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Elicera Therapeutics submits Clinical Trial Application to evaluate its CAR T-cell therapy in B-cell lymphoma

Gothenburg, January 26, 2022 - Elicera Therapeutics AB (publ) ("Elicera"), a clinical stage cell and gene therapy company developing next-generation therapies based on CAR T-cells armed with bystander immune activating properties using the company's commercially available platform iTANK, and oncolytic viruses today announced that it has submitted a Clinical Trial Application (CTA) to the Swedish Medical Products Agency and the Ethics Committee´ to evaluate its CAR T-cell therapy, ELC-301, in treatment of B-cell lymphoma.

The study aims to evaluate the safety and efficacy of one dose of CD20 directed CAR T-cells, armed with bystander immune activating properties, using the iTANK-platform, in patients with relapsed and/or refractory B-cell malignancies, by studying tolerance, toxicity, biological effects, and anti-tumor responses. The study design proposes conducting the study in two stages: a dose escalation stage to minimize the risk of serious side effects and to identify the appropriate testing dosage, followed by treatment of the remaining patients with the maximum tolerable dose. More information on study design will be presented upon approval of the CTA.

"This is a major milestone for Elicera and for Swedish CAR T-cell research. Should the application be approved, this will be not only the first time Elicera will enter clinical studies with a CAR T-cell therapy but also the first time that our CAR T-cell arming technology iTANK will be tested in a clinical setting. Moreover, as the only Swedish R&D-company developing CAR T-cell therapies in the country, Elicera has with this submission taken a significant step towards meeting a high unmet medical need for patients who are currently ineligible for treatment with market-approved conventional CAR T-cell therapies," says Jamal El-Mosleh, CEO of Elicera Therapeutics.

Elicera's drug candidate, ELC-301, constitutes a fourth generation CAR T-cell therapy that targets the CD20 antigen which, like CD19, is expressed on all B-cell lymphoma cells. ELC-301 is armed with Elicera's iTANK-technology platform to elicit a dual mode-of-action and a broad attack on cancer by also activating the patients' own killer T-cells against the whole set of relevant antigen targets on tumor cells, not only against CD19 or CD20.

Development and preparations for the ELC-301 study have been aided over the past year by grants from the European Innovation Council (EIC) Accelerator Programme and Vinnova. In combination with existing cash, the EU-funding was sufficient to fully fund the study and the Vinnova grant will to be used to develop an automated CAR T-cell manufacturing process to be implemented as Good Manufacturing Practice (GMP).

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About the iTANK platform

The iTANK- (immunoTherapies Activated with NAP for efficient Killing) technology platform has been developed for arming and enhancing CAR T-cells to meet two of the major challenges CAR T-cell therapies face in the treatment of solid tumors: tumor antigen heterogeneity and a hostile tumor microenvironment. The technology is used to incorporate a transgene into CAR T-cells encoding a neutrophil activating protein (NAP) from the bacterium Helicobacter pylori. NAP secreted from the CAR(NAP) T-cells has been shown to be able to enhance the function of CAR T-cells and importantly activating a parallel bystander immune response against the cancer via CD8+ killer T-cells. This is expected to lead to a broad attack against most antigen targets on cancer cells. The iTANK-platform is used to enhance the company's own CAR T-cells but can also be universally applied to other CAR T-cell therapies under development. Proof-of-concept data was published in Nature Biomedical Engineering in April 2022. The publication, titled "CAR T cells expressing a bacterial virulence factor trigger potent bystander antitumour responses in solid cancers" (DOI number: 10.1038/s41551-022-00875-5) can be found here: https://www.nature.com/articles/s41551-022-00875-5. More information about iTANK-platform is available here: https://www.elicera.com/technology

About ELC-301

ELC-301 a CD20-directed CAR T-cell therapy for the treatment of B-cell malignancies. ELC-301 has been armed with the company's iTANK-platform for activation of endogenous killer T-cells against the whole set of relevant target antigens on tumor cells, thus generating a powerful parallel immune response against cancer.

About Elicera Therapeutics AB

Elicera Therapeutics AB is a clinical stage cell and gene therapy company that develops next-generation therapies based on oncolytic viruses and CAR T-cells, armed with the company's proprietary and commercially available platform, iTANK. The work is based on high-profile long-standing research conducted by Professor Magnus Essand's research group at Uppsala University and has resulted in the development of four drug candidates, including two CAR T-cells and two oncolytic viruses. The iTANK-platform is used to arm the company's own CAR T-cells, in addition to the oncolytic virus ELC-201, but can also be universally applied to other CAR T-cell therapies under development. The company's share (ELIC) is traded on Nasdaq First North Growth Market. Erik Penser Bank has been appointed the Company's Certified Adviser.

For more information, please visit www.elicera.com