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Elicera Therapeutics announces final data from its Phase I/IIa trial demonstrating a favorable safety profile and promising efficacy signals of oncolytic virus ELC-100 in neuroendocrine tumors

Gothenburg, January 9, 2025 – Elicera Therapeutics AB (publ), a clinical stage cell and gene therapy company developing next generation cancer treatments based on its proprietary commercial technology platform iTANK, today announces final data from its Phase I/IIa clinical trial evaluating the oncolytic virus ELC-100 in patients with advanced, end-stage neuroendocrine tumors who had exhausted all currently available therapeutic options and having progressing diseases. The study demonstrates that ELC-100, was generally well-tolerated with no dose-limiting toxicities observed. Importantly, the trial also revealed promising efficacy signals, including partial tumor responses in two out of eight patients evaluable for efficacy, providing early evidence of anti-tumor activity in this highly treatment-resistant population.

Safety results

ELC-100 (formerly referred to as AdVince) was generally well-tolerated, with **no dose-limiting toxicities (DLTs)** observed in any of the 12 treated patients. The safety profile was consistent with the expected mechanism of action of an oncolytic virus, characterized by a manageable inflammatory response. Maximum tolerated dose was established at 1 x 10^{12} virus particles as the highest tested dose.

Encouraging Efficacy signals

Notably, in this highly challenging patient population, consisting of individuals with advanced, end-stage neuroendocrine tumors who had exhausted all currently available treatment options, promising preliminary signals of clinical efficacy were observed. Specifically, **partial responses in 2 of 8 efficacy-evaluable patients**. Twelve weeks after the 4th treatment cycle, 75% of efficacy-evaluable patients (n=8) remained progression free.

Jamal El-Mosleh, CEO of Elicera Therapeutics, commented:

“These are encouraging results from our Phase I/IIa safety trial with ELC-100. In this study of 12 patients with advanced metastatic neuroendocrine tumors, we observed a favorable safety profile with no dose-limiting toxicities and manageable adverse events consistent with the mechanism of an oncolytic virus. Importantly, we saw partial responses in two out of eight patients evaluable for efficacy, which represents meaningful early evidence of anti-tumor activity in a disease setting where new treatment options are needed. We are deeply grateful to the Victory NET Foundation for their generous financial support, which has made it possible to complete this important trial and advance the research and development of innovative therapies for this difficult-to-treat patient population. Given these positive signals, we will now carefully evaluate our strategic options for the continued development of the ELC-100 program.”

About the Phase I/IIa study
The clinical Phase I/IIa-study "Study of Recombinant Adenovirus AdVince in Patients with Neuroendocrine Neoplasms; Safety and Efficacy", enrolled 12 patients in total, in four escalating dose groups. Patients in each dose group received up to eight repeating doses of AdVince via hepatic artery infusion or intra-tumoral injection, with the primary objective of evaluating safety and determining maximum tolerated dose.

Secondary objectives include to evaluate the anti-tumoral efficacy of AdVince infusions on metastatic neuroendocrine tumors and to determine the number of patients with progression-free-survival (PFS) twelve weeks after the 4th treatment cycle.

Efficacy population (n=8): All patients who had received at least one treatment period (four treatment cycles) of investigational product (AdVince, ELC-100) and had both baseline and evaluation of CT data (at the 1-month follow-up visit).

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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.