

PRESS RELEASE
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Ixaka and Minaris Regenerative Medicine Sign Tech Transfer and GMP Manufacturing Agreement for Lead Cell Therapy Candidate REX-001

- *REX-001 is an autologous multi-cell therapy (MCT) in development for the treatment of chronic limb-threatening ischemia (CLTI) in patients with diabetes*
- *REX-001 is currently being evaluated in the randomized double-blind placebo controlled pivotal Phase 3 clinical trial (SALAMANDER trial) and the furthest advanced product in this indication*

London, UK and Munich, Germany - June 27, 2022 - Ixaka Ltd, an integrated cell and gene therapy company, and Minaris Regenerative Medicine GmbH ("Minaris"), a leading contract development and manufacturing service provider for the cell and gene therapy industry, today announced that they have signed an agreement to enable technology transfer as well as clinical and commercial manufacture of REX-001, Ixaka's lead autologous multi-cell therapy (MCT) being developed for the treatment of chronic limb-threatening ischemia (CLTI) in patients with diabetes.

Under the terms of agreement, Minaris will perform technology transfer of REX-001 manufacturing and QC testing activities from Ixaka's Seville facilities to Minaris' facilities near Munich. The move will take place in preparation for the upcoming REX-001-006 Phase 3 clinical trial, which is the second of two Phase 3 studies for REX-001.

REX-001 is an MCT product in clinical development as a patient-specific cellular immunotherapy. The product is produced using cells extracted from a patient's own bone marrow and enriched for white blood cells. Re-administration into the affected limb delivers multiple immune and progenitor cells directly to the diseased vessels to address the complex disease processes that lead to the clinical progression of CLTI (plaque deposition, inflammation, ischemia, vessel degeneration, ulcer formation).

The scope of the manufacturing agreement includes the scale-up and technology transfer with the goal of supplying the Phase 3 clinical trials and supporting commercial supplies in the EU and later in the United States.



Joe Dupere, Chief Executive Officer at Ixaka, commented:

“Partnering with Minaris will provide essential capacity and expertise as we move into the next phase of expansion of our REX-001 Phase 3 clinical trials in Europe and, in time, the United States. We look forward to working with Minaris to bring this life-changing therapy to patients globally.”

Dusan Kosijer, CEO at Minaris Regenerative Medicine GmbH, commented:

“We are pleased to see that cell and gene therapies are leaving their niche of rare diseases and are increasingly being used in major indications such as diabetes-related conditions. We look forward to successfully supporting Ixaka with our clinical and commercial manufacturing experience and are eager to see REX-001 succeed in improving the lives of patients with chronic limb-threatening ischemia.”

– ENDS –

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About Ixaka

Ixaka is a cell and gene therapy company focused on using the natural powers of the body to cure disease.

Ixaka's proprietary technologies enhance the naturally therapeutic power of cells by increasing the presence of curative cells at the site of disease, or by directly modifying cells within the body to improve disease targeting and boost their restorative effect.

Ixaka's technologies – concentrated multi-cell therapies and nanoparticle therapeutics – demonstrate potential for the treatment of a broad range of serious diseases across oncology, cardiovascular, neurological and ocular diseases, and genetic disorders.

Ixaka has offices in London, UK with R&D and manufacturing operations in Seville, Spain and Paris, France and additional manufacturing capability in Frankfurt, Germany.

For more information, please visit www.ixaka.com

Connect with us: Twitter: https://twitter.com/Ixaka_Ltd

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About Minaris Regenerative Medicine

Minaris Regenerative Medicine is a global contract development and manufacturing organization (CDMO) for cell and gene therapies. We offer our clients high value clinical and commercial manufacturing services, development solutions, and technologies. We are pioneers in the field with more than 20 years' experience providing outstanding quality and reliability. Our facilities in the US, Europe, and Asia allow us to supply patients worldwide with life-changing therapies. Minaris Regenerative Medicine is wholly owned by Showa Denko Materials Co., Ltd.

For more information, please visit www.rm.minaris.com

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