CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

125559Orig1s014

OTHER REVIEW(S)

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

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

Memorandum

Date: August 14, 2018

To: Julie K. Golden, M.D., Medical Officer
Division of Metabolism and Endocrinology Products (DMEP)

Patricia Madara, Project Manager, (DMEP)

Monika Houstoun, Associate Director for Labeling, (DMEP)

From: Charuni Shah, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Melinda McLawhorn, Team Leader, OPDP

Subject: OPDP Labeling Comments for PRALUENT® (alirocumab) injection, for subcutaneous use

BLA: 125559/S-014

In response to DMEP's consult request dated July 16, 2018, OPDP has provided a focused review, as requested by DMEP, of the proposed product labeling (PI) and patient package insert (PPI) for PRALUENT® (alirocumab) injection, for subcutaneous use (Praluent). This supplement proposes revisions to the PI based on results from the ESCAPE trial as it relates to the use of Praluent in HeFH patients requiring apheresis.

PI and PPI: OPDP's review of the proposed labeling are based on the draft PI and submitted electronically by the Division of Metabolism and Endocrinology on July 27, 2018. OPDP does not have any comments on the proposed labeling at this time.

Thank you for your consult. If you have any questions, please contact Charuni Shah at (240) 402-4997 or charuni.shah@fda.hhs.gov.

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

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/s/

CHARUNI P SHAH
08/14/2018

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

PATIENT LABELING REVIEW

Date:	July 27, 2018
To:	William Chong, M.D. Acting Director **Division of Metabolism and Endocrinology Products (DMEP)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Sharon W. Williams, MSN, BSN, RN Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)**
Subject:	DMPP Concurrence with Submitted: Patient Package Insert (PPI)
Drug Name (established name):	PRALUENT (alirocumab)
Dosage Form and Route:	injection, for subcutaneous use
Application Type/Number:	BLA 125559
Supplement Number:	S-014
Applicant:	Sanofi-aventis U.S. LLC

1 INTRODUCTION

On October 24, 2017 Sanofi-aventis U.S. LLC submitted for the Agency's review a Supplemental BLA (sBLA) for PRALUENT (alirocumab), injection, for subcutaneous use. The sBLA is submitted to update the USPI with clinical information from the ESCAPE study as it relates to the use of PRALUENT (alirocumab), injection for subcutaneous use in heterozygous familial hypercholesterolemia (HeFH) patients undergoing apheresis.

PRALUENT (alirocumab), injection, for subcutaneous use is indicated for the treatment of adults with HeFH or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-cholesterol (LDL-C).

On December 12, 2017, the Division of Metabolism and Endocrinology Products (DMEP) requested that the Division of Medical Policy Programs (DMPP) review the Applicant's proposed PPI for PRALUENT (alirocumab), injection, for subcutaneous use.

This memorandum documents the DMPP review and concurrence with the Applicant's proposed PPI for PRALUENT (alirocumab), injection, for subcutaneous use.

2 MATERIAL REVIEWED

- Draft PRALUENT (alirocumab) PPI received on October 24, 2017, and received by DMPP on July 26, 2018.
- Draft PRALUENT (alirocumab) Prescribing Information (PI) received on December 12, 2017, revised by the Review Division throughout the review cycle, and received by DMPP on July 26, 2018.

3 CONCLUSIONS

We find the Applicant's proposed PPI is acceptable as submitted.

4 RECOMMENDATIONS

- Consult DMPP regarding any additional revisions made to the Prescribing Information (PI) to determine if corresponding revisions need to be made to the PPI.

Please let us know if you have any questions.

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/s/

SHARON W WILLIAMS
07/27/2018

LASHAWN M GRIFFITHS
07/27/2018