NOW ENROLLING

ASCiminib Monotherapy for **2**nd Line CML With Dose **ESCALAT**ion **(ASC2ESCALATE)**

CABL001AUS08 **NCT05384587**

What is chronic myeloid leukemia (CML)?

CML is a cancer that affects the bone marrow where blood cells are made.[1] It is caused by an abnormal gene called *BCR::ABL1*, which helps cancer cells grow and spread.[2] With the availability of targeted tyrosine kinase inhibitors (TKIs), most patients with CML in chronic phase (CML-CP) live a normal life expectancy. Some patients may not respond to TKI therapy, or may develop mutations that cause refractory disease. For these patients, there is a further need to advance treatment options.[3]

What are the goals of this study?

This study will test asciminib in patients with CML-CP without the T315I mutation.[4,5] The purpose of this study is to assess if asciminib is effective and safe in patients with CML-CP who had previously experienced failure or intolerance with 1 prior TKI therapy.[4,5] Taking part in this research study may not benefit you directly, but we may learn new things that could help treat other patients like you in the future.

Who may participate in this study?[4,5*]

Key study criteria:

- ☑ 18 years old or older
- ☑ Diagnosed with chronic-phase CML
- ☑ Previously used 1 TKI[†] for ≥6 months
- ☑ Do not have the T315I mutation

What will happen during the study?[4,5‡]

- Doctors will collect a medical history and perform exams and tests to determine which patients are eligible for the study
- Eligible participants will be assigned to take study drug asciminib at the same starting dose level. Doses may be increased in individual patients at 6 months and/or 12 months depending on each patient's response to treatment
- Doctors will regularly perform tests and exams to assess clinical benefit and monitor for any side effects
- This study will continue for 24 months

For more information:

- Visit trials.novartisoncology.com
- Visit ClinicalTrials.gov (Identifier: NCT05384587)
- Call 1-844-ONC-INFO (1-844-662-4636)

Study drug(s) are either investigational or being studied for a new use(s). Efficacy (how the drug may help) and safety have not been established and there is no guarantee that the study drug(s) will become commercially available for the use(s) under investigation.

Participation in the study is voluntary. This brochure does not provide a complete list of all requirements and procedures for study participation. Speak with your doctor to see if you may be eligible.

*For complete eligibility criteria, please see ClinicalTrials.gov. †TKIs include: Gleevec® (imatinib), Sprycel® (dasatinib), Iclusig® (ponatinib), Bosulif® (bosutinib), and Tasigna® (nilotinib). The brand names mentioned in this document are the property of their respective trademark owners. ‡This is not a complete list of all study procedures. Additional information regarding the study and all procedures can be obtained by contacting Novartis by phone or on the websites listed above.

References: 1. Mayo Clinic. https://www.mayoclinic.org/diseases-conditions/chronic-myelogenous-leukemia/symptoms-causes/syc-20352417. Accessed May 10, 2021. 2. Schoepfer J, et al. *J Med Chem*. 2018;61(18):8120-8135. 3. Etienne G, et al. *Cancer Med*. 2019;8(11):5173-5182. 4. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT05384587. Accessed June 1, 2022. 5. Data on file. Clinical Trial Protocol CABL001AUS08. Novartis Pharmaceuticals Corp; March 2022.

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