



Victorian
Cancer Trials Link

ASCiminib Evaluation in Newly diagnosed CML with Dasatinib to Augment response in Complex genomic Etiology

Clinical summary

The purpose of this trial is to assess the efficacy of an induction phase of combination targeted therapy with a TKI inhibitor called Asciminib plus low dose Dasatinib in people with newly diagnosed chronic phase chronic myeloid leukaemia (CP-CML) with high-risk genetics.

Eligible participants will receive treatment with Asciminib by itself (monotherapy) daily for the first 4 weeks.

At the end of this period, New Generation Sequencing (NGS) and cytogenetic results will be available from the central and local labs. The presence of additional genomic abnormalities (AGA) will be defined by the central lab for each case as per predefined criteria.

Participants with evidence of AGAs and high risk ACAs will be assigned to the high-risk cohort, and will receive combination treatment of Asciminib plus Dasatinib daily.

All participants with high risk will receive combination therapy between months 2 to 12.

Participants who achieve Molecular Response 4 (MR4) and confirmed at a timepoint 3 months afterwards, will de-escalate to Asciminib monotherapy.

Participants without MR4 at month 12 will de-escalate to Asciminib monotherapy. An extension of combination therapy to the 18th month timepoint is permitted at the discretion of the Investigator.

Participants with intolerance to combination therapy, despite maximal supportive therapy for the same, will de-escalate to Asciminib monotherapy at any time.

All other participants (without evidence of AGAs and high risk ACAs) will be assigned to the standard risk cohort and will continue to receive Asciminib daily monotherapy.

AGA negative participants will then have to achieve predetermined targets: BCR::ABL1 of less than or equal to 10%, at 3 and 6 months, and less than or equal to 1% at 12 and 18 months to continue with Asciminib 80mg daily.

Participants failing to achieve these responses will have Dasatinib daily added to Asciminib daily.

Participants with "warning" under ELN2020 will be offered, at Investigator discretion, Asciminib dose escalation to 80mg twice a day.

Overall treatment duration is 2 years post-enrolment. All treatment will be administered by the study team. Drug accountability will be performed by the administering institutions to assess compliance.

It is hoped this research will improve overall survival and molecular response achievement and minimise treatment related morbidity and mortality for CP-CML patients.

Conditions

This trial is treating patients with Ph-positive Chronic Phase (CP) Chronic Myeloid Leukaemia (CML)

Trial Acronym

CML14 (ASCENDANCE)

Cancer

Chronic Myeloid Leukaemia (CML)

Trial Identifiers

ACTRN12623001338651

ALLG CML14

Age: 18+

Phase: II

For full trial details, visit trials.cancervic.org.au/details/vct1_actrn12623001338651