

RHEACELL GmbH & Co. KG · Im Neuenheimer Feld 517 · D-69120 Heidelberg

## Press Release

### **From chronic to curable? RHEACELL is developing a novel cell-therapy agent for the treatment of chronic venous ulcers.**

Heidelberg-based biopharmaceutical company is conducting a follow-up study with highly purified stem cells (AMESANAR<sup>®</sup>) for the treatment of previously incurable chronic ulcers.

Heidelberg, 19. October 2021 – More than 80,000 people in Germany suffer from chronic venous ulcers (CVU). Triggered by venous insufficiency, wounds and weeping ulcers can develop that may not heal for years. Severely affected patients experience intense pain every day. Until now, there has been no effective treatment – but this could change soon.

A first successfully completed clinical trial (JID Innovations, ahead of print) with a limited number of patients confirmed the safety of the stem-cell agent. Initial data also showed the therapy to be effective. Germany's Federal Institute for Vaccines and Biomedicines (Paul-Ehrlich-Institut) has now approved a follow-up study to investigate the efficacy in a large-scale population. The first patient in this follow-up study has already been treated.

In addition, the company recently received the national marketing authorization (§ 4b German Medicinal Products Act) for the treatment of these patients with AMESANAR<sup>®</sup>. This means that a much larger group of patients can finally be helped.

“These approvals are not only of great significance for those affected, but they are also an important milestone for a new product class in a relatively young research area.” says Dr. Ganss, physician and CEO of RHEACELL.”

Stem-cell-based therapies are becoming increasingly important, especially in incurable diseases. These approvals by Germany's Federal Institute for Vaccines and Biomedicines (Paul-Ehrlich-Institut) are a clear signal of support for the development of cell-based drugs.

RHEACELL is a pioneer in stem-cell-based drug development. In addition to non-healing chronic venous wounds and non-healing diabetic foot wounds, its research focuses on serious and rare diseases such as epidermolysis bullosa (butterfly disease) which mainly affects children.

It's goal is to advance medical progress while maintaining the highest quality and safety standards in order to help people for whom there was previously no hope of a cure.

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Ust -IdNR.: DE 287172027

CVUs occur as a result of insufficient venous return in the lower extremities predominantly caused by venous reflux or obstruction of the leg veins. Increased venous pressure causes impaired microcirculation which, through a cascade of pathophysiological events, eventually leads to tissue breakdown and the development of painful wounds. Until now, there is no conclusive evidence that dressings, topical or systemic agents are effective in promoting the healing of venous ulcers. For severely affected patients, surgery to remove the cause of the increased venous pressure is often the only remaining option.

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#### **RHEACELL GmbH & Co. KG**

RHEACELL is dedicated to drug development based on anti-inflammatory ABCB5-positive mesenchymal stem cells. A key component of RHEACELL's research program is developing new and innovative therapy approaches and testing them in clinical trials. The aim is that patients have new therapy options for previously untreatable or insufficiently treatable diseases.

RHEACELL is the world-wide exclusive licensee for all patents surrounding ABCB5 held by Boston Children's Hospital, a teaching affiliate of Harvard Medical School, Boston, Massachusetts. Dr. Markus Frank, Associate Professor of Pediatrics and Dermatology, Harvard Medical School and discoverer and leading expert on ABCB5, is acting as a scientific adviser to RHEACELL.

RHEACELL is conducting several national and international multicenter clinical trials. RHEACELL holds orphan drug designation through the European Medicines Agency (EMA) and the United States Federal Drug Administration (FDA) for the treatment of epidermolysis bullosa (EB) and limbal stem cell deficiency (LSCD). RHEACELL has also received the "Fast Track Status" for treatment of LSCD from the FDA. The EMA's PDCO has also approved the pediatric investigation plan for RHEACELL's Epidermolysis Bullosa program.

RHEACELL GmbH & Co. KG is a joint venture between Müller Holding (Ulm, Germany) and TICEBA GmbH (Heidelberg, Germany). RHEACELL's development program is supported by Müller and by TICEBA's know-how.

TICEBA - the parent company of RHEACELL – is pioneering the production of ABCB5-positive (ABCB5+) mesenchymal stem cells in accordance with the highest pharmaceutical quality standards – the AMG: German Medicinal Products Act - with more than 15 years of expertise in the field of advanced stem cell research and regenerative medicine - paving the way to the patient for its innovative stem cell therapeutics (ATMP).

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