CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761145Orig1s000

OTHER REVIEW(S)

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

******Pre-decisional Agency Information******

Memorandum

Date: April 24, 2020

To: Kimberly Scott, RN, BSN, OCN, Senior Regulatory Project Manager
Division of Hematologic Malignancies 2 (DHM2)

Stacy Shord, PharmD, BCOP, Associate Director for Labeling, (DHM2)

From: Adesola Adejuwon, PharmD, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Kevin Wright, PharmD, Team Leader, OPDP

Subject: OPDP Labeling Comments for DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj) injection, for subcutaneous use

BLA: 761145

In response to DHM2 consult request dated September 8, 2019, OPDP has reviewed the proposed product labeling (PI) and patient package insert (PPI) for the original BLA submission for DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj) injection, for subcutaneous use (Darzalex Faspro).

PI and PPI: OPDP's comments on the proposed labeling are based on the draft PI received by electronic mail from DHM2 (Kimberly Scott) on April 17, 2020 and are provided below.

A combined OPDP and Division of Medical Policy Programs (DMPP) review was completed, and comments on the proposed PPI were sent under separate cover on April 24, 2020.

Thank you for your consult. If you have any questions, please contact Adesola Adejuwon at (240) 402-5773 or Adesola.Adejuwon@fda.hhs.gov.

27 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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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/

ADESOLA F ADEJUWON
04/24/2020 07:06:48 PM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Medical Policy

PATIENT LABELING REVIEW

Date:	April 24, 2020
To:	Kimberly Scott, RN, BSN, OCN Senior Regulatory Project Manager **Division of Hematologic Malignancies 2 (DHM2)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Morgan Walker, PharmD, MBA, CPH Senior Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Adesola Adejuwon, PharmD, MBA Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Patient Package Insert (PPI)
Drug Name (established name):	DARZALEX FASPRO (daratumumab and hyaluronidase-fihj)
Dosage Form and Route:	injection, for subcutaneous use
Application Type/Number:	BLA 761145
Applicant:	Janssen Research and Development, LLC.

1 INTRODUCTION

On July 12, 2019, Janssen Biotech, Inc. submitted for the Agency's review an original Biologic License Application (BLA) 761145 DARZALEX FASPRO (daratumumab and hyaluronidase-fihj). This original BLA proposes to support the use of subcutaneous daratumumab co-formulated with recombinant human hyaluronidase for the treatment of adult patients with multiple myeloma.

This collaborative review is written by the Division of Medical Policy Programs (DMPP) and the Office of Prescription Drug Promotion (OPDP) in response to a request by the Division of Hematology Products (DHP) on September 6, 2019 for DMPP and OPDP to review the Applicant's proposed Patient Package Insert (PPI) for DARZALEX FASPRO (daratumumab and hyaluronidase-fihj).

2 MATERIAL REVIEWED

- Draft DARZALEX FASPRO (daratumumab and hyaluronidase-fihj) PPI received on July 12, 2019, and received by DMPP and OPDP on April 16, 2020.
- Draft DARZALEX FASPRO (daratumumab and hyaluronidase-fihj) Prescribing Information (PI) received on July 12, 2019, and received by DMPP and OPDP on April 16, 2020.

3 REVIEW METHODS

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60%. A reading ease score of 60% corresponds to an 8th grade reading level.

Additionally, in 2008 the American Society of Consultant Pharmacists Foundation (ASCP) in collaboration with the American Foundation for the Blind (AFB) published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. The ASCP and AFB recommended using fonts such as Verdana, Arial or APHont to make medical information more accessible for patients with vision loss.

In our collaborative review of the PPI we:

- simplified wording and clarified concepts where possible
- ensured that the PPI is consistent with the Prescribing Information (PI)
- removed unnecessary or redundant information
- ensured that the PPI is free of promotional language or suggested revisions to ensure that it is free of promotional language
- ensured that the PPI meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)

4 CONCLUSIONS

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