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FDA NEWS RELEASE

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FDA Approves Ixempra for Advanced Breast Cancer Patients

The U.S. Food and Drug Administration has approved Ixempra (ixabepilone), a new anti-cancer treatment, for use in patients with metastatic or locally advanced breast cancer who have not responded to certain other cancer drugs. The FDA evaluated Ixempra under priority review, completing its assessment of the drug's safety and effectiveness in six months.

"This approval is important because it provides certain patients with a new chemotherapy option in instances where other drugs have failed," said Douglas C. Throckmorton, M.D., deputy director of the FDA's Center for Drug Evaluation and Research. "FDA is working every day to support the development of safe and effective new therapies that benefit patients in need."

Ixempra was approved for use in combination with another cancer drug, capecitabine, in patients who no longer benefit from two other chemotherapy treatments. These prior treatments included an anthracycline (such as doxorubicin or epirubicin) and a taxane (such as paclitaxel or docetaxel).

Ixempra was also approved for use alone in patients who no longer benefit from an anthracycline, a taxane and capecitabine.

According to the American Cancer Society, about 180,000 new cases of breast cancer are diagnosed each year in the United States. Metastatic breast cancer is the most advanced stage of breast cancer and has the potential to spread to almost any region of the body.

Ixempra has been shown to bind to cancer cell microtubules, which are structures within cells that help to support and shape them. Microtubules also play a role in cell division.

The safety and efficacy of Ixempra in combination with capecitabine were evaluated in 752 patients in a randomized clinical trial comparing the combination to capecitabine alone. This combination therapy demonstrated improvements in delaying cancer progression or death compared to capecitabine alone.

The safety and efficacy of Ixempra administered alone were evaluated in a study of 126 patients. Clinically significant tumor shrinkage occurred in 12 percent of the patients.

Ixempra's significant side effects included peripheral neuropathy (numbness, tingling or burning in the hands or feet) and bone marrow suppression. Other commonly observed toxicities included constipation, nausea, vomiting, muscle paint, joint pain, fatigue and general weakness.

Women taking Ixempra should avoid taking drugs that are strong inhibitors of CYP3A4, one of the enzymes that metabolizes Ixempra.

Ixempra should not be taken by women who have had severe allergic reactions to drugs that contain Cremophor or its derivatives, or by women who have baseline bone marrow suppression determined by low white blood cell or platelet count.

The combination of Ixempra and capecitabine should not be given to patients with moderate or severe liver impairment due to the increased risk of toxicity and death.

Ixempra is administered by intravenous infusion. It is distributed by Bristol-Meyers Squibb Company, Princeton, New Jersey.

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