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APPLICATION NUMBER:

214218Orig1s000

CLINICAL PHARMACOLOGY REVIEW(S)

Clinical Pharmacology NDA Memorandum	
NDA (SDN)	214218 (SDN 1)
Type/Category	Original NDA 505(b)(2)
Brand Name	Pemetrexed Injection
Generic name	Pemetrexed Injection
Proposed Indications	The same as Alimta®, expect for use in combination with pembrolizumab and platinum chemotherapy, in patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations
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	Hospira, Inc.
OCP Division	Division of Cancer Pharmacology (DCP) I & II
OND Division	Division of Oncology 2 (DO2)
Submission Date	4/23/2020
PDUFA	2/23/2021
Primary Reviewer	Yibo Wang, Ph.D.
Team Lead	Hong Zhao, Ph.D.

Hospira, Inc. submitted NDA 214218, 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. Per Hospira, an additional packaging configuration (1000 mg/40 mL) was added to enable the required dose (e.g. for patients with a body surface area of 1.8 m^2 would require a dose of 900 mg) to be prepared from one single-use vial.

Hospira requested bridging the proposed drug product to the LD product, Alimta® under 21 CFR 320.24(b)(6). It defers to the Biopharmaceutics review team to assess if it is acceptable to deem the proposed drug product bioequivalent to the LD under 21 CFR 320.24(b)(6) and biowaiver can

be granted.

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

Cc: OOD DO2: RPM – S Woods; MO – K Chon; MTL – E Larkins
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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