from a Real World (ULIS-II) and Phase 3 (AUL) Studies
  - Presenting author: Francois Constant Boyer
- **Abstract ISPR8-2557** – A7.02 Rehabilitation Addressing to Specific Issues – Spasticity Management, Exhibition Area, 9th–12th July
  - Treatment Frequency for Long-Term Efficacy of AbobotulinumtoxinA Injections: a Phase 3 Study in Patients with Lower Limb Spasticity Following Stroke or Traumatic Brain Injury
  - Presenting author: Prof Jean-Michel Gracies
- **Abstract ISPR8-2654** – A2.08 Musculoskeletal Conditions – Miscellaneous, Exhibition Area, 9th–12th July
  - Results from the First Recombinant Botulinum Toxin (BoNT) Ever to Enter Clinical Development. Outcomes of a First-in-Human Study with Recombinant BoNT/E (SXN102308)
  - Presenting author: Laurent Pons

### **About Dysport®**

Dysport® is an injectable form of a botulinum neurotoxin type A product, which is a substance derived from Clostridium bacteria producing BoNT-A that inhibits the effective transmission of nerve impulses and thereby reduces muscular contractions. It is supplied as a lyophilized powder. As of 31 December 2017, Dysport® had marketing authorization in more than 85 countries.

### **About 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.<sup>3</sup> In adults, approximately one in three stroke patients, one in three patients with spinal cord injury, one in six patients with traumatic brain injury, and two in three patients with MS will develop lower limb spasticity.<sup>1,2</sup>

### **INDICATIONS AND IMPORTANT SAFETY INFORMATION**

Dysport® is approved for the treatment of adult upper and lower limb spasticity, pediatric lower limb spasticity and cervical dystonia (referred to spasmodic torticollis in some markets) in many international markets including France and the United States of America. Please refer to national labelling for details of the locally approved prescribing information in each of these indications.

Adverse effects resulting from the distribution of the effects of the toxin to sites remote from the site of administration have been reported. Patients treated with therapeutic doses may present with excessive muscle weakness. The risk of occurrence of such undesirable effects may be reduced by using the lowest effective dose possible and by not exceeding the maximum recommended dose.

Very rare cases of death, occasionally in the context of dysphagia, pneumopathy (including but not limited to dyspnoea, respiratory failure, respiratory arrest) and/or in patients with significant asthenia have been reported following treatment with botulinum toxin A or B. Patients with disorders resulting in defective neuromuscular transmission, difficulty in swallowing or breathing are more at risk of experiencing these effects. In these patients, treatment must be administered under the control of a specialist and only if the benefit of treatment outweighs the risk. Dysport® should be administered with caution to patients with pre-existing swallowing or breathing problems as these can worsen following the distribution of the effect of toxin into the relevant

muscles. Aspiration has occurred in rare cases and is a risk when treating patients who have a chronic respiratory disorder. Dysport® should only be used with caution and under close medical supervision in patients with clinical or sub-clinical evidence of marked defective neuro-muscular transmission (e.g. myasthenia gravis). Such patients may have an increased sensitivity to agents such as Dysport®, which may result in excessive muscle weakness. Caution should be exercised when treating adult patients, especially the elderly, with focal spasticity affecting the lower limbs, who may be at increased risk of fall. In placebo-controlled clinical studies where patients were treated for lower limb spasticity, 6.3% and 3.7% of patients experienced a fall in the Dysport® and placebo groups, respectively. The recommended posology and frequency of administration for Dysport® must not be exceeded. Patients and their care-givers must be warned of the necessity to seek immediate medical treatment in case of problems with swallowing, speech or respiratory problems. For the treatment of spasticity in children, Dysport® should only be used in children 2 years of age or over. As with any intramuscular injection, Dysport® should only be used where strictly necessary in patients with prolonged bleeding times, or infection/inflammation at the proposed site(s) of injection. Dysport® should only be used to treat a single patient, during a single session. Any unused product remaining should be disposed of in accordance with Special Precautions for Disposal and Handling. Specific precautions must be taken during the preparation and administration of the product and the inactivation and disposal of any unused reconstituted solution. This product contains a small amount of human albumin. The risk of transmission of viral infection cannot be excluded with absolute certainty following the use of human blood or blood products.”

#### References:

1. Martin A, et al. Epidemiological, humanistic, and economic burden of illness of lower limb spasticity in adults: a systematic review. *Neuropsychiatric Disease and Treatment*. 2014; 10 (111-122)
2. Sköld A, et al. Spasticity after traumatic spinal cord injury: nature, severity, and location. *Archives of Physical Medicine and Rehabilitation*. 1999; 80 (1548-57)
3. National Institute of Neurological Disorders and Stroke. Spasticity Information Page. <https://www.ninds.nih.gov/Disorders/All-Disorders/Spasticity-Information-Page> Accessed May 16, 2017.

#### **About Ipsen**

Ipsen is a global biopharmaceutical group focused on innovation and specialty care. The group develops and commercializes innovative medicines in three key therapeutic areas - Oncology, Neuroscience and Rare Diseases. Its commitment to Oncology is exemplified through its growing portfolio of key therapies for prostate cancer, neuroendocrine tumors, renal cell carcinoma and pancreatic cancer. Ipsen also has a well-established Consumer Healthcare business. With total sales over €1.9 billion in 2017, Ipsen sells more than 20 drugs in over 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's R&D is focused on its innovative and differentiated technological platforms located in the heart of the leading biotechnological and life sciences hubs (Paris-Saclay, France; Oxford, UK; Cambridge, US). The Group has about 5,400 employees worldwide. Ipsen is listed in Paris (Euronext: IPN) and in the United States through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information on Ipsen, visit [www.ipsen.com](http://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 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 favorable 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 2017 Registration Document available on its website ([www.ipсен.com](http://www.ipсен.com)).



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