Phase I Study of Peptide Alarm Therapy (PAT) Administered by Intratumoral Injection with a PD-1/PD-L1 Inhibitor in Patients with Solid Tumor Cancers Who Have Failed Two Prior Therapies

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

- positive for Cytomegalovirus (CMV) and Epstein–Barr virus (EBV - failed prior treatment with a PD-1/PD-L1 inhibitor. Examples of PD-1/PD-L1 inhibitors are pembrolizumab (Keytruda), nivolumab (Opdivo), cemiplimab (Libtayo), atezolizumab (Tecentriq), avelumab (Bavencio), and durvalumab (Imfinzi). - strenuous activity may be restricted; can do light work; able to walk - people of childbearing potential or with partners of childbearing potential must be willing to abstain from heterosexual activity or use a highly effect form of contraception from the time of study enrollment until at least 4 months after the last dose study drug - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- women who are pregnant or breast feeding - active metastases to the central nervous system - active autoimmune disease that has required systemic treatment in the past 2 years - history of bone marrow and/or solid organ transplant - other active medical conditions - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Interventions:
Drug: Peptide Alarm Therapy (PAT)
Conditions:
Cancer
Keywords:
Clinics and Surgery Center (CSC), metastasis, solid tumor

More Information

Description: This study is testing an “investigational” drug referred to as peptide alarm therapy (PAT) that was specially made for this study. PAT is using the peptide to stimulate the immune system for people who have failed prior treatment with a PD-1/PD-L1 inhibitor. Examples of PD-1/PD-L1 inhibitors are pembrolizumab (Keytruda), nivolumab (Opdivo), cemiplimab (Libtayo), atezolizumab (Tecentriq), avelumab (Bavencio), and durvalumab (Imfinzi). The goal of the 1st part of the study is to identify an acceptable, safe dose of PAT and up to 3 dose levels of PAT will be tested. If dose level 3 is reached without toxicity, it becomes the dose used for the next part of the study. In the 2nd part of the study, additional patients are treated at the PAT dose identified as safe in the 1st part to gain additional safety information and provide an initial estimate of anti-cancer effect.
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