Protocol Title: A Randomized Phase II Study of Anti-PD1 Antibody [MK-3475 (Pembrolizumab)] Alone Versus Anti-PD1 Antibody Plus Stereotactic Body Radiation Therapy in Advanced Merkel Cell Carcinoma

Target Population: Stage III, IIA, IIB, or IV Merkel Cell Carcinoma (MCC)

Summary: This randomized phase II trial studies how well Pembrolizumab with or without stereotactic body radiation therapy works in treating patients with Merkel Cell Cancer that has spread to other places in the body.

Key Eligibility Criteria:
- Patients must have pathologically (histologically or cytologically) proven diagnosis of Merkel Cell Carcinoma (MCC).
- Patients must have measurable disease including at least 2 cancerous deposits.
  - At least 1 deposit must be RECIST measurable while at least 1 deposit must meet criteria for SBRT.
  - NOTE: Non-radiated tumor will be identified prior to randomization on the protocol.
- Patients must have advanced or metastatic MCC defined as evidence of distant metastasis(es) on imaging.
  - Patients with locoregionally confined disease are NOT eligible.
- No prior immunotherapy for advanced/metastatic MCC.
- Patients with known or suspected CNS metastases, untreated CNS metastases, or with the CNS as the only site of disease are excluded.
  - However, subjects with controlled brain metastases will be allowed to enroll.
- Patients having received palliative radiotherapy for extracranial metastasis(es) are eligible as long as there are 2 cancerous deposits that have not received prior radiation therapy (RT) and they meet the following criteria:
  - No prior radiation therapy (> 5 Gy) to the metastasis intended to be treated with SBRT.
- No other active malignancy that the investigator determines would interfere with the treatment and safety analysis.
- ECOG Performance Status 0 – 2.
- Adequate bone marrow, liver, renal, and coagulation function.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03304639