Elicera Therapeutics AB

EIC-grant offers validation for CAR T-project ELC-301

Magnus Brolin & Johan Widmark | 2022-06-03 08:00

With the 2.5 MEUR grant from the European Innovation Council (EIC) Accelerator Programme, Elicera is now fully financed to complete a clinical phase I/II to evaluate its CAR T-cell therapy ELC-301 for treatment of B-cell lymphoma. The grant was awarded in fierce competition (only 5% of applications are approved) and provides validation of Elicera's science and research. Corresponding to a 1.3 SEK per share the grant also releases resources to other portfolio projects. Consequently, we now find support for a fair value of 13 (12) SEK per share in 12 to 24 months.

2.5 MEUR in funding for ELC-301

Elicera is a clinical phase cell and gene therapy company developing immune-oncology therapies focusing on amplified CART T-cells and oncolytic viruses. Elicera now estimate the planned clinical phase I/II for the development of CAR T-cell therapy ELC-301 to be fully financed, after being granted 26 MSEK from the European Innovation Council (EIC) Accelerator Programme. With the grant, the company has now secured 40 MSEK in total for the ELC-301-program which we expect to enter clinical phase I/II in H2'22. The EIC-accelerator program offers funding support and acceleration services for small and mid-sized companies with an approval rate of less than five percent, which is why we believe that the grant offers considerable validation to Elicera's science and research.

Elicera armed with a broad product portfolio

The approved CAR T-cell therapies available today target the CD19-protein and while those have proven to be effective, a large portion of patients are either resistant to the treatment or relapse within twelve months. These patients have then often lost the CD19 target antigen on the recurring tumors. ELC-301, which is the fourth generation CAR T-cell therapy directs toward the CD20-protein instead, which is expressed on all B-cell lymphoma cells. ELC-301 is also armed with Elicera's own CAR T-cell amplifying platform technology iTANK which offers a broader attack on cancer by also activating the patient's own T-cells against the whole set of relevant target antigens on tumor cells, not just CD19 or CD20. In addition to ELC-301 and ELC-100 Elicera have two additional drug candidates in its portfolio ELC-201 and ELC-401, both in the pre-clinical phase.

Stable pipeline of triggers support revaluation potential

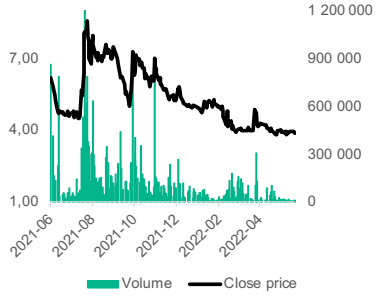
For Elicera's other project, ELC-100, an oncolytic virus for treatment of neuroendocrine tumors, we now look forward to efficacy data from the ongoing phase I/II study during 2022. With a portfolio of immune-oncology projects in clinical and pre-clinical phases, as well as the iTANK platform which is already in the commercial phase, and a stable pipeline of triggers during the year, plus 1.3 SEK per share in EIC-grants for the forthcoming phase I/II with ELC-301, we find ample support for a revalaution of the share. The company's strategy is focused on partnerships after initial clinical phases and with effective measures and potential for early out-licensing for ELC-100, the start of clinical studies for ELC-301 and probable pilot agreements for iTANK in 2022, we see an overall risk-adjusted net present value for these three verticals at 256 MSEK or a fair value 13 (12) SEK per share.

NAV

MSEK	Peak Sales MUSD	Probability LOA	rNPV MSEK	rNPV per share
ELC-100	210	5,3%	45	2,3
ELC-301	540	4,6%	150	7,6
iTank	n.m.	4,6%	60	3,1
SUM			**256**	**12,9**

Source: Emergers

Elicera Therapeutics	
Fair Value, SEK	**13,0**
Current Price, SEK	4,10
Shares (M)	19,78
Market Cap (MSEK)	81
Net Debt (MSEK)	-52
EV (MSEK)	29
Market	First North

