Nexavar approval expanded for common thyroid cancer

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(HealthDay)—U.S. Food and Drug Administration approval for the anti-cancer drug Nexavar (sorafenib) has been expanded to include late-stage differentiated thyroid cancer, the most common type of thyroid cancer.

In a Friday news release about the approval, the agency said thyroid cancer will be diagnosed in an estimated 60,220 Americans this year, and an estimated 1,850 will die from the disease.

Nexavar is designed to inhibit proteins that prompt cancer cells to divide and grow. The new approval is meant for people with differentiated thyroid cancer that no longer responds to radioactive iodine treatment.

The drug was approved for this new use based on clinical studies involving 417 people whose thyroid cancer did not respond to treatment. The drug increased the time recipients lived without cancer progression by about 41 percent compared to those who took a placebo, the FDA said.

The most common side effects of Nexavar included diarrhea, fatigue, infection, hair loss, skin reactions, weight loss, loss of appetite, abdominal pain, and high blood pressure. The agency also warned that increased production of thyroid stimulating hormone—a potential promoter of thyroid cancer—was possible among the drug's users.

Nexavar was FDA-approved to treat advanced kidney cancer in 2005, followed by approval to treat advanced liver cancer in 2007, the agency said.

The drug is marketed by Bayer HealthCare Pharmaceuticals, based in Wayne, N.J.

More information: More Information