

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

Brest,29609,France

Novartis Investigative Site

Recruiting

Quimper,29000,France

Novartis Investigative Site

Recruiting

Amiens,80054,France

Novartis Investigative Site

Recruiting

Lens,62307,France

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Recruiting

Valence Cedex 9,26953,France

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Recruiting

Bordeaux,33076,France

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Recruiting

Brive La Gaillarde,19132,France

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Recruiting

Rennes,35043,France

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Recruiting

Angers Cedex 9,49933,France

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Recruiting

Montpellier,34295,France

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Recruiting

Vesoul,70014,France

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Recruiting

Montpellier,34070,France

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Recruiting

Caen,14033,France

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Recruiting

ST Malo Cedex,35403,France

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Recruiting

Antibes,06600,France

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Recruiting

Nice,06105,France

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Recruiting

Mulhouse cedex,68070,France

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Recruiting

Cannes,06414,France

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Recruiting

Tarbes,65100,France

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Recruiting

Avignon,84000,France

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Recruiting

Nimes,30029,France

Novartis Investigative Site

Recruiting

Strasbourg cedex,67085,France

Novartis Investigative Site

Recruiting

Challes Les Eaux,73190,France

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Recruiting

Tours,37044,France

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Recruiting

Besancon Cedex,25030,France

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Recruiting

Orleans,45100,France

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Recruiting

Saint Priest en Jarez,Loire,42270,France

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Recruiting

Dunkerque,59385,France

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Recruiting

Trevenans,90400,France

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Recruiting

Bordeaux,33000,France

Novartis Investigative Site

Recruiting

Perigueux,24019,France

Novartis Investigative Site

Recruiting

Aix en Provence,13616,France

Novartis Investigative Site

Recruiting

Grenoble,38043,France

Novartis Investigative Site

Recruiting

Troyes,10003,France

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

Novartis Pharmaceuticals

Phone: [+41613241111](tel:+41613241111)

Email: novartis.email@novartis.com

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