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FDA U.S. Food and Drug Administration

News & Events

FDA NEWS RELEASE

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FDA approves new treatment for rare form of thyroid cancer
Vandetanib is first drug approved for medullary thyroid cancer

The U.S. Food and Drug Administration today approved vandetanib to treat adult patients with late-stage (metastatic) medullary thyroid cancer who are ineligible for surgery and who have disease that is growing or causing symptoms.

Thyroid cancer is a cancerous growth of the thyroid gland, which is located in the neck. Medullary thyroid cancer involves specific types of cells that are found in the thyroid gland and can occur spontaneously, or be part of a genetic syndrome.

About 44,600 new thyroid cancer cases were diagnosed in the United States during 2010, and about 1,690 people died from the disease, according to the National Cancer Institute. Medullary thyroid cancer is estimated to represent 3 to 5 percent of all thyroid cancer; its estimated incidence in the United States for 2010 is about 1,300 to 2,200 patients, making it one of the rarer forms of thyroid cancer.

Common symptoms of medullary thyroid cancer may include coughing, difficulty swallowing, enlargement of the thyroid gland, swelling of the neck, a lump on the thyroid, and changes in a person's voice or hoarseness.

Vandetanib targets medullary thyroid cancer's ability to grow and expand. There are currently no FDA-approved treatments for this type of cancer. Vandetanib is administered orally on a daily basis.

Vandetanib's safety and effectiveness were established in a single, randomized international study of 331 patients with late-stage medullary thyroid cancer. Patients in the study were selected to receive vandetanib or placebo (sugar pill).

The study was designed to measure the length of time a patient lived without the individual's cancer progressing (progression-free survival). Patients who received vandetanib had a longer period of time without disease progression when compared to patients receiving placebo. Median progression-free survival was 16.4 months in the placebo arm and at least 22.6 months in the vandetanib arm. It is too early to determine the median progression-free survival in patients treated with vandetanib or to tell whether they will live longer (overall survival) compared to patients treated with placebo.

"Vandetanib's approval underscores FDA's commitment to approving treatments for patients with rare and difficult to treat diseases," said Richard Pazdur, M.D., director of the Office of Oncology Drug Products in the FDA's Center for Drug Evaluation and Research.

Common side effects occurring from vandetanib use include diarrhea, rash, nausea, high blood pressure, headache, fatigue, decreased appetite, and stomach (abdominal) pain. Serious side effects reported during the study resulted in five deaths in patients treated with vandetanib. Causes of death included breathing complications, heart failure, and a bacterial infection in the blood (sepsis).

Vandetanib was shown to affect the electrical activity of the heart, which in some cases can cause irregular heart beats that could lead to death. Vandetanib is being approved with a Risk Evaluation and Mitigation Strategy (REMS) to inform health care professionals about these serious heart-related risks. Only health care professionals and pharmacies certified through the vandetanib REMS program, a restricted distribution program, will be able to prescribe and dispense the drug. Patients will also receive an FDA-approved Medication Guide informing them of the potential risks.

Vandetanib is marketed by AstraZeneca Pharmaceuticals LP of Wilmington, Del. There is no trade name established for this drug at this time.

For more information:

FDA: Office of Oncology Drug Products
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NCI: Thyroid Cancer
2

NCI: Natural History of Medullary Thyroid Cancer
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