PRESS RELEASE

Presentation of Results at the AACPDM Annual Meeting from a Phase III Trial Evaluating an Investigational Use of AbobotulinumtoxinA (Dysport®) in Children with Spastic Equinus Foot Deformity due to Cerebral Palsy

Data selected for oral presentation at 69th Annual Meeting of the American Academy for Cerebral Palsy and Developmental Medicine

BASKING RIDGE, N.J. October 22, 2015 – Ipsen Biopharmaceuticals, Inc., an affiliate of Ipsen (Euronext: IPN; ADR: IPSEY), today announced results from a Phase III study (NCT01249417) evaluating the investigational use of abobotulinumtoxinA (Dysport®) for injection in the treatment of spastic equinus foot, a condition associated with cerebral palsy (CP) in children aged 2-17. The data will be presented during an oral session on Thursday, October 22 at the "Free Paper Session B: Tone Management Strategies and Pain Control" between 10:50 AM –10:57 AM CT at the 69th Annual Meeting of the American Academy for Cerebral Palsy and Developmental Medicine (AACPDM) in Austin, Texas.

This global, multicenter, double-blind, randomized, placebo-controlled study evaluated the efficacy and safety of abobotulinumtoxinA (ABO) versus placebo on the mean change from baseline in ankle joint hypertonicity in 241 children with cerebral palsy. Eligible patients were randomized (1:1:1) to injections of ABO 10U/kg/leg, ABO 15U/kg/leg or placebo into the gastrocnemius and soleus muscles (one or both legs injected). The primary endpoint was change in Modified Ashworth Scale (MAS) from baseline to Week 4. Selected secondary endpoint data presented were the mean Goal Attainment Scale (GAS) score at Week 4.

At Week 4, muscle tone was improved with ABO as measured by the primary endpoint, the Modified Ashworth Scale (MAS). In the intention to treat (ITT) population, the adjusted least squares (LS) mean changes in the MAS score from baseline to Week 4 showed statistically significant differences in favor of the ABO 10U/kg/leg treatment group (p=0.0029) and the ABO 15U/kg/leg treatment group (p=0.0002) as compared to placebo. Treatment related adverse events occurred in 8.9% of the placebo group, 7.5% in the ABO 10U/kg/leg group, and 6.3% in the the ABO 15U/kg/leg treatment. The most common treatment related AE was localized muscular weakness (10U/Kg/leg=2; placebo=1).

"We are encouraged by the most recent study results evaluating the efficacy and safety of abobotulinumtoxinA in children with spastic equinus foot deformity due to cerebral palsy," said Mauricio Delgado, MD, FAAN, FRCPC, Director of Pediatric Neurology, Texas Scottish Rite Hospital for Children, Professor at University of Texas Southwestern Medical Center at Dallas. "To date, this is the largest placebo controlled clinical trial of a botulinum toxin treatment for children with cerebral palsy."

Data presented also included the secondary endpoint of Goal Attainment Scale (GAS). In this study, the most frequently chosen goals were improved walking pattern (70.2% of patients), improved balance (32.3%), and decreased falling (31.1%). As measured by the GAS, where a score of 50 represents goal achieved as expected, patients with ABO showed higher goal achievement than the expected score of 50 (GAS of 50.9 for 15U/kg and 51.5 for 10U/kg), whereas patients on placebo did not reach the expected level (GAS score of 46.2). Treatment effects for GAS were significant for both ABO groups versus placebo (p=0.0031 & p=0.0006, respectively).

The effects of abobotulinumtoxinA and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. 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, particularly in those patients who have underlying conditions that would predispose them to these symptoms.

"Cerebral palsy is the most common motor disability in children in the United States[1]," said Cynthia Schwalm, Chief Executive Officer, Ipsen Biopharmaceuticals, Inc. "Ipsen Biopharmaceuticals has a history of working with children with rare conditions, including our work with children with severe primary IGF-1 deficiency. We are committed to investigating the potential uses of abobotulinumtoxinA in spasticity in different populations."

About Cerebral Palsy
Cerebral Palsy is the most common motor disability in children, affecting the ability to move and to maintain balance and posture. While the specific cause is unknown, CP occurs due to abnormal development of the brain or damage to the developing brain.[1] Signs and symptoms can vary; in addition to movement and coordination problems, CP can cause difficulty swallowing or speaking as well as other neurological issues such as seizures or intellectual disabilities.[2] Most (80%) of the children identified with CP have spastic CP, meaning their muscles are stiff and, as a result, their movements can appear irregular.[1] Many with CP experience foot disorders, with the most common being equinus, in which the foot points downward.[3]

About Dysport® (abobotulinumtoxinA)
Dysport® is an injectable form of botulinum toxin type A (BoNT-A), which is isolated and purified from Clostridium bacteria producing BoNT-A. It is supplied as a lyophilized powder.

Dysport® has approved therapeutic indications in the United States for the treatment of adults with cervical dystonia (CD), as well as for the treatment of Upper Limb Spasticity (ULS) in adult patients to decrease the severity of increased muscle tone in elbow flexors, wrist flexors and finger flexors.

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 spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to lower than the maximum recommended 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). Patients known to be allergic to cow's milk protein should not be treated with Dysport®, as the product may contain trace amounts of this protein.

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 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. 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
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. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been reported for albumin.

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 Rreactions
Most common adverse reactions (≥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 (>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%).

Drug Interactions
Co-administration of Dysport® and aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents), such as 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 vison. 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.

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.

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 for Dysport® available here.

Please see the Dysport® Medication Guide for patients available here.

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2. Mayo Clinic: Cerebral Palsy. Retrieved from: http://www.mayoclinic.org/diseases-conditions/cerebral-palsy/basics/symptoms/con-20030502 on September 28, 2015.

3. The Children's Hospital at Philadelphia. Cerebral Palsy Foot Disorders. Retrieved from: http://www.chop.edu/conditions-diseases/cerebral-palsy-foot-disorders#.ViVOYH6rRxA on October 19, 2015.