

BOTOX[®] (ONABOTULINUMTOXINA) RECEIVES FDA APPROVAL FOR TREATMENT OF UPPER LIMB SPASTICITY IN ADULTS

(IRVINE, Calif., March 9, 2010) – Allergan, Inc. (NYSE: AGN) today announced that the United States Food and Drug Administration (FDA) has approved BOTOX[®] (onabotulinumtoxinA) for the treatment of increased muscle stiffness in the elbow, wrist and fingers in adults with upper limb spasticity.

Spasticity is a debilitating condition impacting approximately 1 million Americansⁱ, many of whom suffer from spasticity in the upper limbs following a stroke. Upper limb spasticity may also occur following a spinal cord or traumatic brain injury or in patients affected by multiple sclerosis or adults with a history of cerebral palsy.

Although not a life-threatening condition, upper limb spasticity can be severely debilitating and painful, producing disfiguring muscle contractions that can result in stiff, tight muscles in the elbow, wrist and fingers, or a clenched fist. This stiffness hinders a patient's ability to perform simple tasks, such as dressing or washing the hand, and often leaves the patient dependent on a caregiver to help with simple activities.

“Upper limb spasticity can manifest weeks, months or even years after the original injury, possibly after a patient has stopped seeing a neurologist, physiatrist or their rehabilitation specialist, which is why it is severely undertreated and there's a low awareness of the condition,” said Mitchell F. Brin, M.D., Allergan's Senior Vice President Global Development, Chief Scientific Officer, BOTOX[®]. The approval of BOTOX[®] marks another important evolution in medical care, as we look to raise greater recognition and understanding of upper limb spasticity among patients affected by the condition, and refer them to a neurologist or physiatrist to explore their various treatment options.”

In patients diagnosed with upper limb spasticity, BOTOX[®] is injected by a trained specialist directly into the affected muscles blocking overactive nerve impulses that trigger these disabling contractions to reduce the severity of increased muscle tone in the elbow, wrist and fingers. In clinical studies, the efficacy of BOTOX[®] persisted up to three months on average. BOTOX[®] is the first and only neurotoxin approved by the FDA for the treatment of upper limb spasticity.

Clinical Studies Evaluating BOTOX[®] For the Treatment of Upper Limb Spasticity

Allergan has conducted multiple studies evaluating the use of BOTOX[®] to treat upper limb spasticity, including three double-blind, placebo-controlled studies, two of which were published in *The New England Journal of Medicine*,ⁱⁱ and *Archives of Physical and Medical Rehabilitation*ⁱⁱⁱ.

The first double-blind, placebo-controlled trial compared the safety and efficacy of BOTOX[®] treatment (200-240 units (U)) with placebo over a 12-week period in 126 patients who had suffered a stroke at least 6 months prior and experienced increased wrist and finger flexor tone (scores of at least 3 for wrist flexor tone and at least 2 for finger flexor tone based on the Ashworth Scale). The Ashworth Scale is a globally accepted measure of muscle tone^{iv}, which rates passive movement from 1 (normal muscle tone) to 4 (extreme increase in muscle tone).

The study found that BOTOX[®] neurotoxin produced a statistically significant reduction in both wrist flexor and finger flexor muscle tone seen at the week 6 primary endpoint (P < .05 versus placebo).^{v,vi} Further, evaluation by the Physician's Global Assessment score, an investigator's measure of a patient's response to treatment, correlated with the Ashworth scores, showing a statistically significant difference favoring BOTOX[®] versus placebo at the primary endpoint (week 4).^{vii,viii}

The second study compared three doses of BOTOX[®] (360 U, 180 U, 90 U) with placebo over 24 weeks in 91 patients at least 6 weeks post-stroke with increased elbow flexor and wrist flexor tone (a score of at least 2 for elbow flexor tone and at least 3 for wrist flexor tone based on an expanded Ashworth Scale).^{ix} In this study, the 360 U group achieved statistically significant reduction versus placebo in wrist flexor tone at the week 6 primary endpoint.

Similar results were observed in a clinical study that compared the same dosing regimens of BOTOX[®] (360 U, 180 U, 90 U) with placebo over 12 weeks in 88 patients at least 6 weeks post-stroke with increased elbow tone and wrist and/or finger tone (scores of at least 2 for elbow flexor tone and at least 3 for wrist and/or finger flexor tone based on the Ashworth Scale)^{xi}. This study showed BOTOX[®] decreased muscle tone and achieved statistically significant decreases in wrist flexor tone, finger flexor tone and elbow flexor tone in the 360 U group at week 4.^{xii}

"For patients who suffer from upper limb spasticity, simple activities can be so challenging they must rely on a caregiver to pry open their hand and stretch back their fingers so they can wash their hands or get dressed," said Allison Brashear, M.D., Professor and Chair, Department of Neurology at Wake Forest University Baptist Medical Center in Winston-Salem, NC. "In the clinical studies, we saw improvement in muscle tone in patients injected with BOTOX[®], which was maintained for up to three months with no further injection."

