



## NEWS RELEASE

### **Teijin Receives Marketing Approval for Merz's Xeomin® Botulinum Toxin Type A in Japan**

**Frankfurt, Germany, June 29, 2020** --- Merz Pharmaceuticals GmbH, a leading neurotoxin company and subsidiary of Merz Pharma GmbH & Co. KGaA, and Teijin Pharma Limited, the core company of the Teijin Group's healthcare business, jointly announced today that Teijin Pharma has been granted approval by Japan's Ministry of Health, Labor and Welfare (MHLW) to market *Xeomin*® (incobotulinumtoxinA) for intramuscular injection in 50, 100 or 200 units for the treatment of upper limb spasticity.

*Xeomin*® is effective in treating peripheral cholinergic nerve endings by weakening the contraction of voluntary muscles, and it relieves muscle tone by inhibiting the release of a neurotransmitter called acetylcholine. The highly purified neurotoxin, the only active ingredient in *Xeomin*®, is made by removing complexing proteins from botulinum toxin type A, which is produced by *Clostridium botulinum*, using purification technology developed by Merz Pharma GmbH & Co. KGaA. The lack of complexing proteins enables *Xeomin*® to reduce the production of neutralizing antibodies capable of lowering efficacy.

*Xeomin*® is being distributed by Merz Pharmaceuticals GmbH in more than 70 countries to treat patients with upper limb spasticity, cervical dystonia, blepharospasm, or hypersalivation. Teijin Pharma signed an exclusive license and co-development agreement for *Xeomin*® in Japan with Merz Pharma GmbH & Co. KGaA in 2017. In August 2019, Teijin Pharma applied for marketing approval based on a significant improvement in the modified ashworth scale (MAS) score of the wrist flexion, which was observed in a phase-III clinical trial conducted by Merz in Japan.

Upper limb spasticity is a symptom of upper motor neuron syndrome, which is expressed mainly by increased muscle tone of upper limbs and the hyperexcitability of the stretch reflex as a sequela of stroke. The main symptoms are motor paralysis, hyperflexion, appearance of pathological reflexes, and sensory disturbances that complicate or impede activities in daily living.

Conventional treatment of upper limb spasticity includes physical rehabilitation and the use of oral muscle relaxants or neuromuscular blockers such as botulinum toxin type A. Injections of botulinum toxin type A are a Grade A recommendation in the Japanese Guidelines for the Management of Stroke 2015.

"At Merz Therapeutics, we do everything to bring better outcomes to more patients. Therefore, we are very proud of our partnership with Teijin to make *Xeomin*<sup>®</sup> available to physicians and patients in Japan," said Stefan Brinkmann, CEO Merz Therapeutics. "We are confident that this treatment option can help patients with upper limb spasticity in Japan to experience more good days and achieve their unique goals."

"Teijin Pharma already provides various pharmaceuticals and medical devices that help to contribute to improving quality of life of patients suffering from musculoskeletal diseases," said Ichiro Watanabe, president of Teijin Pharma Limited. "We, responding to demographic change and increased health consciousness, are launching effective new drugs and providing other solutions to realize more sustainable societies. Teijin Pharma continues to contribute to improving the quality of life (QOL) of patients by providing new treatment options for diseases with high unmet needs."

### About *Xeomin*<sup>®</sup>

Brand name	<i>Xeomin</i> <sup>®</sup> 50 units for intramuscular injection <i>Xeomin</i> <sup>®</sup> 100 units for intramuscular injection <i>Xeomin</i> <sup>®</sup> 200 units for intramuscular injection
Nonproprietary name	incobotulinumtoxinA
Dosage form	Injection (vial)
Indication	Upper limb spasticity
Dosage and administration	In general, for adults, <i>Xeomin</i> <sup>®</sup> should be injected into multiple tonic muscles.* The maximum dose per administration is 400 units, however, the dose should be appropriately reduced to the minimum depending on the type and number of targeted tonic muscles. Repeated doses are permissible if the effect of a previous dose diminish. The dosing interval should be 12 weeks or longer, but may be shortened to 10 weeks depending on the symptoms.  *Tonic muscles: flexor carpi radialis, flexor carpi ulnaris, flexor digitorum dorsi, flexor digitorum brevis, radial biceps, biceps brachii, brachial musculature, pronation of the pronator, flexor progenitor, flexor pollicis longus, adductor pollicis longus, flexor pollicis brevis/opposite thumb muscle, etc.

*Xeomin*<sup>®</sup> is the registered trademark of [Merz Pharma GmbH & Co. KGaA](#).

### 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](http://www.merz.com).

### **About the Teijin Group**

Teijin (TSE: 3401) is a technology-driven global group offering advanced solutions in the fields of environmental value; safety, security and disaster mitigation; and demographic change and increased health consciousness. Originally established as Japan's first rayon manufacturer in 1918, Teijin has evolved into a unique enterprise encompassing three core business domains: high-performance materials including aramid, carbon fibers and composites, and also resin and plastic processing, films, polyester fibers and products converting; healthcare including pharmaceuticals and home healthcare equipment for bone/joint, respiratory and cardiovascular/metabolic diseases, nursing care and pre-symptomatic healthcare; and IT including B2B solutions for medical, corporate and public systems as well as packaged software and B2C online services for digital entertainment. Deeply committed to its stakeholders, as expressed in the brand statement "Human Chemistry, Human Solutions," Teijin aims to be a company that supports the society of the future. The group comprises more than 170 companies and employs some 20,000 people across 20 countries worldwide. Teijin posted consolidated sales of JPY 853.7 billion (USD 8.0 billion) and total assets of JPY 1,004.2 billion (USD 9.4 billion) in the fiscal year that ended on March 31, 2020.

Please visit [www.teijin.com](http://www.teijin.com)

### **Press Contact**

Merz Therapeutics, a business of Merz Pharmaceuticals GmbH

Global Communications

+49 69 1503 1265

[Elisa.antz@merz.de](mailto:Elisa.antz@merz.de)