

## Clinical Pharmacology Review Memo

<b>Application Type</b>	BLA
<b>Application Number</b>	761343
<b>SDN</b>	35
<b>Received Date</b>	October 16, 2023
<b>BsUFA Goal Date</b>	April 16, 2024
<b>Clinical Division</b>	Dermatology and Dentistry
<b>OCP Division</b>	Division of Inflammation and Immune Pharmacology (DIIP)
<b>Product Code Name</b>	AVT04
<b>Proposed Nonproprietary Name</b>	Ustekinumab-aekn
<b>Proposed Proprietary Name</b>	Selarsdi
<b>Pharmacologic Class</b>	Interleukin-12 and -23 antagonist
<b>Applicant</b>	Alvotech USA Inc.
<b>Applicant Proposed Indication(s)</b>	<ul style="list-style-type: none"><li>• Plaque psoriasis (PsO)</li><li>• Pediatric patients 6 years and older with plaque psoriasis (pPsO)</li><li>• Psoriatic arthritis (PsA)</li><li>• Pediatric patients 6 years and older with psoriatic arthritis (pPsA)</li></ul>
<b>Clinical Pharmacology Reviewer</b>	Anand Balakrishnan Ph.D.
<b>Clinical Pharmacology Team Leader</b>	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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ANAND BALAKRISHNAN  
04/03/2024 02:31:13 PM

CHINMAY SHUKLA  
04/03/2024 03:34:59 PM