# Health Awareness

## Treatment Option In Metastatic Breast Cancer

(NAPSA)—Breast cancer is the second leading cause of cancer deaths in women in the United States. Metastatic breast cancer is the most advanced stage of breast cancer.

For more than 60 years, chemotherapy has been, and continues to be, one of the foundations in the treatment of cancer. Most breast cancer patients will receive chemotherapy at some time during the course of their disease. However, resistance to chemotherapy is a major cause of treatment failure in patients with metastatic breast cancer. Drug resistance is associated with >90 percent of treatment failures in patients with metastatic breast cancer.

In October 2007, the U.S. Food and Drug Administration (FDA) granted approval of the first epothilone chemotherapy, IXEMPRA™ (ixabepilone), as a monotherapy for the treatment of patients with metastatic or locally advanced breast cancer resistant or refractory to anthracyclines, taxanes, and capecitabine. Anthracycline resistance is defined as progression while on therapy or within six months in the adjuvant setting or three months in the metastatic setting. Taxane resistance is defined as progression while on therapy or within 12 months in the adjuvant setting or four months in the metastatic setting. IXEMPRA was also granted approval in combination with capecitabine for the treatment of patients with metastatic or locally advanced breast cancer resistant to treatment with an anthracycline and a taxane, or whose cancer is taxane resistant and for whom further anthracycline therapy is contraindicated.

Your healthcare provider should do blood tests to check your liver function before receiving IXEMPRA and as needed while receiving IXEMPRA. If blood tests show that you have liver problems, do not receive injections of IXEMPRA along with the medicine capecitabine. With liver problems, taking these medicines together could increase your chance of serious infection and death due to a very low white blood cell count (neutropenia).

The most common side effects with IXEMPRA used alone or with capecitabine may include: tiredness; loss of appetite; disorders of toenails and fingernails; hair loss; fever; decreased red blood cells (anemia); joint and muscle pain; headache; decreased platelets (thrombocytopenia); nausea, vomiting, diarrhea, constipation, and abdominal pain; sores on the lip, in the mouth and esophagus; tender, red palms and soles of feet (hand-foot syndrome) that look like a sunburn, the skin may become dry and peel or feel numb and tingle.

"Previously, patients with aggressive metastatic or locally advanced breast cancer no longer responding to currently available chemotherapies had limited treatment options," said Linda Vahdat, M.D., Associate Professor of Clinical Medicine, Director Breast Cancer Research Program, Weill Cornell Medical Center. "The approval of IXEMPRA means that we have an important option for patients with metastatic breast cancer who have rapidly progressed through currently approved chemotherapies."

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**Important Safety Information**

**Indications and Usage:**

*IXEMPRA™ (ixabepilone) is a prescription medicine used to treat breast cancer, when certain other medicines have not worked or no longer work. IXEMPRA is used alone or with another cancer medicine called capecitabine.*

**Important Safety Information about IXEMPRA**

**Your healthcare provider should do blood tests to check your liver function before receiving IXEMPRA and as needed while receiving IXEMPRA. If blood tests show that you have liver problems, do not receive injections of IXEMPRA along with the medicine capecitabine. With liver problems, taking these medicines together could increase your chance of serious infection and death due to a very low white blood cell count (neutropenia).**

**You should not receive IXEMPRA (ixabepilone), if you are:**

- *Allergic to a medicine that contains Cremophor® EL[1] or polyoxyethylated castor oil.*
- *Have low white blood cell or platelet counts.*

**Before you receive treatment with IXEMPRA, a medicine given by injection directly into your vein (intravenous infusion), you should tell your healthcare provider about all your medical conditions, including if you:**

- *Have liver problems.*
- *Have heart problems or a history of heart problems.*
- *Have had an allergic reaction to IXEMPRA. To lower the chance of an allergic reaction, you will receive other medicines about 1 hour before each dose of IXEMPRA.*
- *Are pregnant or plan to become pregnant. IXEMPRA may harm your unborn baby.*
- *Are breast-feeding. It is not known if IXEMPRA passes into breast milk.*
- *Take any medicines, including prescription and non-prescription medicines, vitamins and herbal supplements, including St. John's Wort. IXEMPRA and certain other medicines may affect each other causing side effects.*
- *Have diabetes.*
- *Have had numbness, tingling, or burning in the hands or feet (neuropathy)*

**Things to avoid while taking IXEMPRA:**

- *IXEMPRA contains alcohol and may cause dizziness or drowsiness. Avoid activities that may be dangerous, such as driving or operating machinery.*
- *Do not drink grapefruit juice because it may cause you to have too much IXEMPRA in your blood which can lead to side effects.*

**IXEMPRA may cause serious side effects. Tell your healthcare provider if you have the following:**

- *Numbness, tingling, or burning in the hands or feet (neuropathy). These symptoms may be new or get worse and often occur early during treatment. Your dose of IXEMPRA may need to be decreased, stopped until your symptoms get better, or totally stopped.*
- *White blood cells help protect the body from infections caused by bacteria. If you get a fever or infection when your white blood cells are very low, you can become seriously ill and die. Symptoms may include, fever (temperature over 100.5), chills, cough, burning, or pain when you urinate. You may need treatment in the hospital with antibiotic medicines.*
- *Severe allergic reactions can occur and in rare cases cause death. Allergic reactions are most likely to occur when IXEMPRA is being injected. You may experience itching, hives, rash, flushed face, sudden swelling of face, throat or tongue, chest tightness, trouble breathing, feel dizzy or faint, feel your heart beating (palpitations).*
- *Chest pain, difficulty breathing, palpitations, or unusual weight gain can be caused by decreased blood flow to the heart, problems with heart function and abnormal heart beat.*

*The most common side effects with IXEMPRA used alone or with capecitabine may include: tiredness; loss of appetite; disorders of toenails and fingernails; hair loss; fever; decreased red blood cells (anemia); joint and muscle pain; headache; decreased platelets (thrombocytopenia); nausea, vomiting, diarrhea, constipation, and abdominal pain; sores on the lip, in the mouth and esophagus; ten der, red palms and soles of feet (hand-foot syndrome) that look like a sunburn, the skin may become dry and peel or feel numb and tingle.*

*If you have any questions about your health or medicines, talk to your healthcare provider.*

*Please see accompanying full prescribing information including* **boxed WARNING regarding liver disease**.

[1]*Cremophor is a registered trademark of BASF AG.*

*Brought to you by Bristol-Myers Squibb.*