Merz North America
Emily Browder
Corporate Communications
6501 Six Forks Road
Raleigh, NC 27615
Office (919) 582-8114
Emily.Browder@merz.com
www.MerzUSA.com

PRESS RELEASE

MERZ NEUROSCIENCES ANNOUNCES POSITIVE PHASE III RESULTS OF XEOMIN® (incobotulinumtoxinA) FOR SIALORRHEA AT 2017 MDS MEETING

RALEIGH, N.C. – June 7, 2017 – Merz Neurosciences, a division of Merz North America, announced today positive topline results from its pivotal Phase III clinical trial of Xeomin® (incobotulinumtoxinA) for the treatment of adult sialorrhea, or unwanted drooling, due to Parkinson's Disease and other neurologic disorders during the 21st International Congress of Parkinson's Disease and Movement Disorders (MDS) in Vancouver, BC.

Following the initial 16 week main period of the Phase III, placebo-controlled, randomized, 184 patient trial, both co-primary endpoints were successfully achieved with statistically significant improvement observed in change in unstimulated salivary flow rate (uSFR) and in the patients' Global Impression of Change Scale (GICS) at week four for patients administered 100U incobotulinumtoxinA as compared to baseline pre-injection vs. placebo (p=0.004 and p=0.002, respectively). GICS is a commonly used rating system for treatments of neurological disorders by clinicians. Overall frequency of adverse events was similar between placebo and treatment groups with no new or unexpected adverse events reported. Patients enrolled in the study received placebo (n=36), incobotulinumtoxinA 75 U (n=74), or incobotulinumtoxinA 100 U (n=74).

"The findings from this well-controlled Phase III clinical study are a step towards providing a therapeutic option for adult patients with sialorrhea, a condition in which patient's needs are not yet being met," said Andrew Blitzer, M.D., D.D.S., coordinating investigator and Professor of Clinical Otolaryngology at Columbia University College of Physicians and Surgeons. "Drooling is a burden to both patients and their caregivers. Importantly, the study results demonstrate a duration of efficacy and benefit beyond 4 months after the initial injection."

Results of the study have been accepted by MDS in the Late-Breaking & Study Group Abstract Session.

"We are excited to have achieved these results through the largest controlled study of incobotulinumtoxinA in the treatment of sialorrhea due to Parkinson's disease and other neurological conditions," added David Dobrowski, Vice-President of Research and Development, Merz North America, Inc. "We look forward to discussing these data with the FDA as progress towards a future marketing application."

SIAXI (**S**ialorrhea **I**n **A**dults **X**eomin® **I**nvestigation) is a prospective, randomized, double-blind, placebo-controlled, Phase 3 trial (NCT02091739) to investigate efficacy and safety of incobotulinumtoxinA for the treatment of unintended drooling, called sialorrhea, in Parkinson's disease (PD) and other neurological conditions. Participants were adults (n=184) with chronic, troublesome sialorrhea related to PD, atypical Parkinson syndromes, stroke, or traumatic brain injury. In

the 16-week double-blind main period, subjects received a single treatment with total incobotulinumtoxinA doses of 75 U or 100 U or placebo administered in four injections into bilateral parotid and bilateral submandibular salivary glands.

About Merz Neurosciences

Merz Neurosciences is a division of Merz North America and is deeply committed to offering novel therapeutic options that address the largely unmet medical needs that exist within the area of neuroscience. Merz Neurosciences is an important contributor to the U.S. neurosciences space and offers a portfolio that includes the neurotoxin Xeomin® (incobotulinumtoxinA), the anticholinergic Cuvposa® (glycopyrrolate) Oral Solution and the Prolaryn® injectable implant family of products. To learn more about Merz Neurosciences and their U.S. product portfolio, please visit www.merzusa.com/neurosciences. For more information about Merz Neurosciences and their U.S. product portfolio, please visit www.merzusa.com.

About Merz North America

Merz North America is a specialty healthcare company dedicated to the development and marketing of innovative quality products for physicians and patients across the United States and Canada. Merz products are distributed through two divisions, Aesthetics and Neurosciences, and are developed with the goal of improving patients' health and quality of life by delivering therapies that bring about real progress. Merz North America is a privately-held company based in Raleigh, North Carolina. To learn more about Merz North America, please visit www.merzusa.com.

