CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214657Orig1s000

CLINICAL PHARMACOLOGY REVIEW(S)

Clinical Pharmacology NDA Memorandum	
NDA (SDN)	214657 (SDN 3)
Type/Category	Original NDA 505(b)(2)
Brand Name	Pemetrexed Injection
Generic name	Pemetrexed Injection
Proposed Indications	The same as Alimta®
Dosage Form and Strengths	Injection (25 mg/mL): 100 mg/4 mL, 500 mg/20 mL, 1000 mg/40 mL
Route of Administration	Intravenous infusion
Dosing Regimen	500 mg/m^2 as an intravenous infusion over 10 minutes on Day 1 of a 21-day cycle as a single agent or with cisplatin for patients with creatinine clearance of 45 mL/minute or greater
Sponsor	Sandoz Inc.
OCP Division	Division of Cancer Pharmacology (DCP) I & II
OND Division	Division of Oncology 2 (DO2)
Submission Date	7/7/2020
PDUFA	5/7/2021
Primary Reviewer	Yibo Wang, Ph.D.
Team Lead	Hong Zhao, Ph.D.

Sandoz submitted NDA 214657, Pemetrexed Injection via the 505(b)(2) pathway, relying on FDA's previous findings of safety and effectiveness for the Listed Drug (LD), Alimta® (pemetrexed for injection, 100 mg/vial and 500 mg/vial) for the clinical pharmacology information needed to support the safety and effectiveness of the proposed pemetrexed product.

The proposed drug product Pemetrexed Injection (25 mg/mL) is presented in three packaging configurations: 100 mg/4 mL, 500 mg/20 mL, and 1000 mg/40 mL. Pemetrexed Injection is in a different pharmaceutical dosage form compared to the LD. Alimta ® is a lyophilized powder for injection and requires initial reconstitution with 0.9% sodium chloride solution resulting in a 25 mg/mL pemetrexed solution. Further dilution is required prior to administration by intravenous infusion. The proposed product, Pemetrexed Injection, is a 'ready-to-dilute' 25 mg/mL solution, requiring only a single dilution step to deliver an equivalent pemetrexed solution for infusion.

Sandoz did not conduct in vivo bioavailability and/or bioequivalence (BE) studies to support this NDA. Sandoz requested a waiver of in vivo BE study for the proposed drug product to the LD, Alimta® under 21 CFR 320.22(b)(1). The proposed drug product contains different inactive ingredients compared to the LD (Alimta®). FDA has agreed that no additional clinical studies are required to support this 505(b)(2) application and this agreement was documented in the Pre-IND 149177 written response meeting minutes (DARRTS: 6/9/2020).

No clinical pharmacology studies have been conducted with the proposed pemetrexed product and there are no clinical pharmacology issues to be addressed in this NDA. The proposed labeling does not contain any changes to the clinical pharmacology sections compared to the labeling of the LD

Alimta®. No action is indicated.

SIGNATURES:

Yibo Wang, Ph.D. Reviewer Division of Cancer Pharmacology I	Hong Zhao, Ph.D. Team Leader Division of Cancer Pharmacology II

Cc: OOD DO2: RPM – K Korsah; MO – J Kim; MTL – N Drezner
DCP I: DD – B Booth; DCP II: DD – NA Rahman

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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04/08/2021 01:35:49 PM

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