Press release

Croma-Pharma announces enrollment of first patient in hyaluronic acid dermal filler clinical trial in China

Leobendorf, Vienna, 12 June 2023. Croma-Pharma® ('Croma') announced today that in June the first patient will be enrolled in the clinical trial[1] for the approval of its hyaluronic acid dermal filler Princess® Volume Plus Lidocaine[2] in China.

The randomised, multi-centre, evaluator blinded, parallel group, active controlled Phase 3 trial[1] is being led by Lanhzou Biotechnique Development with the intention to confirm the efficacy and safety of Princess® Volume Plus Lidocaine in respect of mid-facial volume insufficiency and/or mid-facial profile deficient participants. The trial is organised and executed by the clinical research organisation Beijing World-Clinical Research Biotechnology Development; the plan is to enroll 15 clinical centres and approximately 600 patients targeting mid-facial augmentation.

Lanhzou Biotechnique Development is an affiliate of China National Biotech Group (CNBG), a subsidiary of Sinopharm, with whom Croma-Pharma has established a joint venture in China. The aim of the joint venture company, named International Aesthetic Biotech, is to market and distribute products from Croma-Pharma's aesthetic portfolio, e.g. hyaluronic acid dermal fillers, and Lanzhou Biotechnique Development's botulinum toxin in China and Hong Kong, covering synergistic medical aesthetic indications.

The dermal filler market in the Asia-Pacific (APAC) region is estimated to be around 1.4 billion USD in size and to have seen an average growth of around 17 percent annually[3] over the past years, leading to an increasing demand for safe, high-quality products.

'Asia, and China in particular, represent the fastest growing aesthetic medicine markets worldwide. The Chinese market is therefore an important pillar of our expansion strategy and this clinical trial positions us to enter China as one of only three companies with a full portfolio in this market. We are glad to have partnered with CNBG, a strong and significant player, to drive the growth of our complementing medical aesthetic portfolios in China and Hong Kong', comments Andreas Prinz, CEO of Croma-Pharma®.

The Princess® HA filler range comprises Princess® Rich (non-lidocaine), Princess® Filler, Princess® Volume (lidocaine and non-lidocaine types) and Princess® Volume Plus (lidocaine). The products target the individual needs of patients. Princess® Volume is already registered in China and Hong Kong.

References:

1) A randomized, multi-center, evaluator-blinded, parallel assignment, active controlled study to evaluate the efficacy and safety of Princess Voluma Plus and Restylane Perlane Lidocaine for correction of Midface Volume Deficit and/or Midface Contour Deficiency. Source: Lanzhou Biotechnology Development Co. Ltd.: Record Sheet of Clinical Trial of Medical Device
2) Princess® Volume Plus Lidocaine is planned to be indicated for the correction of midface volume deficit and/or midface contour deficiency. Source: Clinical trial synopsis.
3) Medical Insights Dermal Fillers Market Study. February 2022.

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, Australia and New Zealand. It also operates as a contract manufacturer in orthopaedics and ophthalmology. For more information please visit croma.at.

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