Prospective Observational Non-interventional Study to Describe Characteristics and Management of Patients With Giant Cell Tumor of Bone Treated With XGEVA and Its Use in Routine Clinical Practice in France (20150360)

First published: 15/12/2017

Last updated: 06/02/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS21542

Study ID

22265

DARWIN EU® study

No

Study countries

France

Study description

The French Health Authorities requested, in July 2015, a study with the objective to provide long-term data on patients with giant cell tumor of bone treated with XGEVA.

This study should be able to provide real world data on the characteristics of treated patients, the conditions of use of XGEVA, the XGEVA impact on morbidity and the Health related quality of life of the patients.

This study is a prospective observational study.

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Networks

ReSos, National network specialized in pathology and care of bone sarcomas

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

Actual: 06/04/2017

Study start date

Planned: 01/01/2018

Actual: 01/01/2018

Data analysis start date

Planned: 15/03/2025

Actual: 04/04/2025

Date of interim report, if expected
Planned: 15/07/2021

Date of final study report
Planned: 28/02/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20150360 Public+Redacted+Protocol+2017-05-18.pdf (84.02 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Study design:

This is a multicenter, observational non-interventional, prospective study in GCTB patients receiving XGEVA using the French Sarcoma Network.

Main study objective:

To describe patient and disease characteristics of giant cell tumor of bone (GCTB) patients prior to initiation of XGEVA

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

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

Bone giant cell tumour

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

80

Study design details

Outcomes

Socio-demographics (age, sex, living condition, education level, employment status), clinical (localization, soft tissue extension, fracture, pulmonary metastasis, for recurrent tumor: number, localization, biopsy, MRI scanner, soft

tissue extension, fracture, pulmonary metastasis) and radiological (tumor size) disease characteristics prior initiation of XGEVA, Treatment history and line of treatment at XGEVA initiation.
Proportion of patients undergoing surgery within one year from XGEVA initiation.
Treatment pattern of XGEVA and other treatments targeting GCTB administered over the study period. TTP, PFS, RFS. Pain score and impact on patient’s lives.
Time from BPI-SF score prior XGEVA initiation to the first BPI-SF score deterioration. ADRs and SADRs.

Data analysis plan

All analyses will be done using modified intent to treat principle: all included subjects who have received at least one dose of XGEVA treatment (mITT1).
Categorical outcomes will be summarized by the number and percentage of patients in each category, and the corresponding 95% CI.
Continuous data will be described by mean, standard deviation, median, Q1 and Q3 quartiles and minimum and maximum values.
Time to event endpoints will be analyzed using Kaplan Meier estimation and described using median or rate at specific time point with a 95% CI. Follow-up will be calculated using reverse Kaplan Meier estimation.
All BPI SF analyses will be performed in all included subjects who have received at least one dose of XGEVA and with a BPI SF score at baseline (mITT2).
Longitudinal BPI-SF score will be studied using time to event approach and also using mixed model analysis of variance for repeated measurement or pattern mixture models (in case of missing not at random BPI SF score).

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)

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