PRESS RELEASE

Ipsen Announces Updated Indication for Dysport® (abobotulinumtoxinA) for the Treatment of Spasticity in Children

– Dysport is now FDA-approved to treat both upper and lower limb spasticity in pediatric patients two years of age and older, including spasticity caused by cerebral palsy[1] –

– Updated indication follows Ipsen and another manufacturer's decision to selectively waive, with respect to each other's toxin products only, their respective Orphan Drug exclusivities in pediatric patients with cerebral palsy –

Cambridge, Mass., July 9, 2020 – Ipsen Biopharmaceuticals, an affiliate of Ipsen (Euronext: IPN; ADR: IPSEY), announced today that the United States Food and Drug Administration (FDA) has approved the expanded use of Dysport® (abobotulinumtoxinA) in pediatric patients. When Dysport was first FDA-approved in 2016 for pediatric lower limb spasticity, Ipsen was granted Orphan Drug exclusivity for pediatric patients whose lower limb spasticity was caused by cerebral palsy (CP).[1] Similarly, in 2019, Dysport received FDA approval for the treatment of upper limb spasticity in children two years of age and older, excluding upper limb spasticity caused by CP, due to Orphan Drug exclusivity granted to another manufacturer.[1] Ipsen has worked with the FDA and this manufacturer to selectively waive their respective exclusivities to better support patient care. As a result, Dysport is now FDA-approved to treat both upper and lower limb spasticity in pediatric patients two years of age and older, including spasticity caused by cerebral palsy.[1]

"The proactive step to resolve the uncertainty created by the previous CP carveout enables us as physicians to prescribe consistent therapy for pediatric patients experiencing both upper and lower limb spasticity," said Sarah Helen (Sally) Evans, MD, Division Chief of Rehabilitation Medicine in the Department of Pediatrics at the Children's Hospital of Philadelphia. "This update ensures patient care, and treating the child as a whole person, can be the focus for physicians and their caregivers when making treatment decisions for both upper and lower limb spasticity."

"We're proud to have proactively worked with the FDA and another manufacturer to help physicians treat their patients in the manner they deem best for their patients' care." said Kimberly Baldwin, Vice President, Franchise Head, Neuroscience Business Unit, Ipsen. "This effort illustrates our continued commitment to patients, helping to ensure children living with cerebral palsy can access the spasticity treatment that's most appropriate for them."

About Pediatric 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.[2]

Spasticity affects the muscles and joints of the extremities, and particularly impacts growing children.[3] 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 CP, spinal cord injury, multiple sclerosis, stroke, and brain or head trauma.[2,3]

Symptoms of spasticity may include increased muscle tone, rapid muscle contractions, exaggerated deep tendon reflexes, and/or muscle spasms.[2,3] The degree of spasticity can vary from mild muscle stiffness to severe, painful, and uncontrollable muscle spasms.[2]

Spasticity in children is a condition that causes muscle spasms and increased muscle stiffness in either the upper and/or lower limbs including the elbow, wrist, finger and calf muscles.[1] When muscle stiffness in the calf is intensified, it prohibits the ankle from flexing as needed and causes the foot to be pointed down and in.[1,4]

About Dysport® (abobotulinumtoxinA) for Injection
Dysport is an injectable form of botulinum toxin type A (BoNT-A), which is isolated and purified from Clostridium bacteria producing BoNT-A.[1] It is supplied as a lyophilized powder.[1] Dysport has approved indications in the United States for the treatment of adults with cervical dystonia (CD) and for the treatment of spasticity in adult patients.[1] Dysport is also the first FDA-approved botulinum toxin for the treatment of both upper and lower limb spasticity in children two years of age or older.[1]

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

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

- Spasticity in patients 2 years of age and older
- Cervical dystonia in adults

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 and in approved indications, cases of spread of effect have been reported at doses comparable to or lower than the maximum recommended total dose.

Contraindications

Dysport is contraindicated in patients with known hypersensitivity to any botulinum toxin products, cow's milk protein, components in the formulation or infection at the injection site(s). Serious hypersensitivity reactions including anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea have been reported. If such a reaction occurs, discontinue Dysport and institute appropriate medical therapy immediately.

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**.** 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 (e.g., 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.

Most Common Adverse Reactions

Adults with lower limb spasticity (≥5%): falls, muscular weakness, and pain in extremity and with **upper limb spasticity** (≥4%): muscular weakness.

Pediatric patients with lower limb spasticity (≥10%): nasopharyngitis, cough and pyrexia and with **upper limb spasticity** (≥10%): upper respiratory tract infection and pharyngitis.

Adults with cervical dystonia (≥5%): muscular weakness, dysphagia, dry mouth, injection site discomfort, fatigue, headache, musculoskeletal pain, dysphonia, injection site pain, and eye disorders.

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.

Special Populations

Use in Pregnancy

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. Based on animal data, Dysport may cause fetal harm.

Pediatric Use

The safety and effectiveness of Dysport injected into proximal muscles of the lower limb for the treatment of spasticity in pediatric patients has not been established. 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 Dysport for lower limb spasticity reported a greater percentage of fall and asthenia as compared to those younger (10% vs. 6% and 4% vs. 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 full Prescribing Information, including **Boxed Warning** and Medication Guide.

About Ipsen in North America
Ipsen (Euronext: IPN; ADR: IPSEY) is a global biopharmaceutical company focused on innovation and specialty care. The company develops and commercializes innovative medicines in three key therapeutic areas –Oncology, Neuroscience and Rare Diseases. At Ipsen, we focus our resources, investments and energy on discovering, developing and commercializing new therapeutic options to provide hope for patients whose lives are challenged by difficult-to-treat diseases. Ipsen's North American operations are located in Cambridge, Massachusetts, one of the company's three global hubs. Based in the heart of Kendall Square, our fully integrated biopharmaceutical business includes Commercial, Research & Development, Manufacturing, and Global External Innovation and Partnering. Combined with our Canadian headquarters in Mississauga, Ontario, and other locations, Ipsen employs approximately 600 people in North America. For more information please visit www.ipsenus.com or www.ipsen.ca. Connect with us on Twitter and LinkedIn.

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, and the outcome of this study or other studies. 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 preclinical 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 6 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 2019 Universal Registration Document available on its website (www.ipsen.com).

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[1] Dysport (abobotulinumtoxinA) [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; July 2020.
[2] National Institute of Neurological Disorders and Stroke. Spasticity Information Page. https://www.ninds.nih.gov/Disorders/All-Disorders/Spasticity-Information-Page. Accessed May 12, 2020.
[3] American Association of Neurological Surgeons. Spasticity page. http://www.aans.org/Patients/Neurosurgical-Conditions-and-Treatments/Spasticity. Accessed May 12, 2020.
[4] Delgado MR, Tilton A, Russman B, et al. (2016). AbobotulinumtoxinA for Equinus Foot Deformity in Cerebral Palsy: A Randomized Controlled Trial. Pediatrics. 2016;137(2);1-9.