CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216078Orig1s000

CLINICAL REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center For Drug Evaluation and Research
Division of Hematologic Malignancies 2

MEMORANDUM

Date:	12/1/2022	**Tentative Approval**	7/14/2022
From:	M. OConnor, PhD, RN, Clinical Analyst E. Everhart, MSN, RN, ACNP, Associate Director for Labeling		
To:	Electronic Document Record		
Sponsor	Baxter Healthcare Corp.	**Drug:**	Bendamustine Hydrochloride
Subject:	NDA 216078 505(b)(2) Bendamustine Class 1 Resubmission		
Resubmission Date	10/31/2022	**PDUFA Due Date:**	12/31/2022
Through:	Nicholas Richardson, DO, MPH - Clinical Team Lead		

There are no changes included in this resubmission that would alter the conclusion that this NDA can receive final clinical approval for the specified indications. For details regarding the initial submission, please see the clinical review submitted to DARRTs on 6/9/2022 and the labeling review submitted to DARRTS on 5/11/2022. Because no clinical data was included in the application, no financial disclosure information was provided.

Labeling Recommendations

The following minor edits were made:

- In section 2.1, italics were added to a cross reference.
- In section 8.3, an incorrect cross reference was removed.
- In section 15, a missing hyperlink was added.
- In section 16 the phrase (b) (4) was removed to align with current labeling practice.

The USPI is acceptable with the changes described above and is recommended for approval.

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/s/

MADELINE B O'CONNOR
12/01/2022 01:25:01 PM

ELIZABETH E EVERHART
12/01/2022 01:42:31 PM

NICHOLAS C RICHARDSON
12/01/2022 03:07:03 PM

BINDU N KANAPURU
12/02/2022 03:21:14 PM

Memorandum
Clinical Review 505(b)(2) NDA
Division of Hematologic Malignancies 2

Date	09 June 2022
NDA/BLA #	NDA 216078
Applicant	Celerity Pharmaceuticals, LLC
Date of Submission	14 September 2021
PDUFA Goal Date	14 July 2022
Drug	Bendamustine Hydrochloride
Dosage form(s) / Strength(s)	Injection; 100mg/4mL (25 mg/mL)
Clinical Reviewer	Pamela Seam, MD
Clinical Team Lead	Nicholas Richardson, DO MPH
Signatory	Nicole J. Gormley, MD
Applicant Proposed Indication(s)/Population(s)	• Treatment of patients with chronic lymphocytic leukemia • Treatment of patients with indolent B-cell NHL that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen
Recommendation on Regulatory Action	Tentative Approval
Recommended Indication(s)/Population(s) (if applicable)	• Treatment of patients with chronic lymphocytic leukemia • Treatment of patients with indolent B-cell NHL that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen

Summary

On 14 September 2021, DHM2 received a submission for New Drug Application pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for bendamustine hydrochloride by Celerity Pharmaceuticals, LLC. The Listed Drug (LD) identified by the Applicant is BELRAPZO (bendamustine hydrochloride, NDA 205580) injection 100 mg/4mL (25mg/mL).

The active pharmaceutical ingredient, dosage form, concentration, route of administration, dosing regimen and indications sought for the Celerity formulation are the same as the LD. The products differ on their excipient profile (See CMC review for further information).

No clinical data was submitted with this 505(b)2 NDA submission for bendamustine. The proposed indications are the same as those for the listed drug, BELRAPZO. The label was updated to align with the label for the listed drug. Final agreed upon labeling was submitted on 11 May 2022.

Conclusion: Based on the clinical review, NDA 216078 for bendamustine for the *treatment of patients with chronic lymphocytic leukemia and treatment of patients with indolent B-cell NHL that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen* can be granted tentative approval.

See the CDTL Review for additional information for this application.

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/s/

NICHOLAS C RICHARDSON on behalf of PAMELA SEAM
06/09/2022 11:22:15 AM

NICHOLAS C RICHARDSON
06/09/2022 11:22:58 AM

NICOLE J GORMLEY
06/09/2022 02:22:30 PM