MEDICAL OFFICER REVIEW
Division of Pulmonology, Allergy, and Critical Care

Application:	BLA761070 S-020	**Application Type:**	sBLA
Sponsor:	AstraZeneca	**Name:**	benralizumab (Fasenra)
Category:	Antil-IL5Ra	**Route of Administration:**	Subcutaneous
Medical Officer:	Diana Nichols-Vinueza, M.D.	**Indication:**	Add-on maintenance treatment of patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype
Team Leader:	Miya Paterniti, M.D.	**Review Date:**	March 11, 2024

SUBMISSIONS REVIEWED IN THIS DOCUMENT

Document Date	CDER Stamp Date	Submission Type	Comments
February 26, 2024	February 26, 2024	Efficacy Supplement-S20 Resubmission/Class 2	SD1113, eCTD 1105 PBRER (eCTD 1068) DSUR (IND 100237, eCTD 0603).

REVIEW SUMMARY: This is the clinical review for the response to the Complete Response (CR) letter for BLA 761070 S-020 for benralizumab as an add-on maintenance treatment of patients aged 6 to < 12 years with severe asthma, and with an eosinophilic phenotype. Benralizumab is a humanized, afucosylated, monoclonal antibody that binds specifically to the human interleukin-5 receptor alpha subunit on the target cell and directly depletes eosinophils through antibody-dependent cell-mediated cytotoxicity. Benralizumab was approved in 2017 for the same indication for patients 12 years of age and older.

The original supplemental BLA (sBLA), submitted on March 9, 2023, received a CR on January 9, 2024, referring to the deficiencies indicated on Form 483 that was issued following a current good manufacturing practice (CGMP) inspection of the Applicant's contract facility, (b) (4) listed in the sBLA application. Otherwise, the original sBLA supported the efficacy and safety of benralizumab for patients aged 6 to < 12 years as add-on maintenance treatment with severe asthma, and with an eosinophilic phenotype (see January 8, 2024, Unireview). Agreed upon label was submitted December 14, 2023.

This sBLA resubmission consists of the 90-day inspection classification decisional letter and refers to a previously submitted Periodic Benefit-Risk Evaluation Report (PBRER) and Development Safety Update Report (DSUR) to address the safety update requirement outlined in the CR letter.
FDA conducted an inspection of the contract facility at issue ((b) (4) from (b) (4) to (b) (4). FDA determined that the inspection classification of this facility is "voluntary action indicated" (VAI). Based on this inspection, this facility is in a minimally acceptable state of compliance regarding current CGMP.

The PBRER was for the period of November 14, 2022, to November 13, 2023, and the DSUR was from for the period of November 14, 2022, to November 13, 2023. There are no new safety signals identified in the safety update. The sBLA remains approvable from the clinical perspective.

OUTSTANDING ISSUES: None

RECOMMENDED REGULATORY ACTION: Approval

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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03/12/2024 02:58:53 PM

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