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## **Novartis' Zometa Cuts Risk of Breast Cancer Returning (Update2)**

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May 31 (Bloomberg) -- Novartis AG's bone-strengthening drug Zometa unexpectedly cut the risk that breast tumors would return in a study of young women getting the therapy, which protects bones from the ravages of cancer.

The trial, showing just two injections a year of Zometa slashes cancer recurrence by 35 percent, offers a novel way to fight cancer and expands the market for the medication. Novartis, Switzerland's second-largest drugmaker, currently sells Zometa to treat malignancies that spread to the bone. It also is used at a lower dose for osteoporosis.

Breast cancer, the most common tumor in women, will be diagnosed in more than 180,000 patients in 2008, according to the American Cancer Society. In the study of 1,803 patients, about 6 percent of women getting Zometa suffered a relapse within five years, compared with 9 percent who didn't receive the drug, according to the study presented at the American Society of Clinical Oncology meeting today in Chicago.

"We have shown we can keep the cancer away, and that is great news for patients," lead author Michael Gnant, professor of surgery at the Medical University of Vienna, said in an interview. "Future research will focus on optimizing the administration schedule and the dose, and determining which patients will benefit the most from treatment."

Novartis, based in Basel, Switzerland, sells Zometa in more than 80 countries and helped fund the study. It is the first to show the medication can slow cancer in addition to protecting bones. Women getting the drug had fewer problems with all types of recurrences, including local and distant disease, tumors in the opposite breast and in the bone, the study found.

### Hormone-Fueled Cancer

While it is not clear how Zometa slows cancer, researchers think it is because it makes the cell environment hostile to malignant cells, Gnant said.

The study involved younger women who hadn't gone through menopause and had early stage breast cancer that was fueled by hormones. All patients were given

treatment to suppress their ovaries. They also were given the generic drug tamoxifen or AstraZeneca Plc's Arimidex, with or without Zometa.

There were no differences in results between patients getting tamoxifen and Arimidex, the study found. AstraZeneca also funded part of the research.

Few women in the study received chemotherapy, once a standard treatment. The results show many women with early stage disease may fare well without chemotherapy, said Eric Winer, professor at Harvard Medical School and director of the breast oncology program at the Dana-Faber Cancer Institute in Boston.

### Other Cancers

Zometa may also benefit post-menopausal women and patients with other types of cancer, Gnant said.

There were no cases in the study of osteonecrosis, which causes jaw-bone damage, or kidney harm, side effects linked to drugs like Zometa.

Zometa, which belongs to a group of drugs called bisphosphonates, is thought to reduce cells' ability to travel and stick to each other and the bone, to stimulate cancer fighting immune cells, choke the growth of blood vessels that feed cancer cells and cause cells to self destruct.

Zometa had first-quarter sales of \$331 million. It's also sold as Aclasta and Reclast in the U.S. and in Europe as an infusion to treat osteoporosis.

### A New Use

Zometa isn't widely used now for osteoporosis because the drug is given intravenously, and most general practitioners don't have the infusion capabilities needed to administer it, said Julie Gralow, chair of ASCO's communications committee and associate professor at the University of Washington. Cancer doctors do have the equipment, and the study findings are likely to dramatically boost use of the drug, she said in an interview.

``I think this will change practice," Gralow said. ``It will get great uptake in the U.S.," she said.

Though the study included only premenopausal patients with hormone-sensitive breast cancer, the drug is exceedingly safe and will likely be given to a wide range of breast cancer patients, she said.

Another, broader study including women before and after menopause getting a variety of cancer treatments is under way, Gralow said. The results of the study, using a more intensive dose of Zometa, will be available by the end of the year.

Until those results are available, it would be a mistake to prescribe the drug widely for all women with breast cancer, Winer said.

Between 20 percent and 25 percent of breast cancer patients are premenopausal, Winer said. Half of them have tumors that are fueled by hormones, or about 25,000 women a year, he said.

“In my humble view, it's entirely the wrong message that all women should be getting this drug starting tomorrow,” he said in an interview. “It's not a terribly toxic drug, but all drugs have toxicities. Within the narrowly defined group of women who got the drug, this study would give one strong impetus to use Zometa.”

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