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APPLICATION NUMBER:

NDA 22-253 & 22-254

MEDICAL REVIEW(S)

CLINICAL REVIEW

Application Type	22-253, 22254, [redacted] b(4)
Submission Number	0
Letter Date	9/28/07
PDUFA Goal Date	10/28/08 (following extension)
Reviewer Name	Norman Hershkowitz, MD, PhD
Review Completion Date	10/28/08
Established Name	Lacosamide
(Proposed) Trade Name	Vimpat
Therapeutic Class	Anticonvulsant
Applicant	Schwarz Biosciences Inc. (UCB)
Priority Designation	S
Formulation	1) Tablets 50, 100 150, 200, 250 and 300 mg b(4) (22253) 2) iv solution (22254) b(4) [redacted]
Sponsor's Dosing Regimen	100, 200 [redacted] mg BID b(4)
Indication	Epilepsy of Partial Onset
Intended Population	Adjunctive Treatment >16 years

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b(5)

1 EXECUTIVE SUMMARY

The CDTL acted as the primary efficacy reviwer. Therefore, the CDTL review is being reprinted, in part, below so as to serve as the Executive summary.

Introduction

Lacosamide has been developed for two separate indications, partial onset seizures and pain associated with diabetic peripheral neuropathy (DPN). This CDTL Division of Neurology Prodcuts (DNP) review will concentrate on efficacy results in partial onset seizures. That for DPN will be reviewed by Division of Anesthesia, Analgesia and Rheumatologic Products (DAARP). Safety data in this application has been reviewed by both division, and while this review will concentrate on safety in epilepsy, all data will be discussed. Because of specific interest in a potential cardiac signal the Division of Cardiovascular and Renal Products (DCRP) was asked to comment not only on the formal QT study but issues of PR prolongation and general cardiac safety.

Background

According to the Sponsor Lacosamide, (R)-2-acetamido-N-benzyl-3-methoxypropionamide, is a member of a series of functional amino acids. From a mechanistic perspective lacosamide appears to act as a sodium channel blocker, an action shared by a number other anticonvulsants including phenytoin, carbamazepine, oxcarbazepine and lamictal. The Sponsor also notes that lacosamide's anticonvulsant activity may also be related to its ability to bind to collapsin response mediator protein-2 (CRMP-2), a phosphoprotein which is mainly expressed in the nervous system and is involved in neuronal differentiation and control of axonal outgrowth. This reviwer believes that this latter mechanism is highly speculative.

Clinical/Statistical- Efficacy

The clinical efficacy review was performed by this CDTL, Dr. Norman Hershkowitz.

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