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To interview Sonja Vliek or Sabine Linn, contact Julia Gunther at julia.gunther@aacr.org or 267-250-5441. For a photo of Vliek, click [here](#). For a photo of Linn, click [here](#).

Adding Ibandronate to Hormone Therapy did Not Improve Outcomes For Postmenopausal Breast Cancer Patients

A favorable trend warrants longer follow-up for definitive evidence of benefit

SAN ANTONIO — Postmenopausal women with hormone receptor (HR)-positive early-stage breast cancer who received the bisphosphonate ibandronate (Boniva) in addition to adjuvant hormone therapy did not have improved disease-free survival (DFS) outcomes, according to data from the phase III clinical trial TEAM IIB presented at the 2016 [San Antonio Breast Cancer Symposium](#), held Dec. 6–10.

However, a nonsignificant improvement in DFS and reduction in the number of patients developing bone metastasis was observed after three years of therapy among those who received ibandronate, leading the trial investigators to conclude that a longer follow-up may be required to draw definitive conclusions.

“Data from TEAM IIB showed that postmenopausal women who received ibandronate for three years along with hormone therapy had a trend toward improved DFS outcome that was statistically insignificant,” said [Sabine Linn, MD, PhD](#), a medical oncologist in the Department of Molecular Pathology at the Netherlands Cancer Institute.

“We recently reached the required number of DFS events that would help determine conclusive evidence of benefit (or no benefit) from adding ibandronate,” Linn added.

Hormonal therapy usually consists of aromatase inhibitors, which have a negative effect on bone health. About 70 percent of postmenopausal breast cancer patients who develop metastatic disease experience bone metastasis, and it has a major influence on length and quality of life for these patients as they suffer from pain and immobility, explained Sonja Vliek, MD, a resident medical oncology and PhD student working with Linn. Prevention of bone metastases is therefore a major topic in breast cancer research, she added.

In [TEAM IIB](#), 1,116 postmenopausal women with early-stage breast cancer were enrolled in 37 hospitals in the Netherlands and randomly assigned five years of hormonal therapy with or

without 50 mg ibandronate daily, for three years. The primary endpoint was DFS, and secondary endpoints included safety, overall survival, time to bone metastasis, and other sites of recurrence.

Median follow-up was 4.6 years and 67 percent of patients in the test arm adhered to ibandronate treatment for three years.

As of November 2016, 149 DFS events had been reported. Three-year DFS in the ibandronate arm was 94.3 percent, versus 90.8 percent in the control arm, with a nonsignificant 20 percent improvement in DFS in the ibandronate arm.

Three years after randomization, 1.6 percent and 4.7 percent of the patients in the ibandronate arm and control arm developed bone metastasis, respectively; those in the ibandronate arm were 35 percent less likely to have bone metastasis, but this finding was not statistically significant.

There were 36 serious adverse events (SAE) reported in 31 patients from the ibandronate arm and 51 SAEs reported in 39 patients from the control arm. The only SAE related to ibandronate was reports of osteonecrosis of the jaw, which in all patients resolved without complaints after treatment, according to Vlieg.

“If the results from this trial are considered along with the [results from the EBCTCG trial](#), in which a modest benefit of overall survival was observed for postmenopausal women by adding a bisphosphonate to standard adjuvant systemic therapy, the evidence to treat postmenopausal women with early breast cancer with adjuvant bisphosphonate increases,” said Linn.

“Patients should discuss this adjuvant treatment with their physicians to outweigh the possible side effects from the possible gain in survival,” she added.

Further analyses of the data are planned as soon as the last patient reaches the three-year follow-up period (May 2017), Vlieg noted. The investigators plan to follow the patients for up to 10 years to analyze the long-term effects.

Limitations of the study include that it was not placebo-controlled and was possibly under-powered, Vlieg said.

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