Cancer Research Consortium of West Michigan
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# FAST FACTS

## EA6174: STAMP: Surgically Treated Adjuvant Merkel cell carcinoma with Pembrolizumab, a Phase III Trial

Eligibility Criteria

1. Patient must be ≥ 18 years of age.
2. Patients must have an ECOG performance Status: 0, 1, or 2. (However, those patients with a performance state of 3 because they are wheel chair bound due to congenital or traumatic events more than one year before the diagnosis of Merkel cell carcinoma are eligible)
3. Patient must not be pregnant or breast-feeding due to the unknown effects of the study drug in this setting.

   All patients of childbearing potential must have a blood test or urine study within 2 weeks prior to randomization to rule out pregnancy.

   A patient of childbearing potential is anyone, regardless of sexual orientation or whether they have undergone tubal ligation, who meets the following criteria: 1) has achieved menarche at some point, 2) has not undergone a hysterectomy or bilateral oophorectomy; or 3) has not been naturally postmenopausal (amenorrhea following cancer therapy does not rule out childbearing potential) for at least 24 consecutive months (i.e., has had menses at any time in the preceding 24 consecutive months).

   Patient of child bearing potential? _____ (Yes or No)

   Date of blood test or urine study: _____

4. Patients on Arm A MK-3475 (Pembrolizumab) must not conceive or father children by using accepted and effective method(s) of contraception or by abstaining from sexual intercourse from the time of registration, while on study treatment, and continue for 120 days after the last dose of study treatment. For patients on Arm B only receiving radiation therapy, contraception use should be per institutional standard.
5. Patient must have a histological confirmation of diagnosis of Merkel cell carcinoma (MCC), pathologic stages (AJCC version 8) I-IIIb.
   - Stage I patients with negative sentinel lymph node biopsy are ineligible. Patients who have a positive biopsy or for whom no biopsy was done are eligible.
   - Patients with distant metastatic disease (stage IV) are ineligible.
   - The primary tumor must have grossly negative margins. (Microscopically positive margins are allowed).
   - Cancers of unknown primary that have regional disease only are eligible.
   - Complete nodal dissection is not required for eligibility.

6. Patients with all macroscopic Merkel cell carcinoma (either identified by physical exam or imaging) have been completely resected by surgery within 16 weeks before randomization.

   All patients must have disease-free status documented by a complete physical examination and conventional imaging studies within 8 weeks prior to randomization.

7. Patient may not have a history of distant metastatic disease.
   **NOTE:** loco-regional recurrent disease is acceptable, as long as this is not metastatic (prior surgery with or without radiation therapy is acceptable).

8. For patients with initial presentation of Merkel cell carcinoma, patient must have no previous systemic therapy or radiation therapy prior to surgery for Merkel cell carcinoma and cannot have completed adjuvant radiation therapy for Merkel Cell Carcinoma more than 6 weeks prior to randomization. Patients actively undergoing radiation therapy or having completed adjuvant radiation therapy within 6 weeks of randomization are eligible, as long as resection date is within 16 weeks of randomization. Patients with prior radiation at a non-Radiation Oncology Core (IROC) provider are eligible for the trial. If the patient has not received radiation, and treatment at a Radiation Oncology Core (IROC) provider is not possible, the patient can start and complete radiation prior to randomization, with recommendations to follow radiation protocol guidelines with submission of treatment records.
9. Patient must have the following required values for initial laboratory tests obtained within 4 weeks prior to randomization.
   - White Blood Count (WBC) ≥ 2000/uL:
   - WBC: _____ Date Obtained: _____
   - Absolute neutrophil count (ANC) ≥ 1000/uL:
   - ANC: _____ Date Obtained: _____
   - Platelets ≥ 75 x $10_3$/uL:
   - Platelets: _____ Date Obtained: _____
   - Hemoglobin ≥ 8 g/dL (≥ 80 g/L; may be transfused):
   - Hemoglobin: _____Date Obtained: _____
   - Creatinine ≤ 2.0 x ULN:
   - Creatinine: _____ Institutional ULN : _____
   - AST and ALT ≤ 2.5 x ULN:
   - AST: _____ Institutional ULN: _____
   - ALT: _____ Institutional ULN: _____
   - Total Bilirubin ≤ 2.0 x ULN, (except patients with Gilbert's Syndrome, who must have a total bilirubin less than 3.0 mg/dL)
   - Bilirubin: _____ Institutional ULN: _____
   - Gilberts Syndrome?_____(Yes/no)
10. Patients who are HIV+ with undetectable HIV viral load are eligible provided they meet all other protocol criteria for participation.
11. Patients with HBV or HCV infection are eligible provided viral loads are undetectable. Patients on suppressive therapy are eligible.
12. Patients must not be on active immunosuppression, have a history of life threating virus, have had other (beside non-melanoma skin cancers, or recent indolent cancers e.g.: resected low grade prostate cancer) invasive cancer diagnoses in the last two years, or have had immunotherapy of any kind within the last 2 years prior to randomization.

13. Patients must not have a history of (non-infectious) pneumonitis that required steroids or has current pneumonitis.
14. Operative notes from patient's surgical resection must be accessible.

**Schema**