

Memo to File

NDA: 020241 (S-53)
NDA: 020764 (S-46)

NDA: 022251 (S-17)
Generic Name: Lamotrigine
Trade Name: Lamictal®
Dosage Forms: Oral Tablets, Chewable Dispersible Tablet, Orally Disintegrating Tablets

(b) (4)

Sponsor: Glaxo Smith Kline
Submission Type: (b) (4) Supplement
Classification: Standard
Submission Date: 7/18/2014

OCP Division: DCP1
OND Division: DPP

CP Reviewer: Kofi A. Kumi, Ph.D.
CP Team Leader: Hao Zhu, Ph.D.

Background

(b) (4)

Lamotrigine is an antiepileptic drug (AED) approved for:

- Epilepsy - adjunctive therapy in patients aged 2 years and older
 - partial-onset seizures
 - primary generalized tonic-clonic seizures
 - generalized seizures of Lennox-Gastaut syndrome
- Epilepsy - monotherapy in patients aged 16 years and older
- Bipolar disorder in adults

The sponsor conducted a single placebo-controlled study, SCA102833, “The Evaluation of LAMICTAL as Add on Treatment for Bipolar I Disorder in Children and Adolescents 10 – 17 Years of Age”, to fulfill requirements of the Pediatric Research Equity Act (PREA), and the results are provided in this Supplemental New Drug Application (sNDA).

Study SCA102833 was a multicenter, parallel group, placebo-controlled, double-blind, randomized withdrawal study to evaluate the efficacy, safety, and tolerability of LAMICTAL as add-on maintenance therapy compared to maintenance mono- or dual therapy in male and female children and adolescents, 10 through 17 years of age, who had been diagnosed with Bipolar I Disorder. Maximum duration of participation was 60 weeks including a Screening Phase (~2 weeks), an open-label phase (up to 18 weeks), a double-blind, randomized withdrawal phase (up to 36 weeks) and an up to 4 week taper and follow-up phase.

Reviewer Comments

As SCA102833 is the only new study that was submitted in the sNDA, there was no clinical pharmacology review conducted. No changes in the clinical pharmacology sections were made to the approved label. Please refer to the medical review for details of the evaluation of the safety (b) (4)

/s/: Kofi A. Kumi, Ph.D., Clinical Pharmacology Reviewer

RD/FT Initialed by Hao Zhu, Ph.D., Team Leader, Clinical Pharmacology

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/s/

KOFI A KUMI
05/14/2015

HAO ZHU
05/14/2015