# EA6134/DREAMseq

**For Patients with BRAFV600 Mutant Melanoma**

**EA6134 Available Through ECOG-ACRIN Cancer Research Group**

**DREAMseq (Doublet, Randomized Evaluation in Advanced Melanoma Sequencing)**

**A Phase III Trial**

## Patient Population

See Section 3.0 for Complete Eligibility Details

**Eligibility Criteria Step 1:**

- Age ≥18 years, ECOG PS 0-1, & adequate lab values
- Unresectable stage III/IV disease; measurable disease defined per protocol; histological/cytological confirmation of melanoma that is metastatic or unresectable & clearly progressive; uveal melanoma is not permitted
- Must have BRAFV600 mutation, identified by a FDA-approved test (see protocol) at a CLIA-certified lab; information about the assay must be provided if a CLIA-certified lab used a non-FDA approved method
- May have had prior systemic therapy in the adjuvant setting, but this adjuvant treatment must not have included a CTLA4/PD1 pathway blocking antibody or a BRAF/MEK inhibitor; may not have had any prior systemic treatment for advanced (measurable metastatic) disease
- Must have discontinued prior treatments in the timeframes stated per protocol
- No currently known active and definitive CNS metastases; treated brain mets may be eligible (see protocol)
- No evidence of cardiovascular risks per protocol
- No known HIV infection; no active autoimmune disease/history of autoimmune disease that might recur, which may affect vital organ function/require immune suppressive treatment (see protocol)
- Patients taking inhibitors/inducers of CYP3A/CYP2C8 are ineligible
- No history of retinal vein occlusion
- No evidence of interstitial lung disease/pneumonitis

**Eligibility Criteria Step 2 (Crossover):**

- Must meet all eligibility criteria for Step 1 (see protocol for exceptions)
- Must have melanoma that is metastatic and clearly progressive on prior therapy; must be at least 1 week from documented PD on Step 1
- Must not have other current malignancies

## Treatment Plan

See Section 5.0 for Complete Treatment Details

1 cycle = 42 days; see protocol for RECIST-defined PD

**Arm A:**

- Immunotherapy induction—investigators can choose between 2 induction regimens:
  - Nivolumab 1 mg/kg IV Day 1 & 22 of cycles 1 & 2; Ipilimumab 3 mg/kg IV Day 1 & 22 of cycles 1 & 2
  - Nivolumab 3 mg/kg IV Day 1 & 22 of cycles 1 & 2; Ipilimumab 1 mg/kg IV Day 1 & 22 of cycles 1 & 2
- Immunotherapy maintenance:
  - Nivolumab 3 mg/kg IV Day 1, 15 & 29 of cycles 3-14 (max 84 weeks/72 weeks of maintenance)
  - At disease progression, crossover to Arm C

**Arm C:**

- Dabrafenib 150 mg PO twice daily days 1-42 of each 6 week cycle; Trametinib 2 mg PO daily days 1-42 of each 6 week cycle
- Treatment will continue for as long as patient is responding & tolerating therapy

**Arm B:**

- Dabrafenib 150 mg PO twice daily days 1-42 of each 6 week cycle; Trametinib 2 mg PO daily days 1-42 of each 6 week cycle
- Treatment will continue for as long as patient is responding & tolerating therapy; at disease progression, crossover to Arm D

**Arm D:**

- Immunotherapy induction—investigators to choose between the two regimens in Arm A induction
- Immunotherapy maintenance:
  - Nivolumab 3 mg/kg IV Day 1, 15 & 29 of cycles 3-14 (max 84 weeks/72 weeks of maintenance)

## Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN), [https://open.ctsu.org](https://open.ctsu.org)

**Protocol Information**

ECOG-ACRIN Operations-Boston: 857-504-2900, [http://ecog-acrin.org](http://ecog-acrin.org) (Member Login)

Please Enroll Your Eligible Patients!