**Protocol Title:** Randomized Phase II / III Study of Nivolumab Plus Ipilimumab Plus Sargramostim Versus Nivolumab Plus Ipilimumab in Patients with Unresectable Stage III or Stage IV Melanoma

**Target Population:** Stage III – IV Skin Melanoma

**Summary:** To compare the Overall Survival (OS) of Nivolumab / Ipilimumab / Sargramostim (GM-CSF) versus Nivolumab / Ipilimumab.

**Key Inclusion Criteria:**

- Known v-raf Murine Sarcoma Viral Oncogene Homolog B1 (BRAF) Mutational Status of Tumor, either:
  - Wild-type
  - Mutated
- Unresectable Stage III or Stage IV Melanoma.
  - Patients must have histological or cytological confirmation of Melanoma that is metastatic or unresectable and clearly progressive.
- Measurable disease.
- Prior systemic therapy in the adjuvant setting allowed (e.g. Interferon, BRAF, or Mitogen-Activated Protein Kinase [MEK] Agents).
  - Patients may have had prior anti-Cytotoxic T-Lymphocyte Antigen 4 (CTLA-4) in the adjuvant setting, if at least 1 Year from last dose of treatment has passed prior to beginning treatment.
  - Patients may not have had any prior Programmed Cell Death (PD)-1/PD-Ligand (PD-L)1 Agent in the adjuvant setting.
- No prior Ipilimumab and/or anti-PD-1/PD-L1 Agent in the metastatic setting allowed.
- Patients must have discontinued chemotherapy, immunotherapy or other investigational agents used in the adjuvant setting ≥ 4 Weeks prior to randomization and recovered from adverse events due to those agents.
  - Mitomycin and Nitrosoureas must have been discontinued ≤ 6 Weeks prior to entering study.
  - Patients must have discontinued radiation therapy ≥ 2 Weeks prior to entering the study and recovered from any adverse events associated with treatment.
- Patients are ineligible if they have any currently active Central Nervous System (CNS) Metastases.
- Patients must not have autoimmune disorders or conditions of immunosuppression that require current ongoing treatment with systemic corticosteroids (or other systemic immunosuppressants), including oral steroids (e.g., Prednisone, Dexamethasone) or continuous use of topical steroid creams or ointments or ophthalmologic steroids.

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**For additional information:** [https://clinicaltrials.gov/ct2/show/NCT02339571](https://clinicaltrials.gov/ct2/show/NCT02339571)