RHEACELL®
Innovative Stem Cell Therapies

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Press Release

GERMANY APPROVES NOVEL CELL THERAPY EXTRACTED FROM SKIN

Germany's Federal Institute for Vaccines and Biomedicines (Paul-Ehrlich-Institut) grants RHEACELL national approval for its cell therapy product AMESANAR® for the use in patients with chronic wounds

Heidelberg, 06. October 2021 – Chronic wounds not only put great strain on the health system, but also have a major impact on the quality of life of affected patients.

RHEACELL, a German biopharmaceutical company focused on clinical development of novel stem cell therapeutics, has been granted national approval under § 4b of the German Medicinal Products Act for its novel cell therapy product AMESANAR®. AMESANAR® (allogeneic ABCB5-positive mesenchymal stromal cells), manufactured by TICEBA GmbH from donor skin, is an Advanced Therapy Medicinal Product (ATMP) and can be used in patients with chronic wounds caused by chronic venous insufficiency.

The approval represents a major advance for those affected, as well as an important milestone for biopharmaceutical industry efforts directed at the development of cell-based drugs: This first approval of a somatic cell therapy medicinal product derived from skin validates the concept that translation of highly innovative cell therapies to clinical use is achievable. Currently RHEACELL is preparing for market entry in Germany. AMESANAR® will be available to patients at hospitals and specialized clinics in Germany.

RHEACELL's ongoing clinical development programs focus not only on chronic wounds, but also on additional serious or rare diseases such as epidermolysis bullosa (butterfly disease), which mainly affects children.

RHEACELL hopes to alleviate the suffering of affected patients by concentrating on the development of cell therapies for rare diseases and diseases where no cure is available.

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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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