
Preparation of a clinical trial of CAR-NK cells in patients with Her2-expressing tumors

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Her2 (ErbB2) is a tumor antigen expressed by approximately a third of all breast, ovarian and colon cancers, as well as osteosarcomas and other tumors. Such tumors respond particularly poorly to standard therapy. We are planning to treat patients with Her2-expressing tumors with Natural Killer cells (NK cells) genetically engineered to carry a Chimeric Antigen Receptor (CAR), a molecular tool that allows the specific targeting and killing of Her2-expressing cells. Leveraging the CAR-Her2-specific cell line NK-92/5.28.z which we are currently already exploring in clinical trials for patients with recurrent Glioblastoma, where the cells are injected into the tumor cavity, in this project we will prepare a trial in the above-mentioned cancer indications and apply for the necessary permits according to §42 of the German Medicines Act (AMG). Preparation specifically entails validation of the GMP process for manufacturing of therapeutic doses of NK-92/5.28.z for intravenous injection as well as preparation of a study protocol and investigational medicinal product dossier (IMPD) followed by submission thereof together with an application to the European regulatory agency for the clinical trial. The anticipated result of the project is readiness to commence a clinical phase I trial in adult patients with different Her2-expressing tumors.
