# CENTER FOR DRUG EVALUATION AND RESEARCH

**APPLICATION NUMBER:** 

# 125319Orig1s085, 086, 087

## **PRODUCT QUALITY REVIEW(S)**



#### Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research Office of Biotechnology Products

#### Memorandum of Review

Date:

9/16/2016

To:

File for STN: 125319/85, 86, 87

From:

Chikako Torigoe, CDER/OBP/DBRRII

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Through:

Rashmi Rawat, Team Leader, CDER/OBP/DBRRII

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Juhong Liu, Acting Review Chief, CDER/OBP/DBRRII

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Date: 2016.09.21.12304:12-04700\*

Subject:

Addition of new indications: Tumor necrosis factor receptor associated

periodic syndrome (TRAPS), hyperimmunoglobulin D

syndrome/mevalonate kinase deficiency (HIDS/MKD), familial

Mediterranean fever (FMF)

Applicant:

**Novartis** 

**Product:** 

Canakinumab (Ilaris), human IgG1(κ) against IL-1β

Indications:

Cryopyrin-associated periodic syndromes, systemic juvenile idiopathic

arthritis

Supplement Receipt Date: SUPPL-85: 3/23/2016, SUPPL-86: 3/28/2016, SUPPL-87: 3/29/2016

PDUFA Goal Date: 9/23/2016

Link: \\Cdsesub1\evsprod\BLA125319\125319.enx

**Recommendation:** From product quality perspective, the liquid in vial dosage form is comparable to the currently approved powder for solution dosage form.

#### **Review Summary**

These three supplements propose the addition of new indications for canakinumab. These indications are TRAPS, HIDS/MKD and FMF. For the clinical studies of these indications, a new presentation of canakinumab drug product, 150 mg/mL solution for injection in vial, was used. The product quality information and the results of comparability assessments of this new drug product presentation with the currentlyapproved canakinumab powder for solution for injection were submitted in the

supplement 85 and in the CMC supplement 88. The CMC supplement 88 contains the manufacturing, comparability and labeling information on the new liquid in vial drug product presentation. The review of the comparability study of product quality of liquid in vial dosage form to powder for solution concluded that both dosage forms are comparable. However, the supplement 88 was issued a complete response on 7/29/2016 due to microbiological issues.

The review of the product quality information and the results of comparability assessment of the two drug product dosage forms, liquid in vial and the currently-approved powder for solution for injection is on file for the supplement 88. The review of the proposed label that includes the information on the new drug product presentation was performed by Jibril Abdus-Samad in OBP and is on file for the supplement 88.

#### **Environmental Assessment**

The sponsor requested a categorical exclusion from the environmental assessment requirement pursuant to 21 CFR 25.15 (d) based on the exclusion allowed by 21 CFR 25.31 (b and c) and the request is acceptable.

**Conclusion:** From the product quality perspective, canakinumab liquid in vial dosage form is comparable to the currently approved powder for solution for injection dosage form.

BLA-125319-SUPPL-85 » Manufacturing Facility Inspection

### **Overall Manufacturing Inspection Recommendation**

Task Summary	Task Details	Documents	Approvals	Updates	Application Life Cycle
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BLA-125319-SUPPL-86 » Manufacturing Facility Inspection

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BLA-125319-SUPPL-87 » Manufacturing Facility Inspection

### **Overall Manufacturing Inspection Recommendation** Task Summary Task Details Documents Approvals Updates Application Life Cycle Inspection Management Form As of Sep 2, 2016 10:06 am G **Inspection Management Form** BLA-125319-SUPPL-87 (b) (4) NOVARTIS PHARMACEUTICALS CORPORATION | 2416082 | SVL SMALL VOLUME PARENTERAL, LYOPHILIZED | -NOVARTIS PHARMA STEIN AG | 3002653483 | SVL SMALL VOLUME PARENTERAL, LYOPHILIZED | Approve Facility + NOVARTIS PHARMA STEIN AG | 3002653483 | SVS STERILE-FILLED SMALL VOLUME PARENTERAL DRUGS | Approve Facility + NOVARTIS PHARMA AG | 3002807772 | CTL CONTROL TESTING LABORATORY | Approve Facility -(b) (4) NOVARTIS PHARMA SAS CENTRE DE BIOTECHNOLOGIE | 3004864869 | TRP THERAPEUTIC RECOMBINANT PRODUCTS | Approve Facility -(b) (4) **Overall Manufacturing Inspection Recommendation** Approve Withhold

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Submission Manufacturing Facilities								
Facility Status	Completion Date	Project Name	FEI	DUNS	Global ID	Facility Name		
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