Clinical Pharmacology Review Memo

Application Type	BLA
Application Number	761343
SDN	35
Received Date	October 16, 2023
BsUFA Goal Date	April 16, 2024
Clinical Division	Dermatology and Dentistry
OCP Division	Division of Inflammation and Immune Pharmacology (DIIP)
Product Code Name	AVT04
Proposed Nonproprietary Name	Ustekinumab-aekn
Proposed Proprietary Name	Selarsdi
Pharmacologic Class	Interleukin-12 and -23 antagonist
Applicant	Alvotech USA Inc.
Applicant Proposed Indication(s)	• Plaque psoriasis (PsO) • Pediatric patients 6 years and older with plaque psoriasis (pPsO) • Psoriatic arthritis (PsA) • Pediatric patients 6 years and older with psoriatic arthritis (pPsA)
Clinical Pharmacology Reviewer	Anand Balakrishnan Ph.D.
Clinical Pharmacology Team Leader	Chinmay Shukla Ph.D.

This is a resubmission of BLA 761343 which was previously issued a complete response letter (October 11, 2023).

The clinical pharmacology review was completed and included in the Biosimilar Multidisciplinary Evaluation and Review (BMER) for the original submission. No new clinical pharmacology related information was provided by the Applicant in the current submission.

In the current review cycle, Office of Study Integrity and Surveillance (OSIS) inspection for the clinical and bioanalytical sites were requested for this application. In their assessment (memos dated January 5, 2024 and March 19, 2024), OSIS didn't identify any major issues and concluded that data from the reviewed studies were reliable.

From a clinical pharmacology perspective, there are no issues that would preclude the approval of this submission.

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/s/

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04/03/2024 02:31:13 PM

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04/03/2024 03:34:59 PM