CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761104Orig1s000

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	BLA
Application Number(s)	761104
Priority or Standard	Priority
Submit Date(s)	November 30, 2017 and January 29, 2018
Received Date(s)	November 30, 2017 and January 29, 2018
PDUFA Goal Date	September 29, 2018
Division/Office	Division of Hematology Products/Office of Hematology and Oncology Products
Review Completion Date	September 12, 2018
Established Name	Moxetumomab pasudotox
(Proposed) Trade Name	Lumoxiti
Pharmacologic Class	CD22-directed cytotoxin
Code name	CAT-8015
Applicant	AstraZeneca AB
Formulation(s)	Lyophilized powder
Dosing Regimen	0.04 mg/kg administered as a 30-minute intravenous infusion on Days 1, 3, and 5 of each 28-day cycle
Applicant Proposed Indication(s)/Population(s)	Treatment of adult patients with relapsed or refractory hairy cell leukemia who received at least two prior systemic therapies, including with a purine nucleoside analog
Recommendation on Regulatory Action	Approval
Recommended Indication(s)/Population(s) (if applicable)	Treatment of patients with relapsed or refractory hairy cell leukemia who received at least two prior systemic therapies, including a purine nucleoside analog

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