



Croma-Pharma announces submission for their botulinum toxin to treat glabellar (frown) lines to the German authority BfArM

On July the 8th 2020, Croma-Pharma GmbH (Croma) has stated that the company submitted the drug file of its botulinum toxin product to the German authority BfArM. The filing of the dossier stands for the next essential step towards Croma's complete aesthetic portfolio in Europe, which already comprises of a comprehensive HA filler range, threads, PRP and skincare products.

Croma has licensed the product from the Korean toxin producer Hugel Inc. for Europe and established a joint venture company in 2018 with Hugel, Inc., in order to develop and commercialize Croma's HA filler products together with Hugel's botulinum toxin product in the US, Canada, Australia and New Zealand.

The filing to BfArM marks the first milestone in Croma's approach to a European wide regulatory approval.

"We are pleased to announce that our toxin has finally been submitted – since quite some time hence, a European company will launch a botulinum toxin, which makes us both, happy and proud. Combining our present product and service offering with the last "missing link" will definitely boost our business and will have a feelable impact not only on our marketing and sales approach, but for sure also on our corporate culture.", CEO Andreas Prinz points out in a first statement.

Croma's botulinum toxin submission in Europe is based on 2 completed randomized, placebo-controlled Phase III pivotal trials (BLESS I and II) that enrolled a total of 917 subjects in Europe and the US. A third confirmatory pivotal trial to support the US submission (BLESS III) is currently ongoing in sites in Europe and the US and has completed its interim analysis after all 355 patients completed their visits for the primary endpoint.

About Croma-Pharma GmbH

Founded in 1976, Croma-Pharma GmbH (Croma) is an Austrian family-owned company that specializes in the industrial production of hyaluronic acid syringes for the fields of medical aesthetics, ophthalmology and orthopaedics. Croma currently runs 12 international sales companies and distributes its products in more than 70 countries. Within its global sales network, Croma focuses with own branded products on minimally invasive aesthetic medicine. Besides a broad range of HA fillers from the own production site, Croma markets PDO lifting threads, a Platelet Rich Plasma (PRP) system and a personalized skincare technology in its core strategic markets.

About Hugel, Inc:

Established in Korea in 2001, Hugel is a global leader in medical aesthetics providing botulinum toxin formulation BOTULAX / LETYBO, HA filler The CHAEUM / DERMALAX,

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and derma cosmetic WELLAGE / PR4 brands. Dedicated to provide proven, high quality medical aesthetic solutions that satisfy both consumers' and practitioners' needs, Hugel is leading Korean market for both botulinum toxin and HA filler products and is distributing its products to over 40 countries. Visit: www.hugel.co.kr

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