Effectiveness, Efficacy, and Safety of XGEVA (denosumab) in Chinese Patients With Giant Cell Tumor of Bone (GCTB): A Systematic Literature Review (20220044)

First published: 28/09/2022

Last updated: 05/12/2023

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50352

EU PAS number

EUPAS49061

Study ID

50352

DARWIN EU® study

No

Study countries

- ☐ China
- ☐ Taiwan
- ☐ United States

Study status

Finalised

Research institutions and networks

Institutions

Amgen

☐ United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 22/08/2022

Actual: 22/08/2022

Study start date
Planned: 11/11/2022

Actual: 04/11/2022

Data analysis start date
Planned: 12/12/2022

Actual: 19/12/2022

Date of final study report
Planned: 01/04/2023

Actual: 01/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Original denosumab 20220044.pdf(489.33 KB)

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:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The objective of this systematic review is to evaluate published evidence on the safety and clinical effectiveness of XGEVA among mainland Chinese and Chinese patients in Taiwan, Hong Kong, and Macau with GCTB, and to

characterize the benefit-risk profile associated with use of this drug in these Chinese GCTB patients, in context of the global body of evidence of XGEVA treated GCTB patients.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This systematic literature review will include randomized clinical trials (RCTs), case reports, observational studies published in peer reviewed journals, as well as RCTs and observational studies published as abstracts and/or posters at conferences

Study drug and medical condition

Name of medicine

XGEVA

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

DENOSUMAB

Medical condition to be studied

Bone giant cell tumour

Population studied

Age groups

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)

Estimated number of subjects

0

Study design details

Data analysis plan

A qualitative synthesis of results will be performed, and a narrative summary provided in the text of the final report.

Documents

Study results

20220044_ORSR Abstract_28MAR2023_Redacted.pdf(104.26 KB)

Data management

Data sources

Data source(s), other

PubMed (MEDLINE) United States, Embase United States, Google Scholar United States, Cochrane Library United States, Clarivate Analytics United States

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Systematic review of all published studies of XGEVA among mainland Chinese and Chinese patients in Taiwan, Hong Kong, and Macau with GCTB.

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