In the double-blind, placebo controlled studies of BOTOX[®] for the treatment of upper limb spasticity, the most common adverse events occurred in less than 7 percent of patients and included pain in extremity, fatigue, muscle weakness, nausea and bronchitis.^{xiii}

About BOTOX[®]

BOTOX[®] is a prescription-only medical product that contains tiny amounts of highly purified botulinum toxin protein refined from the bacterium, *Clostridium botulinum*. BOTOX[®] has a unique, protected molecular structure that stabilizes the core toxin in BOTOX[®] from degradation. When injected at approved and labeled doses into a specific muscle or gland, BOTOX[®] neurotoxin is expected to diffuse locally and expected to produce a safe and effective result by producing a localized and temporary reduction in the overacting muscle or gland, usually lasting up to approximately 3 to 6.7 months depending on the individual patient and indication. Specifically, the incidence of immunogenicity in patients treated with BOTOX[®] for upper limb spasticity is 0.53%.

BOTOX[®] was first approved by the FDA 20 years ago for the treatment of strabismus and blepharospasm, two eye muscle disorders, making it the first botulinum toxin type A product approved in the world. Since its first approval, BOTOX[®] has been recognized by regulatory authorities worldwide as an effective treatment for 21 different indications in approximately 80 countries, benefiting patients worldwide. In the United States, BOTOX[®] is also approved to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults, and to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis) when medicines used on the skin (topical) do not work well enough.

In addition to its therapeutic uses, the same formulation of BOTOX[®] with dosing specific to glabellar lines was approved by the FDA in 2002 under the trade name BOTOX[®] Cosmetic (onabotulinumtoxinA). The FDA approval of BOTOX[®] for the treatment of upper limb spasticity in adult patients marks the fifth therapeutic indication for the product in the United States since 1989.

In addition to 20 years of clinical experience, the safety and efficacy of BOTOX[®] have been well-established in approximately 50 randomized, placebo-controlled clinical trials and in approximately 11,000 patients treated with BOTOX[®] and BOTOX[®] Cosmetic in Allergan's clinical trials^{xiv}. Worldwide, approximately 26 million vials of

BOTOX[®] and BOTOX[®] Cosmetic have been distributed and approximately 29 million treatment sessions have been performed over the past 20 years (1989-2009)^{xv}. With approximately 2,100 articles on BOTOX[®] and BOTOX[®] Cosmetic in scientific and medical journals,^{xvi} BOTOX[®] neurotoxin is one of the most widely researched medicines in the world.

BOTOX[®] is a prescription medicine that is injected into muscles and used:

- to treat increased muscle stiffness in elbow, wrist, and finger muscles in adults with upper limb spasticity.
- to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults.
- to treat certain types of eye muscle problems (strabismus) or abnormal spasm of the eyelids (blepharospasm) in people 12 years and older.

BOTOX[®] is also injected into the skin to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis) when medicines used on the skin (topical) do not work well enough.

BOTOX[®] Cosmetic is a prescription medicine that is injected into muscles and used to improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults younger than 65 years of age for a short period of time (temporary).

It is not known whether BOTOX[®] is safe or effective in children younger than:

- 18 years of age for treatment of spasticity
- 16 years of age for treatment of cervical dystonia
- 18 years of age for treatment of hyperhidrosis
- 12 years of age for treatment of strabismus or blepharospasm

BOTOX[®] Cosmetic is not recommended for use in children younger than 18 years of age.

It is not known whether **BOTOX[®]** and **BOTOX[®] Cosmetic** are safe or effective for other types of muscle spasms or for severe sweating anywhere other than your armpits.

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING:

BOTOX[®] and BOTOX[®] Cosmetic may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems after treatment with BOTOX[®] or BOTOX[®] Cosmetic:

- **Problems swallowing, speaking, or breathing. These problems can happen hours to weeks after an injection of BOTOX[®] or BOTOX[®] Cosmetic** usually because the muscles that you use to breathe and swallow can become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with **BOTOX[®]** or **BOTOX[®] Cosmetic**.
- Swallowing problems may last for several months. People who already have swallowing or breathing problems before receiving **BOTOX[®]** or **BOTOX[®] Cosmetic** have the highest risk of getting these problems.
- **Spread of toxin effects.** In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include: loss of strength and muscle weakness all over the body, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice (dysphonia), trouble saying words clearly (dysarthria), loss of bladder control, trouble breathing, trouble swallowing.

These symptoms can happen hours to weeks after you receive an injection of **BOTOX[®]** or **BOTOX[®] Cosmetic**.

There has not been a confirmed serious case of spread of toxin effect away from the injection site when **BOTOX[®]** has been used at the recommended dose to treat severe underarm sweating, blepharospasm, or strabismus, or when **BOTOX[®] Cosmetic** has been used at the recommended dose to treat frown lines.

