

Ipsen Announces Four Poster Presentations of Dysport® (abobotulinumtoxinA) Data at the 2017 Child Neurology Society Annual Meeting

Data Includes Analyses of Treatment Utilization and Managed Medicaid Costs for Pediatric Patients with Cerebral Palsy

BASKING RIDGE, N.J., October 4, 2017 – Ipsen Biopharmaceuticals, Inc., an affiliate of Ipsen (Euronext: IPN; ADR: IPSEY) (Ipsen), today announced that four abstracts regarding Dysport® (abobotulinumtoxinA) data have been accepted for poster presentations at the annual meeting of the Child Neurology Society (CNS) on October 4-7, 2017 in Kansas City, Missouri.

“We are pleased to present important new data in children aged two and older with lower limb spasticity and adults with upper limb spasticity,” said **David Cox, VP North American Medical, HEOR & Regulatory Affairs, Ipsen**. “Additionally, we are proud to add to the body of data and showcase findings from a large-scale study analyzing treatment utilization rates for pediatric patients with Cerebral Palsy, as this information can be used to help clinicians understand how to better and more efficiently manage treatment protocols for affected children.”

Dysport® (abobotulinumtoxinA) and all botulinum toxin products have a Boxed Warning in the US 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. Dysport® is contraindicated in patients with known hypersensitivity to any botulinum toxin preparation or to any of the components; or in the presence of infection at the proposed injection site(s); or in patients known to be allergic to cow’s milk protein. The potency Units of Dysport® are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products. Please scroll below for additional Important Safety Information.

The following four posters will be presented on Thursday, October 5 between 12:30-2:00 pm and 4:30-6:00 pm CDT and on Friday, October 6 between 7:00-8:15 am CDT at the Sheraton Crown Center (Exhibit Hall A).

Poster Presentations:

- **AbobotulinumtoxinA injection in muscles in pediatric patients with lower limb spasticity**
 - Poster #113
- **Safety and tolerability of abobotulinumtoxinA in the management of pediatric lower limb spasticity: Pooled analysis of repeat injection, open-label trials**
 - Poster #126

- **Safety profile of abobotulinumtoxinA for lower limb spasticity in preschool aged children (2-5 years) compared with older children: Pooled analysis of controlled clinical trials**
 - Poster #127
- **Epidemiology and Spasticity Management Patterns of Pediatric Cerebral Palsy Patients Enrolled in Managed Medicaid in the United States**
 - Poster #122

INDICATIONS

Dysport® (abobotulinumtoxinA) for injection is indicated for the treatment of:

- Spasticity in adult patients
- Adults with cervical dystonia
- Lower limb spasticity in pediatric patients 2 years of age and older.

The safety and effectiveness of Dysport® injected into upper limb muscles or proximal muscles of the lower limb for the treatment of spasticity in pediatric patients has not been established. Safety and effectiveness in pediatric patients with lower limb spasticity below 2 years of age have not been evaluated.

Safety and effectiveness in pediatric patients with cervical dystonia or upper limb spasticity have not been established.

IMPORTANT SAFETY INFORMATION

Warning: Distant Spread of Toxin Effect

Postmarketing reports indicate that the effects of Dysport® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including upper limb spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to lower than the maximum recommended total dose.

Contraindications

Dysport® is contraindicated in patients with known hypersensitivity to any botulinum toxin preparation or to any of the components; or in the presence of infection at the proposed injection site(s); or in patients known to be allergic to cow's milk protein. Hypersensitivity reactions including anaphylaxis have been reported.

Warnings and Precautions

Lack of interchangeability between botulinum toxin products

The potency Units of Dysport® are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products, and, therefore, units of biological activity of Dysport® cannot be compared to or converted into units of any other botulinum toxin products assessed with any other specific assay method.

Dysphagia and Breathing Difficulties

Treatment with Dysport® and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or swallowing. When distant side effects occur, additional respiratory muscles may be involved (see Boxed Warning). Deaths as a complication of severe dysphagia have been reported after treatment with botulinum toxin. Dysphagia may persist for several weeks, and require use of a feeding tube to maintain adequate nutrition and hydration. Aspiration may result from severe dysphagia and is a particular risk when treating patients in whom swallowing or respiratory function is already compromised. Patients treated with botulinum toxin may require immediate medical attention should they develop problems with swallowing, speech, or respiratory disorders. These reactions can occur within hours to weeks after injection with botulinum toxin.

Pre-existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of Dysport®.

Human Albumin and Transmission of Viral Diseases

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD, or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

Intradermal Immune reaction

The possibility of an immune reaction when injected intradermally is unknown. The safety of Dysport® for the treatment of hyperhidrosis has not been established. Dysport® is approved only for intramuscular injection.

