

ABSTRACT

Title:

Post-marketing Surveillance (PMS) Study of XGEVA®(Denosumab) in South Korea,
28 December 2020, Amgen Korea Limited

Keywords:

Observational, prospective, multicenter, efficacy, safety

Rationale and Background:

This post-marketing, non-interventional study estimated incidence rates of adverse events (AEs), serious AEs (SAEs) and adverse drug reactions (ADRs) among subjects receiving denosumab (on-label) and other factors that were considered to affect safety and efficacy; as required by Ministry of Food and Drug Safety.

Research Question and Objectives:

Primary objective: estimate incidence of AEs, SAEs, and ADRs.

Secondary objectives:

- Investigate efficacy by evaluating incidence of skeletal-related events (SREs), except in giant cell tumor of bone (GCTB) subjects.
- Describe characteristics of subjects.

Study Design:

A prospective, observational, multicenter study in subjects treated with denosumab in post-marketing setting in South Korea. There was no control group. Safety and efficacy data, and patient characteristics for at least 300 evaluable subjects, were captured.

Setting:

Incidence of AEs, SAEs, ADRs; and other factors that might affect safety and efficacy were estimated.

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.

Three hundred and eighteen (318) subjects were enrolled across 23 sites.

Subjects and Study Size, Including Dropouts:

Case report forms were collected from 318 subjects. Two subjects were excluded from safety evaluation as they did not receive denosumab. In safety analysis, 316 subjects were included (285 in SRE set; 31 in GCTB set) and in efficacy analysis, 285 subjects were included. Subjects completing week 52 dose of denosumab were considered long term user (88 in SRE set, 2 in GCTB set).

Variables and Data Sources:

All data was extracted from information generated/gathered through routine medical practice. Subjects were followed from first dose until end of 12-month period, death, discontinuation of treatment, withdrawal of consent, loss to follow-up, whichever occurred first.

Adverse events were also collected from solicited and spontaneous sources and post-marketing study.

Results:

Safety analysis: Unexpected events are events not listed in reference safety information (Korean product information for denosumab dated 23 October 2019).

In SRE set, incidence of AEs was 40%, unexpected AEs was 30.2%, ADRs was 4.6%, unexpected ADRs was 2.8%. Incidence of SAEs was 19.6%, serious ADRs was 0.4%, fatal AEs was 10.2%. Incidence of AEs leading to discontinuation of denosumab was 8.8% and of ADRs leading to discontinuation of denosumab was 1.4%.

In GCTB set, incidence of AEs was 12.9%, unexpected AEs was 9.7%, ADRs was 9.7%, unexpected ADRs was 6.5%. No SAEs or fatal AEs were reported. Incidence of AEs leading to discontinuation of denosumab was 3.2%; no ADRs leading to discontinuation of denosumab were reported.

Efficacy analysis: Among 285 subjects, incidence of SREs was 5.3%. Incidence of SREs was 6.3% in breast cancer subjects, 5.9% in lung cancer subjects, 3.8% in prostate cancer subjects, 6.5% in subjects with other cancer.

Long term users: Among 88 subjects from SRE set, incidence of AEs was 31.8% and ADRs was 2.3%. Among 2 subjects in GCTB set, no AEs were reported.

Results Other than Post-Marketing Surveillance Study: 41 AEs were reported from 20 subjects.

Discussion:

Information including AE, SAE/ADRs, unexpected ADRs was collected continuously and reported periodically as planned and no other action was required.

Marketing Authorization Holder:

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