4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0964]

GlaxoSmithKline Intellectual Property Development Ltd. England; Announcement of the Revocation of the Biologics License for BLENREP

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the revocation of the biologics license for BLENREP (belantamab mafodotin-blmf) powder for injection. GlaxoSmithKline Intellectual Property Development Ltd. England (GSK) requested withdrawal (revocation) of the biologics license and has waived its opportunity for a hearing.

DATES: The biologics license application (BLA) is revoked as of February 6, 2023.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On August 5, 2020, FDA approved the BLA for BLENREP (belantamab mafodotin-blmf) powder for injection held by GlaxoSmithKline Intellectual Property Development Ltd. England (GSK), c/o GlaxoSmithKline, 1250 South Collegeville Rd., Collegeville, PA 19426, indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent, under the Agency's accelerated approval regulations, 21 CFR part 601, subpart E. On November 2, 2022, FDA and GSK met to discuss the results of the confirmatory study required as a condition of BLENREP's accelerated approval, entitled "Study of Single Agent Belantamab Mafodotin Versus Pomalidomide Plus Low-dose Dexamethasone (Pom/Dex) in Participants with

Relapsed/Refractory Multiple Myeloma (DREAMM-3 trial)" and considerations regarding withdrawal (revocation) of the biologics license for BLENREP because the confirmatory DREAMM-3 trial did not meet its primary endpoint to demonstrate superior progression-free survival. On November 18, 2022, GSK requested withdrawal (revocation), in writing, of the biologics license for BLENREP (belantamab mafodotin-blmf) powder for injection (BLA 761158) under § 601.5(a) (21 CFR 601.5(a)) and waived its opportunity for a hearing. On February 6, 2023, the Agency issued a letter to GSK revoking the biologics license for BLENREP (belantamab mafodotin-blmf) powder for injection (BLA 761158).

Therefore, under § 601.5(a), the Agency revoked the biologics license for BLENREP (belantamab mafodotin-blmf) powder for injection (BLA 761158), effective as of February 6, 2023, the date of FDA's letter revoking the biologics license for BLENREP.

Dated: March 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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