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Investigational osteoporosis drug, abaloparatide, lowers fracture risk

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Abaloparatide-SC, an injectable drug being studied for the treatment of postmenopausal osteoporosis, reduces the rate of new spinal fractures by a statistically significant 86 percent and as well as statistically significant reductions in the fracture rate at other parts of the body, a phase 3 clinical trial finds. Results of the ACTIVE fracture prevention trial will be described in a late-breaking oral presentation Thursday at the Endocrine Society's 97th annual meeting in San Diego.

"The investigational drug abaloparatide-SC, if approved, may offer patients the potential to reduce their risk of fracture and increase bone density at all sites, even the most difficult to treat, such as the hip and wrist," said lead investigator Paul Miller, MD, medical director of the Colorado Center for Bone Research in Lakewood, Colo.

In osteoporosis, bones become weak and prone to fractures, or breaks. These osteoporotic fractures can become disabling and, past research shows, can even lead to premature death.

Abaloparatide is a new manmade form of human parathyroid hormone-related protein, a naturally occurring bone-building hormone, according to its manufacturer, Radius Health, which funded this study. The Waltham, Mass., drugmaker is studying the medication in various forms, including a transdermal patch, in addition to the subcutaneous (meaning "under the skin"), or SC, injection studied in the ACTIVE trial.

The international ACTIVE trial studied whether abaloparatide-SC can

reduce fractures in postmenopausal women with severe osteoporosis who have a high fracture risk. The investigators compared rates of new fractures in 690 women who received a daily injection of abaloparatide (80 micrograms) and 711 women who received inactive placebo shots. Neither group of women knew which treatment they received. A third group, of 717 women, knowingly received a daily injection of teriparatide (20 micrograms), a drug that is already on the market for osteoporosis treatment. All patients also received calcium and vitamin D supplements.

Over 18 months of treatment, the abaloparatide-treated group had the greatest reduction in the rate of new vertebral, or spinal, fractures shown on x-rays, Miller reported. Compared with the placebo group's new vertebral fracture rate of 4.2 percent, women who were treated with abaloparatide had a new vertebral fracture rate of about 0.58 percent, representing an 86 percent reduction in the rate of broken bones at the spine, according to Miller.

"We believe this reduction seen in the abaloparatide-SC treated group could be the largest reduction ever demonstrated in the vertebral fracture rate for any potential therapeutic drug being researched for the treatment of postmenopausal osteoporosis," Miller said.

For nonvertebral fractures, which included the hip, wrist, and femoral neck (a part of the hip at the top of the thighbone), Miller said the abaloparatide treatment had a statistically significant 43 percent fracture-rate reduction compared to that of placebo. The rate of vertebral and nonvertebral fractures combined fell by 45 percent in the abaloparatide-treated group versus placebo. Additionally, the time to the first nonvertebral fracture was significantly delayed for women receiving abaloparatide than for those who received placebo, he said.

Results of patients' bone mineral density tests also were compared

between the two drug treatment groups. Miller said, "Abaloparatide-SC resulted in more bone growth, at a faster rate, at more skeletal sites, and in more patients than teriparatide."

Provided by The Endocrine Society