

ENVASARC: Envafolelimab And Envafolelimab With Ipilimumab In Patients With Undifferentiated Pleomorphic Sarcoma Or Myxofibrosarcoma

Status: Recruiting

Eligibility Criteria

Age: 12 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

- Histologically confirmed locally advanced or metastatic undifferentiated pleomorphic sarcoma (UPS) or grade ≥ 2 myxofibrosarcoma (MFS)
- Documented progression following systemic chemotherapy
- At least one measurable lesion
- Eastern Cooperative Oncology Group performance status of 0 or 1
- Adequate hematologic and organ function

Exclusion Criteria:

- More than two prior lines of chemotherapy for UPS/MFS
- Prior immune checkpoint inhibitor or immunomodulatory therapy
- Active autoimmune disease that has required systemic treatment
- Major surgery within 4 weeks of dosing of investigational agent
- Active additional malignancy
- Pericardial effusion, pleural effusion, or ascites
- Central nervous system metastases and/or carcinomatous meningitis
- Active hepatitis or cirrhosis
- Interstitial lung disease
- Unwilling to apply highly effective contraception during the study
- Other concurrent severe and/or uncontrolled medical conditions that would, in the investigator's judgment, contraindicate patient participation in the clinical study

Conditions & Interventions

Interventions:

Biological: Envafolelimab, Drug: Ipilimumab

Conditions:

Undifferentiated Pleomorphic Sarcoma, Myxofibrosarcoma

Keywords:

sarcoma

More Information

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Phase: Phase 2

IRB

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