

The following is a message from the FDA's Office of Oncology Drug Products Director, Dr. Richard Pazdur:

On September 19, 2008, the US Food and Drug Administration (FDA) approved iobenguane I 123 injection (AdreView, GE Healthcare), a diagnostic radiopharmaceutical, for use in the detection of primary or metastatic pheochromocytoma or neuroblastoma as an adjunct to other diagnostic tests. Iobenguane accumulates in adrenergically innervated tissues as well as tumors derived from the neural crest. The uptake of iobenguane I 123 injection by metabolically active pheochromocytoma or neuroblastoma allows scintigraphic visualization of these tumors. The safety and efficacy of iobenguane I 123 injection were evaluated in a single arm clinical study of patients with known or suspected neuroblastoma or pheochromocytoma. Diagnostic efficacy was determined for 211 patients by comparison of focal increased radionuclide uptake on planar scintigraphy at 24 hours. Diagnostic efficacy was determined for 211 patients by comparison of focal increased radionuclide uptake on planar scintigraphy at 24 ± 6 post-administration of iobenguane I 123 injection against the definitive diagnosis (standard of truth). The standard of truth was a diagnosis of presence or absence of pheochromocytoma in 127 patients and neuroblastoma in 84 patients. The diagnosis was determined by histopathology or, when histopathology was unavailable, a composite of imaging, plasma/urine catecholamine and/or catecholamine metabolite measurements and clinical follow-up. In the detection of either neuroblastoma or pheochromocytoma, the iobenguane I 123 injection sensitivity and specificity were determined independently based on results of three image readers who were fully masked to clinical information. The sensitivity ranged from 77% to 80% and the specificity ranged from 69% to 77%. Performance characteristics were similar between the groups of patients who had either a pheochromocytoma or neuroblastoma truth standard. During the 24 hours following iobenguane administration, adverse reactions were mild to moderate in severity and were predominately isolated occurrences (≤ 2 patients) of one of the following reactions: dizziness, rash, pruritis, flushing or injection site hemorrhage. No serious adverse reactions were reported. The recommended dose of iobenguane I 123 injection is 10 mCi (370 mBq) for patients ≥ 16 years of age or patients < 16 years of age who weigh ≥ 70 kg. The dose for patients < 16 years of age who weigh < 70 kg is based upon a scale described in the product insert. Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at <http://www.fda.gov/cder/foi/label/2008/222901bl.pdf>