Azedra approved for rare adrenal tumors

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(HealthDay)—Azedra (iobenguane) has been approved by the U.S. Food and Drug Administration to treat people 12 and older with rare adrenal gland tumors that can't be surgically removed and have spread beyond the original site.

The adrenal glands sit above the kidneys and produce the stress hormones epinephrine and norepinephrine. The rare tumors known as pheochromocytomas spike production of these hormones, leading to possible symptoms including high blood pressure, headache, irritability, excessive sweating and rapid heartbeat. Sometimes, such tumors develop outside the adrenal gland, where they're called paragangliomas, the FDA said in a news release.

"Many patients with these ultra-rare cancers can be treated with surgery or local therapies, but there are no effective systemic treatments for patients who experience tumor-related symptoms such as high blood pressure," said Dr. Richard Pazdur, director of the FDA's Oncology Center of Excellence.

Azedra was evaluated in a clinical study involving 68 people. About 25 percent required half or fewer drugs to combat high blood pressure for at least six months, the agency said.

The most common side effects of Azedra included low levels of white blood cells, low blood platelet count, fatigue, nausea, dizziness, hypertension and vomiting.

The drug's label includes a warning that users should minimize exposure to radiation; the warning applies especially to younger patients, the FDA said. Among a number of additional warnings, pregnant women shouldn't take Azedra since it can harm a fetus.

Azedra is produced by Progenics Pharmaceuticals, based in Tarrytown, N.Y.

More information: Visit the FDA to learn more.