Asciminib Prospective Non Interventional Study as 3rd Line Therapy or More to Treat Adult Patients With CML- CP in Real World Setting in France

Last Update: Jan 14, 2025
Scemblix® (Asciminib): Prospective Non Interventional Study as 3rd Line Therapy or More to Treat Adult Patients With CML-CP in Real World Setting in France
ClinicalTrials.gov Identifier:
NCT06092879
Novartis Reference Number:CABL001AFR04
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

The purpose of this study is to enhance the knowledge on asciminib treatment in a broader and real-life population by collecting additional data to characterize the treatment patterns of patients treated with asciminib, with a primary objective represented by maintenance on treatment at 12 months. The ASSURE-3 study is a national, multicentric, non-interventional, prospective study in real-life conditions with primary data collection in adult patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP) previously treated with two or more Tyrosine Kinase Inhibitors (TKIs). It will be conducted in France with hematologists, onco-hematologists, physicians with documented involvement in managing Ph+ CML-CP patients in routine practice, practicing in public or private health care institutions. Each patient will be followed during 15 months at M0, M1 and then every 3 months (rhythm of visits according to the routine clinical care), or until premature discontinuation of asciminib treatment.

Historical data will be abstracted retrospectively by the participating physicians from patient files, to collect information using an electronic case report form (eCRF). Primary data will be collected during inclusion and follow-up visits

Condition
Chronic Myeloid Leukemia
Overall Status
Recruiting
Number of Participants
168
Start Date
Mar 06, 2024
Completion Date
Dec 15, 2026
Gender

All
Age(s)
18 Years - 99 Years (Adult, Older Adult)

Interventions

Other

Asciminib

There is no treatment allocation. Patients administered Asciminib by prescription will be enrolled

Eligibility Criteria

Inclusion Criteria:

1. Patient aged ≥ 18 years at inclusion,
2. Patient with Ph+ CML-CP previously treated with two or more TKIs,
3. Patient for whom a decision has been taken by the treating physician (investigator) to initiate treatment with asciminib according to his own practice, the drug label / Summary of Product Characteristics (SmPC), and regardless of study participation,
4. Patient having given their non objection to participate to the study

Exclusion Criteria:

1. Patient with CML in accelerated phase (AP) or blastic phase (BP) at enrolment,
2. Patient with known history of T315I mutation,
3. Patient who previously received asciminib treatment,
4. Patient currently participating to an interventional clinical trial,
5. Patient with known contra-indication to asciminib according to the SmPC.

France

Novartis Investigative Site

Recruiting

Nimes,30029,France

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Recruiting

Strasbourg cedex,67085,France

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Recruiting

Challes Les Eaux,73190,France

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Orleans,45100,France

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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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