An observational cohort study to investigate the risk factors for interstitial lung disease (ILD) among breast cancer patients treated with abemaciclib or endocrine monotherapy using the Medical Data Vision (MDV) database in Japan (I3Y-JE-B008)

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Study Planned

Administrative details

EU PAS number

EUPAS104511

Study ID

104512

DARWIN EU® study

No

Study countries

Japan

Study description

The primary objective of this study is to investigate risk factors of ILD among patients with HR+/HER2– breast cancer receiving abemaciclib-containing regimens or endocrine monotherapy (both historical and concurrent cohorts) under the real world setting in Japan, and the secondary objective is to describe the baseline characteristics, incidence and prevalence of ILD in each of the study cohorts. The exploratory objective is to compare the incidence rate of ILD in patients initiating abemaciclib relative to reference cohorts of endocrine monotherapy.

Study status

Planned

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Seiko Mizuno

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 19/07/2019

Study start date
Planned: 30/11/2018

Date of final study report
Planned: 01/12/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly Japan K.K.

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The primary objective of this study is to investigate risk factors of ILD among patients with HR+/HER2– breast cancer receiving abemaciclib-containing regimens or endocrine monotherapy (both historical and concurrent cohorts) under the real world setting in Japan

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01EF03) abemaciclib

abemaciclib

Medical condition to be studied

Interstitial lung disease

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

3312

Study design details

Data analysis plan

The prevalence, incidence, and incidence rate of ILD for all treatment cohorts will be calculated. Kaplan-Meier method will be used to display the time until patients develop the first ILD (event-free period). The historical endocrine monotherapy cohort will be used for the primary comparator and the concurrent endocrine monotherapy cohort will be used.In the univariable Cox regression analysis, variables will be selected as candidates for the multivariable analysis based on statistical significance as well as clinical

importance/relevance. Multivariable Cox proportional hazard analysis will be used to identify potential risk factors associated with time to ILD onset by each of the three treatment cohorts from variables identified from the univariable analysis, with or without potential interaction terms. Additional multivariable Cox regression analysis that will be conducted to include treatment cohorts as independent variable along with other candidate variables.

Data management

Data sources

Data source(s), other

MDV Japan

Data sources (types)

Administrative healthcare records (e.g., claims)

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