



TPIV 200 Platinum-sensitive Ovarian Cancer

Therapeutic area

Oncology

Target indication

Ovarian cancer

Development stage

Phase 2

Description

The standard of care for ovarian cancer is treatment with carbo *cis* platinum. Patients that respond to therapy have a better chance of survival than those who fail therapy or whose cancer is platinum resistant. The overall prognosis for ovarian cancer is not promising with the average time to relapse being around 18 months. The use of TPIV 200 that 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. The product 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 6 months. Alternative dosing strategies are being explored.

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 1stQ of 2017. There are currently two trials running and enrolling patients – one is using TPIV 200 as a stand-alone therapy in triple negative breast cancer, the second is in a combination trial with Astra Zeneca’s checkpoint inhibitor, durvalumab. This study looks at patients who have failed chemotherapy for ovarian cancer. In addition, two additional trials will begin in early 2017- the aforementioned trial in platinum sensitive ovarian cancer 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.

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.