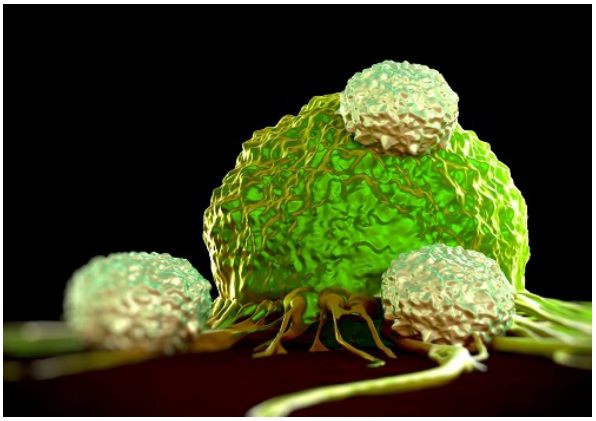
CAR-T acknowledged by FDA committee

Reprogramming of individual T-cells strengthens fight against cancer

Novartis recently announced a unanimous recommendation of their CAR-T cell therapy CTL019 by the US Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC). CTL019 is an investigational chimeric antigen receptor T cell (CAR-T) therapy for patients with relapsed or refractory B-cell acute lymphoblastic leukemia. This recommendation of a FDA committee marks a milestone not only for the Pharma giant, but for the fast growing CAR-T technology field as a whole.



Race for the optimal CAR-T cell approach continues

The recent success puts Novartis ahead in the CAR-T group. With several large Pharma and startup companies researching varying CAR-T strategies, the movement has the potential to reshape much of the medical landscape in years to come. First however, any new approach will have to withstand the scrutiny of clinical trials - and pass as well or better than the new gold standard.

Improving transduction and cell survival

CAR-T technology is based on T-cells that are isolated from an individually patient and then genetically modified. The genetic "reprogramming" enables the immune cells to recognize and fight cancerous tissue once they are reintroduced into the patient. The approach holds large promise due to its high specificity and low danger of inciting immune-reaction against the re-implanted cells. Its success however ultimately hinges on how **efficiently** the limited amount of available patient cells can be treated. A common approach to treat T-cells is to exploit lentivirus particles as gene delivery tools. However, even with these highly specialized vectors, T-cell survival during ex-vivo treatment is limited. This is why viral technology experts at SIRION Biotech developed a way to

- **improve T-cell transduction efficiency and**
- **improved T-cell survival**

- by applying **LentiBOOST™**, a polymeric reagent, that is simply added to the transduction reaction.

Easily applied LentiBOOST™ increases transduction efficiencies and survival of primary T-cells during treatment.

It increases the final T-cell **yield by a factor of up to 4** in large scale manufacturing processes - critically increasing the chances of success for any commercial CAR-T application. Increased transduction efficiencies at lowered MOIs help reduce cost of goods. The reagent is available in clinical grade and already applied in clinical trials (III and I) for the genetic treatment of hematopoietic stem cells.

SIRION Biotech is continuously expanding their viral vector and transduction booster platforms to adapt to the various challenges of modern gene- and cell-therapy trials - Making vector systems and transduction methods more **efficient, safe and productive**.

About the company

Highest Technological Standards

SIRION Biotech is world leader for innovating virus vector technologies and also provides **custom services** to academic and industrial partners worldwide. SIRION is the only company mastering **all 3 major virus types** that are used regularly for genetic manipulation of cell systems.

- Customized viral vectors
- Cooperative vector development for clinical applications
- Technology licensing

Technological features include

- Advanced expression control systems
- All-in-one Lentivirus, AAV and Adenovirus vectors
- Potent transduction boosters

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A true dual-citizen of American and German descent, Carl has worked on both sides of the Atlantic. With his well based knowledge of cellular, neuro- and cardiac physiology and his unique bilingual background, he maintains fast and precise communications between the SIRION headquarters in Germany and US clients.

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