Postmarketing Surveillance Study of XGEVA (Denosumab) in South Korea (20160198)

First published: 17/04/2017

Last updated: 22/04/2021

Study Finalised

Administrative details

EU PAS number

EUPAS18114

Study ID

40681

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study description

The primary objective of this study is to estimate the incidence of adverse events, serious adverse events, and adverse drug reactions among patients receiving XGEVA® in a postmarketing setting as required by the Ministry of

Food and Drug Safety.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 20 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.
medinfo@amgen.com

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: 29/08/2016

Actual: 29/08/2016

Study start date

Planned: 13/10/2017

Actual: 24/10/2017

Data analysis start date

Planned: 14/08/2020

Actual: 13/08/2020

Date of interim report, if expected

Planned: 28/11/2019

Date of final study report

Planned: 16/04/2021

Actual: 22/04/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

01.20.01 Protocol Ver 1.0 2016-08-29 redacted final.pdf(483.34 KB)

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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

To provide descriptive data on the use of XGEVA® incidence of adverse events and adverse drug reactions, incidence of SREs, and patient characteristics in a postmarketing setting

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study is to estimate the incidence of adverse events, serious adverse events, and adverse drug reactions among patients receiving XGEVA® in a postmarketing setting as required by the MFDS.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, observational, multicenter study in patients with approved indications who are being treated with XGEVA®

Study drug and medical condition

Name of medicine

XGEVA

Medical condition to be studied

Metastases to bone

Population studied

Short description of the study population

The study population comprises patients treated with XGEVA in a clinical setting which includes any primary through tertiary healthcare setting where XGEVA is prescribed. Patients will be screened for eligibility, receive a single dose of XGEVA during their initial visit/day 1 (which could be the same day as screening), and return for follow-up visits approximately Q4W for subsequent doses (provided the patient remains on treatment).

Inclusion criteria: subjects receiving first dose on day-1 of study; consenting to participate in study and provide medical information.
Exclusion criteria: subjects denying consent; untreated severe hypocalcemia; known hypersensitivity to denosumab/its components.

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

300

Study design details

Outcomes

Incidence of adverse events and adverse drug reactions (including seriousness and causality to drug), inclusive of reaction at local injection sites, will be collected as they become available throughout the follow-up period and reported. Subject level incidence will be reported and summarized by classification according to the adverse event coding, (1) SREs will be assessed either by collecting patient-reported events or through findings as part of routine clinical practice, (2) Describe characteristics of patients receiving XGEVA® in the postmarketing setting.

Data analysis plan

Descriptive analysis of the collected safety and efficacy endpoints will be conducted at interim analyses (every 6 months for the first 2 years from approval, then annually thereafter) and final analysis when all patients have the opportunity to complete the final study visit. Categorical outcomes will be summarized by the number and percentage of subjects in each category. Continuous outcomes will be summarized by the number of nonmissing values, mean, standard deviation, median, lower and upper quartiles, and minimum and maximum values. Kaplan-Meier estimates and their 95% confidence interval (CI) will be provided for time-to-event endpoints. For the incidence, 95% CI will be presented based on an exact method. The analysis will include all enrolled patients (enrollment is triggered once an eligible, consenting patient receives their first dose of XGEVA®).

Documents

Study results

Denosumab_20160198_Study_Report_Abstract_Observational_Final_Analysis_Redacted (3).pdf(228.01 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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