PRESS RELEASE

Ipsen Biopharmaceuticals Canada Inc. Announces Health Canada Approval of DYSPORT THERAPEUTIC™ (abobotulinumtoxinA) for the Treatment of Lower Limb Spasticity in Children Aged Two and Older

-- Approval is based on the first large-scale neurotoxin trial to demonstrate meaningful functional improvement in pediatric lower limb spasticity[1]--

MISSISSAUGA, ON (Canada), January 9, 2018 – Ipsen Biopharmaceuticals Canada Inc., the Canadian affiliate of Ipsen (Euronext: IPN; ADR: IPSEY) today announced that Health Canada has approved DYSPORT THERAPEUTIC™ (abobotulinumtoxinA) for the treatment of lower limb spasticity in pediatric patients two years of age and older. Those treated with DYSPORT THERAPEUTIC showed statistically significant improvements across co-primary efficacy assessments including ankle plantar flexor muscle tone and response to treatment as measured by the Physician's Global Assessment (PGA) scale.[2] Additionally, improvement in patient functionality including walking, balance, falling and endurance was observed at week 4 vs placebo as measured by Goal Attainment Scaling (GAS).[2]

"With the Health Canada approval of DYSPORT THERAPEUTIC, children with cerebral palsy and their parents can look forward to another therapy which improves stiffness and movement that are hallmarks of cerebral palsy. It is wonderful news for this community since when it comes to medication and cerebral palsy, one size does not fit all," said **Janice Bushfield, Executive Director, Cerebral Palsy Association in Alberta, Calgary, Alberta.**

"The stiffness that accompanies pediatric lower limb spasticity can be painful and disabling for children who suffer from movement disorders, including cerebral palsy. In clinical trials, evidence demonstrated that abobotulinumtoxinA is an effective addition to current options in treating children with cerebral palsy and other disorders affected by lower limb spasticity. Additional choices for this patient population are required since current regimens may not be suitable for every child and treatment needs to be individualized," said **Dr. Michael Shevell, Chair, Department of Pediatrics, Faculty of Medicine, McGill University, Montreal, Quebec.**

DYSPORT THERAPEUTIC allows contracted muscles to relax by blocking overactive nerve signals. This may lead to improved functionality including improved walking and balance, decreased frequency of falling and tripping and improved endurance.[2]

"The approval of DYSPORT THERAPEUTIC, in this pediatric indication, demonstrates Ipsen Canada's ongoing commitment to spasticity and neuromuscular disorders. We are proud to play a role in improving the lives of families who are affected by pediatric lower limb spasticity by continuing to expand the indications for this important treatment option," said **Paul Reider**, **General Manager for Ipsen Biopharmaceuticals Canada Inc**.

Lower limb spasticity or increased stiffness or tightness in the lower limb muscles, is usually caused by damage to the spinal cord or parts of the brain that control movement.[3] For example, cerebral palsy is the most common physical disability in childhood[4,5] and approximately two-thirds of all cerebral palsy patients suffer from spasticity[6] and 80 per cent of children with cerebral palsy have some difficulty with walking as a result of lower limb spasticity.[7]

Because of this damage, the nerve signals between the brain, spinal cord, and muscles are interrupted, which may lead to stiffness or muscle spasms.[3] As a result, the muscles tense up so much that the ankle cannot flex as needed, so the foot is often pointed down and in, leading children to walk on their toes.[3]

About the Phase III Pivotal Study[2]
Regulatory approval of DYSPORT THERAPEUTIC for the treatment of pediatric lower limb (PLL) spasticity was based on the results from an international Phase III study. The trial included 235 patients who were botulinum toxin naïve or previously treated with a botulinum toxin more than six months before study entry. The results showed those treated with DYSPORT THERAPEUTIC (10 Units/kg/leg or 15 Units/kg/leg) demonstrated a statistically significant improvement in muscle tone measured by the Modified Ashworth Scale (MAS) as compared to placebo at week 4 and at week 12. Statistically significant improvement in the mean Physician Global Assessment (PGA) score was also observed in both DYSPORT THERAPEUTIC groups versus placebo at weeks 4 and 12. Statistically significant improvement in patient functionality, as measured by Goal Attainment Scaling (GAS) was also observed at week 4 in both DYSPORT THERAPEUTIC groups, whereas patients treated with placebo did not meet the expected level of improvement.

The most commonly observed adverse reactions (≥ five per cent of patients) are: influenza-like illness, myalgia (muscle pain) and muscular weakness.[1]

A majority of patients in the clinical study were retreated between 16 and 22 weeks; however, some had a longer response.[1] More than 20 per cent of subjects in both treatment groups had not received retreatment by week 28.[2] The degree and pattern of muscle spasticity at the time of re-injection may necessitate alterations in the dose of DYSPORT THERAPEUTIC and muscles to be injected.[2]

The full Product Monograph for Canada is available here.

About DYSPORT THERAPEUTIC (abobotulinumtoxinA)
DYSPORT THERAPEUTIC 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.

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 Depositary Receipt program (ADR: IPSEY). For more information on Ipsen, visit www.ipsen.com.

About Ipsen Canada
Located in Mississauga, Ontario, Ipsen Biopharmaceuticals Canada Inc. is the Canadian affiliate of Ipsen and an integrated business unit within North America. Ipsen Biopharmaceuticals Canada Inc. thrives on teamwork and collaboration, and encourages its employees to innovate. A vital part of the company culture is its close tie with its corporate headquarters in Basking Ridge and Paris, a tie that provides employees with a rich global perspective and a broadened awareness of international cultures and business practices. Ipsen Biopharmaceuticals Canada Inc. encourages employees to share best practices, rewards team players, and facilitates and fosters collaboration within its staff. Every person on its staff is important, and their ideas and insights are critical to Ipsen's success in Canada and globally. The company focuses resources, investments, and energy on discovering, developing, and commercializing new therapeutic options for oncologic, neurologic, and endocrine diseases. Ipsen is driven by accountability to customers and patients, and strives for operational excellence and innovation. For more information on Ipsen, please visit www.ipsen.ca.

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