Protocol Title: Randomized Phase II Study of Nivolumab With or Without Ipilimumab in Patients with Metastatic or Unresectable Sarcoma

Target Population: Metastatic or Unresectable Sarcoma
- Dedifferentiated Liposarcoma
- Gastrointestinal Stromal Tumor
- Metastatic or Unresectable Liposarcoma
- Metastatic Undifferentiated Pleomorphic Sarcoma
- Stage III, IVA, or IVB Bone Sarcoma
- Stage III – IV Soft Tissue Sarcoma

Summary: To evaluate the confirmed response rate of single agent Nivolumab and dual agent Nivolumab plus Ipilimumab in patients with locally advanced / unresectable or Metastatic Soft Tissue Sarcoma.

Key Inclusion Criteria:
- Patients must have a Formalin-Fixed, Paraffin-Embedded (FFPE) Tumor Block OR 1 Representative Hematoxylin and Eosin (H&E) and 20 Unstained Sarcoma Tissue Slides available for submission to central pathology review.
  - Note: This review is mandatory prior to registration to confirm eligibility.
- Patients must have histologically confirmed Bone or Soft Tissue Sarcoma by central pathology review.
  - Patients must have histologically confirmed:
    - Liposarcoma (LPS) (only Dedifferentiated and Pleomorphic)
      - Note: Well-Differentiated Liposarcoma NOT eligible
    - Undifferentiated Pleomorphic Sarcoma (UPS) / Malignant Fibrous Histiocytoma (MFH)
    - Gastrointestinal Stromal Tumor (GIST)
- Measurable disease.
- Locally advanced / unresectable or metastatic disease.
- ≥ 1 prior systemic therapy for Sarcoma, including adjuvant systemic therapy.
- No prior therapy with Ipilimumab or Nivolumab, or any agent targeting Programmed Cell Death 1 (PD-1), PD-L1 or Cytotoxic T-Lymphocyte-Associated Protein 4 (CTLA-4)
- No treatment with biologic therapy, immunotherapy, chemotherapy, investigational agent for malignancy, or radiation ≤ 28 Days before study registration.
  - No treatment with Nitrosourea or Mitomycin ≤ 42 Days before study registration.
  - For GIST, Tyrosine Kinase Inhibitor can be continued for up to 3 Days prior to initiation of study treatment.

Contacts:
- Principal Investigator: Marc Matrana, MD
- Research Nurses (RN): Amanda Woolery (amanda.woolery@ochsner.org, ext. 20275)
  Sharon Jerdonek (sharon.jerdonek@ochsner.org, ext. 23929)

For additional information: https://clinicaltrials.gov/ct2/show/NCT02500797