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Elicera Therapeutics receives conditional approval from the Medical Products Agency on its CAR T-cell Clinical Trial Application to test ELC-301 (CARMA-study)

Gothenburg, April 28, 2023 - Elicera Therapeutics AB (publ) ("Elicera"), a clinical stage cell and gene therapy company developing next-generation therapies based on oncolytic viruses and CAR T-cells armed with bystander immune activating properties using the company's commercially available platform iTANK, today announced that it has received approval from the Swedish Medical Products Agency (MPA) on its Clinical Trial Application (CTA) to evaluate its CAR T-cell therapy, ELC-301, in treatment of patients with B-cell lymphoma (CARMA-study), conditional on certain further validations of its GMP-process. Elicera is acting co-sponsor together with Uppsala university.

The clinical phase I/IIa-study, also called the CARMA-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 clinical trial will be conducted at the Academic hospital in Uppsala and at Karolinska University Hospital in two stages: a dose escalation stage (Phase I) to minimize the risk of serious side effects and to identify the appropriate testing dosage, followed by treatment in Phase IIa of the remaining six patients with the optimal dose identified in Phase I. A total of 12 patients are expected to be able to evaluate for safety and efficacy with the maximum tolerable dose. The dose escalation stage is expected to be completed and reported latest during first half of 2025 and stage 2 is expected to be completed and reported about 6-12 months later. The CARMA-study as a whole is expected to be completed and reported during 2027 after all patients have been followed for at least two years. The MPA grants the application for a clinical trial on the condition that Elicera carries out certain further validations of the GMP-process, which is estimated to be completed and finally approved during Q3 this year.

"This is a major milestone for Elicera and for Swedish CAR T-cell research and development. This will be not only be 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 conditional approval taken a significant step towards meeting a high unmet medical need for patients who currently do not have any potentially curative treatment options," 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 CARMA-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 is sufficient to fully fund the CARMA-study and the Vinnova grant will to be used to develop an automated CAR T-cell manufacturing process to be implemented according to Good Manufacturing Practice (GMP).

For further information please contact:
Jamal El-Mosleh, CEO, Elicera Therapeutics AB
Phone: +46 (0) 703 31 90 51
jamal.elmosleh@elicera.com

About CAR T-cell therapies
CAR T-cell therapy was named "Advance of the year 2018" by ASCO (American Society of Clinical Oncology), one of the world's largest cancer organizations, thanks to the curative potential shown by the treatment in various types of blood cancer such as leukemia and lymphoma. Between 30-40% of patients with various types of blood cancer are expected to achieve a complete ongoing response and for this patient group there are currently six approved CAR T-cell therapies around the world. So far, however, no CAR T-cell therapy has been approved for the treatment of solid tumors. Solid tumors have a very immunosuppressive tumor microenvironment that counteracts the CAR T-cell's ability to attack the cancer cells. In addition, solid tumors have a high degree of heterogeneity, meaning that different parts of the tumor have different genetic mutations, which makes it difficult to direct the CAR T-cell to target all cancer cells. Elicera has developed a technology platform called iTANK that can address both challenges and for which proof-of-concept data was published in one of the world's most prestigious scientific journals, Nature Biomedical Engineering, in 2022.

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