

1. ABSTRACT

- **Title**

EVENTITY® Risk Minimisation Materials Effectiveness Measurement in Australia

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- **Keywords**

Osteoporosis, educational materials, romosozumab, myocardial infarction, stroke

- **Rationale and Background**

EVENTITY® (romosozumab) is a humanized immunoglobulin G2 monoclonal antibody with high affinity and specificity for sclerostin. It is indicated for the treatment of osteoporosis in postmenopausal women at high risk of fracture. EVENTITY is also indicated for treatment to increase bone mass in men with osteoporosis at high risk of fracture. To support the safe use of EVENTITY, Amgen developed educational materials (additional risk minimisation measures [aRMMs]) for endocrinologists, rheumatologists, geriatricians, general physicians, patients, and their caregivers to address the cardiovascular risks associated with EVENTITY. These risks include myocardial infarction (MI) and stroke.

Amgen Australia was required by the Therapeutics Goods Administration (TGA) to assess the effectiveness of the educational materials in addressing the cardiovascular risks in patients prescribed EVENTITY after implementation in Australia. This study was conducted before Product Information (PI) update in January 2024 and at the time of conducting the survey, cardiovascular risk was under Warnings and Precautions section of the PI.

- **Research Question and Objectives**

The objective of this study was to measure the effectiveness of the educational materials (prescriber guide and patient alert card) on awareness, utilisation, and adequacy targeted to endocrinologists, rheumatologists, geriatricians, and general physicians in addressing the cardiovascular risks (MI and stroke) associated with the use of EVENTITY.

There were 3 key research objectives:

- measure awareness of the educational materials amongst specialists (endocrinologists, rheumatologists, geriatricians, and general physicians)
- identify if specialists distribute the educational materials to their patients and/or caregivers when prescribing EVENTITY
- determine adequacy of the content of the educational materials to support specialists in prescribing EVENTITY to patients.

- **Study Design**

The survey was conducted by a market research vendor with the help of a questionnaire targeted to healthcare professionals (HCPs ie, endocrinologists, rheumatologists, geriatricians, and general physicians), to assess the effectiveness of the educational materials provided to specialists. Safety data collection and recording requirements were conducted in accordance with the Amgen Market Research safety reporting requirements.

- **Setting**

The research vendor team contacted relevant specialists and sent a link to the survey component of the study for the participant to complete. Participation in the research was voluntary and was conducted under the Australian Market Research guidelines.

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

To be eligible for inclusion in this study, specialists were required to fulfil the following criteria:

- must have been recruited from the Amgen Australia-approved contact list of specialists who could prescribe EVENITY and other osteoporosis treatments with relevant consent
- must have been qualified as a rheumatologist, endocrinologist, geriatrician, or general physician
- must have spent at least 50% of their time in patient care
- must have completed the study research's informed consent form.

- **Data Source and Methods**

An online survey was conducted by a third-party research vendor to assess the effectiveness of the educational materials in terms of awareness, utilisation, and adequacy provided to specialists.

This was a 10-minute online survey. It included screening questions followed by the main survey (10 questions) and profiling questions.

- **Results**

Overall, among the 755 specialists (endocrinologists, rheumatologists, geriatricians, and general physicians) from the Amgen Australia-approved contact list, 735 (97%) were contacted, of which 113 (15%) responded. Of the 113 participants who responded, 51 (45%; endocrinologists: 25, rheumatologists: 20, and geriatricians: 6) completed the survey.

Overall, among 51 participants who completed the survey, most (60%) had 11 to 30 years of practice. The average years of practice was 19 years. The primary practice region for most of the participants (75%) was the capital city.

Among 51 participants, 25% were aware of both the educational materials while 51% were aware of at least 1 of the educational materials. Awareness rates were numerically higher among endocrinologists compared with rheumatologists (aware of both educational materials: 36% vs 20%; aware of at least 1 educational material: 60% vs 50%).

Among 26 participants who remembered seeing the aRMMs materials when asked about the main safety precautions, 85% mentioned cardiovascular risks without prompts (endocrinologists [N = 15]: 93%, rheumatologists [N = 10]: 70%, geriatrician [N = 1]: 100%).

Among 26 participants who remembered seeing the aRMMs materials, 88% recalled cardiovascular risks of MI or stroke when prompted (endocrinologists [N = 15]: 93%, rheumatologists [N = 10]: 80%, geriatrician [N = 1]: 100%).

Among 15 participants who were aware of the EVENITY patient alert card, 60% used it (endocrinologists [N = 10]: 80%, rheumatologists [N = 5]: 20%, geriatrician: none).

Among 51 participants who completed the survey, most (79% to 94%) either strongly agreed or agreed on the following:

- the materials explain the important identified safety risk (precautions for use outlined in the PI) for EVENITY ie, cardiovascular risk (MI and stroke): 94% (strongly agree: 35% and agree: 59%)
- the guide for prescribers explains how to manage the cardiovascular risk for EVENITY: 79% (strongly agree: 22% and agree: 57%)
- the patient alert card provides patients with a good understanding of how to identify suggestive signs and/or symptoms that require immediate medical attention: 86% (strongly agree: 33% and agree: 53%)
- these materials increase my confidence that patients can be safely treated with EVENITY: 79% (strongly agree: 10% and agree: 69%).

Among 25 endocrinologists who completed the survey, most (72% to 92%) either strongly agreed or agreed to the measures for evaluating adequacy of aRMMs materials.

Among 20 rheumatologists who completed the survey, most (65% to 100%) either strongly agreed or agreed to the measures for evaluating adequacy of aRMMs materials.

Among 6 geriatricians who completed the survey, most (83% to 100%) either strongly agreed or agreed to the measures for evaluating adequacy of aRMMs materials.

• **Discussion**

Based on the study results, Amgen concludes the aRMMs (prescriber guide and patient alert card) adequately highlight the cardiovascular risks of MI and stroke to both HCPs and patients.

Given the recent update to EVENITY PI and Consumer Medicine Information (CMI) to include contraindication for MI and stroke, Amgen proposes that the aRMMs materials remain in place to continue to support and inform HCPs and patients of this important identified risk.

Marketing Authorization Holder

Amgen Australia Pty Ltd.

• **Names and Affiliations of Principal Investigators**

Not applicable.