CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-137

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

Clinical Pharmacology and Biopharmaceutics NDA Review

Brand name: Fludarabine Phosphate Injection

Generic name: Fludarabine Phosphate Injection

Type of dosage form and strength(s): sterile solution intended for intravenous administration

Indication(s): the proposed indication is for, "The treatment of adult patients with B-cell chronic lymphocytic leukemia (CLL) who have not responded to or whose disease has progressed during treatment with at least one standard alkylating-agent containing regimen."

NDA number, type: NDA 22-137, 505 (b) (2)

Applicant name: EBEWE Pharma

Submission date (letter date): 22-November-2006 N 000

OCPB Division name: Division of Pharmaceutical Evaluation I

OND: Division name: Division of Oncology Drug Products

OCPB Reviewer name: Gene M. Williams, Ph.D.

OCPB Team Leader name: Brian P. Booth Ph.D.

Table of Contents

1. *Executive Summary*

1.1 Recommendations

This NDA is acceptable from the clinical pharmacology and biopharmaceutics perspective.

1.2 Identify recommended Phase 4 study commitments if the NDA is judged approvable

No Phase 4 commitments are recommended.

1.3 Summary of Clinical Pharmacology and Biopharmaceutics Findings

Fludarabine phosphate for injection was approved in 1991 with the trade name "Fludara." Fludara is supplied as a white, lyophilized solid cake. Each vial contains 50 mg of fludarabine phosphate. The current application is for fludarabine phosphate for injection supplied as a simple solution (50 mg in 2 mL).

No clinical pharmacology or efficacy and safety studies were conducted with the new formulation. Both Fludara and the new product are administered as simple solutions. With the exception of the instructions for reconstitution/dilution, the proposed package insert is a reproduction of the Fludara package insert.

2. Question-Based Review

No clinical pharmacology or efficacy and safety data was acquired with the new formulation.

3. Detailed Labeling Recommendations

With the exception of the instructions for reconstitution/dilution, the proposed package insert is a reproduction of the Fludara package insert. The proposed package insert is attached as Appendix 4.1.

4. *Appendices*

4.1 Applicant's Proposed Package Insert

Appendix 4.1 Applicant's Proposed Package Insert

Appears This Way
On Original

6 Page(s) Withheld

_____ Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Clin Pharm/Bio- 4

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/s/

Gene Williams
8/8/2007 05:51:44 PM
BIOPHARMACEUTICS

Brian Booth
8/23/2007 09:09:34 AM
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