Disease Registry on Patients with Advanced NSCLC Harboring METex14 Skipping Alterations (MOMENT)

First published: 07/06/2022

Last updated: 02/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS47602

Study ID

47603

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ United States

Study description

The purpose of this multi-national disease registry is to collect prospectively (with longitudinal follow-up) high-quality, standardized, and contemporaneous data to capture changes in the non-small cell lung cancer (NSCLC) treatment landscape and outcomes over time. The registry will capture data on participants, demographic, clinical characteristics (including biomarker data), treatment patterns, and effectiveness and safety outcomes for advanced NSCLC with mesenchymal-epithelial transition exon 14 (METex14) participants treated with systemic therapy. This is a disease registry, which is an organized system using non-interventional methods to collect data on a patient population defined by a particular disease, exposure, or condition, and which is followed over time. Non-interventional means that after participants enrollment, participants will be treated according to the routine clinical treatment decision by the physician. The registry will not impose any treatment or procedure for participants.

Study status

Ongoing

Research institutions and networks

Institutions

Merck Healthcare KGaA

Germany

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Institution

Contact details

Study institution contact

Communication Center Merck KGaA

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Study contact

service@merckgroup.com

Primary lead investigator

Communication Center Merck KGaA

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/06/2022

Study start date

Planned: 30/06/2022

Actual: 04/03/2022

Date of final study report

Planned: 31/03/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck KGaA

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

Main study objective:

It will aim to collect prospectively (with longitudinal follow-up) high-quality, standardized, & contemporaneous data to capture changes in the NSCLC treatment landscape & outcomes over time. The registry would capture data on patient and clinical characteristics treatment patterns, and effectiveness and

safety outcomes for advanced NSCLC METex14 patients treated with systemic therapy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Non-small cell lung cancer

Additional medical condition(s)

METex14 Skipping Alterations

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

700

Study design details

Outcomes

Best Overall Response (BOR), Overall Survival (OS), Number of Participants with Adverse Events (AEs), and Number of Participants with Adverse Reactions (ARs)

Data analysis plan

Not applicable

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)

Disease registry

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