

BNT211 is a product candidate that may help the body's natural defense by recognizing and destroying cancer cells that have a certain protein on their surface.

CAR-T¹ cell therapy

Targeting a protein named CLDN6 that is expressed on multiple solid tumors

Aim: Detect and destroy tumor cells



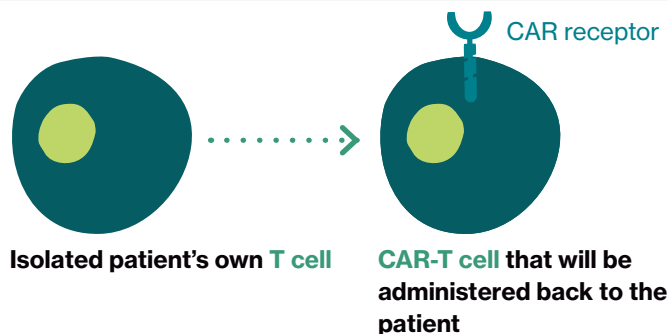
mRNA vaccine (CARVac²)

Providing patient's immune cells with the building plan for CLDN6

Aim: Boost CAR-T cell activity

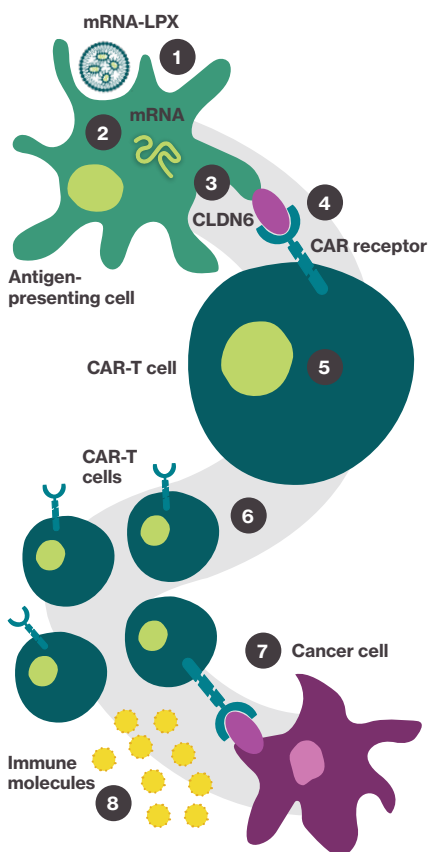
CAR-T cell therapy

- Patient's own T cells are modified
- Target CLDN6 is not present on healthy adult cells
- Aimed to be suitable for patients with CLDN6-expressing tumors such as ovarian, endometrial, testicular, gastric, lung, and rare cancers



mRNA vaccine (CARVac)

We additionally activate the CAR-T cells with our mRNA technology which boosts their power to target cancer cells



- 1 Formulated mRNA coding for CLDN6 enters the antigen-presenting cell
- 2 mRNA is released
- 3 CLDN6 is produced based on information in mRNA and docks to the cell surface
- 4 CAR-T cell binds CLDN6 on the antigen-presenting cell
- 5 The binding between CAR-T cell and CLDN6 activates the signaling in CAR-T cell
- 6 Due to signaling the CAR-T cells expand in number
- 7 Stimulated CAR-T cell directly targets the cancer cell for elimination
- 8 Immune molecules that contribute to cancer elimination are released by CAR-T cells

Safety

- CLDN6 CAR T cells as monotherapy or combined with CARVac (mRNA) were well tolerated by patients at evaluated dose levels in Phase 1/2 clinical trial

Efficiency

- All 21 evaluable patients showed robust, dose-dependent CAR-T cell expansion
- Strongest responses seen in lymphodepleted testicular cancer patients treated at dose level 2 with overall response rate of 57% and a disease control rate of 85%
- Efficacy assessment of the 21 evaluable patients showed a best overall response rate (ORR) of 33% and a disease control rate (DCR) of 67%

Outlook

- Further optimization of the automated manufacturing process planned
- Recommended phase 2 dose will be identified for the newly established manufacturing process

ESMO 2022 Update

(1) CAR-T stands for Chimeric Antigen Receptor T cells. Chimeric refers to the fact that the receptor combines the antigen domain (target) and a stimulating domain (for activating T cells).
 (2) CARVac stands for CAR-T Cell Amplifying RNA Vaccine.

Full process of delivering the personalized CAR-T therapy to the patient

01 Collection of patient's T cells



The patient's white blood cells including T cells are being separated from the blood sample in a process called apheresis in the clinic and afterwards shipped to the GMP facility at 2-8 °C.

02 Automatized Manufacturing



Newly automatized manufacturing process is performed in a closed system uniting all the steps in a single workflow. This aims at increasing the robustness and the number of patient products that can be manufactured.

03 Quality control and packaging



The batches are going through the process of quality control and packaging, followed by the shipping at temperatures below -130 °C to the respective clinic, where they can be stored in a cryoshipper before treatment of the patient.

04 Therapy administration to the patient



The patient receives the therapy according to the approved regimen, with medical staff closely supervising the patient in the clinical trial.