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## **Xeomin<sup>®</sup> (incobotulinumtoxinA) Receives European Approval for Treatment of Chronic Sialorrhea in Adults**

**First and only botulinum neurotoxin approved for this indication in Europe**

**Frankfurt, Germany – 29 May 2019** – Merz, a global leader in neurotoxin therapy, announced today the European approval of Xeomin<sup>®</sup> (incobotulinumtoxinA) for the symptomatic treatment of chronic sialorrhea (drooling) due to neurological disorders in adult patients.<sup>1</sup> Xeomin<sup>®</sup> is the first and only neurotoxin with this approved indication in the EU, which follows the US FDA approval in July 2018.<sup>2</sup>

“At Merz, we are committed to bringing more good days to patients living with severe neurological disorders,” stated Stefan Brinkmann, Managing Director and Region Head EMEA at Merz. “We are confident that this new treatment option can help improve quality of life for sialorrhea patients, as well as for their relatives and caregivers. In many European countries, an approved medication for sialorrhea treatment in adults has not been available before now.”

Sialorrhea is a common but undertreated symptom accompanying neurological conditions such as Parkinson's disease, acquired brain injury, amyotrophic lateral sclerosis (ALS), cerebral palsy (CP) or stroke. Patients who experience sialorrhea suffer from a negative impact on activities of daily living, as well as social stigma and impaired quality of life. Left untreated, sialorrhea could be associated with perioral skin breakdown and pain around the mouth, choking, speech disorder, dehydration and aspiration pneumonia.<sup>3</sup>

Xeomin<sup>®</sup> is the first and only neurotoxin with this approved indication in the EU. This is the fourth therapeutic indication for Xeomin<sup>®</sup>, which was first introduced in 2005 in Germany and was approved in 13 EU member states in 2007 for the treatment of cervical dystonia and blepharospasm in adult patients. In 2009, Xeomin<sup>®</sup> received approval for the treatment of upper limb spasticity in adult patients. Xeomin<sup>®</sup> is approved in 31 EU/EEA member states for the treatment of different neurological indications and is registered in more than 60 countries worldwide.

### **About the SIAXI Study**

The approval of Xeomin<sup>®</sup> for adult patients with sialorrhea by European authorities 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 ( $n=74$ ). More detailed information about the study results can be found [here](#).

<sup>1</sup> Product information Xeomin, May 2019

<sup>2</sup> [US Prescribing Information Xeomin](#), May 2019

<sup>3</sup> McGeachan AJ et al. Pract Neurol 2017, 17:96-103



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### **About Xeomin® (incobotulinumtoxinA)**

Xeomin® (incobotulinumtoxinA) is a purified neurotoxin type A (150kD) free from complexing proteins that prevents the release of the neurotransmitter acetylcholine from nerve endings at muscles and salivary glands. This prescription medicine is used intramuscularly to treat increased muscle stiffness, e.g. in the arm or shoulder of adults with upper limb spasticity, or abnormal head position that happens with cervical dystonia (spasmodic torticollis) in adults, and to treat abnormal spasm of the eyelids (blepharospasm). The mode of action is similar in salivary glands by reducing saliva production after injection thereby reducing the frequency and severity of sialorrhea. IncobotulinumtoxinA is a highly potent active ingredient. Safety instructions, warnings and typical side effects for this agent should be taken into consideration.<sup>1</sup>

### **About Merz**

Merz is a global, family-owned aesthetics and neurotoxin company based in Frankfurt, Germany. Privately-held for 110 years, the company is distinguished by its commitment to innovation, long-term perspective and focus on profitable growth. In addition to its comprehensive portfolio of medical aesthetics products across the device, injectable and skincare categories, Merz also develops neurotoxin therapy to treat neurologically-induced movement disorders. In fiscal year 2017/18, Merz generated revenue of EUR 1.024,4 million; the company has a total workforce of 3,151 employees worldwide and a direct presence in 28 countries. More information is available at [www.merz.com](http://www.merz.com).

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