Viscofan BioEngineering submits Master File documentation (MAF) for medical grade Viscolma® collagen suspension

Technical documentation facilitates FDA-compliant product developments

Weinheim, July 07, 2021 *– Viscofan BioEngineering, the business unit for biomedical research and development of Naturin Viscofan GmbH has submitted Master File documentation (MAF) for Viscolma® collagen suspension to The Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA).*

The FDA has established the master file system to facilitate sound scientific evaluation of medical device developments that require another party's product. MAF documents enable the review of data and other information by preserving the trade secrets of the external product.

As Lluis Quintana, Corporate Director of Viscofan BioEngineering states: "The MAF will ensure our U.S.-collaborators needing medical grade collagen suspension that Viscofan BioEngineering will work directly with the FDA for compliance. They can now use MAF for their technical documentation on Viscolma® to facilitate FDA-applications."

Medical grade Viscolma® is a suspension of ultrapure collagen type I fibers extracted from bovine skin in a highly standardized industrial process under ISO 13485 certified quality management. The insoluble collagen fibers retain their highly native structure and represent a natural 3D-scaffold for cells, promoting attachment, growth and differentiation. The putty-like Viscolma® contains up to 15% collagen in water and exhibits excellent biocompatibility and biodegradability.

The unique features of this natural collagen suspension enable broad medical use, such as the development of products and therapies in regenerative medicine, tissue engineering, medical device technology, implantology, ATMPs (Advanced Therapy Medicinal Products), or as bioink in 3D bioprinting.

Viscolma® is also the raw material for all of Viscofan BioEngineering's collagen membranes and together with partners, the company is developing its own innovative pipeline, currently having several products in preclinical and clinical testing. Lluis Quintana is looking ahead: "We intend to expand collaborations to enable breakthroughs in medical engineering and regenerative medicine."

About Viscofan BioEngineering

Viscofan BioEngineering is the biotech business unit of Naturin Viscofan GmbH – a company of the Viscofan group. We apply partly proprietary technologies and standardized extraction methods to process collagen from bovine skin for the development and industrial-scale production of novel collagen biomatrices in research and medical grade. The combination of premium products with an exceptional scientific support positions Viscofan BioEngineering at the forefront of regenerative medicine. The comprehensive portfolio is based on collagen membranes, suspension, and solutions to serve cell biology and biomedical markets. The products are suitable for a broad range of novel applications, such as innovative tissue engineering, new surgical procedures, advanced medical devices, or 3D bioprinting. Together with its partners, Viscofan BioEngineering is also developing its own pipeline of products for regenerative medicine.

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Medical grade Viscolma® collagen suspension is the basis for biomedical product developments in regenerative medicine, tissue engineering, medical device technology, or 3D bioprinting.