Doctor's Note — Clinical Trial Summary

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TRIAL

Sunitinib Malate or Valproic Acid in Preventing Metastasis in Patients With High-Risk Uveal Melanoma

NCT ID: NCT02068586 Phase: PHASE2 Sponsor: Sidney Kimmel Comprehensive Cancer Center at Thomas Jefferson University Status: Active, Not Recruiting

SUMMARY

This randomized phase II trial studies how well sunitinib malate or valproic acid works in preventing high-risk uveal (eye) melanoma from spreading to other parts of the body. Sunitinib malate may stop the transmission of growth signals into tumor cells and prevents these cells from growing. Valproic acid may change the expression of some genes in uveal melanoma and suppress tumor growth.

KEY ELIGIBILITY CRITERIA

- * Age \>= 18 years old
- * Histologically-confirmed primary uveal melanoma
- * Definitive local treatment for primary tumor, including surgical resection (enucleation) or radiation therapy (radioactive plaque or external proton beam)
- * High risk for distal recurrence defined as any of the following conditions: A) Confirmed both monosomy 3 and 8q amplification; B) Class II tumor
- * Less than 6 months from the date that local treatment (surgical or radiation) of the primary tumor was finalized
- * Karnofsky performance status (PS) scores of 70 or greater
- * If female, no pregnancy
- * If of child-bearing potential (\< one year post-menopausal), must agree to practice an effective method of avoiding pregnancy (including oral or implanted contraceptives, intrauterine device, condom, diaphragm with spermicidal, cervical cap, abstinence or sterile sex partner) from the time informed consent is signed (women only) or the time of initiation of sunitinib (sunitinib malate) (men only); both men and women must agree to continue using such precautions while receiving sunitinib or valproic acid and for 30 days after the final dose
- * Absolute neutrophil count (ANC) \>= 1500/mm\^3
- * Platelets \>= 100,000/mm\^3

Total sites: 1 | 0 currently recruiting