Adverse reactions

Most common adverse reactions ($\geq 2\%$ and greater than placebo in either Dysport® group) in **adults with upper limb spasticity** for Dysport® 500 Units, Dysport® 1000 Units, and Placebo,

respectively, were: nasopharyngitis (4%, 1%, 1%), urinary tract infection (3%, 1%, 2%), muscular weakness (2%, 4%, 1%), musculoskeletal pain (3%, 2%, 2%), dizziness (3%, 1%, 1%), fall (2%, 3%, 2%), and depression (2%, 3%, 1%).

Most common adverse reactions ($\geq 5\%$ and greater than placebo in either Dysport® group) in **adults with lower limb spasticity** for Dysport® 1000 Units, Dysport® 1500 Units, and Placebo, respectively, were: falls (9%, 6%, 3%), muscular weakness (2%, 7%, 3%), pain in extremity (6%, 6%, 2%). Muscular weakness was reported more frequently in women (10%) treated with 1500 units of Dysport compared to men (5%).

Most common adverse reactions ($\geq 5\%$ and greater than placebo) in **adults with cervical dystonia** for Dysport® 500 Units and Placebo, respectively, were: muscular weakness (16%, 4%), dysphagia (15%, 4%), dry mouth (13%, 7%), injection site discomfort (13%, 8%), fatigue (12%, 10%), headache (11%, 9%), musculoskeletal pain (7%, 3%), dysphonia (6%, 2%), injection site pain (5%, 4%), and eye disorders (7%, 2%).

Most common adverse reactions ($\geq 10\%$ 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%), pharyngitis (5%, 0%, 11%, 3%, 8%), cough (7%, 6%, 14%, 10%, 6%), and pyrexia (7%, 12%, 8%, 7%, 5%).

Drug interactions

Co-administration of Dysport® and aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents), or muscle relaxants, should be observed closely because the effect of botulinum toxin may be potentiated. Use of anticholinergic drugs after administration of Dysport® may potentiate systemic anticholinergic effects such as blurred vision. The effect of administering different botulinum neurotoxins at the same time or within several months of each other is unknown. Excessive weakness may be exacerbated by another administration of botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of Dysport®.

Use in Pregnancy

Based on animal data Dysport® may cause fetal harm. There are no adequate and well-controlled studies in pregnant women. Dysport® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pediatric Use

Based on animal data Dysport® may cause atrophy of injected and adjacent muscles; decreased bone growth, length, and mineral content; delayed sexual maturation; and decreased fertility.

Geriatric Use

In general, elderly patients should be observed to evaluate their tolerability of Dysport®, due to the greater frequency of concomitant disease and other drug therapy. Subjects aged 65 years

and over who were treated with DYSPOORT® for lower limb spasticity reported a greater percentage of fall and asthenia as compared to those younger (10% versus 6% and 4% versus 2%, respectively).

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact Ipsen at 1-855-463-5127. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Dysport® [Full Prescribing Information](#) including **Boxed Warning** and [Medication Guide](#).

About Ipsen in North America

Ipsen Biopharmaceuticals, Inc. is the US affiliate of Ipsen, a global specialty-driven pharmaceutical group. The US head office is located in Basking Ridge, New Jersey. Ipsen Biopharmaceuticals Canada, Inc. is an integrated business unit within North America and has its head office located in Mississauga, Ontario. Ipsen Bioscience, Inc., the Ipsen US research and development center focused on peptide research in oncology and endocrinology, is located in Cambridge, Massachusetts. At Ipsen Bioscience, we focus on creating a highly cooperative and passionate R&D organization through partnerships, innovation, and continuous learning to effectively deliver new treatments for patients. At Ipsen, we focus our resources, investments, and energy on discovering, developing, and commercializing new therapeutic options for oncologic, neurologic, and endocrine diseases. For more information on Ipsen in North America, please visit www.ipsenus.com or www.ipsen.ca.

About Ipsen

Ipsen is a global specialty-driven biopharmaceutical group focused on innovation and specialty care. The group develops and commercializes innovative medicines in three key therapeutic areas - Oncology, Neurosciences 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 close to €1.6 billion in 2016, 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 5,100 employees worldwide. Ipsen is listed in Paris (Euronext: IPN) and in the United States through a Sponsored Level I American Depository Receipt program (ADR: IPSEY). For more information on Ipsen, visit www.ipsen.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 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 fulfill 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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PRESS RELEASE



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Dysport® (abobotulinumtoxinA) for injection, for intramuscular use 300- and 500-Unit vials

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