



**MERZ AESTHETICS ANNOUNCES PRIMARY ENDPOINT MET  
IN POST-MARKET CLINICAL STUDY OF  
XEOMIN<sup>®</sup> (incobotulinumtoxinA) VS. BOTOX<sup>®</sup>  
(onabotulinumtoxinA) FOR GLABELLAR FACIAL LINES**

Merz North America  
Mariana Smith Bourland  
Corporate Communications  
6501 Six Forks Road  
Raleigh, NC 27615  
Phone (336) 339-0172  
[Mariana.Smith@merz.com](mailto:Mariana.Smith@merz.com)

[www.MerzUSA.com](http://www.MerzUSA.com)

RALEIGH, N.C. – MARCH 19, 2015 – BUSINESS WIRE – Merz Aesthetics, a division of [Merz North America](#) (US affiliate of the global Merz Pharma Group), today announced positive results from a post-market, parallel group clinical trial designed to evaluate the efficacy of Xeomin<sup>®</sup> (incobotulinumtoxinA) in the treatment of moderate to severe glabellar facial lines, when compared to Botox<sup>®</sup> Cosmetic (onabotulinumtoxinA).

“We are pleased that data from our most recent post-market study further demonstrates the efficacy of Xeomin<sup>®</sup> (incobotulinumtoxinA),” stated Jim Hartman, Vice President and Head of U.S. Aesthetics/OTC for [Merz North America](#). “Merz remains dedicated to providing our physician partners with clinical data that they need to choose and apply the treatment options that result in desired outcomes for their patients.”

Results show that this trial met its primary efficacy endpoint, defined as  $\geq 1$ -point improvement from baseline on the Facial Wrinkle Scale (FWS) at maximum frown, 1 month after a single treatment. Similar efficacy profiles were demonstrated between the two treatment groups at all timepoints (1, 2, 3 and 4 months post-treatment). The most common adverse events seen in both treatment groups were headache, infection and facial asymmetry.

“The results of this clinical trial offer evidence that there are multiple effective options for injectors and patients seeking a neurotoxin for aesthetic use,” said [Dr. Fredric Brandt](#), MD, co-lead investigator and board-certified dermatologist with private practices in Manhattan and Miami. As one of the world’s foremost leaders in injectables, Dr. Brandt has spent years developing innovative methods, new injection techniques and novel uses and benefits that have gained him a reputation as a pioneer within the skincare industry.

Botulinum toxin type A is a well-established treatment for glabellar frown lines. In 2011, Xeomin<sup>®</sup> (incobotulinumtoxinA) was approved by the FDA for improvement in the appearance of moderate-to-severe glabellar frown lines with a recommended dosage of 20 units (U). Head-to-head comparison studies conducted worldwide have demonstrated that Xeomin<sup>®</sup> (incobotulinumtoxinA) and Botox<sup>®</sup> (onabotulinumtoxinA) result in comparable safety and efficacy for both cosmetic use and therapeutic uses, including blepharospasm and cervical dystonia<sup>1</sup>.

---

<sup>1</sup> Data on file

“This data is consistent with previously published head-to-head comparison studies and demonstrates that Xeomin<sup>®</sup> (incobotulinumtoxinA) and Botox<sup>®</sup> (onabotulinumtoxinA) result in similar efficacy and safety profiles for the treatment of glabellar facial lines,” stated [Dr. Michael Kane](#), MD, co-lead investigator on the study. A board-certified plastic surgeon in private practice in Manhattan, Dr. Kane frequently lectures on topics relating to aesthetic plastic surgery and has published hundreds of papers throughout his career.

“Given the fact that this is the first large, multicenter, parallel-group study to investigate the comparable efficacy of Xeomin<sup>®</sup> (incobotulinumtoxinA) to Botox<sup>®</sup> (onabotulinumtoxinA) in the treatment of glabellar frown lines, these study results have meaningful implications for patients and physicians alike,” stated Dr. Michael Gold, MD, FAAD. Dr. Gold was one of the study’s key investigators, enrolling and following the largest group of patients throughout the trial. In addition to his work as a board-certified dermatologist and dermatological surgeon in private practice in Nashville, Tennessee, Dr. Gold also serves as an Assistant Clinical Professor of Dermatology at the Vanderbilt University School of Medicine. He plays an integral role in the development of new pharmaceutical products and medical devices through his clinical research, and presents regularly at national and international dermatology and cosmetic meetings.

Complete analysis of the data from this clinical trial is in progress, and Merz Aesthetics looks forward to presenting study results at an upcoming scientific conference, as well as to submitting data to a peer reviewed journal.

#### **About Xeomin<sup>®</sup> (incobotulinumtoxinA)**

XEOMIN<sup>®</sup> (incobotulinumtoxinA) is a prescription medicine that is injected into muscles and used to temporarily improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults.

