A Phase IV Study of Safety and Efficacy of Everolimus in Taiwanese Patients With Tuberous Sclerosis Complex Who Have Renal Angiomyolipoma (TSC-AML)

Last Update: Oct 21, 2024
Phase IV, Prospective Single Arm Study of Safety and Efficacy of Votubia (Everolimus) in Taiwanese Adults With Tuberous Sclerosis Complex Who Have Renal Angiomyolipoma
ClinicalTrials.gov Identifier:
NCT05252585
Novartis Reference Number:CRAD001M2402
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All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this prospective study is to assess the safety and efficacy of everolimus in Taiwanese patients with renal angiomyolipoma (AML) associated with tuberous sclerosis complex (TSC) . Only patients who fulfil the local reimbursement criteria of everolimus for TSC-AML will be included in this study. This open-label, prospective, single-arm, multicenter Phase IV post approval commitment (PAC) study is planned to be conducted in approximately 10 patients with confirmed diagnosis of TSC-AML and who fulfil the local reimbursement criteria of everolimus for TSC-AML treatment.

The study will have a 30-day screening phase, and each patient will be on treatment up to 52 weeks. Enrollment will end at the latest within 52 weeks from Day 1 of the study, regardless of the number of patients actually recruited. After completion of the treatment phase/end of treatment (EOT), eligible patients will enter a 4-week safety follow up (FU) phase. Patients who continue to be on treatment beyond 52 weeks, based on the investigator's judgment will not be included in the 4-week safety FU phase.

Condition
Renal Angiomyolipoma
Phase
Phase4
Overall Status
Recruiting
Number of Participants
10
Start Date
May 01, 2023
Completion Date

Feb 21, 2026
Gender
All
Age(s)
18 Years - 65 Years (Adult, Older Adult)

Interventions

Drug

Everolimus

Everolimus tablets for oral use. The recommended everolimus starting dose will be 10 mg orally taken once daily for all patients, except for those with impaired liver function, for whom the everolimus dose will be: * Child-Pugh grade A: 7.5 mg once daily (for patients with mild hepatic impairment) * Child-Pugh grade B: 5.0 mg once daily (for patients with moderate hepatic impairment)

Eligibility Criteria

Inclusion Criteria:

1. Adult male or female patients from ≥ 18 years of age.
2. Signed informed consent must be obtained prior to participation in the study.
3. Participants with TSC associated with renal AML which is eligible for treatment with everolimus per local reimbursement criteria.

Exclusion Criteria:

1. Patients with severe hepatic impairment (Child-Pugh class C)
2. Any severe and/or uncontrolled medical conditions.
3. Pregnant or breast-feeding females.
4. Patients with hypersensitivity to the active substance, to other rapamycin derivatives, or to any of the excipients.

Taiwan

Novartis Investigative Site

Recruiting

Taipei,10002,Taiwan

Novartis Investigative Site

Recruiting

Taichung,Taiwan ROC,40201,Taiwan

Novartis Investigative Site

Recruiting

Taoyuan,Taiwan ROC,33305,Taiwan

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct05252585*

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