A two-stage, prospective observational study describing the use and effectiveness of XGEVA®/ANJIAWEI® for the prevention of skeletal related events in patients with bone metastases from solid tumors relative to ZOMETA® in the People's Republic of China (20190036)

First published: 13/04/2023

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/105058

EU PAS number

EUPAS104114

Study ID

105058

DARWIN EU® study

No

Study countries

China

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/08/2020

Actual: 15/08/2020

Study start date
Planned: 29/02/2024

Actual: 05/03/2024

Data analysis start date
Planned: 05/03/2029

Date of final study report
Planned: 19/07/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen, Inc.

Study protocol

Protocol-Published Original denosumab 20190036 .pdf(2.52 MB)

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:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

Describe utilization of XGEVA® and ZOMETA® for prevention of skeletal-related events (SREs) in participants with bone metastases secondary to breast, prostate, lung cancer; assess baseline characteristics/prognosis for SREs at initiation of bone targeting agent (BTA); and adverse events of special interest. Describe effectiveness of XGEVA® and ZOMETA® for preventing symptomatic SRE.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Pharmacodynamic study, prospective, observational study

Study drug and medical condition

Name of medicine

XGEVA

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

DENOSUMAB

Anatomical Therapeutic Chemical (ATC) code

(M05BX04) denosumab

denosumab

Medical condition to be studied

Metastases to bone

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

1000

Study design details

Outcomes

The frequency of administration and duration of treatment by XGEVA® and ZOMETA®, Demographic and clinical characteristics of patients that may be related to prognosis for SRE by treatment cohort (XGEVA® and ZOMETA®), Adverse events of special interest (ie, osteonecrosis of the jaw, atypical femoral fracture and hypocalcemia). Time to first symptomatic SRE.

Data analysis plan

Descriptive analyses will be performed to gain an understanding of the qualitative and quantitative nature of the data collected and the characteristics of the patient population and treatment cohorts. Continuous variables will be reported as mean, standard deviation (SD), median, range, and interquartile range (Q1 to Q3), where appropriate. Categorical variables will be summarized as frequency counts and percentage.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, medical records, extrapolating from other real-world studies in China

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