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APPLICATION NUMBER:

212035Orig1s000

NON-CLINICAL REVIEW(S)

MEMORANDUM

DATE: May 26, 2021

TO: File for NDA 212035

FROM: Pedro L. Del Valle, PhD., FATS
Pharmacology-Toxicology Supervisor (Acting)
Division of Pharmacology & Toxicology-CHEN
Office of Cardiology, Hematology, Endocrinology, & Nephrology (OCHEN)

SUBJECT: NDA 212035 SDN 14
NDA type: 505(b)(2)
Applicant: Accord Healthcare Inc.
Drug: Argatroban injection in 0.9% sodium chloride, 1 mg/mL, 50 mL vial.
Indication: Prophylaxis or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia (HIT) and as an anticoagulant in adult patients with or at risk for HIT undergoing percutaneous coronary intervention (PCI).

Accord Healthcare originally submitted NDA 212035, for Argatroban injection in 0.9% sodium chloride, 1 mg/mL, 50 mL on 04/30/2018 under a 505(b)(2) NDA pathway. During the first review cycle the Reference Listed Drug (RLD) was changed from (b) (4) to Eagle Pharmaceuticals Inc. (NDA 022434). NDA 212035 currently refers to the RLD, for ARGATROBAN injection in 0.9% Sodium Chloride, 1 mg/mL, 50 mL, by Eagle Pharmaceuticals Inc (NDA 022434).

Nonclinical Data
No nonclinical study reports are provided with this application. Argatroban is a direct thrombin inhibitor that reversibly binds to the thrombin active site. Argatroban inhibits thrombin with an inhibition constant (Ki) of 0.04 μM. Argatroban is capable of inhibiting the action of both free and clot-associated thrombin.

Labeling
The label was updated during the first review cycle to comply with the Pregnancy and Lactation Labeling Rule (PLLR) content and format requirements. Labeling was resubmitted and reviewed based on the currently listed RLD label (NDA 022434 for ARGATROBAN by Eagle Pharmaceuticals Inc). Revisions were recommended based on the most recently approved RLD.

Regulatory Recommendation
Accord Healthcare Inc.'s Argatroban for injection 505(b)(2) NDA 212035 is approvable from the perspective of Pharmacology-Toxicology.

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/s/

PEDRO L DELVALLE
05/26/2021 09:48:56 PM

MEMORANDUM

Date: January 24, 2019

To: File for NDA 212035

From: Emily Place, PhD MPH
Pharmacology-Toxicology Reviewer
Division of Hematology Oncology Toxicology (DHOT)
Office of Hematology and Oncology Products (OHOP)

Through: Christopher Sheth, PhD
Pharmacology-Toxicology Supervisor
Division of Hematology Oncology Toxicology (DHOT)
Office of Hematology and Oncology Products (OHOP)

Subject: NDA 212035 SDN 1
NDA: 212035
NDA type: 505(b)(2)
Applicant: Accord Healthcare Inc.
Drug: Argatroban injection in 0.9% sodium chloride, 1 mg/mL, 50 mL vial.
Indication: Prophylaxis or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia (HIT) and as an anticoagulant in adult patients with or at risk for HIT undergoing percutaneous coronary intervention (PCI).

Accord Healthcare Inc., is relying on the FDA's previous findings of safety and effectiveness for the listed drug (b) (4) Argatroban Injection in 0.9% Sodium Chloride, (b) (4) (1 mg/mL).

No nonclinical study reports are provided with this application. Argatroban is a direct thrombin inhibitor that reversibly binds to the thrombin active site. Argatroban inhibits thrombin with an inhibition constant (Ki) of 0.04 μM. Argatroban is capable of inhibiting the action of both free and clot-associated thrombin.

1.3 Recommendations

1.3.1 Approvability

Accord Healthcare Inc.'s Argatroban for injection 505(b)(2) NDA 212035 is approvable from the perspective of pharmacology/toxicology.

1.3.3 Labeling

The label was updated to comply with the Pregnancy and Lactation Labeling Rule (PLLR) content and format requirements.

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/s/

EMILY J PLACE
01/24/2019 12:41:41 PM

CHRISTOPHER M SHETH
01/24/2019 12:42:57 PM
I concur.