

**Ipsen Biopharmaceuticals, Inc. Presents Dysport® (abobotulinumtoxinA)
Data at American Academy of Physical Medicine and Rehabilitation
Annual Assembly**

***Findings Will be Presented from Largest-Ever Trial of Dysport® in Cervical Dystonia
and Phase III Trial in Upper Limb Spasticity***

BASKING RIDGE, N.J. November 14, 2014 – Ipsen Biopharmaceuticals, Inc., an affiliate of Ipsen (Euronext: IPN; ADR: IPSEY), today announced multiple presentations of Dysport® data, which will be presented at the Annual Assembly of the Academy of Physical Medicine and Rehabilitation (AAPM&R) November 13-16 in San Diego, California. There will be five poster presentations based on trials that explored the use of Dysport® in both cervical dystonia and upper limb spasticity.

Two presentations will provide findings from the largest placebo-controlled, double-blind study conducted which evaluated the efficacy and safety of Dysport treatment in patients with cervical dystonia. This international, multicenter study involved 61 sites in 11 countries and randomized a total of 369 patients diagnosed with cervical dystonia to one of three treatment arms: current formulation of Dysport® (abobotulinumtoxinA) 500U (n=159), an investigational new formulation of abobotulinumtoxinA 500U (n=156) and placebo (n=54). These studies are being presented on Friday, November 14, 2014 from 1:30 pm - 2:30 pm PST.

- *Dysport®, abobotulinumtoxinA, is effective with a favorable safety profile in the treatment of cervical dystonia: a Phase III, randomized, double-blind, placebo-controlled study* evaluated the efficacy and safety of Dysport®, versus placebo at four (primary endpoint), eight and 12 weeks post injection. Efficacy was measured using the Toronto Western Spasmodic Torticollis Rate Scale (TWSTRS) total score and subscales (disability, severity and pain) as well as several investigator-led assessments. The data showed that significant improvement in TWSTRS total score versus placebo (-14.0 vs baseline for Dysport and -3.9 versus baseline for placebo, $p < 0.05$) at the week 4 primary endpoint. The significant improvement associated with Dysport® treatment on TWSTRS total score was sustained at week 8 and week 12 assessments. Adverse events were experienced by 37.8% of patients receiving Dysport® and 25.5% of patients receiving placebo during the single treatment cycle in the trial.
- *Dysport®, abobotulinumtoxinA, improves disease-specific quality of life in patients with cervical dystonia, as measured by Patient-Reported Outcomes, in a Phase III, randomized, double-blind placebo-controlled study*, which showed that one single injection of Dysport® significantly improved patients' disease-specific quality of life. At week 4, total Cervical Dystonia Impact Profile (CDIP)-58 score was improved as were all eight CIPD-58 subscales (head and neck symptoms, pain and discomfort, sleep, upper limb activities, walking, annoyance, mood and psychosocial functioning) and visual analog scales (VAS) for pain and symptoms.

Additionally, data from a Phase III study of Dysport® in upper limb spasticity will also be shared.

- *Randomized, double-blind placebo-controlled Phase III study of Dysport, abobotulinumtoxinA, in the treatment of adults with upper limb spasticity* showed that 500 and 1000IU of Dysport®



in overactive limb muscles improved muscle tone, spasticity and active range of motion in the spastic upper limb at week 4. The international, multi-center trial involved 243 hemiparetic patients following a stroke or brain trauma and showed gains in active finger, elbow and wrist range of motion and passive function. No unexpected safety events were observed.

“We are very encouraged by this new research, confirming the use of Dysport® as an effective treatment option for cervical dystonia, while continuing to pursue its potential use in other investigational indications, including upper limb spasticity,” said **Cynthia Schwalm, CEO**, Ipsen Biopharmaceuticals, Inc.

Two additional posters explored the population characteristics and top five injected muscles as part of an interim analysis of the “INTEREST IN CD2” study of Dysport®, which is planning to recruit 1,050 patients in 38 countries.

Dysport® is approved for the treatment of upper limb spasticity in many international markets, but not in the United States (U.S.).

The only approved therapeutic indication for Dysport in the U.S. is for the treatment of adults with cervical dystonia (referred to as spasmodic torticollis in other markets). As such, data from the Phase III study in adults with upper limb spasticity are with respect to an investigational use of Dysport® in the U.S. The U.S. Food and Drug Administration (FDA) has accepted Ipsen’s supplemental Biologics License Application (sBLA) for Dysport® in adult upper limb spasticity.

About Cervical Dystonia^{1,2}

Cervical dystonia, or torticollis, is the most common type of dystonia – a movement disorder which causes a person’s muscles to contract uncontrollably. Cervical dystonia is a painful condition in which the neck muscles contract involuntarily, causing the head to turn or twist to one side, forward or backward. It can occur at any age (even infancy) but most often occurs in middle-age women (between the ages of 40 and 70).

