



April 2026

Subject: New Important Safety Information with the Use of LUNSUMIO® (mosunetuzumab-axgb) and LUNSUMIO VELO™ (mosunetuzumab-axgb): Progressive Multifocal Leukoencephalopathy

Dear Health Care Provider:

The purpose of this letter is to inform you of important safety information for LUNSUMIO and LUNSUMIO VELO, both under accelerated approval and indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

Serious Risk of Progressive Multifocal Leukoencephalopathy with the Use of LUNSUMIO® and LUNSUMIO VELO™

Progressive multifocal leukoencephalopathy (PML) is a serious, opportunistic infection caused by the reactivation of John-Cunningham virus (JCV), potentially fatal or resulting in severe disability. The main risk factors for developing PML in the presence of JCV include an altered or weakened immune system.

To date, no cases of PML have been reported in patients treated with LUNSUMIO or LUNSUMIO VELO in clinical trials or post-marketing settings. This update is a proactive measure taken to address a potential risk, as PML has an established association with CD20-targeting agents, including CD20-directed CD3 T-cell engagers.

Updates to the Prescribing Information are planned.

The benefit-risk profile of LUNSUMIO and LUNSUMIO VELO in the approved indication remains favorable.

Prescriber Action

- Monitor patients for any new or worsening neurological toxicities.
- For any case of suspected PML, discontinue treatment with LUNSUMIO or LUNSUMIO VELO and initiate appropriate diagnostic and treatment measures including consultation with a neurologist for further evaluation.

Reporting Adverse Events / Product Complaints and Company Contact

Health Care Providers should report any adverse events suspected to be associated with the use of LUNSUMIO or LUNSUMIO VELO to Genentech at 1-888-835-2555. Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (www.fda.gov/medwatch).

Please report any product complaint suspected to be associated with the use of LUNSUMIO or LUNSUMIO VELO to Genentech at (800) 334-0290.

Should you have any questions about the information in this letter or the safe and effective use of LUNSUMIO or LUNSUMIO VELO, please feel free to contact us at: Genentech Medical Information/Communications Department at (800) 821-8590.

This letter is not intended as a complete description of the benefits and risks related to the use of LUNSUMIO or LUNSUMIO VELO. Please refer to the enclosed full prescribing information for [LUNSUMIO](#) or [LUNSUMIO VELO](#).

Sincerely,



Charlotte Owens, M.D., FACOG
Head of U.S. Medical