ABSTRACT

Title

Post-marketing Surveillance (PMS) Study of Prolia® (Denosumab) in South Korea, December 9, 2020, Amgen Korea Limited

Keywords

Prolia®, Denosumab, Osteoporosis, Post-marketing surveillance

Rationale and Background

The efficacy and safety profile of Prolia® has been established through global clinical studies. This PMS study was planned to be conducted in routine clinical practice to meet local regulations for new medicines approved in South Korea.

Research Objectives

This study was done to collect safety and efficacy data in the post-marketing setting in South Korea.

Study Design

A prospective, observational, multicenter, post-marketing surveillance study

Setting

This study was done at a total of 36 centers in South Korea, which included primary, secondary, and tertiary care settings, during the period from May 10, 2017 to May 21, 2019.

Subjects and Study Size, Including Dropouts

During the study period, case report forms (CRFs) of 3,221 subjects were collected. Among them, 3,185 subjects were included in the safety analysis set, and of those, 1,498 subjects were included in the efficacy analysis set.

Variables and Data Sources

Primary endpoints were incidence of AEs and ADRs; secondary endpoints were %change from baseline in BMD at 12 months of the lumbar spine, total hip, and femoral neck, and patient characteristics receiving Prolia®. Patient data were collected by investigators or site staff at routine clinical visits or as reported in between visits and captured on the electronic CRFs.

Results

1057 AEs occurred in 613 subjects (19.25%), 62 ADRs in 50 subjects (1.57%), 295 SAEs in 227 subjects (7.13%), 4 serious ADRs in 3 subjects (0.09%), 748 unexpected AEs in 478 subjects (15.01%), and 28 unexpected ADRs in 23 subjects (0.72%). 40 AEs led to withdrawal of Prolia® in 36 subjects (1.13%) and 26 fatal AEs were reported in 26 subjects (0.82%). The most frequently occurring SAEs, ADRs, unexpected AEs, and unexpected ADRs by preferred term (PT) were 11 cases of ‘Death’ in 11 subjects (0.35%), 2 cases of ‘Pneumonia’ in 2 subjects (0.06%), 19 cases of ‘Pyrexia’ in 14 subjects (0.44%), and 9 cases of ‘Pain’ in 9 subjects

(0.28%), respectively. Multivariate analysis showed that subjects aged ≥ 75 years, those with medical history, drug allergy, and prior use of calcium showed higher incidence rates of AEs, respectively.

The mean ±SD %change from baseline in BMD at 12 months after Prolia® administration was 7.29±23.60%, 3.55±31.44%, and 3.21±10.74% in subjects measured for lumbar spine, total hip, and femoral neck, respectively. This improvement was shown in 78.29%, 66.12%, and 63.00% of subjects with lumbar spine, total hip, and femoral neck BMDs, respectively. Multivariate analysis showed that %change in lumbar BMDs were increased in subjects who had no experience of using Vitamin D, and %change in femoral neck BMDs were decreased with increasing age, most increased with 2nd dosing, and increased in subjects with no prior use of calcium.

Discussion

Overall, this PMS study found no unusual trends compared to the previously reported results of Prolia®, and no particulars affecting its safety and efficacy. Therefore, this study demonstrated the safety and efficacy of Prolia® for indications approved in Korea. As no additional risks were identified, the benefit-risk assessment of Prolia® remains positive.

Marketing Authorization Holder(s) Amgen Korea Limited