An assessment of physician knowledge and understanding of the risks of vandetanib (Caprelsa®) within the European Union

First published: 08/07/2013

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS4242

Study ID

29466

DARWIN EU® study

No

Study countries

- Austria
- Belgium
- Bulgaria
- Denmark

Finland
France
Germany
Greece
Ireland
Italy
Luxembourg
Netherlands
Norway
Poland
Slovakia
Spain
Sweden
United Kingdom

Study description

Caprelsa was approved for use in the European Union in 2012. At the time of approval it was agreed that AstraZeneca would distribute an educational pack to potential prescribers of Caprelsa to support understanding of the benefit: risk profile of the product.Prior to launch in each EU Member State, AstraZeneca was required to agree with each national competent authority:• The final content and format of the educational material • The physician distribution list for the educational pack (to be used at the time of launch and thereafter).To assess the effectiveness of the educational material, AstraZeneca also committed to implement a survey of prescribers and potential prescribers of Caprelsa.Therefore, a yearly survey will be performed in each country in the European Union twelve months after Caprelsa is launched and will run for three consecutive years. The survey will be a self-administered, internet-based questionnaire accessed through a secure website.

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

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Institution

Contact details

Study institution contact

Trial Transparency Team Trial Transparency Team contact-US@sanofi.com

Study contact

contact-US@sanofi.com

Primary lead investigator

Trial Transparency Team Trial Transparency Team

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/05/2013

Study start date
Planned: 02/09/2013

Actual: 18/09/2013

Date of final study report
Planned: 01/12/2018

Actual: 22/06/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

Final Caprelsa prescriber survey protocol (2) (2).pdf (313.16 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)

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The study objective is to assess the knowledge and understanding of physicians in relation to the key elements in the Caprelsa educational material.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Survey of physician knowledge

Study drug and medical condition

Medicinal product name

CAPRELSA

Medical condition to be studied

Medullary thyroid cancer

Population studied

Short description of the study population

Physicians who were targeted to receive the Caprelsa educational pack at the time of launch.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

1

Study design details

Outcomes

The primary outcome is the level of understanding of the benefit:risk profile of Caprelsa prescribers/potential prescribers as demonstrated by the results of the prescriber survey.

Data analysis plan

The responses to each survey question will be reported as descriptive statistics. The frequency distribution of responses to each question (the number and percentage of respondents who give answers to each response option) will be presented. Each question will be evaluated individually. The following will be reported, as appropriate, as part of this analysis:• The number of invitations

issued to healthcare providers• The number and percentage of healthcare providers eligible for participation• The number and percentage of healthcare providers who completed the survey• Frequency distribution of responses to each survey question (the number of and percentage of respondents who give each answer to each question)Additional analyses may be performed as needed.

Documents

Study results

Vandetanib Physican Survey Study Report - 22JUN2018.pdf (469.24 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

There is no data source per se, this study uses a survey methodology.

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