

Key inclusion criteria

- Adults with Ph+ CML-CP or -AP previously treated with ≥ 2 TKIs and with relapsed, refractory, or intolerant disease^a
- ECOG performance status 0-2

Monotherapy

Study arm 1

Dose escalation

Asciminib in CML
10-200 mg BID, 80-200 mg QD

MTD
RDE

Dose expansion

Asciminib
40 mg BID in CML without *BCR::ABL1*^{T315I}

Asciminib in CML with *BCR::ABL1*^{T315I}
20-200 mg BID, 80-200 mg QD

MTD
RDE

Asciminib
200 mg BID in CML with *BCR::ABL1*^{T315I}

Asciminib in Ph+ ALL/CML-BP
40-280 mg BID

MTD
RDE

Ph + ALL/CML-BP^b

Asciminib (20 and 40 mg BID)
+ nilotinib 300 mg BID in CML

MTD
RDE

Asciminib 40 mg BID
+ nilotinib 300 mg BID in CML

Asciminib (40-80 mg QD, 40 mg BID)
+ imatinib 400 mg QD in CML

MTD
RDE

Asciminib 40 and 60 mg QD
+ imatinib 400 mg QD in CML^c

Asciminib (80 and 160 mg QD, 40 mg BID)
+ dasatinib 100 mg QD in CML

MTD
RDE

Asciminib 80 mg QD
+ dasatinib 100 mg QD in CML

Combination

Study arm 3

Study arm 4