

Press Release

Letybo® receives FDA Approval for the treatment of glabellar lines

Leobendorf, 29th February 2024 – Croma-Pharma announced today that Hugel, Korean toxin manufacturer and partner of Croma, has received approval of the U.S. Food and Drug Administration (FDA) for Letybo® (letibotulinumtoxinA), the company's botulinum toxin product. Letybo® has secured FDA approval, positioning it as the sixth botulinum toxin achieving this milestone globally. This accomplishment leads to further product credibility and instills confidence among healthcare providers. Hugel will be one of only three global players that possesses licenses in the largest aesthetic markets US, Europe and China.

LetibotulinumtoxinA is the number one neurotoxin in South Korea, one of the world's leading aesthetic markets¹. Croma holds the licensing rights for letibotulinumtoxinA from Hugel Inc. for Europe and is therefore one of five suppliers in Europe to have botulinum toxin in its product portfolio. With the phased launches of Letybo® in Europe Croma has significantly enhanced its broad, minimally invasive aesthetics range of hyaluronic acid (HA) fillers, PDO threads, biostimulators and its complementary skincare.

The latest approval was granted for Slovenia on the 15th of February 2024, with this latest registration Letybo® is registered in 33 European markets. The product is characterized by a convincing 94% response rate four weeks after injection*² and a proven consistent efficacy and safety also with repeated injections^{2,3}.

'The FDA approval of Letybo® represents a significant milestone in the product's worldwide reach. It adds a layer of credibility globally, demonstrating a commitment to meeting rigorous standards recognized by one of the world's leading regulatory authorities', commented Andreas Prinz, CEO. 'The FDA approval is expected to further accelerate our growth. We congratulate our partner Hugel on this key accomplishment.'

About Croma

Croma-Pharma® 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 the pharmacist couple Prinz, 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 cromapharma.com.

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References:

1 Data on file

2 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

3 Letybo® SmPC

*Response rate was defined as a \geq 1-point reduction in FWS at maximum frown based on the investigators assessment

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