Do not take **BOTOX[®]** or **BOTOX[®] Cosmetic** if you: are allergic to any of the ingredients in **BOTOX[®]** or **BOTOX[®] Cosmetic**. See the end of this Medication Guide for a list of ingredients in **BOTOX[®]** and **BOTOX[®] Cosmetic**;

had an allergic reaction to any other botulinum toxin product such as *Myobloc*[®] or *Dysport*[™], have a skin infection at the planned injection site.

Tell your doctor about all your medical conditions, including if you have: a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome).

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal products.

BOTOX[®] and BOTOX[®] Cosmetic may cause loss of strength or general muscle weakness, or vision problems within hours to weeks of taking **BOTOX[®] or BOTOX[®] Cosmetic**. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

BOTOX[®] can cause serious side effects. Other side effects of BOTOX[®] or BOTOX[®] Cosmetic include: dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, and eye problems, double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, and dry eyes. Symptoms of an allergic reaction to **BOTOX[®] or BOTOX[®] Cosmetic** may include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you are wheezing or have asthma symptoms, or if you become dizzy or faint.

Tell your doctor if you have any side effect that bothers you or that does not go away.

For additional information refer to the Medication Guide. This Medication Guide summarizes the most important information about **BOTOX[®] or BOTOX[®] Cosmetic**. If you would like more information, talk with your doctor.

Please see **BOTOX[®] full Product Information and Medication Guide**.

Please see **BOTOX[®] Cosmetic full Product Information and Medication Guide**.

Forward-Looking Statement

This press release contains “forward-looking statements,” including the statements by Dr. Brin, and other statements regarding the safety, effectiveness, approvals, adverse events and market potential of **BOTOX[®]** and **BOTOX[®] Cosmetic**. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from Allergan’s expectations and projections. Risks and uncertainties include, among other things, general industry and pharmaceutical market conditions; technological advances and patents attained by competitors; challenges inherent in the research and development and regulatory processes; challenges related to product marketing, such as the unpredictability of market acceptance for new products and/or the acceptance of new indications for such products; inconsistency of treatment results among patients; general economic conditions; and governmental laws and regulations affecting domestic and foreign operations. Allergan expressly disclaims any intent or obligation to update these forward-looking statements except as required by law. Additional information concerning these and other risk factors can be found in press releases issued by Allergan, as well as Allergan’s public periodic filings with the Securities and Exchange Commission, including the discussion under the heading “Risk Factors” in Allergan’s 2009 Form 10-K. Copies of Allergan’s press releases and additional information about Allergan is available on the World Wide Web at www.Allergan.com or you can contact the Allergan Investor Relations department by calling (714) 246-4636.

About Allergan, Inc.

Founded in 1950, Allergan, Inc., with headquarters in Irvine, California, is a multi-specialty health care company that discovers, develops and commercializes innovative pharmaceuticals, biologics and medical devices that enable people to live life to its greatest potential – to see more clearly, move more freely, express themselves more fully. The Company employs more than 8,000 people worldwide and operates state-of-the-art R&D facilities and world-class manufacturing plants. In addition to its discovery-to-development research organization, Allergan has global marketing and sales capabilities with a presence in more than 100 countries.

SOURCE: Allergan

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i Allergan data on file; Global Literature & Information Services

ii Brashear A, Gorden MF, Elovic E, et al; for BOTOX® Post-Stroke Spasticity Study Group. Intramuscular injection of botulinum toxin for the treatment of wrist and finger spasticity after a stroke. *N Engl J Med.* 2002;347(6):395-400

iii Childers MK, Brashear A, Jozefczyk P, Reding M, Alexander D, Good D, Walcott JM, Jenkins SW, Turkel C, Molloy PT. Dose-dependent response to intramuscular botulinum toxin type A for upper-limb spasticity in patients after a stroke. *Arch Phys Med Rehabil* 2004;85:1063–9.

iv BOTOX® Prescribing Information

v Brashear A, Gorden MF, Elovic E, et al; for BOTOX® Post-Stroke Spasticity Study Group. Intramuscular injection of botulinum toxin for the treatment of wrist and finger spasticity after a stroke. *N Engl J Med.* 2002;347(6):395-400

vi Data on file, Allergan, Inc. 2009. CSR 191622-008, Table 11.4.1.4-1

vii Brashear A, Gorden MF, Elovic E, et al; for BOTOX® Post-Stroke Spasticity Study Group. Intramuscular injection of botulinum toxin for the treatment of wrist and finger spasticity after a stroke. *N Engl J Med.* 2002;347(6):395-400

viii Data on file, Allergan, Inc., 2009. CSR 191622-008, Table 11.4.1.2-1

ix BOTOX® Prescribing Information

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xi BOTOX® Prescribing Information

xii CSR BTOX 412-422-8051

xiii BOTOX® Prescribing Information

xiv Allergan data on file; Medical Affairs

xv Allergan data on file; Global Regulatory Affairs

xvi Allergan data on file; Global Literature & Information Services