



REXGENERO

Rexgenero treats first patient in its Phase III programme with lead product REX-001, a novel cell therapy for the treatment of Critical Limb Ischemia (CLI)

London, UK, 25th 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 the treatment of its first patient in a Phase III programme evaluating the Company's lead product, REX-001, in patients with Critical Limb Ischemia (CLI) and Diabetes Mellitus (DM).

REX-001 is a novel autologous cell therapy that has been shown to stimulate the growth of new blood vessels to restore blood supply to the limb, alleviate symptoms and improve quality of life of patients with CLI.

Rexgenero is conducting two pivotal, placebo-controlled, double-blind, adaptive Phase III trials in patients with CLI and DM. The Phase III study in patients with Rutherford stage 4 CLI will assess the efficacy and safety of REX-001 with a primary endpoint of complete relief of ischemic rest pain. The Phase III study in patients with Rutherford stage 5 CLI will assess the efficacy and safety with a primary endpoint of complete ulcer healing. Amputation-free survival is included as a secondary endpoint in both studies.

The designs of both trials, including the patient population and primary endpoints, have been fully endorsed by the European Medicines Agency (EMA). The primary endpoints are the most clinically relevant to patients and physicians, are correlated to the improved clinical condition of patients and are expected to increase the probability of success. The Company plans to enrol a total of 138 patients at approximately 35 clinical sites in Europe with first interim results expected in circa 18 months' time and full data in 2020.

Joe Dupere, Rexgenero's CEO, commented, "We are extremely pleased to announce the first patient infusion in our Phase III programme with REX-001, which if successful could significantly improve the treatment of patients with CLI. The programme has been designed following advice from the EMA and in close collaboration with our Scientific Advisory Board. CLI is a medical condition with a clear need for new improved treatment options. Our goal is to bring innovative cell, gene and tissue therapies to the market addressing high unmet needs which cannot be treated with available therapies. We believe that REX-001 has the potential to be one of the first effective cell therapy products available for patients with CLI."

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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 product 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 Mellitus, 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 planning to develop 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

About Critical Limb Ischemia

Critical limb ischemia (CLI) is an advanced stage of peripheral artery disease (PAD). It is defined as a triad of ischemic rest pain, arterial insufficiency ulcers, and gangrene. The latter two conditions are jointly referred to as tissue loss, reflecting the development of surface damage to the limb tissue due to the most severe stage of ischemia. Patients with CLI and Diabetes Mellitus (DM) represent a large sub-group strongly associated with a high risk of amputation and mortality.

The only current therapy for treating CLI is revascularisation, however, a significant proportion of patients with CLI, are not suitable for a surgical bypass or an endovascular procedure, due to the absence of viable blood vessels, the failure of previous revascularisation procedures or co-morbidities. In the United States and Europe, approximately 4.5 million people are affected with CLI.

The severity of PAD is commonly assessed using the Rutherford classification from stage 0 (asymptomatic) to 6 (severe ischemic ulcers or frank gangrene) with CLI constituting categories 4 to 6.