



REXGENERO

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Atelerix Consortium Awarded £267,000 Innovate UK Grant for Collaboration with the Cell and Gene Therapy Catapult and Rexgenero on Cell Therapy Stabilisation Technologies

London, UK, 21 August 2019: Rexgenero, a regenerative medicine company pioneering the development of advanced cell-based therapies to treat chronic limb-threatening ischaemia (CLI), welcomes the news announced today by Atelerix that it has been awarded a grant of £267,000 from Innovate UK.

The grant will be used to develop gel stabilisation technologies, developed by Atelerix, with the first objective of extending the shelf-life of Rexgenero's cell-based therapies for storage and transport at room temperature. The project will initially focus on developing a stabilisation technology for REX-001, Rexgenero's lead development candidate, but is expected to have broad applicability to a wide range of other cell therapies. The project will benefit from additional expertise and experience provided by the Cell and Gene Therapy Catapult.

Atelerix's patented technology enables the storage and transport of human cells at temperatures between 4°C and 25°C, preserving and extending their functional viability from days to weeks. The technology encapsulates cells in a natural hydrogel for safe shipment and storage. The cells can be recovered when needed by the addition of a gentle, cell-friendly buffer.

REX-001 consists of bone marrow-derived white blood cells extracted from a patient's own bone marrow (autologous). Rexgenero is currently recruiting 138 patients at 35 sites in countries across Europe for its Phase III SALAMANDER trials of REX-001 for the treatment of CLI in diabetic patients.

CLI is a chronic condition and the most serious form of peripheral arterial disease (PAD) in which a build-up of fatty deposits in the arteries restricts blood supply to leg muscles, leading to chronic ischemic at-rest pain, ulcers, or gangrene in one or both legs. It is a major health and societal issue affecting an estimated 3-5 million people in Europe, growing at 1-2% p.a. due to the link with diabetes and ageing.

Extending the shelf-life of REX-001 will provide increased flexibility for transportation to and from the hospital and facilitate use for physicians treating patients with CLI.

Joe Dupere, CEO of Rexgenero commented, "We look forward to initiating this project. Extending the shelf-life of our REX-001 autologous cell therapy is important to ensure that hospitals have the flexibility for less rigid scheduling of operating theatres, making it easier to treat patients and therefore enabling as many patients as possible to be treated with this novel, potentially curative therapy. Room temperature storage and transportation also widens our manufacturing options and should help to drive down cost."

Dr Mick McLean, CEO of Atelerix, added, "We're excited to be part of this collaboration with Rexgenero and the team at the Cell and Gene Therapy Catapult, and we deeply appreciate the support of Innovate UK to bring us together for this important project. The critical logistics of getting viable cell therapies to the patient are often overlooked and extending the shelf life of therapies such as REX-001 at room temperature would open up an entirely new approach for this sector."

Keith Thompson, CEO of the Cell and Gene Therapy Catapult also added, "We have a long-standing relationship with Rexgenero and have collaborated with them previously to support the commercial manufacture of the REX-001 product. This collaboration underlines the strength of expertise that exists within the UK to support the cost-effective commercialization of cell therapies including in the important area of supply chain technologies. It is a great example of bringing together the capabilities of CGT Catapult and the expert companies that make up the complete UK cell and gene therapy ecosystem."

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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 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 Atelerix

Atelerix is a spin out from Newcastle University in the UK that has a transformative technology for the storage and transport of viable cells at room temperature, overcoming the barriers and limitations presented by the current need for cryo-shipping. The Company does this by using its patented process of encapsulating the cells in a natural hydrogel for safe shipment and storage. The cells can be recovered when needed by the addition of a gentle, cell-friendly buffer.

Atelerix's Impact:

- Predictability and reliability in drug discovery models and for cells used as therapies
- Extended shelf life for currently short-lived cell therapy products
- Customers can use cells and assays immediately on arrival
- No need for cryopreservation, nor need for cytotoxic or animal-derived supplements
- Cells retain their natural state and are not damaged or altered

The Company was founded in 2017 and is headquartered in Cambridge (UK) with R&D and manufacturing operations in Newcastle upon Tyne (UK). For more information, please visit www.atelerix.co.uk.

About Cell and Gene Therapy Catapult

The Cell and Gene Therapy Catapult was established as an independent centre of excellence to advance the growth of the UK cell and gene therapy industry, by bridging the gap between scientific research and full-scale commercialisation. With more than 180 employees focusing on cell and gene therapy technologies, it works with partners in academia and industry to ensure these life-changing therapies can be developed for use in health services throughout the world. It offers leading-edge capability, technology and innovation to enable companies to take products into clinical trials and provide clinical, process development, manufacturing, regulatory, health economics and market access expertise. Its aim is to make the UK the most compelling and logical choice for

UK and international partners to develop and commercialise these advanced therapies. The Cell and Gene Therapy Catapult works with Innovate UK. For more information please visit ct.catapult.org.uk or visit <http://www.gov.uk/innovate-uk>.

About Innovate UK

Innovate UK drives productivity and economic growth by supporting business to develop and realise the potential of new ideas.

We connect businesses to the partners, customers and investors that can help them turn ideas into commercially successful products and services and business growth.

We fund business and research collaborations to accelerate innovation and drive business investment into R&D. Our support is available to businesses across all economic sectors, value chains and UK regions.

Innovate UK is part of UK Research and Innovation.

For more information visit www.innovateuk.ukri.org.