

CELTIC-19 granted Advanced Therapy Medicinal Product classification by European Medicines Agency

- *CELTIC-19 – Ixaka’s targeted nanoparticle for CD19 haematological malignancies – has been granted Advanced Therapy Medicinal Product (ATMP) classification by the European Medicines Agency (EMA).*
- *The EMA ATMP status is a positive step forward from the current marketed ex vivo CAR T-cell therapies in the treatment of CD19 malignancies*

London, UK, 08 March 2022: Ixaka Ltd, an integrated cell and gene therapy company, announces that Advanced Therapy Medicinal Product (ATMP) classification has been granted by the European Medicines Agency (EMA) for its Chemically Encapsulated Lentiviral vector for Targeted In Vivo CAR T-cell therapy (CELTIC-19) targeted nanoparticle (TNP) product.

ATMP status was granted to CELTIC-19 due to its potential as a gene therapy medicinal product that targets specific cells and expression of the gene of interest directly within the patient’s body. Such an approach makes it possible to eliminate all the *ex vivo* stages of genetic modification, that are required for the production of currently marketed cell therapy products.

CELTIC-19 is Ixaka’s lead TNP program for CD19 haematological malignancies. It consists of a polymer nanoparticle encapsulating a bald lentiviral vector encoding for a T-cell specific promoter and the chimeric antigen receptor (CAR). The nanoparticle is coated with a CD3 binding molecule allowing *in vivo* targeting and transduction of the T-cells. The construct can then be infused systemically into the bloodstream to target and genetically modify T-cells within the body. This approach allows the generation of CAR T-cells which are potentially more efficacious, safer, and considerably less expensive to produce than established CAR T-cell therapies, which have been shown to be effective and have been approved for use in CD19-malignancies.

CELTIC-19’s numerous advantages over established *ex vivo* CAR T-cells therapies, which include but are not limited to its high specificity and transduction efficiency, retreatment possibility, no cytokine requirement and persistent expression.

Gilbert Wagener, Senior Vice President, Chief Medical Officer at Ixaka commented:

“TNP-based *in vivo* CAR T-cell therapies such as Ixaka’s represent a significant advance over recently approved *ex vivo* CAR T-cell therapies, and hold the promise of delivering more effective, universal, and safer treatment option for patients. It is great to see this potential recognized by the Europeans Medicine Agency.”



Joe Dupere, CEO at Ixaka commented:

“Our nanoparticle-based *in vivo* gene delivery technology is ideally positioned to deliver on the promise of *in vivo* CAR-T therapies to transform cancer treatment without the need for costly dedicated manufacturing sites for T-cell modification. The designation of CELTIC-19 as an Advanced Therapy Medicinal Product further signifies its potential as a ground-breaking new treatment option and is an important step on our continued journey.”

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

For further information, please contact:

Ixaka

Joe Dupere



+44 (0) 203 7007 480
info@ixaka.com
www.ixaka.com

Instinctif Partners (Media Enquiries)

Tim Watson / Siobhan Sandford / Sirine Zeineh / Grace Rutter



+44 7837 674 500
ixaka@instinctif.com
<https://instinctif.com>

