

# Clinical trial protocol

**Title**

Phase I Clinical Trial of Oral Suberoylanilide Hydroxamic Acid in Combination With Bexarotene in Patients With Advanced Cutaneous T-Cell Lymphoma.

**Inclusion Criteria:**

Subjects who meet all the criteria listed below will be considered for study inclusion:

- Ages Eligible for Study: 18 Years and above, Genders Eligible for Study: Both
- Women or men greater than or equal to 18 years of age
- Advanced cutaneous T-cell lymphoma, stage IB or higher including Sezary Syndrome with progressive, persistent, or recurrent disease
- Failure of at least one systemic therapy, not including Targretin
- Eastern Cooperative Oncology Group (ECOG) status less than or equal to 2 (measurement to determine your ability to perform daily activities)

**Exclusion Criteria:**

- Patient has had investigational treatment in the preceding 30 days
- Active hepatitis B or C, history of HIV
- Prior treatment with any HDAC inhibitor
- Patients must be disease free from prior malignancies for greater than 5 years, except for curatively treated basal cell or squamous cell carcinoma of the skin or carcinoma in-situ of the cervix

**Start of the study**

September

**Expected number of patients**

42

**Trial phase**

Phase I

**Drug**

MK0683, vorinostat, Suberoylanilide Hydroxamic Acid (SAHA) /Duration of Treatment up to 6 Cycles (28 days/Cycle)

**International multicenter study**