Reporting and Analysis Plan - Evaluation of Secondary Malignancies in Patients Treated with Dabrafenib in Randomized, Controlled Trials (201710)

First published: 25/08/2014

Last updated: 14/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/39394

EU PAS number

EUPAS7317

Study ID

39394

DARWIN EU® study

No

Study countries

United States

Study description

This meta-analysis supports an FDA-proposed Clinical Post-Marketing Requirement (PMR) dated May 29, 2013 requesting cumulative safety analyses of new malignancies, including cutaneous squamous cell carcinoma, in all ongoing and subsequently initiated randomized controlled clinical trials through 2020 that use Tafinlar (dabrafenib) capsules alone or in combination with other anti-cancer drugs. There are currently four ongoing randomized, comparative trials that will eventually contribute to these analyses: BRF113683, MEK115306, MEK116513, and BRF115532. The results of BRF113683 were reported in the clinical study report titled ‘A Phase III randomized, open-label study comparing dabrafenib to DTIC in previously untreated subjects with BRAF mutation positive advanced (Stage III) or metastatic (Stage IV) melanoma’ (dated June 2012). The other 3 trials have not reached their primary endpoint analysis as of June 2013. The first Interim Report will contain data from only BRF113683 and be submitted in October 2013, subsequent reports will include data from other included studies.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

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: 23/09/2013

Actual: 23/09/2013

Study start date

Planned: 23/09/2013

Actual: 23/09/2013

Date of final study report

Planned: 20/08/2021

Actual: 07/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

Study protocol

GSK2118436-reporting-and-analysis-plan-redact.pdf(196.07 KB)

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)

Other study registration identification numbers and links

201710

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

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 describe more fully the secondary malignancy data from 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

Metastatic malignant melanoma patients treated with Dabrafenib.

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 will use the Safety population (SAFETY) for each study, 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 actual treatment arm (e.g. dabrafenib monotherapy,dabrafenib plus trametinib, DTIC). Comparisons will be made within each study, since the comparator arms differ in each of the randomized studies. 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 Integrated Data 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.

Documents

Study results

EMA PAM Secondary Malignancies Final Report 2020_Redacted.1.pdf(924.43 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

BRF113683 (BREAK-3), MEK115306 (COMBI-d), MEK116513 (COMBI-v), BRF115532 (COMBI-AD) trials

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