1. ABSTRACT

- **Title**

Prospective Observational Study to Describe Characteristics and Management of Patients With Postmenopausal Osteoporosis Treated With Prolia® in Routine Clinical Practice

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- **Keywords**

Prolia, postmenopausal osteoporosis, clinical practice, noninterventional

- **Rationale and Background**

Prolia has been approved for the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

After regulatory approval is granted for pharmaceutical products, many countries request post-launch population use characteristics to ensure that each drug is being used in the population for which it was intended, especially for injectable drugs like Prolia.

- **Research Question and Objective**

The objective of this study was to describe characteristics of postmenopausal women treated with Prolia® (denosumab) in routine clinical practice and to describe the clinical management of osteoporosis in these patients during the first 2 years of treatment with Prolia in the Czech Republic and Slovakia.

- **Study Design**

The decision to treat patients with Prolia was made independent of and before their enrolment in the study. Patients were to receive their scheduled Prolia injection every 6 months.

No study drug was administered as part of the study. Detailed data obtained as part of routine clinical practice were collected at the initial visit and for up to approximately 2 years after entering the study, either directly or from medical records, to characterize Prolia-treated patients.

- **Setting**

The study was conducted at various study centres in the Czech Republic and Slovakia. The recruitment period was from 26 June 2012 to 15 May 2013. The last patient last visit was in May 2015 and the database lock was on 20 July 2015.

- **Subjects and Study Size, Including Dropouts**

Patients were eligible if they were women with a clinical diagnosis of postmenopausal osteoporosis (PMO), a decision was made to treat them with Prolia 60 mg once every 6 months (Q6M), and they had received their first injection of Prolia within 8 weeks before enrolling in this study.

To characterize this Prolia population, a sample size of approximately 300 patients per country (Czech Republic and Slovakia) was planned.

- **Variables and Data Sources**

Available clinical information obtained for routine clinical practice (including those already recorded on the patient medical records for baseline characteristics) were

recorded, including Prolia administration, previous and current therapies, medical history (including fractures), adverse drug reactions and serious adverse drug reactions, and comorbidities.

- **Results**

A total of 600 patients (300 each from the Czech Republic and Slovakia) were enrolled in the study. In the Czech Republic and Slovakia, most of the patients (> 98.0%) received all their injections of Prolia from the initial prescribing study centre, irrespective of the total number of injections received on study. In both Czech Republic and Slovakia, reasons for prescribing Prolia to most of the PMO patients were: history of osteoporotic fracture, multiple risk factors for fracture, failure to respond to other available osteoporosis therapy, intolerance to other osteoporosis therapy, and/or low BMD T-score. A total of 35 patients (11.7%) in the Czech Republic and 21 patients (7.05) in Slovakia discontinued the study. In the Czech Republic and Slovakia, Prolia injections were always administered by a health care professional to all patients. A total of 82.0% of the patients in the Czech Republic and 81.0% of the patients in Slovakia received all 4 postbaseline injections. Dual-energy X-ray absorptiometry (DXA) assessment was done for 99.0% (95% confidence interval [CI]: 97.1, 99.8) of patients prebaseline and 84.3% (79.7, 88.3) of patients postbaseline in the Czech Republic; and 99.7% (98.2, 100.0) of patients prebaseline and 72.0% (66.6, 77.0) of patients postbaseline in Slovakia.

The percentages of patients reporting new fractures and clinical/osteoporotic fractures were 6.0% and 5.0%, respectively in the Czech Republic and 1.3% and 1.0%, respectively in Slovakia. The adverse reactions reported in 2 patients each were musculoskeletal pain in the Czech Republic and alopecia, rash, and hypocalcaemia in Slovakia. All other adverse drug reactions were reported in 1 patient each. One patient in Slovakia had a serious adverse drug reaction of myocardial infarction. One patient sustained an event consistent with the definition of atypical femoral fracture. There were no fatal adverse drug reactions in any of the patients.

- **Discussion**

The reasons for prescribing Prolia in the Czech Republic and Slovakia were as per the approved local labels for most of the patients. Prolia was always administered by a health care professional in both the countries. The percentage of patients reporting new fractures was 6.0% in the Czech Republic and 1.3% in Slovakia. No new safety risks were identified as the reported adverse drug reactions were either consistent with the known safety profile of Prolia or reflected common diseases observed in elderly women.

- **Marketing Authorization Holder**

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