Press Release

Stem cell therapy for Diabetic Foot Ulcer: Positive clinical study results.

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

Heidelberg, August 25, 2020 – Up to 20 percent of diabetic patients develop a diabetic foot syndrome in the course of their disease. This includes diabetic foot ulcer (DFU) disease as one of the most serious complications, characterized by chronic non-healing lower extremity wounds with constant risk of bacterial infection. In particularly severe cases, foot amputation may be required. In Germany alone, approximately 45,000 patients per year are affected. RHEACELL, a Heidelberg-based biopharmaceutical company, has now shown in a recently completed, Paul-Ehrlich-Institute (PEI)-approved Phase IIa clinical trial that allogeneic stem cell therapy can promote wound healing in afflicted patients.

In this clinical trial, patients with diabetic foot ulcers resistant to conventional therapies received the newly developed cell therapy. DFU wounds cause significant physical and mental suffering, including pain and mobility limitations.

Conventional wound treatments mostly result in only temporary symptomatic relief in DFU patients and usually do not lead to wound healing. In contrast, the current study demonstrated that topically grafted, highly purified ABCB5+ allogeneic dermal mesenchymal stem cells (MSCs), shown capable of modulating key immune parameters involved in wound healing, successfully promoted wound size reduction. In approximately 80 percent of DFU patients, the novel therapy reduced ulcer size by an average of 72 percent. Even complete wound closures were observed as a result of treatment.

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+ MSCs 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).

The multicenter 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 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.

Currently, RHEACELL is looking for additional healthcare investors or partners to successfully co-develop the next clinical phases up to market authorization.

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