

HER1 THERAPEUTIC CANCER VACCINE: AN ACTIVE IMMUNOTHERAPY TREATMENT FOR PATIENTS WITH TUMORS EXPRESSING THE RECEPTOR OF EPIDERMAL GROWTH FACTOR (EGF-R)

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Her1 vaccine: It consists of immunizing patients with positive tumors for the epidermal growth factor receptor (EGF-R) with a preparation of EGF-R extracellular domain(HER1-ECD) adjuvanted in VSSP (very small size proteoliposomes) and Montanide ISA51. VSSP adjuvant confers to vaccine the capacity to activate dendritic cells and polarize the immune response towards a TH1 immune pattern, developing TCD8+ cells and antibodies with anti-metastatic effect.

The extracellular domain of the epidermal growth factor receptor was obtained from HEK293 transfectome by using a productive process in a bioreactor in perfusion as mode of fermentation. The protein was purified by immune-affinity chromatography by using specific anti-EGF-R antibody.

Phase I trial, uncontrolled, open and sequential, was conducted in 25 with hormone refractory prostate cancer patients. Five dose levels of HER1-ECD were scaled: 100, 200, 400, 600 and 800 µg in each immunization. The trial showed that the vaccine was safe, not causing severe or very severe related events. The vaccine preparation was shown to be immunogenic. There was a trend towards the survival benefit in some patients.

At the present time another clinical trial is underway in three locations of advanced solid tumors that overexpress the EGF receptor: prostate, colon and head and neck cancer.