CANCER VACCINE INSTITUTE
UW Medicine

Study Title	A Multicenter Phase 2 Study to Evaluate Efficacy and Safety of PRGN-2009 in Combination with pembrolizumab in Patients with Recurrent or Metastatic Cervical Cancer
Study Population	Patients with recurrent or metastatic cervical cancer (histologically or cytologically confirmed) that has progressed after standard of care treatment with pembrolizumab.
Study Design	The investigational product PRGN-2009 is an adenoviral vector expressing a human papillomavirus (HPV) antigen which will be delivered subcutaneously. Patients will receive PRGN-2009 and pembrolizumab. Patients will be monitored by images collected at baseline and every 6 weeks until confirmed progression and response are assessed per RECIST 1.1 (CT CAP or MRI). Research blood samples will be collected at baseline and at each visit for correlative studies from all subjects. Patients will undergo follow-up every 12 weeks for five years or until death, withdrawal of consent, lost to follow-up, study discontinuation or completion of the study. The goal of the study is to assess the safety of the combination of PRGN-2009 with pembrolizumab. In addition, estimate the contribution of PRGN-2009 has on the effect of the combination therapy.
Key Eligibility Criteria	1. Recurrent or metastatic cervical cancer (histologically or cytologically confirmed) 2. Must have been treated with pembrolizumab, either alone or in combination for at least 6 weeks a. Patients that discontinued pembrolizumab treatment due to an adverse event or have an ongoing adverse event due to pembrolizumab treatment are ineligible for the study 3. Histologically or cytologically confirmed HPV positive disease 4. Measurable disease that can be measured by RECIST v1.1 criteria in at least one dimension as ≥1.0cm or ≥1.5 cm for lymph nodes. 5. Adequate organ function determined by laboratory values 6. Negative serum pregnancy test 7. Cannot have prior chemotherapy or radiation therapy with the intent to treat within 14 days of start of study treatment; or any antineoplastic monoclonal antibody within prior 4 weeks 8. Cannot have a diagnosis of immunodeficiency. 9. Cannot have active hepatitis B or C infection based on testing performed within 30 days of enrollment to the study 10. Cannot have a history of pneumonitis or interstitial lung disease 11. Cannot have other malignancy with 1 year prior to study entry 12. Cannot have known central nervous system (CNS) disease 13. Cannot be currently participating or have participated in a study of an investigational agent or have used an investigational device within 4 weeks prior to the first dose of study treatment.

Study Treatment	Enrolled patients will receive: • At least 3 doses of PRGN-2009 every 3 weeks for three administrations, thereafter patients will continue to receive PRGN-2009 administrations every 6 weeks until disease progression, unacceptable toxicity, study closure or withdrawal of consent. • Pembrolizumab will be administered concurrently as intravenous (IV) infusion (400 mg) every 6 weeks until disease progression, unacceptable toxicity, study closure or withdrawal of consent.
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