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Press Release

AMWC 2023: Croma-Pharma to present recent clinical data and new range of skin boosters

Vienna/Leobendorf, 15 March 2023 At the AMWC (Aesthetic & Anti-aging Medicine World Congress) 2023, Croma will share recent clinical data, present its new range of polynucleotide-based skin boosters and offer interactive Q&A sessions for healthcare professionals. The 21st AMWC Congress will be held in Monaco from March 30 to April 1, 2023.

This year, Croma will present data from a recent phase III clinical trial [3,**,] which evaluated the efficacy of its botulinum toxin (letibotulinumtoxinA) in mitigating the negative psychological impact associated with glabellar lines and assessed the patients' satisfaction with their treatment outcome.[2] A symposium for healthcare professionals will focus on the psychological impact of facial expressions and quality of life aspects associated with the treatment with letibotulinumtoxinA. Croma-Pharma launched its botulinum toxin (letibotulinumtoxinA) [1,*] in its 11 core markets in Europe in 2022, adding the missing piece to its comprehensive minimally invasive aesthetics portfolio of hyaluronic acid (HA) fillers, PDO threads, biostimulators and skincare.

Also at the AMWC, Croma will present its new range of polynucleotide-based skin boosters. With the launch of PhilArt, a complete series of injectable skin boosters, Croma further broadens its portfolio. PhilArt is a key pillar of a minimally invasive aesthetics portfolio, and also enables combination therapies and a full-face approach. At a symposium for medical professionals, they will learn about the role of polyonucleotides in holistic aesthetic treatments.

'With our continued presence at the AMWC we want to underline our valued partnership with healthcare professionals from around the globe. Our priority is to support our customers not only with reliable and effective treatments, but also with new treatment options for a holistic aesthetic approach for the benefit of their patients', says Andreas Prinz, CEO of Croma Pharma.

Croma symposia at the AMWC:

Empower your patients: The psychological impact of facial expressions and how letibotulinumtoxinA improves your patient's quality of life
Prof. Margalit Liraz, PhD
Prof. Syed E. Haq & Dr. Beatriz Molina
Thursday, March 30th
Time: 3pm-4pm

PhilArt line of skinboosters
A new era in aesthetic medicine: Polynucleotides for radiant & rejuvenated skin
Prof. Syed E. Haq & Dr. Alexandra Ogilvie & Dr. Konstantin Frank
Friday, March 31st
Time: 2pm-4pm

Croma (Croma-Pharma® GmbH) is a global player in the minimally invasive aesthetics market and a leading European manufacturer of premium quality hyaluronic acid syringes. The company offers a comprehensive and innovative aesthetics portfolio including botulinum toxin, fillers, PDO lifting threads and biostimulators complemented by its own skincare brand.

About Croma:

Croma is a global player in the minimally invasive aesthetics market and a leading European manufacturer of premium quality hyaluronic acid syringes. The company offers a comprehensive and innovative aesthetics portfolio including botulinum toxin, fillers, lifting threads and biostimulators, complemented by its own skincare brand. Founded in 1976 by a pharmacist couple, Croma-Pharma GmbH is a family company headquartered in Austria where it also operates its manufacturing plant. With 550 employees, 13 subsidiaries in Europe and Brazil, two joint ventures and 60 exclusive export partners, it distributes its products in 80 markets globally, including the US/Canada, China and Australia/New Zealand. It also operates as a contract manufacturer in orthopaedics and ophthalmology. For more information, please visit croma.at

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References:

1 Letybo® SmPC, March 2022

2 Cox, SE; Adelglass, J; Gold, M; Joely-Kaufman, J; Mueller, D; Nestor, M; Taylor, S: LetibotulinumtoxinA Attenuated the Psychological Burden of Glabellar Lines and was Associated with High Subject Satisfaction: Results from a Phase 3 Clinical Trial. Abstract ASDS 2022 Annual Meeting

3 Mueller DS, Prinz V, Adelglass J, Cox SE, Gold M, Kaufman-Janette J et al. Efficacy and Safety of Letibotulinum Toxin A in the Treatment of Glabellar Lines: A Randomized, Double-blind, Multicenter, Placebo-controlled Phase 3 Study. Aesthet Surg J. 2022; 42(6): 677- 88

* Letybo® is indicated for the temporary improvement of the appearance of moderate to severe vertical lines between the eyebrows in adults < 75 years old seen at maximum frown (glabellar lines), when the severity of the facial lines has an important psychological impact.

