Study of Efficacy and Safety of Ruxolitinib in Patients With Grade II to IV Steroid-refractory Acute Graft vs. Host Disease

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A Single-arm, Multi-center Study of Ruxolitinib for the Treatment of Chinese Patients With Grade II-IV Corticosteroid-refractory Acute Graft Versus Host Disease
ClinicalTrials.gov Identifier:
NCT06462469
Novartis Reference Number:CINC424C2416
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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 study is to assess the efficacy and safety of ruxolitinib therapy in Chinese adults and adolescents (≥ 12 years old) with Grade II-IV steroid-refractory acute graft versus host disease (SR-aGvHD). Participants will start with a screening period to assess the eligibility; only participants who meet all the inclusion and none of the exclusion criteria will start study treatment from Day 1 to Week 24 or end of treatment. Following safety follow up visits, participants will receive the long-term follow-up until Month 12.

Condition
Steroid-refractory Acute Graft Versus Host Disease
Phase
Phase4
Overall Status
Recruiting
Number of Participants
54
Start Date
Jul 04, 2024
Completion Date
Nov 05, 2026
Gender
All
Age(s)
12 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Drug

Ruxolitinib

Ruxolitinib is taken orally daily at 10 mg BID, given as two 5-mg tablets.

Eligibility Criteria

Key Inclusion criteria

* Male or female Chinese participants aged 12 or older at the time of informed consent. Written informed consent from participant, parent or legal guardian.
* Able to swallow tablets.
* Have undergone alloSCT from any donor source (matched unrelated donor, sibling, haplo-identical) using bone marrow, peripheral blood stem cells, or cord blood.
* Clinically diagnosed Grades II to IV acute GvHD as per standard criteria occurring after alloSCT requiring systemic immune suppressive therapy.
* Evident myeloid and platelet engraftment (confirmed within 48 hours prior to study treatment (ruxolitinib) start):
* Confirmed diagnosis of steroid refractory aGvHD defined as participants administered high-dose systemic corticosteroids (methylprednisolone 2 mg/kg/day \[or equivalent prednisone dose 2.5 mg/kg/day\]), given alone or combined with calcineurin inhibitors (CNI) and either:

1. Progression based on organ assessment after at least 3 days compared to organ stage at the time of initiation of high-dose systemic corticosteroid +/- CNI for the treatment of Grade II to IV aGvHD. OR
2. Failure to achieve at a minimum partial response based on organ assessment after 7 days compared to organ stage at the time of initiation of high-dose systemic corticosteroid +/-CNI for the treatment of Grade II to IV. OR
3. Participants who fail corticosteroid taper defined as fulfilling either one of the following criteria:

* Requirement for an increase in the corticosteroid dose to methylprednisolone ≥2 mg/kg/day (or equivalent prednisone dose ≥2.5 mg/kg/day). OR
* Failure to taper the methylprednisolone dose to \< 0.5 mg/kg/day (or equivalent prednisone dose \<0.6 mg/kg/day) for a minimum of 7 days.

Key Exclusion criteria

* Has received more than one systemic treatment for steroid refractory aGvHD. Participants who received JAK inhibitor therapy for any indication after initiation of current alloSCT conditioning.
* Clinical presentation resembling de novo chronic GvHD or GvHD overlap syndrome with both acute and chronic GvHD features.
* Failed prior alloSCT within the past 6 months. Presence of relapsed primary malignancy after the alloSCT was performed.
* Presence of an active uncontrolled infection including significant bacterial, fungal, viral or parasitic infection requiring treatment.
* SR-aGvHD occurring after non-scheduled donor lymphocyte infusion (DLI) administered for pre-emptive treatment of malignancy recurrence. Note: Participants who have received a scheduled DLI as part of their transplant procedure and not for management of malignancy relapse are eligible.
* Presence of significant respiratory disease, severely impaired renal function, clinically significant or uncontrolled cardiac disease, unresolved cholestatic and liver disorders (not attributable to aGvHD). Disorders and/or current therapy with medications that interfere with coagulation or platelet function.

Other protocol-defined inclusion / exclusion criteria may apply

China

Novartis Investigative Site

Recruiting

Beijing,100028,China

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