AMGEN

EVENITY™
(romosozumab-aqqg)
injection 105 mg/1.17 mL

CORDIALLY INVITES YOU TO ATTEND A PROGRAM

EVENITY™: Build bone and reduce fracture risk in your high-risk PMO patients

SPEAKER:
Natalie Eddy, NP, DNP

Ruth's Chris Steak House
902 East University Drive
Granger, IN 46530
(574) 968-9700

Tuesday, August 27, 2019
5:30 PM, Eastern

PLEASE RSVP TO: Allyson McKnight
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Indication

EVENITY™ is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

The anabolic effect of EVENITY™ wanes after 12 monthly doses of therapy. Therefore, the duration of EVENITY™ use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an antiresorptive agent should be considered.

Important Safety Information

POTENTIAL RISK OF MYOCARDIAL INFARCTION, STROKE, AND CARDIOVASCULAR DEATH

EVENITY™ may increase the risk of myocardial infarction, stroke and cardiovascular death. EVENITY™ should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors. Monitor for signs and symptoms of myocardial infarction and stroke and instruct patients to seek prompt medical attention if symptoms occur. If a patient experiences a myocardial infarction or stroke during therapy, EVENITY™ should be discontinued.

Please see additional EVENITY™ Important Safety Information on next page.

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In a randomized controlled trial in postmenopausal women, there was a higher rate of major adverse cardiac events (MACE), a composite endpoint of cardiovascular death, nonfatal myocardial infarction and nonfatal stroke, in patients treated with EVENITY™ compared to those treated with alendronate.

Contraindications: EVENITY™ is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating therapy with EVENITY™. EVENITY™ is contraindicated in patients with a history of systemic hypersensitivity to romosozumab or to any component of the product formulation. Reactions have included angioedema, erythema multiforme, and urticaria.

Hypersensitivity: Hypersensitivity reactions, including angioedema, erythema multiforme, dermatitis, rash, and urticaria have occurred in EVENITY™-treated patients. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of EVENITY™.

Hypocalcemia: Hypocalcemia has occurred in patients receiving EVENITY™. Correct hypocalcemia prior to initiating EVENITY™. Monitor patients for signs and symptoms of hypocalcemia, particularly in patients with severe renal impairment or receiving dialysis. Adequately supplement patients with calcium and vitamin D while on EVENITY™.

Osteonecrosis of the Jaw (ONJ): ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing, and has been reported in patients receiving EVENITY™. A routine oral exam should be performed by the prescriber prior to initiation of EVENITY™. Concomitant administration of drugs associated with ONJ (chemotherapy, bisphosphonates, denosumab, angiogenesis inhibitors, and corticosteroids) may increase the risk of developing ONJ. Other risk factors for ONJ include cancer, radiotherapy, poor oral hygiene, pre-existing dental disease or infection, anemia, and coagulopathy.

For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are suspected of having or who develop ONJ should receive care by a dentist or an oral surgeon. In these patients, dental surgery to treat ONJ may exacerbate the condition. Discontinuation of EVENITY™ should be considered based on benefit-risk assessment.

Atypical Femoral Fractures: Atypical low-energy or low trauma fractures of the femoral shaft have been reported in patients receiving EVENITY™. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated.

During EVENITY™ treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Any patient who presents with thigh or groin pain should be evaluated to rule out an incomplete femur fracture. Interruption of EVENITY™ therapy should be considered based on benefit-risk assessment.

Adverse Reactions: The most common adverse reactions (≥ 5%) reported with EVENITY™ were arthralgia and headache.

EVENITY™ is a humanized monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

Please see EVENITY™ full Prescribing Information, including Medication Guide.

Notice: This event is conducted in accordance with the PhRMA Code on Interaction with Healthcare Professionals and is limited to invited healthcare professionals. Attendance by guests or spouse is not appropriate. Government employees are subject to state and federal laws and ethics rules that may limit your ability to receive any gifts, including meals, from pharmaceutical companies. If you are a state or federal employee, it is your responsibility to seek guidance and prior approval from your employer or site ethics counselor to attend this event.

State Laws: To comply with law and Amgen policies, Amgen is unable to offer food and beverages to (1) individuals with prescribing authority in Vermont or Minnesota; or (2) individuals employed by prescribers in Vermont who support the provision of healthcare. Additionally, prescribers licensed in New Jersey should note that the meal provided at this event may exceed the allowable $15 limit. Please confirm the value of the meal with your Amgen representative before accepting the meal. You have the opportunity to opt-out of the meal and/or purchase your own meal, if applicable.

Please note that Amgen exercises diligence in reviewing the licensure of attendees and asks that you cooperate by disclosing all licensures in the sign-in/registration process. We appreciate your understanding and support.

Disclosure by Amgen: Amgen reports payments and transfers of value made to healthcare professionals and other healthcare related entities in accordance with federal and state laws, regulations and other transparency obligations. Any items of value provided by Amgen at this event (including the provision of meals and refreshments) may be subject to public disclosure. If you have questions regarding this matter please contact Amgen at 805-447-7422 or HCCSpendInquiry@amgen.com.