Press Release – Pediatric Sialorrhea

XEOMIN® (incobotulinumtoxinA) Receives European Approval for the Treatment of Chronic Sialorrhea in Children

First and only botulinum neurotoxin approved for this indication in Europe

Frankfurt, 31st August 2021 – Today, Merz Therapeutics, a business of the Merz Group and a leader in the field of neurotoxins, has been granted the use of XEOMIN® for the symptomatic treatment in children and adolescents aged 2 to 17 years and weighing ≥ 12 kg of chronic sialorrhea due to neurological / neurodevelopmental disorders on EU level.[1] The national approvals of the country authorities involved will follow in the next weeks. The U.S. Food and Drug Administration granted approval in December 2020, and the Russian Federal Service for Surveillance in Healthcare in spring 2021.

Stefan Brinkmann, CEO Merz Therapeutics: "At Merz Therapeutics, we do everything to bring better outcomes to more patients. As XEOMIN® is already approved for the treatment of adult sialorrhea, we can now offer life-long treatment with our botulinum toxin A, staying a trusted partner for sialorrhea patients as well as their relatives and physicians for a lifetime."

Dr. Marcus Gollub, President, Head of Region Europe complements: "Pediatric sialorrhea is a serious condition that can significantly impact not only the medical condition but also the quality of life of the children and their families. I am happy that with this new indication we are able to take care of the needs of those children suffering from drooling and contribute to a better life for them and their families."

Sialorrhea, also known as drooling, is a symptom that occurs when excessive saliva accumulates in the mouth. It is a chronic impairment often seen in children with neurological disorders (e.g. cerebral palsy or traumatic brain injury) and/or intellectual disability or neurodegenerative diseases.

The approval by European authorities for the use of XEOMIN® for pediatric patients suffering from chronic sialorrhea, was achieved due to the convincing results of the SIPEXI study (**Si**alorrhea **Pe**diatric **X**eomin **I**nvestigation). It was a prospective, randomized, double-blind, placebo-controlled, multicenter phase III study with an extension phase evaluating the safety and efficacy of XEOMIN® in 255 children and adolescents aged 2 – 17 years up to 64 weeks. The study recently got published in *Neurology,* the premier peer-reviewed journal for clinical neurology research.[2]

XEOMIN® is being distributed by Merz Pharmaceuticals GmbH in more than 70 countries to treat patients with upper and lower limb spasticity, cervical dystonia, blepharospasm or hypersalivation. Merz uses state-of-the-art technology in its dedicated facility in Dessau, Germany, meeting the highest international standards for biologic manufacturing. The highly purified 150kDa neurotoxin is the only active ingredient in XEOMIN®. It is produced by removing complexing proteins from botulinum toxin type A, using XTRACT® purification technology developed by Merz Pharma GmbH & Co. KGaA.

[1] European SmPC (Summary of product characteristics), 2021-08-31

[2] Berweck et al. Neurology. 2021 Aug 2:10.1212/WNL.0000000000012573. doi: 10.1212/WNL.0000000000012573.

About Merz Therapeutics

Merz Therapeutics, a business of Merz Pharmaceuticals GmbH, is dedicated to improving the lives of patients around the world. With its relentless research, development, and culture of innovation, Merz Therapeutics strives to serve unmet patient needs and realize better outcomes. Merz Therapeutics seeks to address the unique needs of people who suffer from movement disorders, neurological conditions, liver disease, and other health conditions that severely impact patients' quality of life. Merz Therapeutics is headquartered in Frankfurt, Germany and is represented in more than 90 countries, with a North America affiliate based in Raleigh, North Carolina. Merz Pharmaceuticals GmbH is part of the Merz Group, a privately held, family-owned company that has dedicated more than 110 years to developing innovations that meet patient and customer needs.
Please visit www.merz.com

Press Contact
Agnes Tesch
Merz Therapeutics, a business of Merz Pharmaceuticals GmbH
Global Communications
+49 69 1503 2129
Agnes.tesch@merz.de