TPIV 200 Triple Negative Breast Cancer

Therapeutic area

Oncology

Target indication

Triple Negative Breast cancer

Development stage

Phase 2

Description

Breast cancer treatments have come along way in the last 30 years. With the advent of monoclonal antibodies, patients have been given new ammunition in the fight to survive. One of the hardest groups of breast cancer patients to treat are those with triple negative breast cancer (TNB). These patients don't respond to hormone therapies (progesterone and estrogen) or to immunotherapies such as monoclonal antibodies. They must undergo surgery, radiation and chemotherapy as their sole defense. Once these treatments are exhausted, there are few options left. Patients with TNB over-express the folate receptor alpha protein on their cancer cells. The use of TPIV 200, which targets an over expressed receptor–folate receptor alpha, may have a beneficial effect on these patients by training the immune system to help eradicate cells with this receptor. TPIV 200 is a shelf-stable, lyophilized mixture of five short peptides. It is reconstituted at the site prior to injection. Currently patients are receiving one dose per month for six months.

Mode of action

This new vaccine approach was developed by Dr. Keith Knutson at the Mayo Clinic and is designed to activate both the CD4+ and CD8+ (helper and killer) T-cell compartments. Recent developments in immunology suggest that both CD4+ and CD8+ activation is necessary for a robust immune response against foreign antigens. The peptides administered to the patient are designed to be presented to the immune system to activate T-cell against the target.

Trial results

The Phase 1 trial in 22 patients with triple negative and ovarian cancer showed TPIV was safe and well-tolerated. The trial also showed that 16 out of 16 patients had robust immune responses against all five peptides in the product and that the immune response was durable for well-over six months after the last treatment.

Development plan

The Phase 2 program for TPIV 200 is designed to examine this novel T-cell vaccine both as a stand-alone therapy and as a combination therapy with other standard of care therapies and newer experimental therapies. TapImmune will have four Phase 2 clinical trials enrolling patients by 1st Q of 2017. There are currently two trials running and enrolling patients – one is using TPIV 200 as a standalone therapy in triple negative breast cancer. This trial is designed to look at dosing regimens, immune responses and efficacy. It is an 80-patient open-label trial sponsored by TapImmune and is enrolling in 12 clinical sites. The second trial is a combination trial with Astra Zeneca's checkpoint inhibitor durvalumab and TPIV 200. As mentioned above, this study looks at patients who have failed chemotherapy for ovarian cancer. Two additional trials will begin in early 2017- a clinical trial in platinum-sensitive ovarian cancer (starting to enroll in January 2017) and a large (280 patient) triple negative breast cancer study sponsored by the Mayo clinic with a $13.3M grant from the Department of defense. This trial is a double-blind placebo controlled study designed to look primarily at efficacy and immune responses in TNB patients.

Overall, the strategy is to obtain positive Phase 2 data and then look for a partnership or collaboration to fund the rest of the commercialization for TPIV 200.

Partnership status

Although TapImmune is collaborating with the Mayo Clinic, Astra Zeneca and Memorial Sloan Kettering Cancer Center, there is no business arrangement for the development of TPIV 200. TapImmune has the exclusive world-wide rights to TPIV 200, TPIV 100 and TPIV 110.