



FDA-REQUIRED REMS* SAFETY INFORMATION

Subject:

- **Risk of Ocular Toxicity with BLENREP Treatment**
- **FDA Required BLENREP REMS**

Dear Professional Society:

We request that you share the following with your members.

This letter is to inform you about the risk of ocular toxicity associated with BLENREP and the BLENREP REMS. BLENREP is indicated for the 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.

The U.S. Food and Drug Administration (FDA) has determined a Risk Evaluation and Mitigation Strategy (REMS) is necessary to manage the risk of ocular toxicity. BLENREP is only available through a restricted program; the BLENREP REMS.

Risks of BLENREP:

- BLENREP can cause changes in the corneal epithelium resulting in changes in vision, including severe vision loss and corneal ulcer, and symptoms such as blurred vision and dry eyes.
- Ophthalmic exams must be performed at baseline, prior to each dose, and promptly for worsening symptoms.
- Dose modifications or discontinuation of treatment of BLENREP may be necessary to mitigate the risk of ocular toxicity

REMS Requirements

- Prescribers of BLENREP must be certified in the BLENREP REMS in order to prescribe BLENREP.
- See the Factsheet that is included with this letter for more information about the requirements of the BLENREP REMS.
- To enroll in the BLENREP REMS, visit www.BLENREPREMS.com.

For additional details about the REMS, visit www.BLENREPREMS.com. or contact the BLENREP REMS at 1-855-209-9188.

Sincerely,
GlaxoSmithKline