

Xeomin® (incobotulinumtoxinA) – a *Botulinum Toxin Free From Accessory Proteins* – Now Available in the U.S.

Merz Pharmaceuticals to Offer Patient Support Programs

GREENSBORO, N.C., Oct. 5 / PRNewswire/ - Merz Pharmaceuticals today announced that Xeomin® (incobotulinumtoxinA), a new botulinum toxin type A for the treatment of adults with cervical dystonia (CD) or blepharospasm, is now commercially available in the U.S. XEOMIN was approved by the U.S. Food and Drug Administration (FDA) on July 30, 2010.

XEOMIN is a botulinum toxin type A that is free from accessory proteins. It is FDA-approved for the treatment of adults with cervical dystonia, to decrease the severity of abnormal head position and neck pain in both botulinum toxin-naïve and previously treated patients and blepharospasm in adults previously treated with Botox® (onabotulinumtoxinA).

“We are excited that XEOMIN is now available in the U.S.,” said Jack Britts, President and CEO of Merz Pharmaceuticals, LLC. “XEOMIN is a new treatment option for patients with cervical dystonia or blepharospasm. Merz is committed to patients having access to the product by providing a variety of service offerings and financial assistance programs for patients. We are pleased with the initial response from healthcare professionals and patients and we believe XEOMIN will make a difference in the lives of CD and blepharospasm patients who receive the product. Our Medical and Sales representatives have begun activities supporting the product to healthcare professionals who regularly inject botulinum toxin for the treatment of cervical dystonia and blepharospasm.”

As part of its commitment to the professional and patient communities, Merz will offer a comprehensive product support system that allows a single point of contact for assistance with ordering, product information, reimbursement questions and patient support. Merz will also offer a drug co-pay assistance program for eligible patients, designed to provide direct assistance to patients for their out-of-pocket costs.

“Over the years, botulinum toxin has become an important treatment for cervical dystonia and blepharospasm,” said Stephen Gollomp, M.D., Clinical Professor of Neurology, Thomas Jefferson University, Philadelphia, Penn., and an investigator for XEOMIN. “With the availability of XEOMIN in the U.S., physicians and patients now have a new therapeutic option for the treatment of these conditions.”

To order XEOMIN, call 1-888-4-XEOMIN (1-888-493-6646).

About Dystonia

Dystonias are neurological movement disorders in which sustained muscle contractions cause twisting and repetitive movements or abnormal postures. These movements, which are involuntary and sometimes painful, may affect a single muscle (focal), a group of muscles such as those in the arms, legs, or neck (segmental), or even the entire body (generalized). Symptoms can be mild or severe and dystonias may be markedly disabling.

Although dystonia is thought to be rare, it is possibly undiagnosed or misdiagnosed due to lack of specific clinical criteria. With focal dystonia, such as blepharospasm or cervical dystonia, most people first experience symptoms in middle age.

According to an epidemiology study conducted in Rochester, Minn., focal dystonia, which includes cervical dystonia, and may be characterized by twisting of the neck, and blepharospasm, or excessive eyelid spasm is estimated to affect 295 per million people in the U.S.

About XEOMIN

In nature, *Clostridium botulinum* produces the toxin in association with ancillary accessory proteins. Manufacturers utilize this naturally occurring protein complex to produce therapeutic botulinum toxin products. Now Merz introduces XEOMIN (incobotulinumtoxinA) which employs a proprietary manufacturing process that isolates the therapeutic component and eliminates these accessory proteins.

More than 84,000 patients have been treated with XEOMIN worldwide since 2005. The U.S. is the 20th country to approve XEOMIN for the treatment of cervical dystonia and blepharospasm.

XEOMIN is the only botulinum toxin that does not require refrigeration prior to reconstitution. Merz believes this may simplify product distribution and storage, and help ensure product integrity at the time of injection. XEOMIN will be available in 50-unit and 100-unit vials, which Merz believes may allow for more precise billing and reduce wastage.

IMPORTANT SAFETY INFORMATION

WARNING: Distant Spread of Toxin Effect

Postmarketing reports indicate that the effects of XEOMIN 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

XEOMIN is contraindicated in patients with a known hypersensitivity to the active substance botulinum toxin type A or to any of the components in the formulation and in the presence of infection at the proposed injection site(s).

WARNINGS AND PRECAUTIONS

- **The potency units of XEOMIN are not interchangeable with other preparations of botulinum toxin products. Therefore, units of biological activity of XEOMIN cannot be compared to or converted into units of any other botulinum toxin products.**
- Hypersensitivity reactions have been reported with botulinum toxin products (anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea). If serious and/or immediate hypersensitivity reactions occur further injection of XEOMIN should be discontinued and appropriate medical therapy immediately instituted.
- Treatment with XEOMIN 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 effects occur, additional respiratory muscles may be involved [See *Boxed Warning*]. Deaths as a complication of severe dysphagia have been reported after treatment with botulinum toxin. Dysphagia may persist for several months, 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.
- **Cervical Dystonia:** Patients with smaller neck muscle mass and patients who require bilateral injections into the sternocleidomastoid muscles are at greater risk of dysphagia. Limiting the dose injected into the sternocleidomastoid muscle may decrease the occurrence of dysphagia.

- **Blepharospasm:** Injection of XEOMIN into the orbicularis oculi muscle may lead to reduced blinking and corneal exposure with possible ulceration or perforation. Lower lid injections should not be repeated if diplopia occurred with previous botulinum toxin injections.
- Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junctional 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 XEOMIN.

ADVERSE REACTIONS

- **Cervical Dystonia:** The most commonly observed adverse reactions (incidence $\geq 10\%$ of patients and twice the rate of placebo) for XEOMIN 120 Units and XEOMIN 240 Units, respectively, were: dysphagia (13%, 18%), neck pain (7%, 15%), muscle weakness (7%, 11%), and musculoskeletal pain (7%, 4%).
- **Blepharospasm:** The most common adverse reactions (incidence $\geq 10\%$ of patients and twice the rate of placebo) for XEOMIN were eyelid ptosis (19%), dry mouth (16%), visual impairment (12%), diarrhea (8%), and headache (7%).

DRUG INTERACTIONS

Concomitant treatment of XEOMIN and aminoglycoside antibiotics, spectinomycin, or other agents that interfere with neuromuscular transmission (e.g., tubocurarine-like agents), or muscle relaxants, should be observed closely because the effect of XEOMIN may be potentiated.

USE IN PREGNANCY

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. XEOMIN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Please see full prescribing information for XEOMIN, including Boxed WARNING, available at www.XEOMIN.com.

About Merz

Merz Pharmaceuticals, LLC is a part of the Merz Group of companies and was established in 1995 to develop and commercialize products for the Merz Group. Areas of therapeutic focus include Neurology, Dermatology, and Podiatry.

With a 102 year heritage, the Merz Group is known worldwide for its development of original compounds and formulations for medical professionals and consumers in 90 countries. Globally, Merz is a leader in the development of pharmaceuticals for the treatment of neurological and psychological disorders as well as for aesthetic medicine. Global research is concentrated in fields that have a strong need for therapeutic innovation such as Alzheimer's disease, Parkinson's disease, tinnitus, chronic pain conditions, addictions, and neuromuscular disturbances.

XEOMIN is a registered trademark of Merz Pharma GmbH & Co KGaA. Botox is a registered trademark of Allergan, Inc.

SOURCE: Merz Pharmaceuticals

CONTACT: Lauren Munroe at Medical Dynamics, +1-212-537-9495