

Placebo-Controlled Trial of IFx-Hu2.0 Followed By Pembrolizumab In Checkpoint Inhibitor Naïve Participants With Advanced Or Metastatic Merkel Cell Carcinoma

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. At least 18 years of age. 2. Life expectancy equal to or greater than six months. 3. Eastern Cooperative Oncology Group (ECOG) Performance Status ≤ 2 . 4. Must be recurrent and/or unresectable Stage III or Stage IV American Joint Committee on Cancer (AJCC) (8th edition) and have histologically confirmed Merkel cell carcinoma. 5. Must have at least one injectable lesion equal to or greater than 3 mm. 6. Must have measurable disease as defined by RECIST v1.1. 7. Participants should be CPI naïve i.e., no prior therapy with CPI including but not limited to Pembrolizumab, avelumab, ipilimumab, nivolumab. 8. Tumor tissue from an archival core biopsy or resected site of disease must be provided for biomarker analyses. If archival tissue is not available, then a new biopsy should be performed. 9. Adequate hematological, hepatic, and renal function according to laboratory ranges and medical criteria defined within the study protocol.

Exclusion Criteria:

1. Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with protocol requirements. 2. Participants with known active brain metastases with the exception of treated brain metastases that have imaging proving stability at least 4 weeks prior to the start of study treatment, no new metastases, and not requiring steroids. 3. Participants with recurrent resectable MCC. 4. Participants with prior systemic chemotherapy. 5. Pregnant or breastfeeding females and females desiring to become pregnant or breastfeed within the timeframe of this study. 6. Active, known, or suspected autoimmune disease. Potential Participants with type I diabetes mellitus, residual hypothyroidism due to autoimmune thyroiditis only requiring hormone replacement, skin disorders (such as vitiligo, psoriasis, or alopecia) not requiring systemic treatment are permitted to enroll. Low-grade autoimmune toxicity is NOT an exclusion under this criterion. 7. A condition requiring systemic treatment with either corticosteroids (> 10 mg daily prednisone equivalent) or other immunosuppressive medications within 14 days of randomization. Inhaled or topical steroids are permitted in the absence of active autoimmune disease.

Conditions & Interventions

Interventions:

DRUG: IFx-Hu2.0, DRUG: Placebo, DRUG: Pembrolizumab

Conditions:

Advanced Or Metastatic Merkel Cell Carcinoma

Keywords:

Merkel Cell Carcinoma, Advanced, Metastatic, MCC, pembrolizumab, Innate Immune Agonist, Skin Cancer

More Information

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Number:

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