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[ADD DATE HERE]

Direct Healthcare Professional Communication (DHPC)

BLENREP▼ (Belantamab mafodotin): Revocation of the Great Britain conditional Marketing Authorisation for BLENREP (belantamab mafodotin)

Dear Healthcare professional,

GSK, in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), would like to inform you of the following:

Summary

- **The Great Britain (GB) conditional Marketing Authorisation (cMA) for belantamab mafodotin in the following indication was revoked on 30th August 2024:**

…as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.

- **This is due to a negative benefit risk balance where the risks outweigh the benefits of belantamab mafodotin in monotherapy.**
- **No new patients can be initiated on therapy in the NHS and private settings in GB.**
- **Patients already receiving belantamab mafodotin who are currently deriving clinical benefit from treatment have the option to continue on treatment (via GSK clinical stock) if deemed appropriate by their Healthcare professional.**
- **Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients.**

Background on the concern

Following the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) confirmation of its recommendation to not renew the cMA for belantamab mafodotin (Dec 2023), and recent discussions with the Medicines and Healthcare products Regulatory Agency (MHRA) on the annual renewal of the GB cMA, GSK have accepted the MHRA's decision that the cMA for belantamab mafodotin should be revoked.

As the DREAMM-3 study failed to confirm the effectiveness of belantamab mafodotin in monotherapy, the benefits no longer outweigh its risks leading to its revocation.

On 7th August 2024, GSK sent email communications to relevant HCPs in the NHS and private healthcare settings to inform them of the revocation of the belantamab mafodotin GB cMA and to provide information relating to continuity of care logistics for their patients currently deriving clinical benefit from belantamab mafodotin. **If you have any patients receiving treatment with belantamab mafodotin in the NHS or private healthcare settings, and you have not received a communication from GSK regarding revocation of the cMA and continuity of care, please contact GSK as soon as possible (see "Company contact point" below).**

Investigators can continue to enrol patients in belantamab mafodotin clinical trials, where appropriate.

If you have any questions, please use the contact details below.

Call for reporting

BLENREP▼ (belantamab mafodotin) was subject to additional monitoring. This will allow quick identification of new safety information. Please continue to report ANY suspected adverse drug reactions (ADRs) to drugs identified by the black triangle▼ to the MHRA through the Yellow Card scheme.

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

The non-identical nature of biological medicines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as belantamab mafodotin), please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

Adverse events should also be reported to GSK Limited on 0800 221 441 or by email at uksafety@gsk.com.

Company contact point:

For all questions, please contact the GSK Medical Information Department on 0800 221 441 or via email at medical.information@gsk.com.

Yours faithfully

Dr Mark Toms MBChB FFPM
Country Medical Director, GSK UK