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-

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, Dr. Boonen reported.

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

DR. BOONEN

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 reductions 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. ■