



**CLINICAL DATA FROM MERZ NEUROSCIENCES'
PHASE III STUDY OF XEOMIN (incobotulinumtoxinA) FOR
SPASTICITY TO BE PUBLISHED IN "MUSCLE & NERVE"**

RALEIGH, N.C. – AUGUST 17, 2015 – BUSINESS WIRE – [Merz Neurosciences](#), a division of Merz North America (U.S. affiliate of the global Merz Pharma Group), today announced that data from its Phase 3 PURE: Post-stroke Spasticity Upper Limb Study to Investigate Efficacy and Safety of NT 201 clinical trial for incobotulinumtoxinA has been accepted for publication by the medical journal "[Muscle & Nerve](#)" (John Wiley & Sons). Merz has submitted an sBLA to the FDA to seek approval for the use of incobotulinumtoxinA in the treatment of post-stroke upper limb spasticity and anticipates FDA action prior to the end of this calendar year.

"We are pleased to announce 'Muscle & Nerve's' acceptance of data from our pivotal Phase 3 clinical trial in spasticity," said Glenn Block, Vice President and Head – US Neurosciences for Merz North America. "At Merz Neurosciences, everything we do centers on the needs of the patients and physicians in our areas of focus, and we are proud to be working toward a better experience for movement disorder and spasticity patients via ongoing research and development programs."

The PURE trial, an FDA registration trial of incobotulinumtoxinA for spasticity of the upper limb, met both co-primary endpoints. In the primary analysis, the co-primary variables were improvements in muscle tone defined as 'change in Ashworth Scale score from baseline to Week 4' and improvements in functional outcomes, defined as 'investigator's Global Impression of Change at the Week 4 visit'. Both showed statistical significance, with $p < 0.001$ and $p = 0.003$ respectively. The trial also met a key secondary outcome measure, in which subjects with an improvement ≥ 1 on the Ashworth Scale at Week 4 were classified as responders and showed significant improvements in disability associated with spasticity ($p < 0.001$). Treatment related adverse events were reported for 3.8% and 1.9% of subjects treated with incobotulinumtoxinA and placebo, respectively.

"Targeted, robust research programs are needed in order to continue to deliver meaningful treatment options for individuals living with movement disorders such as upper limb spasticity. Clinical studies such as the PURE trial are essential in helping us to better understand and meet the unique needs of these patients," said Dr. Christina Marciniak, MD, co-investigator and Associate Professor in the Department of Physical Medicine and Rehabilitation, Northwestern University Feinberg School of Medicine. Dr. Marciniak is also an Attending Physician with the Rehabilitation Institute of Chicago, the world's leading hospital and research enterprise in physical medicine and rehabilitation.

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

A [preview of this manuscript is now available online](#) in the Accepted Articles section of “Muscle & Nerve.”

About PURE

The Phase 3 PURE trial was a prospective, multicenter, randomized, double-blind, placebo-controlled main period (12-week duration) with a single incobotulinumtoxinA 400 U treatment or placebo, followed by a 36-week open-label extension in which subjects (n=259) could receive up to three additional treatment cycles. The main period randomization rate of incobotulinumtoxinA to placebo was 2:1.

The study was conducted at 46 sites in North America and Europe. A Primary Target Clinical Pattern (PTCP) for each patient was determined by the investigators and had to be treated with a fixed dose (flexed elbow: 200 U; flexed wrist: 150 U; clenched fist: 100 U). The primary outcome measure was change from baseline in Ashworth Scale Score (AS) score of the PTCP at Week 4. For the responder analysis (a secondary outcome measure), subjects with an improvement ≥ 1 were classified as responders. The Co-primary outcome was Investigator’s Global Impression of Change in spasticity at Week 4, based on clinical experience and using a 7-point Likert scale ranging from -3 = *very much worse* to +3 = *very much improved*. For more information on this trial, please visit <http://clinicaltrials.gov> using the identifier NCT 01392300.

About Merz Neurosciences

Merz Neurosciences 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. Merz Neurosciences is committed to providing high-quality products and outstanding service to physicians in the fields of neurology, physiatry and otolaryngology. 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 Neurosciences is an important contributor to the U.S. neurosciences space, offering a well-balanced product portfolio that includes the neurotoxin Xeomin[®] (incobotulinumtoxinA), the anticholinergic Cuvposa[™] (glycopyrrolate) Oral Solution and the Prolaryn[™] family of products.

For more information about Merz Neurosciences and their U.S. product portfolio, please visit www.merzusa.com.

About Xeomin[®] (incobotulinumtoxinA)

INDICATIONS

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

- to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults.
- to treat abnormal spasm of the eyelids (blepharospasm) in adults who have had prior treatment with onabotulinumtoxinA (Botox®).

IMPORTANT SAFETY INFORMATION

XEOMIN® 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®), onabotulinumtoxinA (Botox®, Botox® Cosmetic), or abobotulinumtoxinA (Dysport®); 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 or call 1-800-FDA-1088.

For more information, please see XEOMIN full [Prescribing Information](#) and [Medication Guide](#).

Botox[®], Dysport[®], and Myobloc[®] 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