



Alternative Test Method for Botulinum Neurotoxin Now Approved in Europe

Frankfurt am Main, December 11, 2015 – The Bundesinstitut für Arzneimittel und Medizinprodukte, Germany’s drug regulatory authority, has approved the in vitro assay developed by Merz for establishing the potency and stability of its products, Xeomin and Bocouture, which both contain botulinum neurotoxin type A. As a result, the company can now largely abandon LD50 animal testing in Europe as well.

After receiving approval from the Food and Drug Administration (FDA), the U.S. regulatory authority, for the cell culture-based alternative test method in February of this year, Merz has obtained a positive response in November 2015 from the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), the FDA’s German counterpart. The BfArM and all the other drug regulatory authorities in the European Union have approved the alternative method for testing the Merz products containing botulinum neurotoxin type A throughout the EU.

“We are extremely pleased with the regulatory authorities’ decision. It represents an important milestone for our products, which are both of such strategic significance to us,” said Dr. Torsten Wagner, the Merz Pharma Board’s Vice President Global Technical Operations.

Well before receiving clearance for its botulinum toxin, Merz devoted considerable energy to producing an alternative to the LD50 animal test. The successful development of the new assay was preceded by considerable research work. To become a substitute for the test method previously approved by the drug regulatory authorities, the alternative assay must achieve a level of precision comparable to that of the LD50 bioassay. In the last year, extensive testing during what is known as the validation process has ensured just such comparability.

Merz is confident that it can stop using the LD50 assay for the release of botulinum neurotoxin type A entirely within a few years. Once the requisite approval has been obtained in all the other countries, all the potency measurements can then be performed using the cell culture-based alternative test method.

Merz’s Xeomin and Bocouture are used in treatments for neurologically induced movement disorders such as cervical dystonia (spasmodic torticollis), eyelid spasms (blepharospasms), and spasticity of the upper

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extremities after a stroke, as well as in minimally invasive aesthetic medicine.

About the Merz Pharma Group

Merz is a privately held pharmaceutical company based in Frankfurt, Germany, with 33 subsidiaries in European countries, North America, Latin America, and Asia-Pacific. The company is active in research, development, and distribution of innovative products in the areas of aesthetic medicine, dermatology and neurologically induced movement disorders.

In the Aesthetics segment Merz offers a balanced portfolio of products for minimally invasive treatments. With the dermal fillers Radiesse, Belotero, and Glytone and the botulinum neurotoxin Bocouture/Xeomin as well as the Neocutis line of anti-aging products, the company is a major player in the global aesthetics market. The company's offerings were supplemented by ultrasound-technology after the acquisition of Ulthera in mid 2014. For the treatment of neurologically induced movement disorders, Merz developed Xeomin, the first botulinum toxin that is free of complex proteins.

With its tetesept and Merz Spezial brands, Merz Consumer Care is the leading provider of OTC medication, dietary supplements and skincare products in the German-speaking countries.

The Merz Pharma Group employs 2,754 people worldwide. The Company generated revenue of EUR 1,157.0 million in fiscal year 2014/15 (previous year: EUR 994.0 million).

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