EMA grants Rexgenero's lead product REX-001 Advanced Therapy Medicinal Product Certificate for Manufacturing Quality and Non-Clinical Data

REX-001 is a novel cell therapy for the treatment of Critical Limb Ischemia (CLI), a disease which affects an estimated one million people in Europe

London, UK, 30th January 2018: Rexgenero Ltd, a clinical-stage regenerative medicine company developing advanced cell-based therapies with a focus on Critical Limb Ischemia (CLI), today announces that the European Medicines Agency (EMA) has granted Rexgenero an Advanced Therapy Medicinal Product (ATMP) certificate for manufacturing quality and non-clinical data. The EMA certification paves the way for the Marketing Authorization Application (MAA) of its lead product REX-001, a novel cell therapy currently in a Phase III programme for the treatment of Critical Limb Ischemia (CLI).

Joe Dupere, Rexgenero's CEO, commented, "We are delighted to have been granted an ATMP certificate for manufacturing quality and non-clinical data for REX-001. This is a major milestone for us as we work to bring this novel cell therapy to patients diagnosed with CLI, a disease with high unmet medical needs. We believe that REX-001 has the potential to be one of the first effective cell therapy products available for patients with CLI, a disease strongly associated with a high risk of amputation and mortality."

Rexgenero received the certificate following a thorough scientific evaluation of the manufacturing quality data and non-clinical data by the EMA's Committee for Advanced Therapies (CAT).

-ENDS-

Contacts:

Rexgenero
Joe Dupere, CEO
T: +44 (0) 203 709 1969
E: info@rexgenero.com

Citigate Dewe Rogerson
Sylvie Berrebi, Shabnam Bashir
T: +44 (0) 20 7638 9571
E: rexgenero@citigatedewerogerson.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).

For more information, please visit www.rexgenero.com