22 November 2022

IMPORTANT PRESCRIBING INFORMATION

Subject: Initiation of the Process of Voluntary Withdrawal of the Biologic License Application for BLENREP® (belantamab mafodotin-blmf) for treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.

Dear Health Care Provider,

This letter is to inform you about an important upcoming change to the Biologic License Application (BLA) for BLENREP® (belantamab mafodotin-blmf) for treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.

Key Messages

BLENREP® was granted accelerated approval on 05 August 2020 based on the primary endpoint of overall response rate (ORR) from the DREAMM-2 study, with full approval contingent upon confirmed clinical benefit from a randomized Phase 3 trial. The DREAMM-3 randomized Phase 3 study investigating belantamab mafodotin monotherapy vs. the combination of pomalidomide and dexamethasone (PomDex) was intended to fulfill the requirements to convert the accelerated approval to full approval.

GSK has initiated the process for withdrawal of the BLA for BLENREP® (belantamab mafodotin-blmf). This decision follows the announcement on 07 November 2022 that the confirmatory randomized DREAMM-3 Phase 3 trial of belantamab mafodotin monotherapy versus PomDex in patients with relapsed or refractory multiple myeloma (RRMM) did not meet its primary endpoint of superior progression-free survival (PFS). The hazard ratio (HR) for PFS was 1.03 (95% CI: 0.72 1.47). However, the observed median PFS is longer for belantamab mafodotin vs. PomDex (11.2 vs 7 months.).

At the time of the primary analysis, the Overall Survival (OS) data had only achieved 37.5% maturity. The median OS were 21.2 and 21.1 months for belantamab mafodotin and PomDex, respectively, with a HR of 1.14 (95% CI: 0.77, 1.68). The DREAMM-3 study will continue to assess long term OS.

The Overall Response Rate (ORR) was 41% for belantamab mafodotin vs. 36% for PomDex, including 25% very good partial response (VGPR) or better for belantamab mafodotin vs. 8% for PomDex. The median Duration of Response (DOR) was not reached for belantamab mafodotin (95% CI: 17.9, --) vs 8.5 months (95% CI: 7.6, --) for PomDex; DOR rates at 12 months were 76.8% and 48.4% for belantamab mafodotin and PomDex respectively.

The safety and tolerability profile of belantamab mafodotin were consistent with the known safety profile. A total of 97% of patients experienced any adverse event (AE) on belantamab mafodotin vs 93% on PomDex. A total of 38% (83/217) of patients died on the belantamab mafodotin arm, and 37% (38/102) of patients died on the PomDex arm. The frequency of serious adverse events (SAEs) was 43% and 39%, respectively, with 7%

fatal SAEs in the belantamab mafodotin arm vs. 11% in the PomDex arm. Keratopathy based on ocular exam as per derived KVA scale was 80% for all belantamab mafodotin treated patients, including 50% Grade 3 or higher. The preliminary safety and efficacy data have been shared with the Independent Data Monitoring Committee (IDMC), and the IDMC recommended to continue the DREAMM-3 study without modification.

Actions Being Taken by GSK

- GSK has stopped new patient enrollment into the BLENREP Risk Evaluation and Mitigation Strategy (REMS) as of the date of issuance of this letter (22 November 2022).
- To ensure patients who are currently deriving clinical benefit continue to have access to BLENREP, GSK will be opening a compassionate use program. Further information on how to enroll patients into the compassionate use program will be provided directly to REMS enrolled prescribers.
- While patients are being transitioned into the compassionate use program, BLENREP will continue to be available.
- The DREAMM-3 study will continue in order to enable additional data collection.
- Additional trials within the DREAMM (Driving Excellence in Approaches to Multiple Myeloma) clinical development program will continue. These trials are designed to demonstrate the benefit of belantamab mafodotin in combination treatment in earlier lines of therapy, and dosing optimization to maintain efficacy while reducing corneal events.

Actions Required by Health Care Providers

- No new patients can be enrolled in the REMS as of the date of this letter (22 November 2022).
- Prescribers are asked to discuss the information in this letter with impacted patients for an individual benefit-risk assessment so that they can make an informed decision regarding their ongoing care
- Prescribers should inform patients currently receiving BLENREP that they must transition to a compassionate use program to continue treatment. Further information on how to enroll patients into the compassionate use program will be provided directly to REMS enrolled prescribers.
- While patients are being transitioned into the compassionate use program, BLENREP will continue to be available for patients currently on treatment. Providers must continue to adhere to all REMS requirements until patients are transitioned into the compassionate use program.
- Health care providers can continue to enroll patients in belantamab mafodotin clinical trials.

Contact for Further Information or Questions

You may contact the GSK Response Center at 1-877-768-0092 if you have any questions about the information contained in this letter or the safe and effective use of BLENREP.

For questions or information related to the BLENREP REMS, please contact the REMS Coordinating Center at 1-855-209-9188, Monday – Friday, 8:00 am to 8:00 pm ET or visit www.BLENREPREMS.com.

Health care providers and patients are encouraged to report adverse events in patients taking BLENREP to GSK at 1-877-768-0092 or by email to WW.GSKAEReportingUS@gsk.com, You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Sincerely,

Erin Hufman, PharmD, Head, US Medical Affairs