Survey of Oncology Practitioners Prescribing XGEVA® in Europe to Evaluate Their Knowledge of XGEVA® Summary of Product Characteristics Pertaining to Osteonecrosis of the Jaw (20110102)

First published: 11/02/2014

Last updated: 30/10/2015

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/11454

EU PAS number

EUPAS5345

Study ID

11454

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Norway
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

Osteonecrosis of the Jaw (ONJ) is an adverse effect of antiresorptive therapy that is well-recognized in patients with advanced cancer. Detailed information regarding this risk is specified in the Summary of Product Characteristics (SPC). The statements in the SPC are the most important mechanism for minimizing the risk for ONJ. The study objective is to measure the knowledge of oncology practitioners prescribing XGEVA® regarding the content pertaining to ONJ in the SPC after commercial availability.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

- [ ] United States

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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

Actual: 13/07/2012

Study start date

Actual: 08/08/2012

Data analysis start date

Planned: 14/08/2014

Actual: 12/06/2014

Date of interim report, if expected
Planned: 05/09/2014

Actual: 13/11/2014

Date of final study report
Planned: 03/09/2015

Actual: 23/09/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

XGEVA_20110102_Protocol_11Feb14.pdf(391.14 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Other

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

Assess physicians knowledge of the SPC pertaining to risk or osteonecrosis of the jaw

Data collection methods:

Primary data collection

Main study objective:

Proportion of participating oncology practitioners prescribing XGEVA® who are aware of the SPC statements pertaining to ONJ (each question pertaining to a SPC statement will be assessed seperately at the end of each survey round)
Time Frame: 12 and 24 months after commercial availability of XGEVA® in the respective country

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Physician survey

Study drug and medical condition

Medical condition to be studied

Osteonecrosis of jaw

Population studied

Short description of the study population

Oncology practitioners enrolled from the participating countries.

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)

Special population of interest

Other

Special population of interest, other

Patients with osteonecrosis of jaw

Estimated number of subjects

420

Study design details

Outcomes

Proportion of participating oncology practitioners prescribing XGEVA® who are aware of the SPC statements pertaining to ONJ (each question pertaining to a SPC statement will be assessed seperately at the end of each survey round)
Time Frame: 12 and 24 months after commercial availability of XGEVA® in the respective country

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Data analysis plan

The study is descriptive in nature and does not test a formal hypothesis. The study endpoints represent the proportion of practitioners prescribing XGEVA® who are aware of SPC statements related to ONJ, measured using a standardized multiple-choice questionnaire. The no. of oncology practitioners eligible to participate, and the no. that agreed to participate in the survey will be captured. Results will be reported overall, and by each of 2 survey rounds corresponding to approx. month 12 and month 24 after commercial availability of XGEVA in the respective countries. Questions not answered will be considered as incorrect answers and included in the denominators. Standard errors will be calculated based on the normal approximation to the binomial distribution. Two-sided 95% confidence intervals will be estimated as the proportion ± 1.96 multiplied by the standard error. Results will be stratified by 2 regions: Nordic countries vs. the 5 largest European countries by population size.

Documents

Study results

20110102 ORSR Abstract_10SEP2015.pdf(153.87 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Randomly selected oncology practitioners from the participating countries

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