CLINICAL PHARMACOLOGY REVIEW

BLA Number:	761059/S-006
Submission Date:	03/10/2022
Submission Type:	BLA supplement
Approved Brand Name:	HADLIMA
Generic Name:	Adalimumab-bwwd
Applicant:	Samsung Bioepis Co., Ltd.
Route of Administration:	Subcutaneous injection
Dosage Form:	Single-dose prefilled autoinjector (HADLIMA PushTouch) Single-dose prefilled glass syringe Single-dose glass vial for institutional use only
Dosage Strength:	40 mg/0.8 mL (all dosage forms) 40 mg/0.4 mL (autoinjector and prefilled syringe only)
Proposed Dosing Regimen:	• Initial dose of 160 mg SC (given in one day or split over two consecutive days) followed by 80 mg two weeks later (Day 15). • Begin 40 mg weekly or 80 mg every other week dosing two weeks later (Day 29).
Proposed Population and Indication(s):	For the treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients
OND Division:	Division of Dermatology and Dentistry (DDD)
OCP Division:	Division of Inflammation and Immune Pharmacology (DIIP)
Reviewer:	Amer Al-Khouja, Ph.D., M.H.S.
Team Leader:	Chinmay Shukla, Ph.D.

1. Executive Summary

The Applicant, Samsung Bioepis Co., Ltd., submitted a BLA supplement to support licensure of adalimumab-bwwd (HADLIMA) for the treatment of moderate to severe hidradenitis suppurativa (HS) in adult patients. Adalimumab-bwwd is a recombinant human IgG1 monoclonal antibody that targets tumor necrosis factor (TNF)-α. Adalimumab-bwwd was initially approved in July 2019 as a biosimilar to HUMIRA (adalimumab). Adalimumab-bwwd is currently approved for the following indications:

- Rheumatoid arthritis (RA) in adults
- Juvenile idiopathic arthritis (JIA) in patients 2 years of age and older
- Psoriatic arthritis (PsA) in adults
- Ankylosing spondylitis (AS) in adults
- Crohn's disease (CD) in adults and pediatric patients 6 years of age and older
- Ulcerative colitis (UC) in adults
- Plaque psoriasis (Ps) in adults

Approval for HS was not initially sought by the Applicant as the reference product was granted Orphan Drug Exclusivity when approved for the treatment of HS in September 2015. The Applicant is now seeking licensure of adalimumab-bwwd for the treatment of HS in adults due to expiration of Orphan Drug Exclusivity for the reference product.

The proposed dosage for treatment of adult HS is the same as that approved for the reference product:

- Initial subcutaneous (SC) dose of 160 mg (given in one day or split over two consecutive days), followed by 80 mg two weeks later (Day 15).
- Begin 40 mg weekly or 80 mg every other week dosing two weeks later (Day 29).

The Applicant did not submit any new clinical studies to support the proposed indication extension. As such, there is no new data to be reviewed by Clinical Pharmacology. Original BLA approval was supported by three clinical studies, including a comparative clinical study in patients with active RA (Study SB5-G31-RA). Additional information was also provided to justify extrapolation of biosimilarity to other indications. Since biosimilarity of this product has already been established with HUMIRA, extrapolation of this information to support approval of this product for the treatment of moderate to severe hidradenitis suppurativa in adult patients is reasonable from a Clinical Pharmacology perspective.

1.1 Recommendation: The Office of Clinical Pharmacology has reviewed this supplemental BLA submission and found it acceptable from a clinical pharmacology standpoint.

1.2 Post-marketing requirements and commitments: None

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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02/15/2023 01:41:07 PM

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02/15/2023 01:52:24 PM