A PROSPECTIVE NON-INTERVENTIONAL SAFETY STUDY IN PATIENTS WITH CHRONIC MYELOID LEUKEMIA RECEIVING NILOTINIB IN DAILY PRACTICE ACCORDING TO UPDATED GUIDELINES

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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/16550

EU PAS number
EUPAS3335

Study ID
16550

DARWIN EU® study
No

Study countries
Austria
Germany

Study description
This non-interventional, observational study will provide real-world safety data on CML CP patients exposed to nilotinib and therefore provide insights into disease management as well as the safety profile of nilotinib.

Study status
Finalised

Research institution and networks

Institutions

Novartis Pharmaceuticals
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Institution

Multiple centres: 15 centres are involved in the study

Contact details

Study institution contact
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Study contact

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Primary lead investigator
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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
10/02/2013
Actual:
10/02/2013

Study start date
Planned:
26/08/2013
Actual:

10/10/2013

Data analysis start date
Planned:
01/07/2020
Actual:
31/12/2015

Date of final study report
Planned:
31/12/2016
Actual:
31/12/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharmaceuticals

Study protocol

CAMN107AAT01_Tasigna_PASS_Protocol_version01_Redacted.pdf(512.23 KB)

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Other study registration identification numbers and links

CAMN107AAT01

Methodological aspects

Study type

Study type list

Study topic:
Disease /health condition
Human medicinal product

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness
Drug utilisation

Data collection methods:
Primary data collection

Main study objective:
This observational study will provide real-world safety data on CML patients exposed to nilotinib and therefore provide insights into disease management, efficacy as well as the safety profile of nilotinib and the adherence to current treatment recommendations (Baccarani et al. 2009, Valent et al. 2011, Rosti et al. 2011) in daily clinical practice.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine
Tasigna

Study drug International non-proprietary name (INN) or common name
NILOTINIB

Anatomical Therapeutic Chemical (ATC) code
(L01XE08) nilotinib

Medical condition to be studied
Chronic myeloid leukaemia

Population studied

Short description of the study population
Patients with chronic myeloid leukemia receiving Nilotinib in daily practice.

Age groups
Adults (18 to < 46 years)
Adults (46 to < 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Special population of interest
Other

Special population of interest, other
Chronic myeloid leukaemia patients

Estimated number of subjects
100

Study design details

Outcomes
The main goal of this non-interventional study is to document the following parameters under specific conditions of daily clinical practice:• Safety and tolerability and all adverse events (AE, serious and non-serious) during treatment with nilotinib and adherence to current treatment recommendations in daily clinical practice, Clinical, cytogenetic, hematologic and molecular responses to nilotinib

Data analysis plan
There are no predefined hypotheses regarding the incidence of specific safety outcomes, the magnitude of effectiveness or treatment practices. Descriptive statistical methods will be used for all variables of evaluation. Efficacy and safety variables will be presented descriptive and will be interpreted in comparison to historic controls and published data.

Documents

Study results
CAMN107AAT01_Redacted CSR.pdf(612.58 KB)

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping
No

Data quality specifications

Check conformance
Unknown

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
Unknown