E7080-M000-508 (STELLAR)

First published: 10/02/2021

Last updated: 12/12/2024

Study Finalised

Administrative details

EU PAS number

EUPAS36854

Study ID

40736

DARWIN EU® study

No

Study countries

- [ ] Australia
- [ ] Austria
- [ ] Belgium
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands

- [ ] Portugal
- [ ] Russian Federation
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom
- [ ] United States

Study description

The primary purpose of this study is to further characterise the hepatotoxicity in participants with advanced or unresectable hepatocellular carcinoma (HCC) treated with lenvatinib, and to further characterise the overall safety profile (serious adverse events SAEs, grade 3 to 5 adverse events AEs, dose modifications and discontinuations due to AEs) in participants with advanced or unresectable HCC treated with lenvatinib.

Study status

Finalised

Research institutions and networks

Institutions

Eisai

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Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Vanessa Christou

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/10/2020

Actual: 26/10/2020

Study start date

Planned: 29/03/2021

Actual: 09/04/2021

Date of final study report

Planned: 30/03/2029

Actual: 14/06/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eisai

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To further characterise the hepatotoxicity in participants with advanced or unresectable hepatocellular carcinoma (HCC) treated with lenvatinib, and to further characterise the overall safety profile (serious adverse events SAEs, grade 3 to 5 adverse events AEs, dose modifications and discontinuations due

to AEs) in participants with advanced or unresectable HCC treated with lenvatinib.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XE29) lenvatinib

lenvatinib

Medical condition to be studied

Hepatocellular carcinoma

Population studied

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)

Estimated number of subjects

1000

Study design details

Outcomes

1. Number of Participants With Hepatotoxicity Treatment-emergent Adverse Events (TEAEs) With Lenvatinib
2. Number of Participants With SAEs With Lenvatinib
3. Number of Participants With Grade 3 to 5 AEs With Lenvatinib
4. Number of Participants with one or More TEAEs Leading to Dose Modifications and Treatment Discontinuations of Lenvatinib, Duration of lenvatinib treatment, the incidence of dose interruptions and dose reductions, the relative dose intensity of lenvatinib, treatment sequencing following lenvatinib treatment. Overall survival. Treatment patterns in patients treated with sorafenib. The association of patient demographic and baseline disease-related characteristics to treatment decisions.

Data analysis plan

This study is descriptive and primarily aims to further characterise hepatotoxicity and overall safety profile in patients with advanced or unresectable HCC treated with lenvatinib.

Study results will be summarised separately by treatment cohort (i.e. lenvatinib or sorafenib) and treatment line, without pre-defined hypotheses. Categorical variables will be reported as counts (n) and frequencies (%). Continuous variables will be reported using mean, standard deviation, median, interquartile range (Q1 to Q3), and range.

Descriptive analyses (including standard univariate analyses) will be conducted to evaluate demographic and clinical characteristics, crude incidence proportions, and rates of prespecified hepatotoxic events.

Time-to-event outcomes (e.g. OS) will be assessed using the Kaplan-Meier method and will be reported as descriptive statistics.

Documents

Study report

e7080-m000-508--final-study-report_synopsis-red-v2.pdf (107.34 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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

No