

Strategic alliance for rare diseases

RHEACELL and AOP Health enter into strategic partnership to commercialize novel somatic cell therapies in Europe

- *RHEACELL, a biopharmaceutical company specializing in the development of somatic cell therapies, and AOP Health Group, a pioneer in integrated therapeutic solutions for rare diseases, have entered into a strategic partnership.*
- *The partnership agreement covers the products EBESANAR® (systemic allogeneic ABCB5+ mesenchymal stem cells for treatment of the rare disease epidermolysis bullosa) and AMESANAR® (topical allogeneic ABCB5+ mesenchymal stem cells for treatment of chronic venous ulcer (CVU) disease).*
- *AOP Health receives the commercialization rights for EBESANAR® and AMESANAR® in Europe, Turkey, Israel and the MENA region (Middle East and Northern Africa).*
- *RHEACELL retains full commercialization rights to EBESANAR® and AMESANAR® in the US and other major markets.*
- *Promising Phase 3 clinical trial for EBESANAR® remains on track with planned submission of European marketing authorization application in Q1 2026.*

Heidelberg/Germany, May 27, 2025. RHEACELL announced today that it has entered into an exclusive partnership agreement with the AOP Health Group, who will commercialize RHEACELL's two stem cell products, EBESANAR® and AMESANAR®, in Europe, Turkey, Israel and the MENA region (Middle East and Northern Africa). RHEACELL retains full commercialization rights to EBESANAR® and AMESANAR® in other major markets, including North America, Asia-Pacific and Latin America, and will seek strategic distribution partners in those markets.

Innovative portfolio in late-stage development

RHEACELL's somatic cell therapeutics are at an advanced stage of clinical development and are seen as a beacon of hope for patients with non-healing

venous wounds (chronic venous ulcers) and the rare pediatric disease - Epidermolysis bullosa ("butterfly disease"). RHEACELL will continue to be responsible for the clinical phase 3 trials study program for EBESANAR[®] and AMESANAR[®]. Initial topline data from the EBESANAR[®] Phase 3 trial is expected by the end of 2025. The AMESANAR[®] Phase 3 clinical trial in chronic venous ulcer disease is also progressing according to plan and is expected to be completed in 2026.

Following expected marketing approval in Europe, **AOP Health** will take the lead in all commercialization and sales activities in the agreed regions, in addition to overseeing medical and regulatory responsibilities. This reflects AOP Health's strong track record of successfully bringing integrated therapies to market across Europe. **RHEACELL** will retain manufacturing rights and produce both therapies at its state-of-the-art facility in Heidelberg. United by a shared commitment, both companies are working toward a clear goal: making advanced therapeutic solutions available to patients with high unmet medical needs as swiftly as possible. The financial terms of the agreement remain confidential.

"This partnership marks a significant milestone for RHEACELL and the further development of our cell therapy programs. Working with such an established partner as AOP Health to commercialize our cell therapeutics will enable us to bring our innovative therapies faster and more efficiently to the markets across Europe," said Dr. Christoph Ganss, MD, CEO of RHEACELL.

"Our mission is to provide patients with rare diseases access to urgently needed therapeutic innovation. This partnership with stem cell pioneer RHEACELL enables us to jointly bring new treatment options to patients living with Epidermolysis bullosa or chronic venous ulcers, who currently have limited or no treatment options. Our teams are fully committed to making these groundbreaking treatments available to all patients affected," said Dr. Martin Steinhart, CEO of AOP Health.

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About RHEACELL

RHEACELL is a leading integrative biopharmaceutical stem cell company based in Heidelberg, Germany. We focus on the development of innovative stem cell therapies for patients suffering from severe immune- and inflammation-related diseases, who have a very high level of suffering and for whom there are currently no adequate treatment options. Our products are based on ABCB5+ mesenchymal stromal cells as a pure active ingredient with a unique mechanism of action - applied topically or systemically, depending on the clinical picture - which enables the targeted control of inflammation and the restoration of normal physiological wound healing.

About AOP Health

AOP Health is a globally active group of companies with roots in Austria, where the headquarters of AOP Orphan Pharmaceuticals GmbH ("AOP Health") is located. Since 1996, the AOP Health Group has been dedicated to developing innovative solutions for unmet medical needs, particularly in the areas of rare diseases and critical care. The Group has established itself internationally as a pioneer for integrated therapy solutions and operates worldwide with subsidiaries, agencies and a strong partner network. Under the claim "Needs. Science. Trust.", the AOP Health Group emphasizes its commitment to research and development and the importance of building relationships with physicians and patient advocacy groups to ensure that the needs of these stakeholders are reflected in all aspects of the company's activities

About EBESANAR®

EBESANAR® is a systemic therapy for patients with Recessive Dystrophic Epidermolysis Bullosa (RDEB) and Junctional Epidermolysis Bullosa (JEB), rare genetic diseases that affect the skin and connective tissues. *EBESANAR®* is administered via bi-monthly intravenous infusions and is intended to treat skin lesions, reduce internal and external disease burden and prevent accumulation of damage to tissues. *EBESANAR®* is currently being studied in a phase 3 trial in the US and Europe. Top line data from this trial is expected to be available in later 2025.

About AMESANAR®

AMESANAR® is a topical therapy for the treatment of non-healing, treatment resistant chronic venous ulcers. *AMESANAR®* is administered topically to patients whose ulcers have not responded to other standard therapies and is intended to support wound healing by activating macrophages which express anti-inflammatory & pro-angiogenic cytokines. *AMESANAR®* is currently being studied in a Phase 3 clinical trial in the US and Europe with top line data expected in 2026.