FDA approves osteoporosis therapy for high-risk postmenopausal women

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(HealthDay)—Evenity (romosozumab-aqqg) was approved for the

treatment of osteoporosis in postmenopausal women with a high risk for fracture, the U.S. Food and Drug Administration announced.

Evenity, a monoclonal antibody, blocks the effects of sclerostin and increases bone formation. It is indicated for use in postmenopausal women who have a history of osteoporotic fracture or risk factors for fracture and those who have failed or developed intolerance to other osteoporosis treatments.

One dose of Evenity includes two consecutive injections once a month delivered by a health care professional. No more than 12 doses should be administered because the drug's bone-forming effect diminishes after 12 doses. If further treatment is required after 12 doses, the FDA says patients should begin an osteoporosis treatment that reduces bone breakdown.

Approval was based on data from two clinical trials of more than 11,000 women with postmenopausal osteoporosis. After one year of treatment in one trial, patients who received Evenity had a 73 percent reduced risk for a new vertebral fracture compared with those who received placebo. In the second year of the trial, following Evenity treatment, patients received one year of denosumab and the benefits were maintained compared with those who received placebo. In the second trial, patients received one year of treatment with Evenity followed by one year of alendronate and had a 50 percent reduced risk for a new vertebral or nonvertebral fracture compared with patients who received alendronate alone for two years.

Researchers found that Evenity increased the risk for cardiovascular death, stroke, and heart attack in the alendronate trial, leading to a boxed warning on Evenity labeling stating these increased risks and warning against its use in patients who have had a heart attack or stroke in the previous year. In patients with other risk factors for heart disease, the

FDA says health care professionals should consider whether the benefits of Evenity outweigh its risks before prescribing the treatment. Evenity should be discontinued in any patient who has a heart attack or stroke during treatment. Commonly reported side effects were joint pain, headache, and injection site reactions.

Approval was granted to Amgen.

More information: More Information