PGX7550: PGx Investigation of Pyrexia by Meta-Analysis of Dabrafenib/Trametinib Melanoma Studies BRF113710, BRF113929, BRF113683 and MEK115306 (200997)

First published: 23/10/2014

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Study Finalised

Administrative details

EU PAS number

EUPAS7766

Study ID

16870

DARWIN EU® study

No

Study countries

☐ United States

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/03/2014

Actual: 21/03/2014

Study start date
Planned: 21/03/2014

Actual: 21/03/2014

Date of final study report
Planned: 31/12/2014

Actual: 17/12/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

200997-reporting-and-analysis-plan-redact.pdf(954.8 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

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

Pharmacogenetics study

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to further follow up previously identified suggestive associations between pyrexia and a genetic variant in IL28B (rs8099917) by meta-analysis of melanoma subjects from BRF113710, BRF113929, BRF113683 and MEK115306

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Pharmacogenetics study

Study drug and medical condition

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

DABRAFENIB

TRAMETINIB

Medical condition to be studied

Malignant melanoma

Population studied

Short description of the study population

Malignant melanoma patients who received Dabrafenib/Trametinib.

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

Malignant melanoma patients

Estimated number of subjects

407

Study design details

Data analysis plan

The initial PGx analysis will focus on the metastatic melanoma subjects from MEK115306 who met the definition of a case or control. These subjects will be meta-analyzed along with the 3 study populations BRF113710, BRF113929, and BRF113683.

Documents

Study results

200997 PGx7550 Synopsis_17Dec14_Final.pdf(34.64 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

Unknown