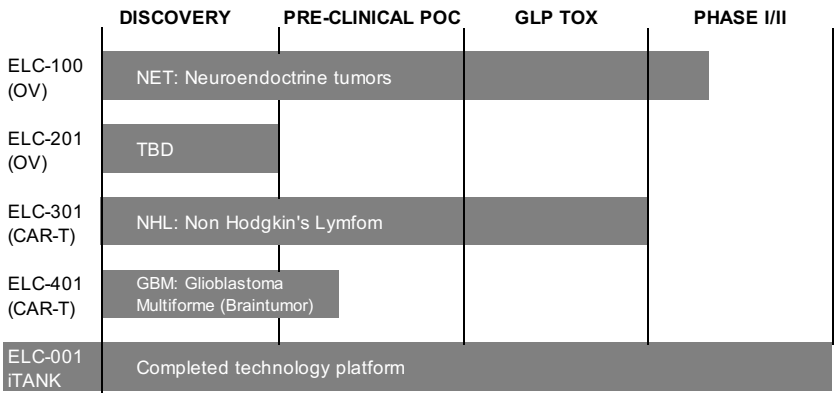


About Elicera

Elicera is a cell and gene therapy company active in so-called immune oncology, ie therapy against cancer based on using the patient's immune system against tumors.

Elicera is developing four drug candidates, two of which are in the field of oncolytic viruses and two in the field of CAR T-cell treatments, as well as a platform technology called iTANK (ImmuoTherapies Activated with Nap for efficient Killing) for further immune boosting in treatment in the said field.

Product portfolio



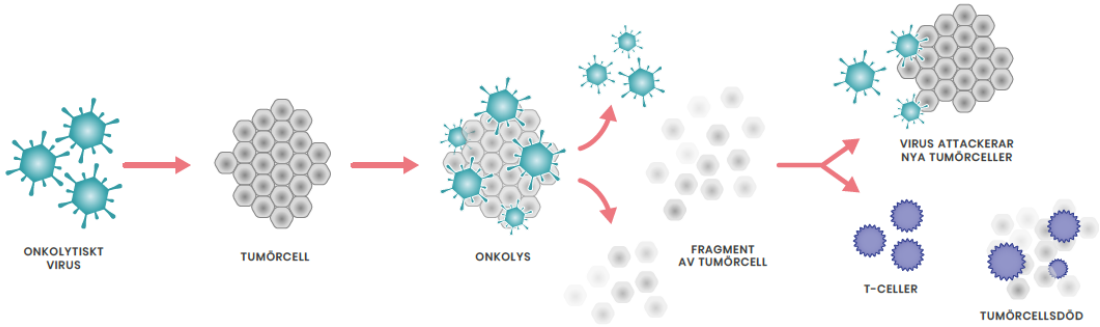
POC: Proof-of-Concept
GLP: Good laboratory practice

Source: Emergers, Elicera

Elicera's drug candidates are based on many years of research conducted by Professor Magnus Essand's research group at Uppsala University. Successful research and development in cell and gene therapy require a deep understanding of how cells and viruses can be genetically modified to trigger a powerful immune response against cancer. Based on Elicera's expertise, the company has developed a technology platform called iTANK (ImmunoTherapies Activated with NAP for efficient Killing) which makes it possible to develop different types of immune-activating treatments, each of which produces a multifaceted attack on the tumors. The iTANK platform can be used to optimize all the company's own CAR T cells under development as well as other companies.

Elicera's drug candidates are likely to achieve the greatest effect in combination with other immunotherapies such as checkpoint inhibitors (CPIs). This makes the company's projects interesting as combination therapies for other companies in immune oncology.

The role of Oncolytic viruses



Source: Elicera

iTANK broad attack against solid tumors

iTANK (Immunotherapies Activated with NAP for Efficient Killing) is Elicera's universal CAR T cell enhancing platform technology that generates a parallel immune response through a multidirectional attack on cancer cells by activating endogenous killer T cells:

- The iTANK platform arms CAR T cells with a transgene encoding a neutrophil activating protein (NAP) from Helicobacter Pylori. When the CAR (NAP) T cell binds to tumor cells, NAP is released which activates surrounding immune cells to further release immune-stimulating cytokines and chemokines.
- This in turn creates a pro-inflammatory environment that directly fights the hostile tumor microenvironment in solid tumors and strengthens the function of CAR T cells.
- The proinflammatory microenvironment will also induce a so-called "bystander" immune activation, which means that antigen-presenting cells will be recruited to the tumor site, where they will pick up the full set of relevant tumor target antigens released from dying tumor cells attacked by CAR T cells. These target antigens will then be presented to CD8 + killer T cells in the lymph nodes and the activated killer T cells will then seek out and destroy tumor cells carrying these target antigens

Taken together, the use of iTANK provides good conditions for counteracting two of the biggest challenges that CAR T cell therapies face in the treatment of solid tumors: antigen heterogeneity and a hostile microenvironment in the tumor. Therefore, iTANK can be an important step on the way to developing effective CAR T-treatments for solid tumors, which is about 90% of all tumors.