About Upper Limb Spasticity²

Over half a million Americans may suffer from spasticity³, which in the upper limbs causes muscles to become stiff, flexed or even spasm and twitch. While not life threatening, upper limb spasticity is painful and can make everyday tasks such as bathing and dressing difficult. The condition most commonly occurs after a stroke, but can also result from a spinal cord or traumatic brain injury or in adults with multiple sclerosis (MS) or cerebral palsy. Symptoms may not appear until weeks, months or even years after the stroke or injury but can include rotated shoulders, bent elbows or wrists and hands clenched into fists.

About Dysport

Dysport® is an injectable form of botulinum toxin type A (BoNT-A), which is isolated and purified from Clostridium BoNT-A bacteria. It is supplied as a lyophilized powder. Dysport® was first registered for the treatment of blepharospasm and hemifacial spasm in the United Kingdom 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), pediatric lower limb spasticity due to cerebral palsy (CP), axillary hyperhidrosis, and glabellar lines.



About abobotulinumtoxinA (Dysport®) in the United States

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

Dysport®'s approved therapeutic indication is for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain in both toxin-naïve and previously treated patients.

Important Safety Information about Dysport® for Healthcare Professionals

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 adults, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and at lower doses.

Contraindications

Dysport is contraindicated in patients with hypersensitivity to any botulinum toxin product or its excipients, including human albumin, lactose, and cow's milk protein, or who have an infection at the proposed injection site.

Lack of interchangeability between botulinum toxin products

The potency Units of Dysport 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. Recommended dose and frequency of administration should not be exceeded.

Dysphagia and breathing difficulties

Immediate medical attention may be required in cases of respiratory, speech, or swallowing difficulties. 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. Concomitant neuromuscular disorder may exacerbate clinical effects of treatment.

Pre-existing neuromuscular disorders

Patients with neuromuscular disorders should be monitored particularly closely when given botulinum toxin as they may be at increased risk of clinically significant effects, including severe dysphagia and respiratory compromise from typical doses.



Human albumin

Dysport contains human albumin. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases or Creutzfeldt-Jakob disease (CJD). No cases of transmission of viral diseases or CJD have ever been identified for albumin.

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.

Drug interactions

Patients receiving concomitant treatment 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 may potentiate systemic anticholinergic effects. The effect of administering different botulinum neurotoxins during the course of treatment with Dysport is unknown.

Special populations

Based on animal data, may cause fetal harm. Dysport should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Care should be exercised when administering Dysport to elderly patients, reflecting the greater frequency of concomitant disease and other drug therapy.

Adverse reactions

The most commonly observed adverse reactions (>5% of patients) with Dysport for the treatment of cervical dystonia are muscular weakness, dysphagia, dry mouth, injection site discomfort, fatigue, headache, neck pain, musculoskeletal pain, dysphonia, injection site pain, and eye disorders.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact Ipsen at 1-877-397-7671.

You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the full Prescribing Information for Dysport available at http://www.dysport.com/hcp/PDFs/Dysport_Patients_PI_Sept2013.pdf

For further information:

Media:

Rob Kloppenburg
Vice President, North America, Communications
Tel.: 908-275-6388
E-mail: robert.kloppenburg@ipsen.com

Erinn White
HealthStar PR
Tel: 917-769-2785
Email: ewhite@healthstarpr.com

Didier Véron
Senior Vice-Président, Public Affairs and Communication
Tel.: +33 (0)1 58 33 51 16

Brigitte Le Guennec
Media and Public Relations Manager
Tel.: +33 (0)1 58 33 51 17



Fax: +33 (0)1 58 33 50 58
E-mail: didier.veron@ipsen.com

Fax: +33 (0)1 58 33 50 58
E-mail: brigitte.le.guenneec@ipsen.com

Financial Community:

Stéphane Durant des Aulnois
Investor Relations Director
Tel.: +33 (0)1 58 33 60 09
Fax: +33 (0)1 58 33 50 63
E-mail: stephane.durant.des.aulnois@ipsen.com

Thomas Peny-Coblentz
Investor Relations Deputy Director
Tel.: +33 (0)1 58 33 56 36
Fax: +33 (0)1 58 33 50 63
E-mail: thomas.peny-coblentz@ipsen.com

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¹ Mayo Clinic: "Cervical Dystonia" retrieved from <http://www.mayoclinic.org/diseases-conditions/spasmodic-torticollis/basics/definition/con-20028215> on November 2, 2014.

² WebMD: Upper Limb Spasticity. Retrieved from <http://www.webmd.com/brain/upper-limb-spasticity> on October 30, 2014.

³ Medscape: Spasticity. Retrieved from <http://emedicine.medscape.com/article/1148826-overview> on November 6, 2014