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APPLICATION NUMBER:

212640Orig1s000

CLINICAL REVIEW(S)

Clinical Review
Rainer W. Paine, MD, PhD
NDA 212640
Exservan (Riluzole Oral Film)

CLINICAL REVIEW

Application Type	505 (b)(2)
Application Number(s)	212640
Priority or Standard	Standard
Receipt Date(s)	01/31/2019
PDUFA Goal Date	11/30/2019
Division/Office	Division of Neurology Products
Reviewer Name(s)	Rainer W. Paine, MD, PhD
Review Completion Date	10/08/19
Established Name	Riluzole Oral Film
(Proposed) Trade Name	Exservan
Applicant	Aquestive Therapeutics
Formulation(s)	Oral Film, 50 mg of riluzole
Dosing Regimen	50 mg every 12 hours
Applicant Proposed Indication(s)/Population(s)	Amyotrophic lateral sclerosis (ALS)
Recommendation on Regulatory Action	Approval
Recommended Indication(s)/Population(s) (if applicable)	Amyotrophic lateral sclerosis (ALS)

Table of Contents

Glossary.....	4
1. Executive Summary	6
1.1. Product Introduction.....	6
1.2. Conclusions on the Substantial Evidence of Effectiveness	6
1.3. Benefit-Risk Assessment	7
2. Therapeutic Context	7
2.1. Analysis of Condition.....	7
2.2. Analysis of Current Treatment Options	7
3. Regulatory Background	8
3.1. Summary of Presubmission/Submission Regulatory Activity	8
3.2. Foreign Regulatory Actions and Marketing History.....	8
4. Sources of Clinical Data and Review Strategy	9
4.1. Table of Clinical Studies.....	9
4.2. Review Strategy.....	10
5. Review of Relevant Individual Trials Used to Support Efficacy	10
6. Review of Safety	10
6.1. Safety Review Approach	10
6.2. Review of the Safety Database	11
6.2.1. Overall Exposure	11
6.2.2. Adequacy of the Safety Assessments	11
6.3. Safety Results	11
6.3.1. Deaths, Serious Adverse Events, and Significant Adverse Events.....	11
6.3.2. Dropouts or Discontinuations Due to Adverse Effects	11
6.3.3. Adverse Events.....	11
6.3.4. Laboratory Findings	12
6.3.5. Vital Signs	12
6.3.6. Swallowing Study 17MO1R-0012.....	13
6.4. Safety in the Postmarket Setting.....	14
CDEP Clinical Review Template	2

Clinical Review

Rainer W. Paine, MD, PhD

NDA 212640

Exservan (Riluzole Oral Film)

6.4.1. Safety Concerns Identified Through Postmarket Experience.....	14
6.5. Integrated Assessment of Safety	14
7. Labeling Recommendations	14
7.1. Drug Labeling.....	14
8. Appendices	15
8.1. References.....	15

Table of Tables

Table 1: Table of Clinical Studies.....	9
Table 2: Treatment-Emergent Adverse Events and Number of Events Summarized per Treatment. Source: Study 162020 CSR	12
Table 3: Penetration Aspiration Scale (PAS). VF = Vocal Folds	13

Clinical Review
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Glossary

AC	advisory committee
AE	adverse event
AR	adverse reaction
BA/BE	bioavailability and bioequivalence
BLA	biologics license application
BPCA	Best Pharmaceuticals for Children Act
BRF	Benefit Risk Framework
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CDTL	Cross-Discipline Team Leader
CFR	Code of Federal Regulations
CMC	chemistry, manufacturing, and controls
COSTART	Coding Symbols for Thesaurus of Adverse Reaction Terms
CRF	case report form
CRO	contract research organization
CRT	clinical review template
CSR	clinical study report
CSS	Controlled Substance Staff
DMC	data monitoring committee
ECG	electrocardiogram
eCTD	electronic common technical document
ETASU	elements to assure safe use
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FDASIA	Food and Drug Administration Safety and Innovation Act
GCP	good clinical practice
GRMP	good review management practice
ICH	International Council for Harmonization
IND	Investigational New Drug Application
iPSP	initial pediatric study plan
ISE	integrated summary of effectiveness
ISS	integrated summary of safety
ITT	intent to treat
MedDRA	Medical Dictionary for Regulatory Activities
mITT	modified intent to treat
NCI-CTCAE	National Cancer Institute-Common Terminology Criteria for Adverse Event

CDER Clinical Review Template

4

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