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APPLICATION NUMBER:

215331Orig1s000

CLINICAL PHARMACOLOGY REVIEW(S)

Clinical Pharmacology NDA Memorandum

NDA (SDN)	215331
Product Name	Bortezomib Injection
Submission Dates	09/27/2021
Submission Type; Code	505 (b)(2)
PDUFA Due Date	07/27/2022
Proposed Dosage Form / Strength	Solution / 3.5 mg/3.5 mL (1 mg/mL) in a single-dose vial 3.5 mg/1.4 mL (2.5 mg/mL) in a single-dose vial
Proposed Dosing Regimen	For intravenous use only. The recommended starting dose is 1.3 mg/m^2 administered as a 3 to 5 second bolus intravenous injection. Dose must be individualized to prevent overdose.
Proposed Indications	• treatment of adult patients with multiple myeloma • treatment of adult patients with mantle cell lymphoma
Applicant	MAIA Pharmaceuticals, INC.
OCP Reviewer	Nan Zheng, Ph.D.
OCP Team Leader	Olanrewaju Okusanya, Pharm.D., MS, BCPS
Clinical Division	DHM2

MAIA Pharmaceuticals, INC. (the Applicant) submitted a NDA for Bortezomib Injection, 3.5 mg/3.5 mL (1 mg/mL) or 3.5 mg/1.4 mL (2.5 mg/mL) in a single-dose vial under Section 505(b)(2). The Listed Drug (LD) is VELCADE (bortezomib) for injection, for subcutaneous or intravenous use, approved as single-dose vial containing 3.5 mg of bortezomib as lyophilized powder for reconstitution and withdrawal of the appropriate individual patient dose.

Compared with the LD, the indications, active moiety, dosing regimen, and route and duration of administration of the Applicant's products are the same as those for the intravenous use of VELCADE. The differences between the Applicant's proposed product and the LD include that the Applicant's product is provided as refrigerated, sterile solution in ready-to-use, single-dose vials while the LD is provided as lyophilized cake or powder for reconstitution. In addition, the Applicant's Bortezomib Injection product is intended for intravenous injection only while the LD can be administered via subcutaneous or intravenous injection.

The Applicant conducted an in vitro study to bridge formulation differences and submitted a biowaiver request. (b) (4) Otherwise, there are no changes to the clinical pharmacology sections of the label.

This NDA submission does not contain any clinical pharmacology studies and does not involve changes to the clinical pharmacology sections of the labeling. Therefore, there are no clinical pharmacology issues if the Applicant's biowaiver request is granted and a clinical pharmacology review is not warranted.

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/s/

NAN ZHENG
06/06/2022 04:27:24 PM

OLANREWAJU OKUSANYA
06/10/2022 09:46:40 AM