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**Novartis drug may help older breast cancer patients**

By Kate Kelland

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Novartis's bone drug Zometa extended survival in older breast cancer patients but failed to improve disease-free survival among younger women patients in a large-scale clinical trial, researchers said on Sunday.

Detailed data presented at the European Multidisciplinary Cancer Congress (EMCC) in Stockholm showed that Zometa, a bisphosphonate drug known generically as zoledronic acid, only improved overall survival rates in patients who had undergone the menopause at least five years earlier.

Researchers said the effect was likely to be linked to levels of reproductive hormones, which are lower in women who have been through the menopause.

"This is not a treatment for ever woman with breast cancer," said Robert Coleman of Britain's Sheffield University, who led the study.

But for women with low levels of female hormones, either due to aging or specific treatments to induce menopause, Zometa "appears very promising."

An analysis of the subset of older patients showed that at a the five-year follow-up, there was a 26 percent reduction in recurrence of tumors, Coleman said, as well as a 26 percent reduction in the risk of an early death.

These strong results could lead to "a major new treatment approach" for post-menopausal patients, he said.

Zometa, which generated sales of $2.1 billion for Novartis in 2010, is an intravenous drug from a widely used class of osteoporosis medicines called bisphosphonates.

It is increasingly being prescribed to help reduce or delay fractures and other skeletal complications in a variety of cancers that have spread to the bones.

From 65 to 75 percent of breast cancer recurrences occur in the bones.

This trial, called AZURE and also published in the New England Journal of Medicine on Sunday, involved 3,360 women with early-stage breast cancer from 174 centers in Britain, Australia, Spain, [Ireland](http://uk.reuters.com/places/ireland), Portugal, Taiwan and Thailand.

Patients randomly allocated receive standard chemotherapy and/or hormone therapy, either with or without the addition of Zometa, a drug that works by inhibiting the cells that break down bone, called osteoclasts.

The results showed that looking across all trial participants, there was no significant difference in disease-free survival or overall survival between patients who received Zometa and those who didn't.

But in a subset of older patients, the addition of the Novartis drug did bring clear benefits.

These women, who had at least five years since their last period, had an overall survival rate at five years of 85 percent on Zometa compared with 79 percent for those not on the drug.

For all other patients, overall five-year survival was similar, at 86 percent in the Zometa group and 85 percent in the control group.

Investigators said that most surprising among the findings was the drug's effect on the rate at which the cancer recurred outside the bone.

The relative risk for developing metastases, or secondary tumors, outside bone during treatment with Zometa was approximately halved in the postmenopausal women compared with the younger patients.

Coleman said the results shed new light on the role bones may play in the progress of the disease.

"The effects on metastasis and recurrence outside bone suggests that the bone marrow is an important sanctuary for tumor cells which can be activated after, sometimes, many years of dormancy," he said.

"With help from bone marrow stem cells, they may then spread via the blood stream to set up metastases at other sites."