** The prospective, randomized, double-blind, placebo-controlled, multicenter phase III clinical trial (N=355) evaluated the safety and efficacy of letibotulinumtoxinA (20U) in the treatment of moderate to severe glabellar lines. Baseline and post-treatment assessments were performed using the following validated subject-administered instruments: Modified Skindex-16 GL-QoL Scale; FACE-Q Appraisal of Lines Between Eyebrows Scale; FACE-Q Age Appraisal VAS Scale; and FACE-Q Satisfaction with Outcome Scale.

Letybo 50 units powder for solution for injection. Abbreviated Prescribing Information. Please refer to the Summary of Product Characteristics (SmPC) before prescribing. Presentation: One vial contains 50 units botulinum toxin type A produced by Clostridium botulinum. After reconstitution each 0.1 mL of the solution contains 4 units. Indication: For the temporary improvement in the appearance of moderate to severe vertical lines between the eyebrows in adults <75 years old seen at maximum frown (glabellar lines), when the severity of the facial lines has an important psychological impact. Dosage and administration: Should only be admin- istered by physicians with expertise in this treatment. Posology: The recommended dose is a total of 20 units divided into five injections of 4 units (0.1 mL) each: 2 injections in each corrugator supercilii muscle and 1 injection in the procerus muscle. Botulinum toxin units are not interchangeable from one product to another. Doses recommended are different from other botulinum toxin preparations. Treatment interval should not be more frequent than every three months. In the absence of any un- desirable effects secondary to the previous treatment session, a further treatment session with at least a three-month interval between the treatment sessions is possible. In case of treatment failure one month after a previous treatment session, i.e., in the absence of significant improvement from baseline, the following approaches may be considered; analysis of the causes of failure, (incorrect muscles injected, injection technique, formation of toxin neutralising antibodies, insufficient dose, re-evaluation of the relevance of treatment with botulinum toxin type A). The efficacy and safety of repeat injections beyond 12 months has not been evaluated. Special populations: No specific dose adjustment is required for use in the elderly older than 65 years of age. There is no relevant use in the paediatric population. Method of administra- tion: Intramuscular use. Refer to SmPC for dose instructions. Care should be taken to ensure not injected into a blood vessel. Contraindications: Hypersensitivity to the active substance or to any of the excipients. Generalised disorders of muscle activity (e.g. myasthenia gravis, Lambert-Eaton syndrome, amyotrophic lateral sclerosis). Presence of acute infection or inflammation at the proposed injection sites. Warnings and Precautions: The anatomy of muscles and the surrounding vascular and nervous structures in the glabellar region, and any alterations due to prior surgical procedures, must be understood prior to administering. Injection into vulnerable anatomic structures must be avoided. Caution in use when the muscle shows excessive weakness or atrophy. Risk of eyelid ptosis following treatment. Procedure-related events: Needle-related pain and/or anxiety have resulted in vasovagal responses, including transient symptomatic hypotension and syncope after treatment with other botulinum toxins. Pre-existing neuromuscular disorders: Patients with unrecognised neuromuscular disorders may be at increased risk of clinically significant systemic effects including severe dysphagia and respiratory compromise from typical doses of botulinum toxin type A. Hypersensitivity reactions: An anaphylactic reaction may occur after injection of botulinum toxin. Epinephrine (adrenaline) or any other anti-anaphylactic measures should therefore be available. Local or distant spread of toxin effects: Adverse reactions possibly related to the spread of toxin distant from the site of administration have been reported. Patients may experience exaggerated muscle weakness. Swallowing and breathing difficulties are serious and can result in death. Use not recommended in patients with a history of dysphagia and aspiration. Patients should be advised to seek immediate medical care if swallowing, speech or respiratory disorders arise. Antibody formation: Too frequent or excessive dosing may enhance the risk of antibody formation. Antibody formation may lead to treatment failure of botulinum toxin type A. Bleeding disorders: Caution in patients with bleeding disorders. Injection may lead to bruising. Pregnancy & Lactation: Not recommended during pregnancy and in women of childbearing potential not using contraception. The use of Letybo during breast-feeding is not recommended. Traceability: The name and the batch number of the administered product should be clearly recorded. Undesirable effects: Most common effects are headache and injection site reaction. For full list of side effects, consult SmPC. Legal Category: POM Croma-Pharma GmbH, Industriezeile 6, 2100 Leobendorf, Austria. Date of preparation: February 2022

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