Protocol Title: A Phase II Study to Evaluate Safety and Anti-tumor Activity Of Avelumab In Combination with Talazoparib In Patients with BRCA Or ATM Mutant Tumors (Javelin BRCA / ATM)

Target Population: Locally Advanced or Metastatic Solid Tumors with BRCA 1/2 or ATM gene defects

Summary: Avelumab in combination with Talazoparib will be investigated in patients with locally advanced or metastatic solid tumors with a BRCA or ATM defect.

Key Inclusion Criteria:
- BRCA1, BRCA2 and/or ATM gene defect.
- Histological diagnosis of locally advanced (primary or recurrent) or metastatic solid tumors that are not amenable for treatment with curative intent.
- Availability a tumor tissue sample from a diagnostic biopsy/surgery or a metastatic tumor biopsy.
- Minimum age 18 years.
- ECOG Performance Status 0 or 1.
- Adequate bone marrow, renal and liver function.

Key Exclusion Criteria:
- Prior anti-cancer therapy or radiation therapy within 2 weeks prior to enrolment.
  - Palliative radiotherapy to metastatic lesion(s) permitted providing that it has been completed at least 2 days prior to enrolment and no significant toxicity are expected.
- Major surgery within 4 weeks prior to study enrollment.
- Current use of immunosuppressive medication at the time of study enrollment.
- Known prior severe hypersensitivity to investigational products or any component in their formulations.
- Known history of immune-mediated colitis, inflammatory bowel disease, pneumonitis, pulmonary fibrosis.
- Active or prior autoimmune disease that might deteriorate when receiving an immunostimulatory agent.
- Prior organ transplantation including allogenic stem-cell transplantation.
- Diagnosis of myelodysplastic syndrome.
- Known symptomatic brain metastases requiring steroids.
- Persisting toxicity related to prior therapy Grade >1.
- Known history of HIV or AIDS.
- Positive HBV or HCV test indicating acute or chronic infection.
- Active infection requiring systemic therapy.
- Clinically significant (active) cardiovascular disease: cerebral vascular accident/stroke or myocardial infarction within 6 months prior to study enrollment; unstable angina, congestive heart failure or a serious cardiac arrhythmia requiring medication.
- Diagnosis of any other malignancy within 2 years prior to study enrollment, except for adequately treated basal cell or squamous cell skin cancer, or carcinoma in situ of the breast, bladder, or cervix, or low-grade prostate cancer or other early-stage low-risk cancers.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03565991