



# REXGENERO

## FOR IMMEDIATE RELEASE

### **First Czech Republic Diabetic Patient with Critical Limb Ischaemia Treated with Novel Regenerative Therapy by Associate Professor Václav Procházka at University Hospital Ostrava**

*Phase III SALAMANDER Trial of Rexgenero's REX-001 Open and Recruiting*

**London, UK, 29 May 2019:** The first diabetic patient in the Czech Republic with a potentially life-threatening cardiovascular disease, called critical limb ischaemia (CLI), has been treated with REX-001, a novel regenerative therapy, in the SALAMANDER clinical trial being undertaken by Associate Professor Václav Procházka, the Principal Investigator at University Hospital Ostrava and an international expert in CLI.

CLI is caused by a severe blockage in the arteries of the lower limbs, which markedly reduces blood flow, and is a serious form of peripheral arterial disease (PAD). Caused by atherosclerosis, PAD is the hardening and narrowing of the arteries over time due to the build-up of fatty deposits called plaque.

CLI is a common condition in Europe and the United States affecting 1-1.5% of the population aged over 40, with an estimated prevalence of 21,000-28,000 in the Czech Republic<sup>1,2,3,4</sup>.

The most prominent features of CLI are severe pain in the feet and legs while a person is resting, and non-healing sores on the feet or legs. Half of all patients with CLI are diabetics<sup>5</sup>. Left untreated, the complications of CLI may result in gangrene, amputation of the affected limb or even death. The global amputation rate is estimated at 25% within one year of diagnosis but varies according to the severity of the condition, with rates of 11% in patients with superficial ulcers and up to 83% in patients with gangrene<sup>6,7</sup>.

REX-001 is one of a new class of regenerative medicines: it is a so-called autologous cell therapy manufactured using the patient's own bone marrow and contains immune cells (lymphocytes, monocytes and granulocytes) and progenitor cells involved in immune modulation and tissue regeneration. It is administered as a single dose within 4 days after collection of bone marrow cells.

The University Hospital Ostrava is the first Hospital in the Czech Republic to recruit patients for the Phase III SALAMANDER trial for the treatment of ischemic ulcers in patients with CLI and diabetes. The clinical trials have been given the name SALAMANDER in reference to the amphibian's ability to regenerate its tail and limbs.

**Associate Professor Václav Procházka, an international expert in CLI and the Principal Investigator at University Hospital Ostrava commented,** "Every day I see patients with CLI who suffer from leg ulcers, pain at rest and in general have a very poor quality of life. There are limited treatment options available, so these patients are in desperate need and cell therapies such as REX-001 offer great potential."

Rexgenero, the company pioneering the development of REX-001, says that it has already demonstrated efficacy in a Phase II trial. In 82% of the patients with non-healing ischemic ulcers, all ulcers were healed within the first 12 months after a single administration of REX-001.

**Karen Reitsma, Vice President, Clinical and Regulatory Development, of Rexgenero commented,** "It is great news to have treated the first patient in the Czech Republic for our Phase III SALAMANDER trials. University Hospital Ostrava is our 14<sup>th</sup> clinical trial site in Europe open and actively recruiting patients with several other new sites gearing up to start recruitment shortly."

**Joe Dupere, CEO of Rexgenero added,** "Treating our first patient with REX-001 in the Czech Republic represents an important milestone as we ramp up patient recruitment across Europe for our Phase III program in diabetic patients with CLI. It is a privilege to be working with Associate Professor Procházka in Ostrava, whose extensive knowledge of this specialist area will be invaluable for the development of REX-001."

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. In addition to this trial site in Ostrava in the Czech Republic, Rexgenero is also recruiting patients for both trials at sites in Spain, Austria, Portugal, Poland, Hungary and The Netherlands.

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

## References

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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 ischaemia (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 University Hospital Ostrava**

The University Hospital in Ostrava is the largest medical facility in the Moravian-Silesian Region. It has 40 clinics, departments and institutes and nearly 1,200 beds. Forty-five-thousand patients are hospitalized in the facility every year. More than half of the patients have a complicated or rare diagnosis. Our physicians perform almost 15,500 surgical interventions and 600,000 outpatient examinations every year. At the same time, the hospital is a teaching centre of the Faculty of Medicine of the University of Ostrava, where a number of our physicians and health professionals are also active. The emphasis on continuous improvement of the quality and safety of the provided care is guaranteed by independent accreditations by Joint Commission International (since 2010), Spojená akreditační komise, o.p.s. (Joint Accreditation Commission, since 2007). All laboratory facilities are accredited by Český institut pro akreditaci, o.p.s. (Czech Institute for Accreditation). The University Hospital Ostrava is the only university hospital in the Czech Republic that meets the requirements of JCI international accreditation.

For more information, please visit [www.fno.cz/](http://www.fno.cz/).