New Research Highlights Important Data On Protecting Bone Health Of Women Undergoing Hormonal Therapy For Early Breast Cancer

(NAPSA)—An estimated 200,000 women in the United States will be diagnosed with invasive breast cancer this year alone.[1] Fortunately, thanks to recent advances in treatments, many women with early breast cancer are reducing the risk of their cancer returning.

Specifically, the introduction of aromatase inhibitors has been a significant improvement in treatment for early breast cancer patients. However, like other cancer therapies, there are some side effects associated with aromatase inhibitors, such as bone loss. If left untreated, bone loss may lead to painful bone fractures. For women undergoing treatment with aromatase inhibitors, it is important that they are aware of the potential for bone loss and ways to help maintain bone health.

Now, however, there is good news for breast cancer patients who are concerned about protecting their bones while undergoing hormonal therapy for early breast cancer. In new data presented at the American Society of Clinical Oncology (ASCO) annual meeting this year, Zometa, a third-generation bisphosphonate approved to treat bone metastases, reduced bone loss in postmenopausal women treated with an aromatase inhibitor. For some women participating in the study, an increase in bone density was also reported.

"These early results are encouraging and indicate the potential protective benefits of Zometa in helping women with breast cancer maintain a healthy bone density while receiving an aromatase inhibitor," said Dr. Adam Brufsky, lead investigator and co-director of Magee Women's Hospital/UPCI Comprehensive Breast Cancer Center in Pittsburgh.

While these investigational data are promising, further research is needed to confirm the findings.

Zometa has been used in more than one million cancer patients worldwide.

Bone metastases are one of the most debilitating complications for cancer patients and seriously impact a patient's ability to perform routine activities. Zometa is approved for the treatment of multiple myeloma and bone metastasis in a broad range of tumors, such as breast cancer, prostate cancer, lung cancer and other solid tumors.

ZOMETA is indicated for patients with multiple myeloma and documented bone metastases from solid tumors in conjunction with standard antineoplastic therapy; prostate cancer should have progressed after treatment with at least one hormonal therapy.

Safety Information

ZOMETA is contraindicated in patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates, or any of the excipients in the formulation of ZOMETA.

Due to the risk of clinically significant deterioration in renal function, which may progress to renal failure, single doses of ZOMETA should not exceed 4 mg and the duration of infusion should be no less than 15 minutes. Risk factors for the deterioration of renal function include impaired baseline renal function and multiple cycles of bisphosphonate treatment.

ZOMETA is not recommended in patients with bone metastases with severe renal impairment. In patients with mild to moderate renal impairment at baseline, lower doses of ZOMETA are recommended based on calculated creatinine clearance. Before each ZOMETA dose serum creatinine should be measured and treatment should be withheld for renal deterioration until serum creatinine has returned to within 10% of the baseline value.

ZOMETA should not be used during pregnancy. Women of childbearing potential should be advised to avoid becoming pregnant. If the patient becomes pregnant while taking this drug, the patient should be apprised of the potential harm to the fetus.

Osteonecrosis of the Jaw (ONJ) has been reported in patients with cancer receiving treatment including bisphosphonates, chemotherapy, and/or corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors. While on treatment, these patients should avoid invasive dental procedures if possible. No data are available as to whether discontinuation of bisphosphonate therapy reduces the risk of ONJ in patients requiring dental procedures.

In post-marketing experience, severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported infrequently in patients taking bisphosphonates.

The most common adverse events (_15%) in bone metastases clinical trials regardless of causality with ZOMETA 4 mg (n=1031) were as follows: bone pain (55%), nausea (46%), fatigue (39%), anemia (33%), pyrexia (32%), vomiting (32%), constipation (31%), dyspnea (27%), diarrhea (24%), weakness (24%), myalgia (23%), anorexia (22%), cough (22%), arthralgia (21%), lower-limb edema (21%), malignant neoplasm aggravated (20%), headache (19%), dizziness (excl. vertigo) (18%), insomnia (16%), decreased weight (16%), back pain (15%), paresthesia (15%).

Caution is advised when bisphosphonates are administered with aminoglycosides, loop diuretics, and potentially nephrotoxic drugs. ZOMETA should be used with caution in patients with aspirin-sensitive asthma.

Patients should be administered an oral calcium supplement of 500 mg and a multiple vitamin containing 400 IU of vitamin D daily.

Please see full prescribing information.

References:

1 American Cancer Society. *What are the key statistics of Breast Cancer?* Retrieved June 8, 2005 from http://www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_are_the_key_statistics_for_breast_cancer_5.asp?sitearea=.