Rexgenero's Lead Product REX-001 Selected for the EUnetHTA Prioritisation List for Joint Assessments

The Prioritisation list consists of just 14 medicinal products that have been identified as being of significant interest by national and regional Health Technology Assessment (HTA) organisations in Europe

London, UK, 7 January 2019: Rexgenero, a clinical-stage regenerative medicine company developing advanced cell-based therapies with a focus on Critical Limb Ischemia (CLI), today announces that its lead product REX-001 has been selected as one of only 14 products to be included in the EU Network for Health Technology Assessment (EUnetHTA) Prioritisation list (EPL) for Joint Assessment. The inclusion of REX-001 (Rexmyelocel-T) in the EPL underscores the novelty of the technology underlying this ground-breaking approach to the treatment of CLI.

The EUnetHTA is a network of government appointed organisations (from EU Member States, EU-accession countries, plus EEA and EFTA countries) and a large number of relevant regional agencies and non-for-profit organisations that produce or contribute to HTAs of new products across Europe.

The EPL was selected from the publicly available European Medicines Agency (EMA) list of medicines under evaluation and was created to further facilitate national implementation and uptake of Joint HTAs. Joint assessments enable products (such as REX-001) to be adopted and gain reimbursement in multiple markets across Europe simultaneously.

REX-001, a highly innovative autologous cell therapy, is currently being studied in two pivotal, placebo-controlled, double-blind, adaptive Phase III trials in patients with Critical Limb Ischemia (CLI) and Diabetes Mellitus (DM). Critical Limb Ischemia (CLI) is a chronic condition and the most serious form of Peripheral Arterial Disease (PAD). It is a major global health problem with a high and growing incidence. CLI is a condition characterised by severe obstruction of the arteries that seriously decreases blood flow to the extremities causing severe recurrent pain and non-healing ulcers. CLI is a poorly treated disease with approximately 25% of patients requiring amputation of the affected limb within the first year. The mortality rate of patients diagnosed with CLI is of 20-25% within one year of diagnosis.

Joe Dupere, Rexgenero's CEO, commented, "We are delighted that our product, amongst hundreds of other European products, has been selected for the EPL list due to significant interest from national and regional HTA organisations. This is a testament to Rexgenero's scientific cell therapy expertise. In Europe, CLI affects between 1-1.5% of the population. Given the limitations of current treatments and the severity of the condition, there is an urgent need for effective new treatments that become available to as many patients as possible. We believe that being selected for the EPL Joint Assessment will help us achieve this goal more rapidly and effectively. We look forward to continued engagement with EUnetHTA in progressing the joint assessment for REX-001."

More information on the EUnetHTA Prioritisation List for Joint Assessments can be found here: https://www.eunethta.eu/assessments/prioritisation-list/

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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