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Denosumab improves disease-free survival for postmenopausal patients w HR+ breast cancer

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Adding denosumab to adjuvant aromatase inhibitor therapy improved disease-free survival for postmenopausal patients with early-stage, hormone receptor (HR)-positive breast cancer, according to results from the phase III ABCSG-18 clinical trial presented at the 2015 San Antonio Breast Cancer Symposium, held Dec. 8-12.

Nearly all postmenopausal women with early-stage, HR-positive breast cancer are treated with an aromatase inhibitor, either alone or in sequence with tamoxifen, for five to 10 years after completing their initial post-diagnosis treatment, explained Michael Gnant, MD, professor of surgery at the Medical University of Vienna in Austria. "This is referred to as adjuvant endocrine therapy, and it compromises bone health," he said.

"Although the FDA has approved adjuvant denosumab as a treatment to increase bone mass in breast cancer patients receiving adjuvant aromatase inhibitor therapy who are at high risk for fracture, in most health care environments, adjuvant denosumab is only used for those patients with established osteoporosis," Gnant continued. "Our new data suggest that this treatment should be offered to all patients with HR-positive breast cancer who are receiving adjuvant aromatase inhibitor therapy, irrespective of their bone health status."

Among the 3,425 postmenopausal patients with early-stage, HR-positive

breast cancer enrolled in ABCSG-18, 1,711 were randomly assigned to 60 milligrams of subcutaneously administered denosumab once every six months and 1,709 were randomly assigned placebo.

The researchers found that after a median follow-up of four years, patients assigned denosumab had an 18 percent reduced risk of disease recurring compared with those assigned placebo. In light of previously published results, which showed that adjuvant denosumab reduced fractures caused by adjuvant aromatase inhibitor therapy by 50 percent, the new finding reported here amplifies the benefit of adjuvant denosumab, Gnant said.

Gnant noted that this analysis was performed as a result of a recommendation from the Independent Data Monitoring Committee (IDMC) and was based on only 370 disease-free survival events. "Therefore, it does not provide perfectly undisputable statistical power, and will have to be confirmed by future analyses with longer follow-up," he said. "I do not, however, have any doubt about the validity of the results, given the fact that the outcome benefits show clearly so early in the follow-up and are numerically bigger than we have seen in the past with bisphosphonates.

"It is also important to mention that the IDMC recommended 'patients choice' unblinding of this placebo-controlled trial because of the dramatic benefit in terms of fractures," Gnant added. "This will occur in 2016, offering eligible trial patients the option of unblinding and subsequent treatment with denosumab if it turns out that they were in the placebo group."

Provided by American Association for Cancer Research

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