CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215331Orig1s000

CLINICAL REVIEW(S)

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: July 27, 2022

FROM: Dave Bak, PharmD, BCNSP, Regulatory Project Manager

SUBJECT: Financial Disclosure

APPLICATION NUMBER: NDA 215331

PRODUCT NAME AND STRENGTH: Bortezomib Injection, 3.5 mg/3.5 mL and 3.5 mg/1.4 mL

APPLICANT NAME: MAIA Pharmaceuticals, Inc.

There are no clinical studies submitted in this 505(b)(2) NDA, thus inclusion of financial disclosure is not required.

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/s/

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07/27/2022 11:29:31 AM

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Combined Clinical and Labeling Review of the Prescribing Information

Product Title	Bortezomib Injection
Applicant	MAIA Pharmaceuticals Inc
Application/Supplement Number	215331
Type of Application/Submission[1]	505(b)(2)
Review Division/Office	Division of Hematologic Malignancies 2/Office of Oncologic Diseases
Is Proposed Labeling in "Old" Format?	N
Is Labeling Being Converted to PLR?	N
Is Labeling Being Converted to PLLR?	N
Proposed Indication(s)	• Treatment of adult patients with multiple myeloma • Treatment of adult patients with mantle cell lymphoma
Approved Indication(s)	
Date FDA Received Application	September 27, 2021
Review Classification (Priority/Standard)	Standard
PDUFA Goal Date	July 27, 2022
Review Date	June 1, 2022
Clinical Reviewer	Candis Morrison, PhD, CRNP
Clinical Team Lead	Bindu Kanapuru, MD
Associate Director for Labeling	Elizabeth Everhart, MSN, ACNP

This joint Associate Director for Labeling (ADL) and Clinical review provides recommendations on the content and format of the United States Prescribing Information (USPI) to help ensure that the USPI:

- Is compliant with Physician Labeling Rule (PLR) [including the Pregnancy and Lactation Labeling Rule (PLLR)] requirements,[2]
- Is consistent with labeling guidance recommendations[3] and with CDER labeling policies, as appropriate,
- Conveys the essential scientific information needed for safe and effective use of the drug,
- Is clinically meaningful and scientifically accurate,
- Is a useful communication tool for health care practitioners, and
- Is consistent with other USPI with the same active moiety, drug class, or similar indication, as appropriate

Regulatory History

- 7/29/2021 Type B Pre-NDA meeting

- 9/25/2021 NDA received pursuant to Section 505(b)(2)
- 11/10/2021 The submission was deemed fileable
- 2/2/2022 Division received Patent Amendment in accordance with 21CFR 314.95(a)
- 4/11/2022 Labeling meeting held; FDA-revised labeling communicated to applicant
- 4/25/2022 Labeling meeting to review applicant response; FDA revised labeling communicated to applicant
- 5/13/2022 Wrap-up and labeling meeting; FDA-revised labeling comments communicated to applicant

Clinical Review:

The Listed Drug identified by the applicant is Velcade(bortezomib) for injection, 3.5 mg/vial, NDA021602.VELCADE is marketed in a single product presentation (3.5 mg as a sterile lyophilized powder in a clear single-use vial) for use as a proteasome inhibitor indicated for treatment of adult patients with multiple myeloma or with mantle cell lymphoma.

The active pharmaceutical ingredient, concentration, dosing regimen and indications sought for the MAIA formulation are the same as the LD. The products differ on their excipient profile and in need for reconstitution of the LD, The MAIA product has two presentations – 3.5 mg/1.4 mL (2.5 mg/mL) and 3.5 mg/3.5 mL (1 mg/mL) – in ready-to-use single-dose vials for intravenous administration only

No clinical data was submitted with this 505(b)(2) NDA.

The Applicant submitted a pediatric study plan PSP in the NDA. A request for waiver of pediatric studies in included in Section 1.9.1.

Labeling Review:

The USPI submitted by the applicant was compared to the approved USPI for the listed drug, Velcade. Edits were made to the title of this product since it does not have a proposed proprietary name. Throughout the USPI, when referring to this product, the title was changed to Bortezomib Injection; when referring to data from the listed drug, the product was referred to as bortezomib.

In section 2 Dosage and Administration, revisions were made to clarify that this product is only indicated as an intravenous injection. In section 11 Description, the pharmacological class 'proteasome inhibitor' was added per 21 CFR 201.57 (c)(12)(e). Revisions were also made to align with recent updates to the listed drug in section 6.2 Postmarketing Experience that added the adverse reactions Guillain Barré syndrome and demyelinating polyneuropathy, as well as changes to align with current labeling practices in the PLLR sections to and to correct some

formatting issues and add missing cross references throughout.

Per 21 CFR 201.57 (d)(8), the Highlights (HL) of the USPI should not exceed ½ page; the HL for this USPI exceeds ½ page and a waiver for this requirement is acceptable.

Labeling Review Conclusion:
At the completion of labeling negotiations, the USPI is acceptable from the ADL standpoint. See the USPI attached to the approval letter for final agreed upon labeling.

Regulatory Recommendation: NDA 215331, Bortezomib Injection for intravenous administration only, can be granted approval for the treatment of adult patients with multiple myeloma and treatment of adult patients with mantle cell lymphoma.

[1] Examples include: Original Biologics License Application (BLA), New Molecular Entity (NME) NDA, Original NDA, NDA Efficacy Supplement, 505(b)(2) New Drug Application (NDA), New Chemical Entity (NCE) NDA, NDA Prior Approval Labeling Supplement, NDA CBE-0 Labeling Supplement

[2] See January 2006 Physician Labeling Rule; 21 CFR 201.56 and 201.57; and December 2014 Pregnancy and Lactation Labeling Rule (the PLLR amended the PLR regulations). For applications with labeling in non-PLR "old" format, see 21 CFR 201.56(a) and (e) and 201.80.

[3] See Prescription Drug Labeling Resources website for PLR labeling guidances. When final, guidances represent the FDA's current thinking on a topic. Applicants can use an alternative approach if it satisfies statutory and regulatory requirements.

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/s/

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