Rexgenero Shortlisted as a Finalist for Clinical Trial of the Year Lifestars Award

London, UK - 11 September 2019 – Rexgenero, a clinical-stage regenerative medicine company pioneering the development of advanced cell-based therapies, has been shortlisted as a finalist for the Clinical Trial of the Year Lifestars Award.

The annual European Lifestars Awards, organised by LSX, the influential community of senior life science decision makers, bring together hundreds of European life science leaders, investors, partners and deal makers, to celebrate the success stories, breakthroughs, transactions and transformational deals and the people, teams and organisations that have played a critical role in the advancement of the industry over the previous 12 months.

The Clinical Trial of the Year category recognises a European life science company that has realised a significant milestone in the clinic for a new therapy, drug, diagnostic tool, digital application or medical device.

Rexgenero has been shortlisted on the basis of their pivotal, placebo-controlled, double-blind and adaptive Phase III SALAMANDER clinical trial for chronic-limb threatening ischemia. The trial will test the efficacy and safety of Rexgenero's cell therapy candidate, REX-001, in patients with Rutherford Category 5 chronic limb-threatening ischemia and ischemic ulcers.

The winner will be announced at the LSX Lifestars Awards Ceremony, London, UK, 19th November.

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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 chronic limb-threatening 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.

About Chronic-Limb Threatening Ischemia
Chronic limb-threatening ischemia (CLI) represents an area of high unmet medical need as there are currently no approved therapies to successfully treat the CLI patient population, estimated to be 3–4 million across Europe and the US. The existing state-of-the-art minimally invasive surgical procedures and reconstruction techniques typically used fail to address the full complexity of the disease, with many CLI patients undergoing amputation as the disease progresses.

About REX-001
REX-001 offers a new treatment paradigm for CLI by using a refined suspension of immune and progenitor cells harvested from the patient's own bone marrow to restore the immune balance, recruit collateral vessels and promote blood vessel regeneration. Rexgenero believes that this multifactorial approach restores blood flow and promotes ulcer healing, preventing major amputations. REX-001 demonstrated convincing results in a Phase II clinical trial, where 82% of patients with non-healing ischemic ulcers were successfully treated over a 12-month period.

About Rexgenero's Phase III SALAMANDER Clinical Trial
REX-001 is progressing through a pivotal, placebo-controlled, double-blind and adaptive Phase III trial at approximately 30 sites across Europe, directly addressing the needs of the patient population. The trial, dubbed SALAMANDER, will test the efficacy and safety of REX-001 in 78 subjects with Rutherford Category 5 CLI and ischemic ulcers, with a primary endpoint of complete ulcer healing. Amputation-free survival is a secondary endpoint. Rexgenero aims to complete recruitment by mid-2020 and obtain top-line results by late 2021.

The innovative and adaptive trial design, including the chosen patient population and unique primary endpoint, has been fully endorsed by the European Medicines Agency.

The clinical differentiation and treatment potential represented by REX-001 offer a significant opportunity for a large patient group within the next 5 years, making the start of the Phase III clinical trial a milestone for Rexgenero and the CLI patient community. For more information, please visit www.cli-treatment.com/en/home.