

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208630Orig1s000

CLINICAL REVIEW(S)

Clinical Review
 Betsy Ballard, MD
 NDA 208630
 Gleolan (5-aminolevulinic acid)

CLINICAL REVIEW

Application Type	NDA
Application Number(s)	208630
Priority or Standard	Fast Type Designation
Submit Date(s)	12/6/2016
Received Date(s)	12/6/2016
PDUFA Goal Date	6/6/2017
Division/Office	DMIP/OND IV
Reviewer Name(s)	Betsy Ballard, MD
Review Completion Date	5/15/2017
Established Name	Gliolan (5-Aminolevulinic Acid)
(Proposed) Trade Name	Gleolan
Applicant	NX Development Corp
Formulation(s)	Oral powder
Dosing Regimen	20mg/kg given a single time 3-4 hours prior to surgery
Applicant Proposed Indication(s)/Population(s)	An imaging agent to facilitate the real time detection and visualization of malignant tissue during glioma surgery.
Recommendation on Regulatory Action	Approval
Recommended Indication(s)/Population(s) (if applicable)	<i>An imaging agent indicated as an adjunct to other neurosurgical tools, to visualize WHO grades III and IV gliomas intra-operatively during glioma surgery.</i> (This is the reviewer's proposed statement and may differ from the indication that will be approved)
Review Team	<u>Clinical Reviewer</u> : BALLARD, BETSY <u>Statistician</u> : MUCCI, ANTHONY <u>Clinical Pharmacology</u> : JOHN, CHRISTY S. <u>Non-Clinical Reviewer</u> : HONCHEL, RONALD <u>Product Quality Reviewer</u> : AMARTEY, JOHN K. <u>Product Quality Reviewer</u> : HABER, MARTIN T. <u>Product Quality Microbiology Reviewer</u> : PFEILER, ERIKA A. <u>CDRH Consultants</u> : OGDEN, NEIL and CHEN, COLIN KEJING (DSD/GSDB I) <u>Regulatory Project Manager</u> : SKARUPA, LISA M

Table of Contents

Glossary	8
1 Executive Summary	10
1.1. Product Introduction.....	10
1.2. Conclusions on the Substantial Evidence of Effectiveness.....	10
1.3. Benefit-Risk Assessment	10
2 Therapeutic Context.....	16
2.1. Analysis of Condition.....	16
2.2. Analysis of Current Treatment Options	17
3 Regulatory Background	19
3.1. U.S. Regulatory Actions and Marketing History.....	19
3.2. Summary of Presubmission/Submission Regulatory Activity	19
3.3. Foreign Regulatory Actions and Marketing History	21
4 Significant Issues from Other Review Disciplines Pertinent to Clinical Conclusions on Efficacy and Safety	21
4.1. Office of Scientific Investigations (OSI)	21
The results of the OSI data confirmation were not available at the time of this review.....	21
4.2. Product Quality	21
4.3. Clinical Microbiology.....	21
4.4. Nonclinical Pharmacology/Toxicology	21
4.5. Clinical Pharmacology	22
4.5.1. Mechanism of Action.....	22
4.5.2. Pharmacodynamics.....	23
4.5.3. Pharmacokinetics.....	23
4.6. Devices and Companion Diagnostic Issues	23
4.7. Consumer Study Reviews.....	24
5 Sources of Clinical Data and Review Strategy	24
5.1. Table of Clinical Studies	24
5.2. Review Strategy	27
CDEB Clinical Review Template 2015 Edition	2

6	Review of Relevant Individual Trials Used to Support Efficacy	28
6.1.	Fluorescence-guided resection of malignant gliomas with 5-Aminolevulinic acid (5-ALA) vs. conventional resection	28
6.1.1.	Study Design	28
6.1.2.	Study Results	32
6.2.	Clinical Phase II Trial of 5-Aminolevulinic Acid Hydrochloride (5-ALA, 5-ALS) for Fluorescence-guided Resection of Malignant Gliomas (ALS-28)	43
6.2.1.	Study Design	43
6.2.2.	Study Results	47
6.3.	Clinical Phase II Trial of MC 506/1 (5-Aminolevulinic Acid hydrochloride, 5-ALA, 5-ALS) for Fluorescence-Guided Resection of Malignant Gliomas in Progression Therapy (ALS-30) ..	50
6.3.1.	Study Design	50
6.3.2.	Study Results	52
7	Integrated Review of Effectiveness	56
7.1.	Assessment of Efficacy Across Trials	56
7.1.1.	Primary Endpoints	56
7.1.2.	Subpopulations	60
7.1.3.	Dose and Dose-Response	60
7.1.4.	Onset, Duration, and Durability of Efficacy Effects.....	60
7.2.	Additional Efficacy Considerations.....	60
7.2.1.	Considerations on Benefit in the Postmarket Setting.....	60
7.2.2.	Other Relevant Benefits.....	60
7.3.	Integrated Assessment of Effectiveness	61
8	Review of Safety	62
8.1.	Safety Review Approach	63
8.2.	Review of the Safety Database	63
8.2.1.	Overall Exposure	63
8.2.2.	Relevant characteristics of the safety population:	63
8.2.3.	Adequacy of the safety database:	63
8.3.	Adequacy of Applicant’s Clinical Safety Assessments	64
8.3.1.	Issues Regarding Data Integrity and Submission Quality.....	64

Clinical Review
Betsy Ballard, MD
NDA 208630
Gleolan (5-aminolevulinic acid)

8.3.2. Categorization of Adverse Events	64
8.3.3. Routine Clinical Tests	64
8.4. Safety Results	65
8.4.1. Deaths	65
8.4.2. Serious Adverse Events	66
8.4.3. Dropouts and/or Discontinuations Due to Adverse Effects.....	66
8.4.4. Significant Adverse Events	66
8.4.5. Treatment Emergent Adverse Events and Adverse Reactions	67
8.4.6. Laboratory Findings	67
8.4.7. Vital Signs.....	68
8.4.8. Electrocardiograms (ECGs)	68
8.4.9. QT	69
The applicant also stated that the post-marketing world-wide data base was queried and there were no cardiac events associated with QT prolongation.	70
8.4.10. Immunogenicity.....	70
8.5. Analysis of Submission-Specific Safety Issues	70
8.5.1. Neurologic Events	70
8.5.2. Photosensitivity	71
8.6. Safety Analyses by Demographic Subgroups	72
8.7. Specific Safety Studies/Clinical Trials	72
8.8. Additional Safety Explorations	72
8.8.1. Human Carcinogenicity or Tumor Development	72
8.8.2. Human Reproduction and Pregnancy	72
8.8.3. Pediatrics and Assessment of Effects on Growth	72
8.8.4. Overdose, Drug Abuse Potential, Withdrawal, and Rebound.....	72
8.9. Safety in the Postmarket Setting	72
8.9.1. Safety Concerns Identified Through Postmarket Experience	72
8.9.2. Expectations on Safety in the Postmarket Setting.....	72
8.10. Additional Safety Issues From Other Disciplines	73
8.11. Integrated Assessment of Safety.....	73
9 Advisory Committee Meeting and Other External Consultations	73

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