Genentech
A Member of the Roche Group

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Subject: A warning about post-operative intraocular inflammation is added to the SUSVIMO® Prescribing Information

Dear Health Care Provider:

The purpose of this letter is to inform you of an important update to the safety information about SUSVIMO® (ranibizumab injection) for intravitreal use via SUSVIMO ocular implant, indicated for the treatment of patients with:

- Neovascular (wet) Age-related Macular Degeneration (AMD) who have previously responded to at least two intravitreal injections of a VEGF inhibitor.
- Diabetic Macular Edema (DME) who have previously responded to at least two intravitreal injections of a VEGF inhibitor.
- Diabetic Retinopathy (DR) who have previously responded to at least two intravitreal injections of a VEGF inhibitor.

The following new warning has been added to the SUSVIMO® Prescribing Information (PI) under Section 5.

5.9 Postoperative Intraocular Inflammation
Postoperative intraocular inflammation has occurred following SUSVIMO implantation. The majority of cases occurred during the first week following implantation and resolved within the first month.

Reason for adding this warning:
The SUSVIMO PI describes intraocular inflammation such as iritis, anterior chamber flare, anterior chamber inflammation, and anterior chamber cell as adverse reactions in Table 2 across all approved indications. This new warning ensures that important information about intraocular inflammation, including the occurrence of most cases in the week following surgery and resolution within the first month, is presented prominently in Section 5 Warnings and Precautions of the PI.

Prescriber Action:
Counsel patients about the risks and benefits of SUSVIMO, including postoperative intraocular inflammation.

Prescribers should refer to the Warnings and Precautions Section 5.9 of the US Prescribing Information for this added warning.

Patients treated with SUSVIMO should be instructed to report to their ophthalmologist if the eye becomes red, sensitive to light, painful, or develops a change in vision (see SUSVIMO Medication Guide).

Reporting Adverse Events / Product Complaints and Company Contact
Health Care Providers should report any adverse events or product complaints suspected to be associated with the use of SUSVIMO to Genentech at 833-EYE-GENE. Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (www.fda.gov/medwatch).

Should you have any questions about the information in this letter, returning the product, or the safe and effective use of SUSVIMO, please contact us at 833-EYE-GENE. This letter is not intended as a complete description of the benefits and risks related to the use of SUSVIMO. Please refer to the enclosed full prescribing information for additional information.

Sincerely,

Beatriz Perez

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