About XEOMIN® (incobotulinumtoxinA)

Xeomin® (incobotulinumtoxinA) is a prescription medicine that is injected into muscles and used to treat increased muscle stiffness in the arm of adults with upper limb spasticity, the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults, and to treat abnormal spasm of the eyelids (blepharospasm) in adults who have had prior treatment with onabotulinumtoxinA (Botox®).

XEOMIN® IMPORTANT CONSUMER SAFETY INFORMATION

Read the Medication Guide before you start receiving XEOMIN® (Zeo-min) and each time XEOMIN® is given to you as there may be new information. The risk information provided here is not comprehensive. To learn more:

- Talk to your health care provider or pharmacist
- Visit www.xeomin.com to obtain the FDA-approved product labeling
- Call 1-888-4-XEOMIN

Uses XEOMIN® is a prescription medicine that is injected into muscles and used to treat:

- increased muscle stiffness in the arm of adults with upper limb spasticity
- abnormal head position and neck pain in adults with cervical dystonia (CD)
- abnormal spasm of the eyelids (blepharospasm) in adults who have had prior treatment with onabotulinumtoxinA (BOTOX®)

It is not known whether XEOMIN® is safe or effective in children.

Warnings

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 anytime (hours to weeks) after treatment with XEOMIN®:

- **Problems with swallowing, speaking, or breathing can happen within hours to weeks after an injection of XEOMIN®** if the muscles that you use to breathe and swallow become weak. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with XEOMIN®.
- 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.

These problems could make it unsafe for you to drive a car or do other dangerous activities.

Do not take XEOMIN® if you: are allergic to XEOMIN® or any of the ingredients in XEOMIN® (see the end of this Guide for a list of ingredients in XEOMIN®), had an allergic reaction to any other botulinum toxin product such as rimabotulinumtoxinB (Myobloc®), onabotulinumtoxinA (Botox®, Botox® Cosmetic), or abobotulinumtoxinA (Dysport®) or have a skin infection at the planned injection site.

Ask a doctor before use 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)
- have had any side effect from any other botulinum toxin in the past
- have a breathing problem such as asthma or emphysema
- have a history of swallowing problems or inhaling food or fluid into your lungs (aspiration)
- have bleeding problems
- have drooping eyelids
- have plans to have surgery
- have had surgery on your face
- 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 of your medical conditions and all of the medicines you take, including: prescription and over-the-counter medicines, vitamins and herbal supplements. 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
- have received injections of botulinum toxin such as rimabotulinumtoxinB (MYOBLOC®), onabotulinumtoxinA (BOTOX®, BOTOX® COSMETIC) and abobotulinumtoxinA (DYSPORT®) 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.
- 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

Ask your doctor if you are not sure if your medicine is one that is listed above.

Possible Side Effects
XEOMIN® can cause serious side effects that can be life threatening. See "Warnings."

The most common side effects of XEOMIN® include:

- dry mouth
- discomfort or pain at the injection site
- tiredness
- headache
- neck pain
- muscle weakness
- 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.

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, dizziness or feeling faint. Tell your doctor or get medical help right away if you have wheezing or asthma symptoms, or if you get dizzy or faint. These are not all the possible side effects of XEOMIN®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Directions

- XEOMIN® is a shot (injection) that your doctor will give you.
- XEOMIN® is injected into your affected muscles.
- Your doctor may change your dose of XEOMIN® until you and your doctor find the best dose for you.

General information about the safe and effective use of XEOMIN
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use XEOMIN for a condition for which it was not prescribed. Do not give XEOMIN to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or doctor for information about XEOMIN that is written for health professionals.

Active Ingredient: incobotulinumtoxinA
Inactive Ingredients: human albumin and sucrose

For more information, please see XEOMIN full Prescribing Information and Medication Guide.

Corporate Contact:
Emily Browder
Corporate Communications
Merz North America
6501 Six Forks Road
Raleigh, NC 27615
Office (919) 582-8114
Emily.Browder@merz.com