PASS INFORMATION

Title	Survey of Oncology Practitioners Prescribing XGEVA® in Europe to Evaluate Their Knowledge of XGEVA® Summary of Product Characteristics Pertaining to Osteonecrosis of the Jaw
Version Identifier of the Final Study Report	20110102, Version 1.0
Date of Last Version of the Study Report	Not applicable
EU PAS Register No:	ENCEPP/SDPP/5345
Clinicaltrials.gov Identifier No:	NCT01998607
Active Substance	Denosumab (ATC code M05BX04 for XGEVA)
Medicinal Product	XGEVA® (denosumab 120 mg)
Product Reference:	EMEA/H/C/002173
Procedure Number:	EMEA/H/C/2173 MEA 010
Marketing Authorization Holder	Amgen Europe B.V.
Joint PASS	No
Research Question and Objectives	This was a cross-sectional survey of 420 practicing oncology practitioners prescribing XGEVA in the 5 largest European countries by population and in 4 Nordic countries. The primary objective was to evaluate the oncology practitioners' knowledge of the XGEVA Summary of Product Characteristics pertaining to osteonecrosis of the jaw. Surveys were conducted in 2 rounds at 12 to 18 months and 24 to 30 months after XGEVA became commercially available in the participating countries. This report provides final results from 420 oncology practitioners surveyed in the study.
Countries of Study	Denmark, Finland, France, Germany, Italy, Norway, Spain, Sweden, and the United Kingdom
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1. ABSTRACT

- **Title**

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

Date: 10 September 2015

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- **Keywords**

XGEVA; Oncology practitioners; Osteonecrosis of the jaw; Survey

- **Rationale and Background**

XGEVA is a fully human monoclonal antibody that inhibits the formation, activation, and survival of osteoclasts, consequently reducing bone resorption and cancer-induced bone destruction. Osteonecrosis of the jaw (ONJ) is a well-recognized adverse effect of antiresorptive therapy in patients with advanced cancer.

- **Research Question and Objectives**

The primary objective of Study 20110102 was to survey European oncology practitioners prescribing XGEVA (denosumab 120 mg every 4 weeks) to evaluate their knowledge of the XGEVA Summary of Product Characteristics (SmPC) pertaining to ONJ.

- **Study Design and Setting**

Eligible consenting practicing oncology practitioners (who have treated ≥ 5 new or continuing patients with bone metastases from solid tumors in the last quarter and have prescribed XGEVA within the last 12 months) were surveyed in the 5 largest European countries by population (France, Germany, Italy, Spain, and the United Kingdom [UK]) and in 4 Nordic countries (Denmark, Finland, Norway, and Sweden). The survey was conducted in 2 rounds at 12 to 18 months (01 January 2013 to 12 June 2014) and 24 to 30 months (28 August 2013 to 15 May 2015) after XGEVA became commercially available in the participating countries, and included a standardized, multiple-choice, internet-based questionnaire to collect the required information. The participants in rounds 1 and 2 were non-overlapping.

Variables and Data Sources

In each survey round, a random sample of oncology practitioners was selected from the master list for each of the countries and stratified by region (European and Nordic) until the target number of eligible participants was reached.

- **Results**

At the end of the survey, 6079 oncology practitioners were contacted; 2927 (48.1%) were reached; 854 (29.2%) answered screening questions. Of those screened, 512 (60.0%) met study eligibility criteria. Of those eligible, 420 (82.0%) consented to and participated in the survey; 300 were from the European region and 120 were from the Nordic region as prespecified in the protocol.

Among participating oncology practitioners, the percentage of correct responses to each of the 6 survey questions were as follows: ONJ has been reported in patients treated with XGEVA (Q1, 76.4%); a dental examination with appropriate preventive dentistry should be considered before treatment with XGEVA in patients with active dental and jaw conditions (Q2, 96.9%); patients should avoid invasive dental procedures, if possible, during treatment with XGEVA (Q3, 56.7%); good oral hygiene practices should be maintained during treatment with XGEVA (Q4, 90.2%); patients suspected of having or who develop ONJ while on therapy with XGEVA should receive care by a dentist or oral surgeon (Q5, 81.7%); and extensive dental surgery to treat ONJ may exacerbate the condition (Q6, 38.1%). For Q3, an additional 30.2% of oncology practitioners provided the conservative answer that invasive dental procedures should be avoided, if possible, during treatment with XGEVA and for 12 months after discontinuing XGEVA.

- **Discussion**

The survey results demonstrated that the oncology practitioners were highly knowledgeable (76.4% to 96.9% correct responders) about 5 of the 6 ONJ risk statements. Although 86.9% of participants understood correctly that invasive dental procedures should be avoided during XGEVA treatment per the SmPC, only 38.1% were aware that dental surgery to treat ONJ may exacerbate the condition. Lower awareness about the statement related to extensive dental surgery could be because oncology practitioners are not responsible for providing surgical treatment to patients with ONJ. Overall, the survey responses support adequate awareness of the ONJ risk of XGEVA among the prescribing oncology practitioners.

- **Marketing Authorization Holder**

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- **Names and Affiliations of Principal Investigators**

Not applicable