PRESS RELEASE

Merz Pharma GmbH & Co. KGaA
Global Corporate Communications
Katja Marx
Eckenheimer Landstrasse 100
60318 Frankfurt am Main
Phone +49 69 1503 1176
katja.marx@merz.de

www.merz.com

Merz Announces European Approval of Bocouture for the Treatment of Upper Facial Lines

Frankfurt am Main, March 17, 2016 – Merz Pharma Group today announced that Bocouture® has been approved by European regulatory authorities for the treatment of upper facial lines, including horizontal frown lines, lateral periorbital lines and glabellar frown lines. Bocouture is the only neurotoxin approved in Europe* for this combined upper facial lines indication.

"Merz is a global leader in the aesthetics space and is proud to be able to provide patients and physicians in Europe with the first and only aesthetic neurotoxin approved for combination treatment of upper facial lines," stated Philip Burchard, CEO of Merz Pharma Group. "This expanded indication for Bocouture in Europe is a result of our ongoing investments in research and development and our focus on meeting the needs of our aesthetic customers."

Recent market research[1] has indicated that the rejuvenation of upper facial lines is one of the most requested aesthetic procedures among both existing patients and those considering treatment. In clinical practice, many patients request combined treatment of upper facial lines in a single session to achieve optimal treatment outcomes.

"As the only neurotoxin treatment approved for the simultaneous treatment of upper facial lines, Bocouture supports physicians in their day to day practice and enables them to provide their patients with safe and effective treatments with confidence," said Can Gumus, Vice President of Global Marketing Aesthetics for Merz Pharmaceuticals. "We are very proud of the fact that, while Bocouture was not the first toxin to enter the European market, it is the first product to achieve this important milestone."

The approval of this novel treatment indication is based on the results of a pivotal randomized, double-blind, placebo-controlled Phase 3 study with 156 patients from France, Germany and United Kingdom receiving treatment of upper facial lines with Bocouture. Clinical trial data demonstrates that Bocouture has a favorable safety and efficacy profile in treating upper facial lines, both combined and separately, with treatment effects maintained for up to 4 months.

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[1] A market research study commissioned by Merz Aesthetics included 2899 aesthetic treatment patients and 2080 treatment considerers aged 18-64. The treated patient group comprised 2329 women and 570 men who have undergone cosmetic treatments, including dermal fillers and botulinum toxin. The respondents were from 10 countries around the world: Germany, France, United Kingdom, Russia, Australia, China, South Korea, Argentina, Brazil and Mexico.

* European regulatory authorities reached consensus on approvability of Bocouture® for the indication Upper Facial Lines in 15 countries of the European Union. After successful completion of the application procedure national approvals will now be granted by the member states.

Manadatory text/basic information: BOCOUTURE®

BOCOUTURE® 4 units/0.1 ml powder for solution for injection

Active substance: Botulinum toxin type A (150 kD), purified from Clostridium Botulinum cultures (Hall strain), free from complexing proteins. Prescription-only medicine!

Qualitative and quantitative composition: One vial contains: *5*0 units of Botulinum toxin type A (150 kD), free from complexing proteins, human albumin, sucrose. Due to the differences in the potency assays, unit doses are specific to BOCOUTURE®. Therefore the recommended dose units for BOCOUTURE® are not interchangeable with those for other Botulinum toxin preparations.

Therapeutic indications: For temporary improvement in the appearance of upper facial lines in adults below 65 years when the severity of these lines has an important psychological impact for the patient:

- moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar frown lines) and/or
- moderate to severe lateral periorbital lines seen at maximum smile (crow's feet lines) and/or
- moderate to severe horizontal forehead lines seen at maximum contraction.

Contraindications: Hypersensitivity to the active substance or to any of the excipients, generalised disorders of muscle activity (e.g. myasthenia gravis, Lambert-Eaton syndrome), infection or inflammation at the proposed injection site. Do not use during pregnancy unless clearly necessary. Do not use during breast-feeding.

Undesirable effects: Undesirable effects usually occur within the first week following injection and are temporary in nature. They may be related to the active substance, the injection procedure, or both. Application-related: Localised pain, inflammation, paraesthesia, hypoaesthesia, tenderness, swelling, oedema, erythema, itching, localised infection, haematoma, bleeding and/or bruising. Caused by the injection procedure: Pain and/or anxiety may lead to vasovagal responses such as transient symptomatic hypotension, nausea, tinnitus, and syncope. Undesirable effects of the substance class Botulinum toxin type A: Localised muscle weakness, blepharoptosis (possibly caused by the injection technique) are an expression of the pharmacological effect. Toxin spread: When treating other indications with Botulinum toxins, undesirable effects related to spread of the toxin distant from the site of administration have been reported very rarely (exaggerated muscle weakness, dysphagia, and aspiration pneumonia with a fatal outcome in some cases). These cannot be completely ruled out with the use of BOCOUTURE®. Hypersensitivity reactions: Rare reports of severe and/or immediate hypersensitivity reactions such as anaphylaxis, serum sickness, urticaria, soft tissue oedema, and dyspnoea, sometimes either following the administration of conventional Botulinum toxin type A complex preparations alone or in combination with other active substances known to cause similar reactions.

The following undesirable effects were reported from clinical experience with BOCOUTURE®:

Vertical lines between the eyebrows seen at maximum frown (glabellar frown lines)

Common (≥1/100 to <1/10): headache, muscle disorders (elevation of eyebrow); *Uncommon (≥1/1,000 to <1/100):* Bronchitis, nasopharyngitis, influenza-like illness, depression, insomnia, facial paresis (brow ptosis), eyelid oedema, eyelid ptosis, blurred vision, pruritus, skin nodule, muscle twitching, muscle spasm, sensation of heaviness, injection site: haematoma, pain, tenderness, fatigue.

Lateral periorbital lines seen at maximum smile (crow's feet lines)

Common (≥1/100 to <1/10): Eyelid oedema, dry eye, injection site: haematoma.

Upper facial lines:

Very common *(≥1/10):headache; Common (≥1/100 to <1/10):hypoaesthesia , eyelid ptosis, dry eye, facial asymmetry, sensation of heaviness, nausea, injection site: haematoma, pain.*

Post-marketing experience: Flu-like symptoms and hypersensitivity reactions such as swelling, oedema (also apart from the injection site), erythema, pruritus, rash (local and generalized), and breathlessness have been reported.

Merz Pharmaceuticals GmbH, 60048 Frankfurt/Main, Germany. <Phone: +49 69 1503-1>.

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Further information is provided in the Summary of Product Characteristics and the Package Leaflet.

PLEASE CHECK YOUR LOCAL APPROVAL STATUS

About the Merz Pharma Group

Merz is a privately held pharmaceutical company based in Frankfurt, Germany, with 36 subsidiaries in Europe, 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 an ultrasound technology for non-invasive skin tightening and rejuvenation 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).

Corporate Contact:

Merz Pharma GmbH & Co. KGaA
Head of Global Corporate Communications
Katja Marx
Eckenheimer Landstrasse 100
60318 Frankfurt am Main
Phone +49 69 1503 1176
Email: katja.marx@merz.de