A phase 1a/b study to evaluate the safety and efficacy of OPB-101, an autologous mesothelin (MSLN) CAR T cell therapy with antigen-dependent expression of OUTSMART designed IL-2 cytokine in platinum-resistant ovarian cancer

Status: Recruiting

Eligibility Criteria

Sex: Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- confirmed diagnosis of high grade serous epithelial ovarian, peritoneal, or fallopian tube cancer - recurrent platinum-resistant disease, cancer has recurred within 6 months of the last dose of platinum-based chemotherapy - received at least 2 but no more than 3 prior lines of systemic chemotherapy including a platinum based chemotherapy - may not be able to do strenuous activity but able to walk and do work of a light or sedentary nature, e.g., light house work, office work - women childbearing potential must be willing to abstain from heterosexual activity or to use 2 forms of effective methods of contraception from the time of informed consent until 12 months after the last dose of therapy - see link to clinicaltrials.gov for complete inclusion criteria

Exclusion Criteria:

- women who are pregnant or breastfeeding - uncontrolled bacterial, fungal, or viral infections - active invasive cancer other than the cancer under study - significant lung disease - active central nervous system (CNS) involvement - dependent on intravenous hydration or total parenteral nutrition - see link to clinicaltrials.gov for complete exclusion criteria

Conditions & Interventions

Conditions:
Cancer
Keywords:
Clinics and Surgery Center (CSC)

More Information

Description: This study will enroll patients with ovarian cancer who have experienced their cancer worsening after at least two previous treatments. This study will give these patients OPB-101, a genetically engineered CAR-T cell therapy product - a product that will be created from the patient's own T-cells - that the researchers hope has been designed to more accurately recognize and destroy the cancer cells. The goal of this study is to make sure OPB-101 is safe to give, if it is effective against this type of cancer, and to find the best dose of OPB-101 to give patients.
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