The publication in Nature Biomedical Engineering on iTANK entitled “CAR T cells expressing a bacterial virulence factor trigger potent bystander antitumor responses in solid cancers” (DOI number: 10.1038 / s41551-022-00875-5) can be found via the following link: https://www.nature.com/articles/s41551-022-00875-5.

Financing

What is expected to cost the most money in the future are primarily the clinical trials and GMP production of CAR-T cells. At the end of the fourth quarter, cash amounted to 52 MSEK, which is expected to last until mid-2023. In addition, the warrant from the unit issue can bring in an additional SEK 38 million during December 2022, plus any over-allotment of SEK 7 million. However, it is dependent on a price increase of 45% compared with the subscription price in the listing issue, or about 140% from the current price level to the exercise price of SEK 12. With the 26 MSEK grant from the European Innovation Council (EIC) Accelerator Programme, Elicera is now fully financed to complete a clinical phase I/II to evaluate its CAR T-cell therapy ELC-30.

Valuation

Our net asset value is based on risk-adjusted discounted net present value calculations of the main projects and the iTANK platform. These show the total value of the projects in the portfolio of 256 MSEK. As the company makes progress with the various projects and reduces the risk, we see the potential for a continued long-term revaluation against the levels of the international comparison objects.

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Risks and sensitivity analysis

In addition to the above-mentioned risks of failure in clinical development, which is an inherent operational risk in all companies that develop drugs, there are a couple of specific risks to note.

The cytokine storm

An important challenge and side effect of existing CAR-T treatments is the cytokine storm that the treatment causes. Over 75% of patients treated with CAR-T experience Cytokine Release Syndrome (CRS) and 25-50% suffer from severe CRS, which involves intensive care. It should be noted, however, that the very idea of iTANK is to create a release of cytokines and chemokines to create a pro-inflammatory environment that triggers the immune system against cancer. The increased release of cytokines with iTANK should therefore reasonably mean an exacerbated CRS. At the same time, it is worth remembering that even severe CRS is considered an acceptable risk and side effect for the stage IV patients currently treated with CAR-T and there are normally no other effective treatment options. However, increased CRS with iTANK risks affecting the possibility of licensing agreements for projects in stage III and stage II cancer, where the alternatives are more numerous and the susceptibility to serious side effects greater. Elicera has also tested iTANK preclinically in mice without seeing any serious side effects and believes that the effect is most likely local and not systemic. The first clinical CAR-T cell study will also be done as a dose-escalation study where you start with a lower dose and gradually increase it as you see that it does not cause any serious side effects.

Sensitivity analysis

In addition to the risk of negative outcomes in the clinical trials, an important risk in all drug development is the risk of delays. The table below shows justified value as a function of the discount rate and delays of ELC-100 and ELC-301, measured as shifts in the discount rate in steps of -1 year.

Fair value as a function of delay and discount rate

		Discount rate				
		8%	10%	12%	14%	16%
Delay Year	4	14,9	11,8	9,6	7,8	6,5
	3	15,6	12,6	10,2	8,4	7,0
	2	16,4	13,3	10,9	9,1	7,6
	1	17,3	14,2	11,8	9,9	8,3
	0	18,2	15,1	12,7	10,7	9,1

Source: Emergers

Management

Agneta Edberg, Chairman, has over 20 years of experience in life science. She is previously chairman of, among others, Immunicum AB, listed on NasdaqOMX Small Cap, and has several board assignments in listed companies. Agneta Edberg owned 100,000 shares before the listing issue. Jamal El-Mosleh, CEO, has over 13 years of experience as CEO of several biotech companies, including 10 years as CEO of the immunology company Immunicum AB. Jamal El-Mosleh owned 2,664,000 shares before the issue. Magnus Essand is a CSO and co-founder. Essand is a professor of gene therapy and is, among other things, the author of 95 publications and has received several awards and research grants. Essand has clinical experience with CAR-T cells and oncolytic viruses.

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