Generic Name:
Romosozumab-aqqg
Trade Name:
Evenity
Company:
Amgen
Notes:

FDA approved romosozumab-aqqg to treat osteoporosis in postmenopausal women at high risk of fracture. Women at high risk have a history of osteoporotic fracture or multiple risk factors for fracture, or have experienced treatment failure or intolerance to other osteoporosis therapies.

Romosozumab-aqqg is a monoclonal antibody that blocks the effects of the protein sclerostin and works mainly by increasing new bone formation. One dose consists of two injections, one immediately following the other, given once a month by a health professional. The bone-forming effect wanes after 12 doses, so more than 12 doses should not be used. If osteoporosis therapy is needed after the 12 doses, patients should begin an osteoporosis treatment that reduces bone breakdown.

Safety and efficacy of the agent were demonstrated in two clinical trials involving a total of more than 11,000 women with postmenopausal osteoporosis. In the first trial, one year of treatment with romosozumab-aqqg lowered the risk of a new vertebral fracture by 73% compared with placebo. This benefit was maintained over the second year of the trial, when the agent was followed by 1 year of denosumab (another osteoporosis therapy) compared with placebo followed by denosumab.

In the second trial, one year of treatment followed by 1 year of alendronate (another osteoporosis therapy) reduced the risk of a new vertebral fracture by 50% compared with 2 years of alendronate alone. Romosozumab-aqqg followed by alendronate also reduced the risk of fractures in nonvertebral fractures compared with alendronate alone.

The agent increased the risk of cardiovascular death, heart attack, and stroke in the alendronate trial but not in the placebo trial. Therefore, romosozumab-aqqg contains a boxed warning stating that it may increase the risk of heart attack, stroke, and cardiovascular death and should not be used in patients who have had a heart attack or stroke within the previous year.

Health professionals should also consider whether the benefits of romosozumab-aqqg outweigh its risks in those with other risk factors for heart disease. The drug should be discontinued in any patient who experiences a heart attack or stroke during treatment.

In clinical trials, common adverse effects included joint pain, headache, and injection-site reactions.

Medication Monitor Categories:
New Drug Approvals