FDA Approval for Lenvatinib for Thyroid Cancer Indication

The Food and Drug Administration has approved the use of Lenvima (lenvatinib) for the treatment of patients with differentiated thyroid cancer (DTC) whose disease has progressed despite receiving the use of radioactive iodine therapy. Lenvima, made by Eisai, is a kinase inhibitor that works by blocking certain proteins from helping cancer cells grow and divide.

"The development of new therapies to assist patients with refractory disease is of high importance to the FDA," Richard Pazdur, MD, Director of the agency's Office of Hematology and Oncology Products, said in a news release. "The approval gives patients and health care professionals a new therapy to help slow the progression of DTC."

Lenvima had received priority review designation last year (***OT 11/10/14 issue***), and this new approval came two months ahead of the prescription drug user fee goal date of April 14. The FDA's priority review designation shortens the time to complete a drug's review and aims to deliver a decision on marketing approval designation for drugs that may offer major advances in treatment or provide a treatment where no adequate therapy exists within six months under the Prescription Drug User Fee Act (PDUFA).

Efficacy was evaluated in a trial of 392 patients with progressive, radioactive iodine-refractory DTC who were randomly assigned to receive either Lenvima or a placebo. Initial results from the trial were presented at the American Society of Clinical Oncology Annual Meeting in June (***OT 7/25/14 issue***).

Patients receiving Lenvima lived a median of 18.3 months without progression of disease, compared with a median of 3.6 months for patients receiving the placebo. Sixty-five percent of the patients treated with Lenvima saw a reduction in tumor size, compared with the two percent of patients who had received the placebo. The final results from the trial were published just a few days before the approval, online ahead of print in *The New England Journal of Medicine* (***DOI: 10.1056/NEJMoa1406470***).

The most common side effects for Lenvima were hypertension, fatigue, diarrhea, arthralgia/myalgia, decreased appetite, decreased weight, nausea, stomatitis, headache, vomiting, proteinuria, palmar-plantar erythrodysesthesia syndrome, abdominal pain, and dysphonia.

Lenvima's serious side effects include cardiac failure, arterial thromboembolic events, hepatoxicity, renal failure and impairment, gastrointestinal perforation or fistula formation, QT Interval Prolongation, hypocalcemia, Reversible Posterior Leukoencephalopathy Syndrome, hemorrhage, risks to an unborn child if a patient becomes pregnant during treatment, and impairing suppression of the production of thyroid-stimulating hormone.