CINC424A2X01B Rollover Protocol

Last Update: Sep 18, 2025
Open Label, Multi-center, Phase IV Study of Ruxolitinib or Ruxolitinib and Panobinostat Combination, for Patients Who Have Completed Prior Global Novartis or Incyte Sponsored Studies
ClinicalTrials.gov Identifier:
NCT02386800
Novartis Reference Number:CINC424A2X01B
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 is a long term safety study for patients that have been treated with either ruxolitinib or a combination of ruxolitinib with panobinostat, on a Novartis or Incyte sponsored study, who have been judged by the study Investigator to benefit from ongoing treatment. This roll-over protocol allows patients from multiple protocols, who are still receiving clinical benefit, to continue their treatment in one study that covers multiple indications. The population for the roll-over study should be consistent with the population defined in the parent studies. The primary eligibility criteria for a patient to enter the roll-over protocol is the participation and completion of a Novartis or Incyte study with ruxolitinib monotherapy or combination of ruxolitinib and panobinostat. Efficacy parameters will not be measured; however safety data and an evaluation of clinical benefit will be collected.

Condition
Primary Myelofibrosis, Polycythemia Vera, Graft Versus Host Disease, Acute Myeloid Leukemia, Thalassemia
Phase
Phase4
Overall Status
Recruiting
Number of Participants
356
Start Date
Mar 05, 2015
Completion Date
Sep 16, 2027
Gender
All
Age(s)
1 Year - 100 Years (Child, Adult, Older Adult)

Interventions

Drug

panobinostat

panobinostat capsules - participants to continue receiving panobinostat in combination with ruxolitinib as per the parent study
Drug

ruxolitinib

ruxolitinib tablets or pediatric oral solution - participants continue ruxolitinib as they received in parent study

Eligibility Criteria

Key Inclusion criteria:

1. Patient is currently enrolled in a Novartis GDD or GMA-sponsored or Incyte-sponsored clinical study, are receiving either ruxolitinib or combination of ruxolitinib and panobinostat, and fulfilled all of the requirements of the parent protocol.
2. Patient is currently benefiting from the treatment with ruxolitinib monotherapy or combination of ruxolitinib and panobinostat, as determined by the investigator
3. Patient has demonstrated compliance, as assessed by the investigator, with the parent study protocol requirements
4. Patient currently has no evidence of progressive disease, as determined by the investigator, following previous treatment with ruxolitinib or combination of ruxolitinib and panobinostat

Key Exclusion criteria:

1. Patient has been permanently discontinued from study treatment in the parent study due to any reason.
2. Patient's indication is currently approved and reimbursed in the corresponding country for ruxolitinib monotherapy or combination of ruxolitinib and panobinostat.
3. Pregnant or nursing (lactating) women.
4. Female patients of childbearing potential (e.g. are menstruating) who do not agree to abstinence or, if sexually active, do not agree to the use of highly effective contraception, throughout the study and for up to 30 days after stopping study treatment.

Other protocol-defined Inclusion / Exclusion criteria may apply.

South Korea

Novartis Investigative Site

Recruiting

Seoul,03080,South Korea

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://uat2.arctic.novartis.com/clinicaltrials/study/nct02386800*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT02386800
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