

FDA Approves Merz Pharmaceuticals' Xeomin® (incobotulinumtoxinA) for the Treatment of Cervical Dystonia and Blepharospasm

GREENSBORO, N.C., Aug. 2 / PRNewswire/ - Merz Pharmaceuticals today announced that the United States (U.S.) Food and Drug Administration (FDA) has approved Xeomin® (incobotulinumtoxinA), a botulinum toxin type A for the treatment of adults with cervical dystonia or blepharospasm. According to an epidemiology study conducted in Rochester, Minnesota, the prevalence of focal dystonia, which includes cervical dystonia and blepharospasm, is estimated at 295 per million people in the U.S.

"This is an important regulatory milestone for XEOMIN and is key to establishing our neurology business in the U.S.," said Jack Britts, President and CEO of Merz Pharmaceuticals, LLC. "We at Merz understand, and are committed to, addressing the complexities of treating and living with these neurological disorders."

The FDA approval of XEOMIN is based on the results of two pivotal U.S. clinical trials involving adult patients diagnosed with either cervical dystonia or blepharospasm. Additionally, active comparator studies conducted in Europe evaluating XEOMIN versus Botox® (onabotulinumtoxinA) were included among the data submitted in support of the registration filing in these conditions.

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 allowing dosing flexibility for administration.

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. While focal dystonia, such as blepharospasm or cervical dystonia, can affect people at any age, most people first experience symptoms in middle age.

According to an epidemiology study conducted in Rochester, Minnesota, 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. Dystonias can be disabling, painful and often interfere with patients' daily activities.

About XEOMIN

In nature, *Clostridium botulinum* produces the toxin in association with ancillary complexing 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 ancillary complexing proteins. XEOMIN has been formulated to have high biologic activity with a low protein load.

XEOMIN is a botulinum toxin type A that is free from complexing 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). Please see important safety information below.

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.

Important Safety Information About XEOMIN
WARNING: Distant Spread of Toxin Effect

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 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. See full prescribing information for complete boxed warning.

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.**
- Spread of toxin effects may cause swallowing and breathing difficulties that can lead to death. Immediate medical attention may be required in cases of respiratory, speech or swallowing difficulties. Use with caution in patients with compromised respiratory function or dysphagia. Concomitant neuromuscular disorders may exacerbate clinical effects of treatment.
- 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.
- 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.

ADVERSE REACTIONS

Cervical Dystonia: The most commonly observed adverse reactions ($\geq 5\%$ of patients and $>$ placebo) were: dysphagia, neck pain, muscle weakness, injection site pain, and musculoskeletal pain.

Blepharospasm: The most commonly observed adverse reactions ($\geq 5\%$ of patients and $>$ placebo) were: eyelid ptosis, dry eye, dry mouth, diarrhea, headache, visual impairment, dyspnea, nasopharyngitis, and respiratory tract infection.

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

About Merz

Merz Pharmaceuticals, LLC is a part of Merz, Inc., a wholly owned U.S. subsidiary 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 along with the #1 non-prescription product for scars, Mederma[®], and Mederma[®] Stretch Marks Therapy.

With a 102 year heritage, Merz (KGaA) 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.

SOURCE: Merz Pharmaceuticals

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