

## **Phase-I-trial approved for novel stem cell therapy for patients with ischemic cardiomyopathy**

### ***Viscofan BioEngineering advances collagenous carrier material as their first medical product to clinical development***

*Weinheim, Germany, July 04, 2018 – Viscofan BioEngineering, the biomedical business unit of the world market leader for collagenous sausage casings Viscofan announced today that the Spanish Agency for Medicines (AEMPS) has given green light to carry out a clinical phase-I-trial with Viscofan BioEngineering's first product for regenerative medicine. The novel therapy consisting of stem cells on a collagenous carrier membrane can now be tested on ten patients suffering from severe cardiac insufficiency.*

Ischemic cardiomyopathy typically occurs as a consequence of heart infarction and is the leading cause of death in the developed world, representing 33% of deaths of patients above 35 years. The chronic weakening of the heart muscle caused by scarring and dilation of parts of the ventricle severely decreases quality of life of patients. Moreover, it also has considerable economic consequences for the public healthcare system, consuming approximately 54% of the total cost for public healthcare in the EU in 2012.

Despite the urgent need and extensive investments of the pharmaceutical industry there is no successful treatment available yet. In spite of high expectations, cell therapies tested so far produced inconclusive results. "High cell mortality rates after implantation are apparently the main reason for failure to show consistent efficacy in existing clinical trials", states Dr. Felipe Prosper from the University Clinic of Navarra and director of the scientific group that developed the concept behind the new implant.

An interdisciplinary team of industry, universities and hospitals cooperates since 2016 in the "Cardiomesh" project that is funded by the Spanish Ministry to develop a novel, improved cell therapy. The product VB-C01, classified as an "Advanced Therapy Medicinal Product", is composed of an elastic collagen membrane combined with stem cells derived from fat tissue. "The product developed by Viscofan BioEngineering is pioneer in using a robust, nature-like and biodegradable support to deliver the cells to the heart" says Dr. Fernández-Avilés, Hospital Gregorio Marañón, Principal Investigator in this clinical trial. "In contrast to existing approaches where cells are injected into the heart tissue, the cells previously attach to the collagen matrix and form a robust cell-matrix association that is then sutured directly to the site of the damaged tissue. This enhances cell survival and their local-specific efficacy and resulted in enhanced elasticity and vascularization of the affected heart tissue in preclinical tests. Consequently and most importantly, also heart functionality was significantly improved."

“We are excited about bringing our first medicinal product into the clinic after decades of R&D efforts. This is a very important milestone for Viscofan in the development of its biomedical division”, says Dr. Lluís Quintana, Corporate Manager of Viscofan BioEngineering and coordinator of the Cardiomesh project. “This project is of particular significance because of the tremendous need cardiomyopathy patients have and because of the excellence of the clinical partners that are involved in this international initiative.”

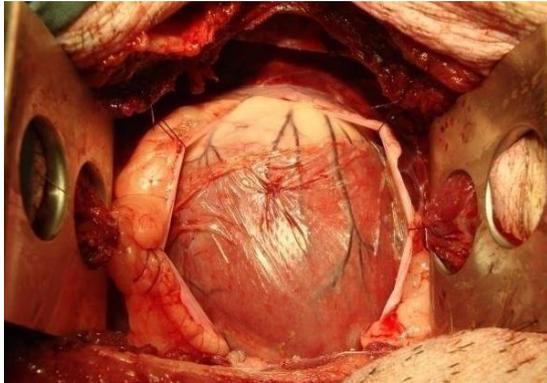
The official approval paves the way for the selection of appropriate patients. Treatment of the first patient is expected to start after summer.

### **About Viscofan BioEngineering**

*Viscofan BioEngineering is the biomedical business unit of Naturin Viscofan GmbH – the centre of excellence for collagen within the Viscofan group. With a background of 85 years of experience in production and processing of bovine dermal collagen at industrial scale, the company's activities are focused on the development and manufacturing of unique collagen products for cell biology research, biomedical development and the health food industry. With proprietary technologies Viscofan BioEngineering specializes in the extraction of strong, gently prepared and ultrapure collagen type-I fibers and processes them to highly biocompatible scaffolds with unique properties. The comprehensive portfolio is based on collagen membranes, suspension, solutions and hydrolysate suitable for a broad range of novel applications, such as innovative tissue engineering, new surgical procedures, advanced medical devices or improved nutraceuticals. Together with its partners, Viscofan BioEngineering is also developing its own pipeline of products for regenerative medicine.*

### **CONTACT**

Dr. Lluís Quintana  
Corporate Manager, Viscofan BioEngineering  
Tel.: +49 (0)6201 / 86-236  
quintana@bio.viscofan.com  
www.viscofan-bioengineering.com



*Advanced therapy of heart failure after infarct: Stem cells are grown on a collagen membrane and then sutured to the damaged heart tissue.*

*Image: Courtesy of Dr. Felipe Prosper, University Clinic of Navarra/Spain (Arana M et al., Biomaterials 35 (2014), 143-151)*



*The collagen membrane „Collagen Cell Carrier“ is thin, elastic, yet robust and biocompatible.*

*Image: ©Viscofan BioEngineering, 2018*



*Collagen membranes in medical quality are produced in cleanrooms at Viscofan's German plant in Weinheim.*

*Image: ©Viscofan BioEngineering, 2018*