

Reclast Cut Fractures by 67% in Osteoporotic Men

VITALS

Major Finding: New osteoporotic fractures occurred in 1.6% of men on zoledronic acid and in 4.9% of those on placebo after 2 years of either active treatment or placebo.

Data Source: Multinational, randomized, phase III clinical trial of 1,199 men with primary or secondary osteoporosis.

Disclosures: Dr. Boonen disclosed that he has received research grants from and serves as a consultant to Novartis.

BY BRUCE JANCIN

FROM THE ANNUAL MEETING OF
THE AMERICAN SOCIETY FOR BONE
AND MINERAL RESEARCH

DENVER – Once-yearly intravenous zoledronic acid in men with osteoporosis reduced their risk of vertebral fractures by 67% over 2 years, compared with placebo, in a large, multinational, phase

III, randomized clinical trial.

“This is the first clear demonstration of antifracture efficacy for an osteoporosis agent in male osteoporosis,” said Dr. Steven Boonen in presenting the study results at the meeting.

“These findings suggest the use of zoledronic acid as a treatment option in male patients, particularly because annual infusions ensure

that patients will have the full effect of treatment for at least the next year,” added Dr. Boonen, professor of geriatric medicine and head of the gerontology and geriatrics section at Catholic University of Leuven (Belgium).

He reported on 1,199 men (mean age, 66 years) with primary osteoporosis or osteoporosis secondary to hypogonadism who were ran-



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domized in a double-blind fashion to a once-yearly 15-minute infusion of 5 mg of zoledronic acid (Reclast) or placebo at 134 centers.

At enrollment, 32% of the men had one or more vertebral fractures.

The primary study end point was the proportion of subjects with one or more new vertebral fractures during 2 years of follow-up.

The rate was 1.6% in men assigned to zoledronic acid and 4.9% in placebo-treated controls, which translated to a highly significant 67% relative risk reduction.

The 12-month rate was 0.9% in the

zoledronic acid group vs. 2.8% in controls, for a 68% relative risk reduction,



Bone mineral density was roughly 6% greater at the spine in the zoledronic acid group.

DR. BOONEN

Dr. Boonen reported.

The incidence of moderate to severe

vertebral fractures was similarly reduced by 63% in zoledronic acid recipients, compared with controls.

Men on zoledronic acid had a stable 60% reduction in levels of the bone turnover biomarker CTx, compared with the placebo group, throughout the study.

At 2 years, bone mineral density was roughly 6% greater at the spine and 2% greater at the total hip in the zoledronic acid group, compared with controls, he said.

"All of these findings are remarkably similar in magnitude to the risk reduc-

tions that have been documented with zoledronic acid in the pivotal fracture trial in postmenopausal osteoporosis," the geriatrician observed.

Men on zoledronic acid also experienced a smaller height loss, compared with controls (mean, 2.34 vs. 4.49 mm).

No major safety issues arose in the study. Similar numbers of patients in both study arms dropped out of the trial because of adverse events, Dr. Boonen reported.

At present, zoledronic acid's approved indications include treatment to increase bone mass in men with osteoporosis. ■

For adults with moderately to severely active rheumatoid arthritis,
in combination with methotrexate

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Patients treated with SIMPONI® (golimumab) are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Discontinue SIMPONI® if a patient develops a serious infection.

Reported infections with TNF blockers, of which SIMPONI® is a member, include:

- Active tuberculosis (TB), including reactivation of latent TB. Patients frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent TB before SIMPONI® use and during therapy. Treatment for latent infection should be initiated prior to SIMPONI® use.
- Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Consider empiric anti-fungal therapy in patients at risk for invasive

fungal infections who develop severe systemic illness.

- Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.

The risks and benefits of treatment with SIMPONI® should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Do not start SIMPONI® in patients with clinically important active infections, including localized infections. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with SIMPONI®, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

Risk of infection may be higher in patients greater than 65 years of age, patients with co-morbid conditions and/or patients taking concomitant immunosuppressant therapy. Other serious infections observed in patients treated with SIMPONI® included sepsis, pneumonia, cellulitis, abscess and hepatitis B infection.

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