A PMS of Jakavi® in Patients With Steroid-Refractory Graft-versus-Host Disease (SR-GvHD) in Korea

Last Update: Jan 14, 2025
A Post Marketing Surveillance of Jakavi® (Ruxolitinib) in Patients With Steroid-Refractory Graft-versus-Host Disease (SR-GvHD) in Korea
ClinicalTrials.gov Identifier:
NCT05621733
Novartis Reference Number:CINC424C2415
See if you Pre-qualify
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

This study is a prospective, open-label, multi-center, non-comparative, observational study to assess safety and effectiveness of Jakavi® (ruxolitinib) in the real-world clinical setting in Korean Graft-versus-Host disease (GvHD) patients The dosage and duration of treatment may be considered and decided by the investigator in accordance with prescribing information of Jakavi®. All participants who receive at least one dose of the drug and are in the follow-up assessment or early discontinuation (withdrawal) will be the safety population. This study will enroll patients who are newly starting Jakavi® and patients who have been taking Jakavi® prior to study participation. Considering the current clinical practice, a 24 weeks follow-up period of ruxolitinib treatment is needed to assess the safety and the durable effectiveness of the treatment. Mandatory additional safety monitoring will be conducted following the last dose of the treatment for further AE assessments.

Condition
Graft-versus-Host Disease
Overall Status
Recruiting
Number of Participants
127
Start Date
Apr 07, 2023
Completion Date
May 13, 2026
Gender
All
Age(s)
12 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Other

ruxolitinib

Prospective observational study. There is no treatment allocation. Patients prescribed with ruxolitinib in the commercial setting are eligible to enroll into this study.

Eligibility Criteria

Inclusion Criteria:

1. Patients who diagnosed with GvHD and currently receiving or going to receive Jakavi® treatment according to locally approved label
2. Patients who are willing to provide written informed consent prior to study enrollment

Exclusion Criteria:

1. Patients under 12 years old
2. Patients with contraindication according to locally approved label of Jakavi®
3. Patients who receive or are going to receive any investigational medicine during the observation period.

Korea, Republic of

Novartis Investigative Site

Recruiting

Jinju,660-702,Korea, Republic of

Novartis Investigative Site

Recruiting

Seoul,05505,Korea, Republic of

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Recruiting

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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/nct05621733*

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