#### **About Merz Aesthetics**

Merz Aesthetics is a division of Merz North America, a specialty healthcare company that develops and commercializes treatment solutions in aesthetics, dermatology and neurosciences in the U.S. and Canada. As part of the Merz Pharma Group of companies, our ambition is to become the most admired, trusted and innovative aesthetics and neurotoxin company. By developing products that improve patients’ health and help them to live better, feel better and look better, Merz will continue to make significant contributions to the well-being of individuals around the world. Merz Aesthetics is an important contributor to the U.S. aesthetics space, offering a well-balanced product portfolio that includes the dermal fillers Radiesse<sup>®</sup> and Belotero Balance<sup>®</sup> and the neurotoxin Xeomin<sup>®</sup> (incobotulinumtoxinA). For more information about Merz Aesthetics and their U.S. product portfolio, please visit [www.merzusa.com](http://www.merzusa.com).

XEOMIN and BELOTERO are registered trademarks of Merz Pharma GmbH & Co. KGaA. Merz Aesthetics is a trademark of Merz Pharma GmbH & Co. KGaA. RADIESSE is a registered trademark of Merz North America, Inc.

## **IMPORTANT SAFETY INFORMATION for XEOMIN<sup>®</sup>, INCLUDING BOXED WARNING**

### **WARNING: DISTANT SPREAD OF TOXIN EFFECT**

Postmarketing reports indicate that the effects of XEOMIN<sup>®</sup> (incobotulinumtoxinA) for injection, for intramuscular use, 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.

### **INDICATION**

XEOMIN<sup>®</sup> (incobotulinumtoxinA) is a prescription medicine that is injected into muscles and used to temporarily improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults.

### **IMPORTANT SAFETY INFORMATION**

XEOMIN<sup>®</sup> (incobotulinumtoxinA) 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 any time (hours to weeks) after treatment with XEOMIN:

- **Problems with swallowing, speaking, or breathing can happen after an injection of XEOMIN** if the muscles that you use to breathe and swallow become weak. If these problems are severe, you could die. People with certain breathing problems may need to use muscles in their neck to help them breathe and may be at greater risk for serious breathing problems with XEOMIN.
- Swallowing problems may last for several months, and during that time you may need a feeding tube to receive food and water. If swallowing problems are severe, food or liquids may go into your lungs. People who already have swallowing or breathing problems before receiving XEOMIN 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, trouble saying words clearly, loss of bladder control, trouble breathing, trouble swallowing.

**Do not take XEOMIN if you:** are allergic to XEOMIN or any of the ingredients in XEOMIN; had an allergic reaction to any other botulinum toxin product such as rimabotulinumtoxinB (Myobloc<sup>®</sup>), onabotulinumtoxinA (Botox<sup>®</sup>, Botox<sup>®</sup> Cosmetic), or abobotulinumtoxinA (Dysport<sup>®</sup>); have a skin infection at the planned injection site.

**Before you take XEOMIN, 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), as you may be at increased risk of serious side effects including difficulty swallowing or breathing. Tell your doctor if you have: had any side effect from any other botulinum toxin in the past; breathing problems such as asthma or emphysema; a history of swallowing problems or inhaling food or fluid into your lungs (aspiration); bleeding problems; drooping eyelids; plans to have surgery; had surgery on your face. Also tell your doctor if you are pregnant or plan to become pregnant (it is not known if XEOMIN can harm your unborn baby); are breastfeeding or plan to breastfeed (it is not known if XEOMIN passes into breast milk).

**Tell your doctor about all the medicines you take,** including prescription and nonprescription medicines, vitamins and herbal products. Using XEOMIN with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received XEOMIN in the past.**

**Especially tell your doctor if you** have received any other botulinum toxin product in the last four months or in the past. Be sure your doctor knows exactly which product you received. The dose of XEOMIN may be different from other botulinum toxin products that you have received. Tell your doctor if you: have recently received an antibiotic by injection; take muscle relaxants; take an allergy or cold medicine; take a sleep medicine; take a blood thinner medicine. XEOMIN may cause loss of strength or general muscle weakness, blurred vision, or drooping eyelids within hours to weeks of taking XEOMIN. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

**XEOMIN may cause other serious side effects including allergic reactions.** Symptoms of an allergic reaction to XEOMIN may include: itching, rash, redness, swelling, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you get wheezing or asthma symptoms, or if you get dizzy or faint.

**Other side effects of XEOMIN include:** dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, muscle weakness, and eye problems, including double vision, blurred vision, drooping eyelids, swelling of

your eyelids, and dry eyes. Reduced blinking can also occur. Tell your doctor or get medical help right away if you have eye pain or irritation following treatment. Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of XEOMIN. For more information, ask your doctor or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**Please see accompanying XEOMIN [full Prescribing Information](#) and [Medication Guide](#).**

Botox<sup>®</sup>, Dysport<sup>®</sup> and Myobloc<sup>®</sup> are registered trademarks of their respective owners.

**Corporate Contact:**

Mariana Smith Bourland  
Corporate Communications  
Merz North America  
6501 Six Forks Road  
Raleigh, NC 27615  
Cell (336) 339-0172  
[Mariana.Smith@merz.com](mailto:Mariana.Smith@merz.com)