Press Release

Chronic Venous Ulcers: Stem cell therapy improves non-healing wounds.

Heidelberg-based biopharmaceutical company demonstrates efficacy and safety of ABCB5-positive stem cells in CVU patients in clinical phase IIa trial.

Heidelberg, September 8, 2020 – Approx. 1% of Germany's adult population suffers from chronic wounds, i.e. skin lesions that do not heal within 8 weeks. The number of patients affected is anticipated to rise, because of increasing incidence of underlying diseases. Chronic venous ulcer disease (CVU) accounts for the majority of chronic wounds. CVU occurs due to malfunctioning venous valves of the lower extremities. In this disorder, blood stagnates in the ankle regions and, as a result, damages surrounding tissues. CVU are frequently very painful. Current conservative treatment strategies such as pressure wound dressings are often unsuccessful. Surgery is often the last hope for severely affected patients.

The current news is therefore encouraging: In a regulatory agency-approved Phase IIa clinical study, RHEACELL, a company specializing in stem cell therapies, was able to accrue safety and initial efficacy data for ABCB5-positive mesenchymal stem cells (ABCB5+ MSCs) in the treatment of CVU.

This study demonstrated successfully that topically applied, highly purified ABCB5+ MSCs modulated the patient's immune system to promote wound healing. In approximately 70 percent of patients, chronic venous ulcers decreased on average by 82 percent in size and even complete wound closures were observed.

The starting material for generating ABCB5+ MSCs in high numbers is allogeneic human donor skin. These stem cells are manufactured by TICEBA GmbH, Heidelberg, in a patented process. Using this method, highly purified stem cells can be manufactured in large numbers, reliably isolated and finally produced as a highly purified, homogeneous drug substance [highly functional manufactured stem cells (H.F.M stem cells)]. These ABCB5+ MSCSs are classified by the European Medicines Agency (EMA) as an Advanced Therapy Medicinal Product (ATMP) which is manufactured under good manufacturing practice (GMP) in accordance with §13 paragraph 1 of the German Medicinal Products Act (AMG).

This multicenter clinical trial was conducted in Germany. Following demonstration of efficacy and safety of the ATMP, the data obtained will be used for further clinical development of the drug. The next phase clinical trial development is currently in preparation.

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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.

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 Holding with an investment of 60 million Euro and by TICEBA GmbH's scientific, technical and regulatory know-how.

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