CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209607Orig1s000

MULTI-DISCIPLINE REVIEW

Summary Review
Office Director
Cross Discipline Team Leader Review
Clinical Review
Non-Clinical Review
Statistical Review
Clinical Pharmacology Review

NDA/BLA Multi-Disciplinary Review and Evaluation

Application Type	NDA
Application Number	209607
Priority or Standard	Priority
Submit Date	10-31-2017
Received Date	10-31-2017
PDUFA Goal Date	7-30-2018
Division/Office	DOP2/OHOP
Review Completion Date	7-24-2018
Established Name	^{131}I Iobenguane
(Proposed) Trade Name	AZEDRA
Pharmacologic Class	Radiopharmaceutical
Code name	
Applicant	Progenics Pharmaceuticals Inc.
Formulation	Solution
Dosing Regimen	Dosimetric dose: 5 – 6 mCi (0.1 mCi/kg for patients ≤ 50 kg) Therapeutic dose: 500 mCi (8 mCi/kg for patients ≤ 62.5 kg) every 12 weeks for two doses
Applicant Proposed Indication	Treatment of patients age (b) (4) years and older with iobenguane avid malignant and/or recurrent pheochromocytoma or paraganglioma
Recommendation on Regulatory Action	Approval
Recommended Indication	Treatment of patients age 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy

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