FDA APPROVES XEOMIN® (incobotulinumtoxinA) FOR ADULT PATIENTS WITH SIALORRHEA
First and only neurotoxin approved for this indication in the United States

RALEIGH, N.C. – JULY 3, 2018 – Merz North America announced today that the U.S. Food and Drug Administration (FDA) has approved the supplemental Biologics License Application (sBLA) for XEOMIN® (incobotulinumtoxinA) for the treatment of chronic sialorrhea, or excessive drooling, in adult patients. XEOMIN is the first and only neurotoxin with this approved indication in the U.S.

“Until now, there has not been an FDA approved treatment for this debilitating condition,” said Kevin O’Brien, Vice President and U.S. Head of Neurosciences, Merz North America. “This approval represents a significant milestone in addressing the unmet needs for more than 600,000 adults who suffer from chronic sialorrhea, and underscores our commitment to improving the lives of those living with movement disorders.”

Sialorrhea is a common symptom among patients who suffer from neurological disorders including Parkinson’s disease, amyotrophic lateral sclerosis (ALS), cerebral palsy (CP) or who have experienced a stroke. The condition can occur from difficulty retaining saliva inside the mouth, issues with swallowing and from problems controlling facial muscles.

The FDA granted this application a priority review designation upon acceptance. Priority reviews are granted to drugs that will potentially provide significant improvements in the safety and effectiveness of the treatment, diagnosis or prevention of serious conditions.

XEOMIN was approved by the FDA for adult patients with sialorrhea and is based on a Phase III, randomized, double-blind, placebo-controlled, multicenter 184 patient trial. Both co-primary endpoints were successfully achieved. A statistically significant improvement was observed in change in unstimulated salivary flow rate (uSFR) and Global Impression of Change Scale (GICS), both at week four as compared to baseline pre-injection for subjects administered 100 U incobotulinumtoxinA 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. Subjects enrolled in the study received placebo (n=36), incobotulinumtoxinA 75 U (n=74), or incobotulinumtoxinA 100 U (n=74).

This is the fourth neurological indication for XEOMIN, which was first approved by the FDA in 2010 for the treatment of cervical dystonia and blepharospasm (in patients previously treated with onabotulinumtoxinA) in adult patients and later in 2015 for upper limb spasticity in adult patients.

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 its U.S. product portfolio, please visit www.merzusa.com/neurosciences. For more information about Merz Neurosciences and its U.S. product portfolio, please visit www.merzusa.com.
About Merz North America, Inc.
Merz North America, Inc. 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. Privately-held, Merz North America is headquartered in Raleigh, North Carolina. To learn more about Merz North America, Inc., please visit www.merzusa.com.

About XEOMIN® (incobotulinumtoxinA)
XEOMIN® (incobotulinumtoxinA) is a prescription medicine that is injected into muscles or glands and used to treat adults with sialorrhea, 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® (incobotulinumtoxinA) 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 1-844-4MYMERZ

Uses
XEOMIN is a prescription medicine used in adults:
- that is injected into glands that make saliva and is used to treat long-lasting (chronic) drooling (sialorrhea).
- that is injected into muscles and used to:
  - treat increased muscle stiffness in the arm because of upper limb spasticity.
  - treat the abnormal head position and neck pain with cervical dystonia (CD) in adults
  - who have and have not had prior treatment with botulinum toxin.
  - treat abnormal spasm of the eyelids (blepharospasm) in adults who have had prior treatment with onabotulinumtoxinA (BOTOX®).

It is not known if XEOMIN is safe and effective in children under 18 years of age.

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
- 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 symptoms can happen hours to weeks after you receive an injection of XEOMIN. 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.

**Before receiving XEOMIN, tell your doctor about all of 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)
- 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 the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. **Talk to your doctor before you take any new medicines after you receive XEOMIN.**

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

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

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

Possible Side Effects
XEOMIN can cause serious side effects including:
See “Warnings.”

- Injury to the cornea (the clear front surface of the eye) in people treated for blepharospasm. People who receive XEOMIN to treat spasm of the eyelid may have reduced blinking that can cause a sore on their cornea or other problems of the cornea. Call your healthcare provider or get medical care right away if you have eye pain or irritation after treatment with XEOMIN.
- XEOMIN may cause other serious side effects including allergic reactions. Symptoms of an allergic reaction to XEOMIN may include: itching, rash, redness, swelling, wheezing, trouble breathing, or dizziness or feeling faint. Tell your doctor or get medical help right away if you get wheezing or trouble breathing, or if you get dizzy or faint.

The most common side effects of XEOMIN in people with chronic sialorrhea include:
- needing to have a tooth pulled.
- (extracted)
- dry mouth
- diarrhea
- high blood pressure

The most common side effects of XEOMIN in people with upper limb spasticity include:
- seizure
- nasal congestion, sore throat and runny nose
- dry mouth
- upper respiratory infection

The most common side effects of XEOMIN in people with cervical dystonia include:
- difficulty swallowing
- neck pain
- muscle weakness
- pain at the injection site
- muscle and bone pain

The most common side effects of XEOMIN in people with blepharospasm include:
- drooping of the eyelid
- dry eye
- dry mouth
- vision problems
- shortness of breath
- nasal congestion, sore throat, and
• diarrhea
• headache
• runny nose
• respiratory infection

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.

General information about the safe and effective use of XEOMIN
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or doctor for information about XEOMIN that is written for health professionals.

Active Ingredient: botulinum toxin type A
Inactive Ingredients: human albumin and sucrose

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

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