



# REXGENERO

**FOR IMMEDIATE RELEASE**

## **Rexgenero Successfully Expands Manufacturing of REX-001 through Partnership with German Red Cross Blood Donor Service**

*Enables new sites to participate in the European Phase III SALAMANDER trials*

**London, UK, 28 May 2019:** Rexgenero, a regenerative medicine company developing advanced cell-based therapies to treat critical limb ischaemia (CLI), today announces that it has successfully expanded manufacturing of its lead development candidate REX-001 through a partnership with the German Red Cross Blood Donor Service in Frankfurt, Germany, signed earlier this year.

REX-001 is an autologous cell-based therapy and is manufactured using the patient's own bone marrow. It contains immune cells (lymphocytes, monocytes and granulocytes) and progenitor cells involved in immune modulation and tissue regeneration. Manufacturing is time critical as it is important to ensure administration of the fresh product within 48 hours. Successfully transferring the manufacturing technology to this second GMP facility in Europe is a key milestone to ensure sufficient supply to patients enrolled in Rexgenero's European Phase III SALAMANDER trials of REX-001 for the treatment of CLI in patients with diabetes.

REX-001 is already manufactured at Rexgenero's own GMP manufacturing facility in Seville, Spain and used predominantly at clinical trial sites in Spain and Portugal. Under a manufacturing partnership, the German Red Cross Blood Donor Service will manufacture REX-001, principally for use at additional trial sites in Germany, Poland, Czech Republic, Hungary, The Netherlands, the U.K. and Austria. However, both sites are able to manufacture and deliver product for most clinical sites within the limited time frame, ensuring manufacturing flexibility and backup possibilities.

The German Red Cross Blood Donor Service is one of the largest blood donor services in Europe and has significant expertise in GMP manufacturing of cell-based investigational medicinal products. The manufacture of REX-001 is overseen by Professor Halvard Bönig, Institute for Transfusion Medicine and Immunohematology, Goethe-University and German Red Cross Blood Service Baden-Württemberg-Hessen, Frankfurt am Main, Germany.

**Edwin Wagena, COO of Rexgenero commented,** "I would like to congratulate Professor Halvard Bönig and his team at the German Red Cross Blood Donor Service for successfully manufacturing REX-001 in Germany. This new manufacturing site complements the activities of our own facility in Spain and enables us to reduce delivery time to clinical trial sites across Central and Eastern Europe."

**Liesbeth de Jong, Vice President, Manufacturing and Research & Development at Rexgenero added,** "Successfully transferring the manufacturing technology for REX-001 to the German Red Cross Blood Donor Service confirms we have full control over all aspects of the manufacturing process. Manufacturing REX-001 involves a lot of technical expertise and know-how so it is excellent news that Professor Bönig and his team can now also manufacture REX-001. This will significantly increase the capacity and flexibility of product supply in our Phase III program."

REX-001 Phase III SALAMANDER clinical trials are open and recruiting patients at sites in Spain, Austria, Portugal, Poland, the Czech Republic, Hungary and The Netherlands.

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**For further information, please contact:**

**At Rexgenero**

Joe Dupere, CEO  
+44 (0)20 3700 7480  
[info@rexgenero.com](mailto:info@rexgenero.com)

**For media enquiries**

**Instinctif Partners**  
Sue Charles/Ashley Tapp  
+44 (0)20 7866 7923  
[Rexgenero@instinctif.com](mailto:Rexgenero@instinctif.com)

**About Rexgenero**

Rexgenero is a clinical-stage regenerative medicine company developing innovative cell-based therapies targeting serious diseases with unmet medical needs.

The Company's lead candidate REX-001, is a highly innovative autologous cell therapy that is being studied in a Phase III clinical programme in patients with critical limb ischemia (CLI) with diabetes, a poorly treated disease with a high risk of amputation and death. REX-001 has been shown to be effective in Phase I/II and Phase II trials, alleviating CLI in the majority of patients, offering the potential to increase the quality of life of CLI patients by reducing pain, alleviating ulcers, increasing mobility, improving sleep and reducing the need for amputation. Rexgenero is developing REX-001 in a range of indications and, pending approval, intends to launch and market this specialty product in major territories.

Rexgenero is a privately-owned company, which draws on an exceptional understanding of the fundamental science of cell therapies developed by the Andalusian Health Authority (Servicio Andaluz de Salud) and Andalusian Initiative of Advanced Therapies.

The Company was founded in 2015 and is headquartered in London (UK) with R&D and manufacturing operations in Seville (Spain) and Frankfurt (Germany).

For more information, please visit [www.rexgenero.com](http://www.rexgenero.com).

**About the REX-001 Phase III SALAMANDER Trials**

Rexgenero is planning to treat a total of 60 patients with CLI and rest pain and 78 patients with CLI and non-healing ischemic ulcers in two independent Phase III SALAMANDER trials in approximately 30 hospitals across Europe. Clinical trials sites are open and recruiting patients in Spain, Austria, Portugal, Poland, the Czech Republic, Hungary and The Netherlands. The trials are given the name SALAMANDER in reference to the amphibian's ability to regenerate its tail and limbs.

For more information about the REX-001 Phase III SALAMANDER trials, please visit the [clinical trial website](#).

**About the German Red Cross Blood Donor Service**

The German Red Cross Blood Donor Service Baden-Württemberg-Hessen (BSD) is one of the world's largest blood and transfusion medicine services. As a research-oriented pharmaceutical manufacturer, BSD is heavily invested in ATMP development and manufacturing, in collaboration with both academic and commercial entities.

For more information, please visit [www.blutspende.de/ueber-uns/institute-einrichtungen/frankfurt/institut-frankfurt.php](http://www.blutspende.de/ueber-uns/institute-einrichtungen/frankfurt/institut-frankfurt.php)