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Elicera Therapeutics Receives Medical Products Agency Approval to Advance CARMA Study into Phase IIa in B-cell Lymphoma

Uppsala, September 17, 2026 – Elicera Therapeutics AB (publ) announced today that the Swedish Medical Products Agency (Läkemedelsverket) has approved a substantial modification to the clinical trial authorization for the CARMA study, permitting the study to proceed into its Phase IIa part. Patient recruitment can now be started, with six patients to be treated at the recommended Phase II dose.

The CARMA study, conducted in collaboration with Uppsala University as the co-sponsor, consists of two parts: a dose-escalation study (Phase I) with 12 patients, which is now complete, and a dose-expansion study (Phase IIa) with 6 patients. The CAR T-cell therapy ELC-301 incorporates the iTANK platform technology, which, through its parallel immune activation, aims to provide a broader and more effective attack on cancer cells.

As previously communicated, no dose-limiting toxicities were reported in Phase I, and the study's independent Data Safety and Monitoring Board (DSMB), after reviewing the safety data, recommended the highest dose level as the Phase II dose. Following the Medical Products Agency's approval of a substantial modification to the clinical trial authorization, Phase IIa patients can now be recruited and treated at this recommended dose level.

The latest data reported from the CARMA study, press released on August 11, showed that among eleven patients treated and evaluated in the Phase I dose-escalation part, all had achieved disease control, and 91 percent (10/11) had obtained an objective tumor response, including six patients (55%) with complete metabolic response (CMR) (disease free status) as best response. Four of these six patients remained in ongoing complete response at their most recent assessment, with two of them confirmed disease-free for at least twelve and eighteen months, respectively.

"The Medical Products Agency's approval to move the CARMA study into Phase IIa is a significant milestone for Elicera. It means our clinical teams can now start treating patients at the dose we've identified as optimal, building directly on the depth and durability of response we've already seen during Phase I. I'm grateful to the patients, investigators and clinical teams in Uppsala and Stockholm who have made this possible. Our focus now is on enrolling patients as quickly as possible so we can bring this therapy closer to patients who need it," says Elicera's CEO, Johan Liwing

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About the CARMA Study
CARMA is a phase I/IIa clinical study evaluating the safety and efficacy of the CAR T-cell therapy ELC-301 in the treatment of patients with B-cell lymphoma. The study is divided into a dose-escalation phase (phase I) and a dose-expansion phase (phase IIa). Phase I primarily aims to establish the optimal dose and safety profile in up to 12 patients, while phase IIa will further evaluate the efficacy of the maximum tolerated dose in an additional six patients. Phase I is planned to include three cohorts (dosing groups), with three patients in the first and second cohorts, and six patients in the third dcohort, who are expected to receive the maximum tolerated dose. The CARMA study is being conducted at Uppsala University Hospital and Karolinska University Hospital in Huddinge.

About ELC-301
ELC-301 is a fourth-generation CAR T-cell therapy targeting the CD20 antigen, armed with the company's iTANK platform to activate a broader and more comprehensive parallel immune response against cancer. CAR T-cells are a form of cell therapy created by genetically modifying a patient's T-cells to express a synthetic receptor (chimeric antigen receptor, CAR). This receptor is specifically designed to target a single tumor antigen—a molecule visible on the surface of cancer cells—and enables the T-cells to locate, bind to, and destroy the cancer cells.

About the iTANK-platform
The iTANK 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: a very diverse set of tumor antigen targets and a very hostile tumor microenvironment. The technology is used to incorporate a transgene into CAR T-cells encoding a neutrophil activating bacterial protein (NAP). 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 triggers potent bystander antitumor 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 Elicera Therapeutics AB
Elicera Therapeutics AB (publ) has developed the patented gene technology platform iTANK that enables the arming of new and existing CAR T-cell therapies targeting aggressive and relapsing cancer forms. Elicera Therapeutics thereby addresses a well-defined and vast market. The company's CAR T-cell therapies have shown a potent effect toward solid tumors which are recognized as particularly difficult to treat and constitute the majority of cancer cases. The company addresses a global multibillion market in cell therapy through its offering of non-exclusive licensing of the iTANK-platform to companies in the pharmaceutical industry. Elicera Therapeutics has four internal development projects in immune therapy that separately have the potential to generate substantial value through exclusive out-licensing agreements. The company's share is traded on Nasdaq First North Growth Market. For additional information, visit www.elicera.com.