Asciminib Roll-over Study

Last Update: May 21, 2025
An Open Label, Multi-center Asciminib Roll-over Study to Assess Long-term Safety in Patients Who Have Completed a Novartis Sponsored Asciminib Study and Are Judged by the Investigator to Benefit From Continued Treatment
ClinicalTrials.gov Identifier:
NCT04877522
Novartis Reference Number:CABL001A2001B
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 who have completed a Novartis sponsored asciminib study and are judged by the investigator to benefit from continued treatment This is an open-label, multi-center, global roll-over study designed to assess long term safety and provide continued treatment to participants who have previously participated in an asciminib Novartis sponsored study and who, in the opinion of the investigator, would benefit from continued treatment as in their parent study but are unable to access this treatment outside of the clinical study.

Condition
Chronic Myelogenous Leukemia, Leukemia, Myelogenous, Chronic, BCR-ABL Positive
Phase
Phase4
Overall Status
Recruiting
Number of Participants
347
Start Date
Aug 30, 2022
Completion Date
Aug 30, 2030
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Asciminib single agent

Taken orally, twice daily (BID) or once daily (QD), in fasting state
Drug

Bosutinib

Taken orally, once daily, with food
Drug

Dasatinib

Taken orally, once daily in a fasted state, 1 or 2 hours before a meal
Drug

Imatinib

Taken orally, once daily, in the morning with low-fat meal
Drug

Nilotinib

Taken orally, twice daily, on an empty stomach

Eligibility Criteria

Key Inclusion Criteria:

1. Participant with PH+ CML or PH+ ALL currently receiving treatment with asciminib (single agent or in combination with imatinib, nilotinib or dasatinib), imatinib, nilotinib or bosutinib alone within a Novartis-sponsored study and, in the opinion of the Investigator, would benefit from continued treatment.
2. Participant has demonstrated compliance on the parent study protocol and is willing and able to comply with scheduled visits, treatment plans and any other study procedures.

Key Exclusion Criteria:

1. Participant has been discontinued from parent study treatment.
2. Participant currently has unresolved toxicities reported as possibly related to study treatment in the parent study.
3. Participant's ongoing treatment is currently approved and reimbursed at country level.
4. Pregnant or nursing (lactating) women.
5. Women of child-bearing potential, unless they are using highly effective methods of contraception and willing to continue while taking study treatment.
6. Sexually active males receiving imatinib, nilotinib, bosutinib or dasatinib unwilling to follow the relevant contraception requirements in the local prescribing information.
7. Applicable for participants on bosutinib treatment at the end of the CABL001A2301 and on other TKIs for CABL001A2202 study that switch to asciminib treatment:

* Asymptomatic (grade 2) pancreatitis if not resolved within 28 days
* QTcF\>480msec or inability to determine QTc interval
* any grade 3 or 4 toxicity not resolved to grade 2 or lower within 28 days before starting asciminib treatment

Other protocol-defined Inclusion/Exclusion criteria may apply.

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