# Survival follow up of JO25567, a randomized phase 2 study comparing erlotinib and bevacizumab combination with erlotinib alone in NSCLC patients harboring EGFR mutation.

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Study  Finalised

## Administrative details

**EU PAS number**

EUPAS25131

**Study ID**

25132

**DARWIN EU® study**

No

**Study countries**

☐ Japan

**Study description**

A follow up study to JO25567 comparing overall survival in NSCLC patients harboring EGFR mutation between two treatment groups - bevacizumab plus erlotinib versus erlotinib alone.

**Study status**

Finalised

# Research institutions and networks

# Institutions

Novartis Pharmaceuticals

# Contact details

**Study institution contact**

Minoru Watanabe global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

**Primary lead investigator**

Minoru Watanabe

Primary lead investigator

# Study timelines

**Date when funding contract was signed**

Actual: 23/04/2014

**Study start date**

Actual: 13/06/2014

**Date of final study report**

Actual: 19/06/2018

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Chugai Pharmaceutical Co., Ltd.

# Study protocol

Protocol (v1.2).pdf (1.04 MB)

# Regulatory

**Was the study required by a regulatory body?**

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

# Other study registration identification numbers and links

JO29424

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The study followed patients with EGFR mutated NSCLC who completed Study JO25567 with the aim to compare the overall survival of the patients who received bevacizumab plus erlotinib to those who were treated with Erlotinib alone.

## Study Design

**Non-interventional study design**

Cohort

# Study drug and medical condition

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

BEVACIZUMAB

**Medical condition to be studied**

Non-small cell lung cancer

# Population studied

**Short description of the study population**

Patients with EGFR mutated NSCLC who completed Study JO25567: a
Randomized Phase 2 Study Comparing Erlotinib and Bevacizumab Combination
with Erlotinib Alone in NSCLC Patients Harboring EGFR Mutation.

**Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

**Special population of interest**

Other

**Special population of interest, other**

Non-small cell lung cancer patients

**Estimated number of subjects**

75

# Study design details

### Outcomes

The primary efficacy endpoint in this study was Overall Survival, defined as the time from the date of randomization in the JO25567 study to the date of death irrespective of the cause.

### Data analysis plan

Overall Survival curves for each treatment group are estimated using the Kaplan-Meier product limit method. Median values of OS and survival rate, along with two-sided 95% CI, are calculated. A log-rank test was also applied to compare the distribution between groups. Associated 95% confidence interval are calculated using the Greenwood formula. Furthermore, the Cox regression analysis was applied and the hazard ratios and their 95% confidence intervals estimated. Kaplan-Meier curve were displayed and created raw output of LIFETEST procedure.

# Documents

### Study results

Synopsis.pdf (246.14 KB)

# Data management

# ENCePP Seal

# 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**

No