June, 2026

Direct Healthcare Professional Communication

Columvi (glofitamab-gxbm): New Important Safety Update Regarding Serious Cases of Progressive Multifocal Leukoencephalopathy reported with the use of Columvi

Dear Healthcare Professional,

Roche Products Saudi Arabia in agreement with The Saudi Food and Drug Authority (SFDA) would like to inform you of the following important safety information for Columvi

Summary:

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

Background on the safety concerns:

COLUMVI (glofitamab) is a full-length, humanized anti-CD20/anti-CD3 bispecific monoclonal antibody indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.

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.**

CALL FOR REPORTING

Healthcare professionals should report any adverse events which are suspected to be associated with the use of Columvi, in accordance with the requirements via the national spontaneous reporting systems to:

The National Pharmacovigilance Centre (NPC – Saudi Food & Drug Authority (SFDA))

Land Line: 19999.

Web-page: http://ade.sfda.gov.sa

Email: npc.drug@sfda.gov.sa

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COMPANY CONTACT POINT

Should you have any questions regarding the use of Columvi, please feel free to contact us at jeddah.medinfo@roche.com

Yours sincerely,

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THIS DOCUMENT IS APPROVED BY THE EXECUTIVE DIRECTORATE OF PHARMACOVIGILANCE AT SFDA