New Drug Approvals

Generic Name (Trade Nameâ€”Company)	**Uses**/Notes
July 31, 2018	
Iobenguane I 131	FDA approved iobenguane I 131 injection for I.V. use to treat adults and adolescents aged 12 and older with rare tumors of the adrenal gland (pheochromocytoma or paraganglioma) that cannot be surgically removed, have spread beyond the original tumor site, and require systemic anticancer therapy. This is the first FDA-approved drug for this use. Efficacy of the agent was shown in a single-arm, open-label, clinical trial in 68 patients that measured the number of patients who experienced a 5% or greater reduction of all antihypertensive medications lasting for at least 6 months. This endpoint was supported by the secondary endpoint, overall tumor response measured by traditional imaging criteria. The study met the primary endpoint, with 17 (25%) of the 68 evaluable patients experiencing a 50% or greater reduction of all antihypertensive medication for at least 6 months. Overall tumor response was achieved in 15 (22%) of the patients studied. In clinical trials, the most common severe adverse effects included lymphopenia, neutropenia, thrombocytopenia, fatigue, anemia, increased international normalized ratio, nausea, dizziness, hypertension, and vomiting. Because it is a radioactive therapeutic agent, Iobenguane I 131 includes a warning about radiation exposure to patients and family members, which should be minimized while the patient is receiving the agent. The risk of radiation exposure is greater in pediatric patients. Other warnings and precautions include a risk of myelosuppression, underactive thyroid, elevations in blood pressure, renal failure or kidney injury, and pneumonitis. Myelodysplastic syndrome and acute leukemias were observed in patients who received the agent, and the magnitude of this risk will continue to be studied.

(Azedra—Progenics Pharmaceuticals)

FDA approves first treatment for rare adrenal tumors

Iobenguane I 131 can cause harm to a developing fetus; women should be advised of this potential risk and to use effective contraception after receiving the agent. Radiation exposure associated with Iobenguane I 131 may cause infertility in males and females.

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