ARIA: Real-world utilization and outcomes with dacomitinib first-line treatment for EGFR mutation-positive advanced non-small cell lung cancer among Asian patients – A multi center chart review (A7471067)

First published: 02/12/2021

Last updated: 02/12/2021

Study | Ongoing

Administrative details

EU PAS number

EUPAS44543

Study ID

44544

DARWIN EU® study

No

Study countries

China

India

Malaysia

Study description

This is a longitudinal, multi-center cohort study with mixed prospective and retrospective data collection. Data will be collected from eligible adults with EGFR mutation-positive advanced NSCLC treated with dacomitinib as first-line therapy from the date of advanced NSCLC diagnosis to the date of death, lost to follow-up, withdrawal of consent or end of study, whichever occurs first.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

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Study contact

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Primary lead investigator

Chew Hooi Wong

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/03/2020

Actual: 20/03/2020

Study start date

Planned: 05/05/2021

Actual: 11/06/2021

Date of final study report

Planned: 31/10/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

1. To describe demographics, as well as clinical and disease characteristics of patients on first-line dacomitinib therapy for treatment of EGFR mutation-

positive advanced NSCLC. 2. To describe starting dose of dacomitinib as first-line therapy, dose modification (if any), related timing and reason for dose modification, interruption or discontinuation. 3. To describe DOT and TTF of dacomitinib

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

VIZIMPRO

Medical condition to be studied

EGFR gene mutation

Population studied

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)

Estimated number of subjects

Study design details

Outcomes

1. Demographics, as well as clinical and disease characteristics of patients on first-line dacomitinib therapy for treatment of EGFR mutation-positive advanced NSCLC. 2. Starting dose of dacomitinib as first-line therapy, dose modification (if any), related timing and reason for dose modification, interruption or discontinuation. 3. DOT and TTF of dacomitinib, 1. Real-world PFS of patients. 2. All adverse events (AEs) for patients treated with dacomitinib. 3. TTF, PFS, overall survival (OS) and AEs, as well as starting dose and dose modification of dacomitinib in a subgroup of patients with common EGFR mutations (exon 19 deletion or exon 21 L858R substitution) enrolled in China.

Data analysis plan

There will be no hypothesis testing in this study. All statistical analyses will be descriptive and no P-values will be reported in this study.

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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