E2607

For Patients with Mucosal, Acral and Vulvovaginal Melanomas

E2607 Available Through ECOG-ACRIN

A Phase II Trial of Dasatinib in KIT-Positive Patients with Unresectable Locally Advanced or Stage IV Mucosal, Acral and Vulvovaginal Melanomas

**Patient Population**

See Section 3.0 for Complete Eligibility Details

**Pre-Registration (Step 0)**

- Age ≥ 18 years and ECOG PS 0 or 1
- Histological or cytological confirmed melanoma that is metastatic or unresectable; must have measurable disease (RECIST); must have a history of melanoma subtypes per protocol
- c-KIT mutation status determination, local vs. central assessments per protocol
- No ocular melanoma or evidence of bleeding diathesis
- No clinically significant cardiovascular disease

**Registration (Step 1)**

- c-KIT mutation determined by PCR and sequencing per protocol
- Must have measurable disease (RECIST)
- At least 4 weeks must have elapsed since last chemotherapy, radiotherapy or immunotherapy
- Patients with a history or clinical evidence of brain metastasis must have completed RT or surgical treatment and have no evidence of CNS progression for at least 8 weeks at the time of registration; patients must not require corticosteroids for treatment of cerebral edema from brain metastases
- Must have adequate lab values
- Must not be taking cytochrome P450 enzyme-inducing antiepileptic drugs, rifampin, or St. John’s Wort
- No uncontrolled hypertension
- No QTc prolongation or serious intercurrent illness

**Treatment Plan**

See Section 5.0 for Complete Treatment Details

One cycle = 21 days

Dasatinib 70 mg PO twice daily (two tablets; one 50 mg tablet and one 20 mg tablet) on an open-label, single-arm basis

Patients who are tolerating treatment may continue on therapy until disease progression

- Medication should be taken everyday; once in the morning and once in the evening with or without food
- There are no breaks between cycles
- There is no adjustment of dose for BSA
- Patients should be evaluated for signs and symptoms of underlying cardiopulmonary disease prior to initiating dasatinib and during treatment
- Symptoms of pulmonary arterial hypertension (PAH) should be investigated as outlined in Section 5.4. If PAH is confirmed, dasatinib should be permanently discontinued

**Patient Enrollment**

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

**Protocol Information**


Please Enroll Your Eligible Patients!
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Schema

1 cycle = 21 days
Stage 1 Accrual: 57 patients
Stage 2 Accrual Goal: 33 KIT-positive patients in Step 1

1. Acral melanoma*
2. Mucosal melanoma
3. Vulvovaginal melanoma

Metastatic melanoma of following subtype:

Rev. 11/11

PRE-REGISTER

PRE-REGISTER

Rev. 11/11

c-KIT+ mutation status determined:
1. Locally determined prior to pre-registration
2. Unknown, local testing not available

REGISTER

REGISTER

Dasatinib
70 mg po twice daily

EVA

LUA

Continue treatment until progression or unacceptable toxicity

CR, PR, or SD

Progression or Unacceptable Toxicity

Discontinue Protocol Treatment

* Acral melanomas are defined as melanomas occurring on the palms, soles, or subungual sites
1. Patients are to have a tumor assessment every 6 weeks.
2. Local cKIT report must indicate cKIT positive mutation status with at least one mutation in exon 9, 11, 13, 17 or 18 of the cKIT gene. Patient may proceed directly to registration to treatment.
3. Submit tissue and supporting documentation within 5 working days following pre-registration (see Section 10). Patient can not be registered to treatment (Step 1) until site receives verification of positive c-KIT mutation status from the central laboratory performing the assessments.