Genentech
A Member of the Roche Group

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Subject: New Important Safety Update: Serious Cases of Progressive Multifocal Leukoencephalopathy reported with the Use of COLUMVI® (glofitamab-gxbm)

Dear Health Care Provider:

The purpose of this letter is to inform you of important safety information for COLUMVI, which is under accelerated approval and indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.

Serious Risk of Progressive Multifocal Leukoencephalopathy with the Use of COLUMVI®

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.

Cases of PML have been reported in clinical trials, compassionate use program, and post-marketing experience with COLUMVI at an unknown frequency, reflecting the infrequent nature of this event. In clinical trials involving 1,468 patients, the reported rate of PML was 0.1% (two cases), which both resulted in fatalities.

Updates to the Prescribing Information are planned.

The benefit-risk profile of COLUMVI in the approved indication remains favorable.

Prescriber Action

- Monitor patients for new or worsening neurological toxicities.
- For any case of suspected PML, discontinue treatment with COLUMVI 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 COLUMVI 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 COLUMVI to Genentech at (800) 334-0290.

Should you have any questions about the information in this letter or the safe and effective use of COLUMVI, 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 COLUMVI. Please refer to the enclosed full prescribing information.

Sincerely,

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