PRESS RELEASE

Ixaka announces positive interim Phase 3 clinical trial data for its lead cell therapy candidate REX-001

- *The positive interim analysis of the efficacy and safety results from the first 30% of enrolled patients evaluated 12 months after treatment with REX-001 in a Phase 3 trial (NCT03174522) provides further support for the hypothesis that REX-001 is an effective and safe treatment for chronic limb-threatening ischaemia (CLTI)*
- *REX-001 is an autologous multi-cell therapy (MCT) in development for the treatment of CLTI in patients with diabetes and the furthest advanced product in this indication*
- *REX-001 is currently being evaluated in the randomized double-blind placebo controlled pivotal Phase 3 clinical trial (SALAMANDER trial) with interim analyses 12 months after 30% and 50% of patients have been enrolled*
- *Enrolment is accelerating with over 50% of patients already treated*

London, UK, 08 September 2021: Ixaka Ltd, an integrated cell and gene therapy company, announces positive interim results of its lead REX-001 drug candidate from a Phase 3 clinical trial, which evaluated the safety and efficacy results 12 months after treatment with REX-001 or placebo in patients diagnosed with chronic limb-threatening ischemia (CLTI) and diabetes. Following assessment of the interim efficacy and safety data, the independent Data Monitoring Committee (DMC) recommended continuation of the trial unchanged.

Following unblinded prespecified statistical analysis of safety and efficacy results from the first 30% of enrolled patients, the DMC recommended continuation of the study as planned in the protocol, confirming that the expected effect of REX-001 compared to placebo in the trial is on track and that the benefit-risk was acceptable. There were no significant safety concerns.

This positive interim analysis supports the hypothesis that REX-001 is an effective and safe treatment for CLTI and is consistent with the effect observed in previous clinical trials, where treatment with REX-001 resulted in complete ulcer healing in over 70% of patients. The Phase 3 trial with REX-001 includes two planned interim analyses after 30% and 50% of patients enrolled have reached the 12-month follow-up visit. Ixaka remains blinded to the data until the completion of the trial.

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).

"We are delighted with the positive outcome in this interim analysis of the Phase 3 trial for REX-001 in CLTI. With such poor treatment options available and the high number of patients affected, this is a significant milestone in this devastating disease. The positive interim analysis confirms the potential of REX-001 as an effective treatment of the disease", **commented Joe Dupere, CEO at Ixaka**

"This first Phase 3 interim analysis is a critical milestone for our lead cell therapy candidate REX-001. The positive benefit-risk evaluation by the DMC provides reassurance that REX-001 is an effective and safe treatment for CLTI, and that it is on the right path towards marketing authorization l", **commented Gilbert Wagener, Senior Vice President, Chief Medical Officer at Ixaka.** "*Based on these results, I am confident that we can provide our innovative and much-needed product to patients suffering from CLTI in the near future."*

The SALAMANDER trial is a randomized double-blind placebo-controlled adaptive trial including diabetic patients with Rutherford category 5 CLTI and with complete ulcer healing as the primary endpoint. The SALAMANDER trial follows previous clinical trials including a Phase 2 randomized controlled trial where complete ulcer healing occurred in 75% of treated patients (compared to 14% healing in the control group). The SALAMANDER trial is actively recruiting in multiple sites in Europe, including sites in the UK, Spain, Austria, Portugal, Poland, Hungary, the Netherlands, the Czech Republic, Latvia, Lithuania and Georgia.

– ENDS –

For further information, please contact:

At Ixaka	**For media enquiries**
Joe Dupere, CEO +44 (0)20 3700 7480 info@ixaka.com	**Instinctif Partners** Tim Watson / Siobhan Sanford +44 7837 674 500 / + 44 7534 247 411 ixaka@instinctif.com

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 targeted 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; LinkedIn: https://www.linkedin.com/company/ixaka-limited/