1. ABSTRACT

- **Title**

Postmarketing Surveillance Study of EVENITY® (Romosozumab) in South Korea

- **Keywords**

Osteoporosis, non-interventional, postmarketing surveillance (PMS), South Korea

- **Rationale and Background**

To comply with MFDS regulatory requirements, Amgen Korea conducted a PMS study to evaluate the safety and effectiveness of EVENITY in clinical practice.

- **Research Question and Objectives**

1) To estimate the incidence rates of adverse events (AEs), serious adverse events (SAEs), and adverse drug reactions (ADRs) among patients receiving EVENITY® on label in the postmarketing setting in South Korea.

2) To Investigate the effectiveness of EVENITY® by assessing percent change from baseline in bone mineral density (BMD).

CCI [redacted]

- **Study Design**

This is a prospective, observational, single-arm, multicenter study in patients who are prescribed EVENITY® on label in a postmarketing setting in South Korea.

- **Setting**

In accordance with the regulations, a re-examination period of 6 years (31 May 2019 ~ 30 May 2025) was given to this PMS. This PMS aimed to evaluate the safety and effectiveness in 3,000 patients prescribed EVENITY® according to the approved label.

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

During this re-examination period, case report forms (CRFs) for a total of 3,238 subjects were collected by 47 investigators from 36 study sites. Of these, 3,113 subjects were included in the safety analysis set. Among the subjects in the safety analysis set, 1,909 subjects were included in the effectiveness analysis set.

- **Data Source(s) and Methods**

The data source for this study was subject medical chart notes. Study site staff extracted data from the subject notes into the study-specific electronic database provided by the sponsor. No patient data was collected beyond 30 days after their last dose.

- **Variables**

o Primary outcome assessment: Incidence of AEs, SAEs, and ADRs.

o Secondary outcome assessment: Treatment response as determined by percent change from baseline in BMD of the lumbar spine and/or total hip and/or femoral neck at

M12, or as close as possible to the last dose of EVENITY® but no later than 30 days after the last dose of EVENITY®.

o Exploratory outcome assessment: CCI [redacted]
CCI [redacted]

- **Results**

AEs were reported in 30.45% (948/3,113 subjects, 1,575 events) and ADRs were reported in 4.59% (143/3,113 subjects, 212 events). SAEs were reported in 7.07% (220/3,113 subjects, 281 events) and SADRs were reported in 0.10% (3/3,113 subjects, 3 events). Unexpected AEs were reported in 26.18% (815/3,113 subjects, 1,295 events) and unexpected ADRs were reported in 2.51% (78/3,113 subjects, 100 events). Unexpected SAEs were reported in 6.84% (213/3,113 subjects, 271 events) and unexpected SADRs were reported in 0.06% (2/3,113 subjects, 2 events). AEs leading to EVENITY discontinuation were reported in 2.70% (84/3,113 subjects, 115 events). Fatal events were reported in 0.39% (12/3,113 subjects, 15 events).

For 1,909 subjects in the effectiveness analysis set, the mean (±std) percent change (%) of BMD at month 12 after EVENITY administration versus at baseline was 14.37±12.63% at lumbar spine in 315 subjects, 2.53±6.78% at total hip in 316 subjects, and 3.21±8.70% at femoral neck in 321 subjects.

CCI [redacted]

- **Discussion**

Regarding safety outcomes, AEs were relatively common, but most were mild and not directly related to EVENITY®. No new safety concerns were identified, and the overall safety profile was consistent with the established prescribing information.

In conclusion, during the re-examination period, EVENITY® demonstrated a favorable benefit-risk profile for its approved indications, with meaningful improvements in BMD and no new safety concerns identified. The incidence of AE will continue to be monitored to ensure appropriate management in real-world use.

- **Marketing Authorization Holder(s)**

Amgen Inc

- **Names and Affiliations of Principal Investigators**

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