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Rexgenero Presents Update on Phase III Clinical Trials with REX-001, a Cell-based Therapy for Critical Limb Ischaemia

At the Alliance for Regenerative Medicine's Cell and Gene Therapy 'Meeting on the Med' in Barcelona

London, UK, 24 April 2019: Rexgenero, a regenerative medicine company pioneering the development of advanced cell-based therapies to treat critical limb ischaemia (CLI), today presented an update on its two Phase III SALAMANDER trials being conducted across Europe for its lead development programme REX-001 to treat CLI in patients with diabetes.

During Rexgenero's presentation at the Cell and Gene Therapy Meeting on the Med in Barcelona, organised by the Alliance for Regenerative Medicine (ARM), Joe Dupere, CEO provided an update on the Phase III programme with REX-001. Twelve of the 25 planned trial sites are now open and treating patients in Spain, Austria, Portugal, Poland, Czech Republic, and Hungary, with additional hospitals expected to be initiated by the end of the year in three additional countries.

REX-001 consists of bone marrow-derived white blood cells extracted from the patient (autologous) and has shown efficacy in 80% of patients in Phase II and I/II studies. Rexgenero is planning to treat 138 patients in two Phase III SALAMANDER trials. The presentation highlighted encouraging clinical improvements in two patients treated in Spain with REX-001 out of protocol, as they did not meet the trial criteria.

CLI is a chronic condition and the most serious form of PAD, in which a build-up of fatty deposits in the arteries restricts blood supply to leg muscles. CLI is characterized by chronic ischemic at-rest pain, ulcers, or gangrene in one or both legs. The condition represents an area of high unmet medical need with very limited treatment options currently on the market, highlighting the importance of Rexgenero's pipeline of clinical candidates.

Joe Dupere, CEO of Rexgenero commented, "We are at a hugely exciting time for the company and, more importantly, for patients with CLI, as our Phase III trial sites for REX-001 are now treating patients in many countries including Spain. With our Spanish heritage, the location of ARM's Meeting on the Med is particularly significant for Rexgenero. We are on track to open further clinical trial sites across Europe."

Rexgenero was incorporated in 2015 to progress therapies developed by the Andalusian Health Authority – the government-run health system for the autonomous community of Andalusia – and the Andalusian Initiative of Advanced Therapies. Rexgenero has expanded with the headquarters now in London, UK, but retaining R&D and manufacturing operations in Seville (Spain) as well as manufacturing in Frankfurt (Germany). Spain is a world leader in advanced stem cell therapies and has invested hundreds of millions of euros into the industry.

Rexgenero benefits from its close association with the clinical and cell therapy communities in Spain. The [Phase III SALAMANDER trials](#) are open in Spain and are actively recruiting patients in Cordoba, Cadiz, Badalona and Barcelona.

The Phase III SALAMANDER trials use a highly innovative trial design with novel primary endpoints that increase the sensitivity of the study and increase likelihood of success.

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Alliance for Regenerative Medicine (ARM) Cell and Gene Therapy 'Meeting on the Med'

ARM's Meeting on the Med is a highlight on the Cell & Gene Therapy conference calendar, bringing together company executives, investors, patient advocates and large pharma representatives for expert-led panels, in-depth keynote speeches, interactive fireside chats, and over fifty presentations by leading publicly traded and privately held companies from around the globe.

For more information, please visit www.meetingonthemed.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.