Reporting and Analysis Plan - ECHO Analyses From Randomized Controlled Trials of Dabrafenib to Evaluate the Potential for Cardiac Valve Abnormalities (201709)

First published: 25/08/2014

Last updated: 18/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/40754

EU PAS number

EUPAS7313

Study ID

40754

DARWIN EU® study

No

Study countries

United States

Study description

This meta-analysis supported an FDA post-marketing requirement (PMR) to further investigate independently reviewed echocardiogram (ECHO) results for subjects treated with dabrafenib, either as monotherapy or in combination with other anti-cancer therapies on randomized controlled clinical trials. These analyses evaluated the potential for cardiac valve abnormalities in patients treated with dabrafenib based on preclinical findings. The study was cancelled with no patients.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Clinical Disclosure Officer Clinical Disclosure Officer

Study contact

trialandresults.registries@novartis.com

Primary lead investigator

Clinical Disclosure Officer Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/09/2013

Actual: 17/09/2013

Study start date

Planned: 17/09/2013

Actual: 17/09/2013

Date of final study report

Planned: 20/09/2021

Actual: 17/09/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

Study protocol

gsk2118346-rap-cardiacvalve-redact.pdf(196.56 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

CDRB436A2401

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Meta-analysis

Data collection methods:

Secondary use of data

Main study objective:

The objective of this analysis is to fully describe the results of the independently reviewed ECHO data of subjects treated with dabrafenib.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

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

DABRAFENIB

Medical condition to be studied

Metastatic malignant melanoma

Population studied

Short description of the study population

Subjects treated with dabrafenib, either as monotherapy or in combination with other anti-cancer therapies on randomized controlled clinical trials

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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

Metastatic malignant melanoma patients

Estimated number of subjects

500

Study design details

Data analysis plan

All analyses of the independently reviewed ECHO data will use the Safety population (SAFETY), which comprises all randomized subjects who received at least one dose of study medication and will be based on the actual treatment received if this differed from that to which the subject was randomized. All analyses will be presented by treatment arm (e.g. dabrafenib monotherapy, dabrafenib plus trametinib, DTIC). All programming will be performed using SAS* version 9.1.3 or greater and S-Plus version 7.0 or higher in a UNIX†

environment. All data analyses and tables, listings, and figures will use the formats in the IntegratedData Standards Library (IDSL), unless there is no standard for a particular analysis. Any non-standard data displays will follow the general format of the IDSL and Therapeutic Standards Team (TST) data displays to the extent possible.

Data management

Data sources

Data source(s), other

BRF113683, MEK115306, MEK116513, BRF115532

Data sources (types)

Other

Data sources (types), other

Phase III randomized studies

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