# 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

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**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.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### Sanofi

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**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.

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**Age groups**

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

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**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.

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**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