

Lilly reveals phase III trial data on back pain

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Singapore: Eli Lilly and Company published data from a phase III trial comparing the effects of FORTEO (teriparatide, rDNA origin injection) and risedronate on back pain in postmenopausal women with osteoporotic vertebral fractures. The results of the study have been published in *Osteoporosis International*.

The study showed no difference between FORTEO and risedronate on the primary endpoint of at least a 30 percent reduction in worst back pain from baseline to six months of therapy, as assessed by a numeric rating scale in each treatment group. However, there were statistically significant differences in favor of FORTEO in some exploratory measures, including greater increases in bone mineral density (BMD) and fewer patients with new vertebral fractures.

Dr Peyman Hadji, lead investigator and department head, endocrinology, osteoporosis and reproductive medicine, Philipps-University of Marburg, said that, "With many available options to treat osteoporosis, this study is important because it compares two established osteoporosis medicines in a direct head-to-head design."

Dr Bruce Mitlak, distinguished medical fellow, bone muscle and joint platform, Eli Lilly and Company, said that, "The study provides additional information regarding the use of FORTEO in patients who are considered at high risk for osteoporotic fractures. The results may help guide healthcare professionals in treating severe osteoporosis."

In the study, the overall safety profile was consistent with the known FORTEO safety profile seen in this patient population. The overall incidence of serious adverse events, treatment-emergent adverse events and adverse events leading to discontinuation were similar between the FORTEO and risedronate treatment groups. There were nine deaths in the study (four in the FORTEO group and five in the risedronate group), but none of the deaths were considered related to treatment.

FORTEO is used in both men and postmenopausal women with osteoporosis who are at high risk for having broken bones (fractures). FORTEO is used in both men and women with osteoporosis due to use of glucocorticoid medicines, such as prednisone, for several months, who are at high risk for having broken bones (fractures). FORTEO can be used by people who have had a fracture related to osteoporosis, or who have several risk factors for fracture, or who cannot use other osteoporosis treatments.

During the drug testing process, the medicine in FORTEO caused some rats to develop osteosarcoma, which, in humans, is a serious but rare bone cancer. Osteosarcoma has been reported rarely in people who took FORTEO, and it is unknown if people who take FORTEO have a higher chance of getting the disease. Before patients take FORTEO, patients should tell their healthcare provider if they have Paget's disease of bone, are a child or young adult whose bones are still growing or have had radiation therapy.