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APPLICATION NUMBER:
022328Orig1s000

MEDICAL REVIEW(S)

CLINICAL REVIEW

Application Type NDA (Complete Response)
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Priority or Standard Class 1 Resubmission

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Reviewer Name(s) Christopher D Breder, MD PhD
Review Completion Date 25 Oct 2011

Established Name Zolpidem tartrate lozenge
(Proposed) Trade Name Intermezzo
Therapeutic Class Sedative Hypnotic
Applicant Transcept Pharmaceuticals

Formulation(s) sublingual lozenge
Dosing Regimen x 1 qMiddle of the Night
(MOTN) PRN
Indication(s) Treatment of insomnia
following MOTN awakening
Intended Population(s) Insomnia patients

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Table of Contents

1	RECOMMENDATIONS/RISK BENEFIT ASSESSMENT	5
1.1	Recommendation on Regulatory Action	5
1.2	Risk Benefit Assessment.....	5
1.3	Recommendations for Postmarket Risk Evaluation and Mitigation Strategies ...	5
1.4	Recommendations for Postmarket Requirements and Commitments	5
2	INTRODUCTION AND REGULATORY BACKGROUND	5
2.1	Summary of Presubmission Regulatory Activity Related to Submission	5
3	SIGNIFICANT ISSUES RELATED TO OTHER REVIEW DISCIPLINES	8
3.1.	Pharmacokinetics	8
4	REVIEW OF EFFICACY	11
	Efficacy Summary.....	11
4.1	Indication.....	11
4.1.1	Methods	11
4.1.2	Demographics.....	11
4.1.3	Analysis of Primary and Key Secondary Endpoint(s).....	11
4.1.4	Analysis of other Secondary Endpoints(s)	12
4.1.5	Other Endpoints	14
5	REVIEW OF SAFETY.....	16
	Safety Summary	16
5.1	Methods.....	16
5.2	Supportive Safety Results	16
5.2.1	Common Adverse Events	16
5.3	Other Safety Explorations.....	18
5.3.1	Time Dependency for Adverse Events.....	18
6	APPENDICES	20
6.1	Additional PK Investigations by Medical Reviewer	20
6.1.1	Analysis of Postdose Zolpidem Concentrations by Gender and Dose.....	20

Clinical Review
Christopher D. Breder, MD PhD
N022328 / 0046
Intermezzo / zolpidem tartrate lozenge

Table of Tables

Table 1 Mean Intermezzo Pharmacokinetic Parameters after Single Dose of Intermezzo 3.5, 1.75, and 1.0 mg in Females and Males (Study ZI-05-009)	8
Table 2 Mean (SD) Plasma Concentration at 3, 4, and 5 hours in Females Following the 1.75 mg dose and in males Following the 3.5 mg Dose.....	9
Table 3 The Predictive Probabilities of Exceeding Threshold Plasma Concentration Values (female subjects).....	9
Table 4 Predictive Probabilities of Exceeding Threshold Plasma Concentration Values (male subjects).....	10
Table 5 Mean (%CV) Intermezzo 3.5 mg Cmax and Plasma Levels at 3, 4, and 5 hours in males	10
Table 6 Adverse Events for Females (1.75 mg) and Males (3.5 mg) from the ZI-10 Study.....	16
Table 7 Adverse Events at the 3.5 mg Dose Level from the ZI-12 Study	17

Clinical Review
Christopher D. Breder, MD PhD
N022328 / 0046
Intermezzo / zolpidem tartrate lozenge

Table of Figures

Figure 1 Cumulative % of Patients Asleep (After MOTN Awakening) at Sequential 10-Minute Intervals by PSG (Study ZI-06-010)	12
Figure 2 LPS Post MOTN Awakening in Females by Dose Group.....	13
Figure 3 LPS Post MOTN Awakening in Males by Dose Group.....	15
Figure 4 Distribution of Plasma Zolpidem Concentrations 3 hours Post-dose by Gender and Dose	21
Figure 5 Distribution of Plasma Zolpidem Concentrations 4 hours Post-dose by Gender and Dose	22
Figure 6 Distribution of Plasma Zolpidem Concentrations 5 hours Post-dose by Gender and Dose	23

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