Vaccination With 6MHP, With or Without Systemic CDX-1127, in Patients With Stage II-IV Melanoma

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Main

Inclusion Criteria:

1. Patients with stage IIB, IIC, III, or IV melanoma at original diagnosis or at restaging after recurrence, rendered clinically free of disease by surgery, other therapy, or spontaneous remission within 6 months prior to registration. 2. Patients with small radiologic or clinical findings of an indeterminate nature may be eligible. 3. Patients with high-risk stage IIA melanoma (by DecisionDx Melanoma test, Castle Biosciences, Inc., Friendswood, TX) may be eligible. 4. Participants may have had cutaneous, uveal, mucosal primary melanoma, or an unknown primary melanoma. Diagnosis of melanoma must be confirmed by cytological or histological examination. Staging of cutaneous melanoma will be based on version 8 AJCC staging system. 5. Participants who have had brain metastases will be eligible if all of the following are true:

• Each brain metastasis must have been completely removed by surgery or each unresected brain metastasis must have been treated with stereotactic radiosurgery.

• No brain metastasis is > 2 cm in diameter at the time of registration.

• Any neurologic symptoms attributable to brain metastases have returned to baseline.There is no evidence of new or enlarging brain metastases.

• The most recent surgical resections or gamma-knife therapy for malignant melanoma must have been completed ≥ 1 week and ≤ 6 months prior to registration. 6. ECOG performance status of 0 or 1. 7. Ability and willingness to give informed consent. 8. Adequate organ function 9. Age 18 years or older at registration. Main

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Exclusion Criteria:

1. The following medications or treatments at any time within 4 weeks of registration:

• Chemotherapy

• Interferon (e.g. Intron-A®)

• Radiation therapy (Stereotactic radiotherapy, such as gamma knife, can be used ≥ 1 week and ≤ 6 months prior to registration)

• Allergy desensitization injections

• High doses of systemic corticosteroids

• Growth factors (e.g. Procrit®, Aranesp®, Neulasta®)

• Interleukins (e.g. Proleukin®)

• Any investigational medication

• Targeted therapies specific for mutated BRAF or for MEK 2. Nitrosoureas within 6 weeks of registration. 3. Checkpoint molecule blockade therapy within 12 weeks of registration. 4. Known or suspected allergies to any component of the vaccine. 5. Previous vaccination with 6MHP. 6. Prior treatment with CDX-1127 or other CD27 agonistic antibody. 7. Pregnancy. 8. HIV positivity or evidence of active Hepatitis C virus. 9. Female participants must not be breastfeeding. 10. A medical contraindication or potential problem in complying with the requirements of the protocol in the opinion of the investigator. 11. New York Heart Association classification as having Class III or IV heart disease. 12. Uncontrolled diabetes, defined as having an HgbA1c > 8.5%. 13. Prior autoimmune disorders requiring cytotoxic or immunosuppressive therapy, or autoimmune disorders with visceral involvement. Participants with an active autoimmune disorder requiring these therapies are also excluded. 14. Participants with known addiction to alcohol or drugs who are actively taking those agents, or participants with recent (within 1 year) or ongoing illicit IV drug use. 15. Participants who have received a live vaccine within 30 days of registration. 16. Body weight < 110 pounds at registration, due to the amount and frequency with which blood will be drawn. 17. Participants with prior autoimmune pneumonitis.

Conditions & Interventions

Interventions:
Biological: 6MHP, Drug: Montanide ISA-51, Drug: polyICLC, Drug: CDX-1127
Conditions:
Melanoma
Keywords:
peptide, vaccine, adjuvant, 6MHP, polyICLC, varlilumab, CDX-1127, Montanide ISA-51

More Information

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IRB
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