14 January 2026

Columvi® (glofitamab): New important identified risk of haemophagocytic lymphohistiocytosis

Dear Healthcare Professional,

Roche Products (New Zealand), in agreement with Medsafe, would like to inform you of the following:

Summary

Haemophagocytic lymphohistiocytosis (HLH) is a new important identified risk for Columvi and will be added as a warning in the New Zealand Data Sheet.

HLH is a life-threatening syndrome characterised by fever, elevated ferritin, hepato- and/or splenomegaly, cytopenias, elevated transaminases, elevated LDH, coagulation abnormalities, and hypofibrinogenemia. HLH should be considered when presentation of cytokine release syndrome (CRS) is atypical or prolonged. For suspected HLH, Columvi must be interrupted and treatment for HLH initiated.

Background on the safety concern

Columvi (glofitamab) is a full-length, fully humanised, immunoglobulin G1 (IgG1), T-cell- engaging bispecific antibody (TCB) 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
- in combination with gemcitabine and oxaliplatin for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are not candidates for autologous stem cell transplant (ASCT).

Haemophagocytic Lymphohistiocytosis (HLH)

HLH is a severe hyperinflammatory syndrome driven by pathologic activation of cytotoxic T-lymphocytes and macrophages ultimately leading to cytokine storm and organ damage if not treated appropriately. In adults, infections and malignancies are common triggers for HLH, and lymphomas represent the most common trigger for malignancy-associated HLH, with an incidence of 1-20% in lymphoma patients (Wang et al. 2017). HLH secondary to T-cell engaging therapies, also described as Immune Effector Cell-associated HLH like Syndrome (IEC-HS), is an emergent toxicity associated with life-threatening complications, where early detection and

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management is essential. HLH, including fatal cases, have been reported in Columvi clinical trials, patient access programs, and marketing experience. HLH may resemble severe CRS with respect to clinical signs and symptoms, but may differ by presenting with a delayed onset, rapid increases in serum ferritin, and differences in cytokine profile. While symptoms may overlap with CRS, emergent treatment recommendations for HLH are distinct from those of CRS. For any case of suspected HLH, Columvi should be interrupted, and treatment for HLH should be considered per clinical practice guidelines e.g. institutional guidelines or expert consensus guidelines (Hines et al. 2023). Expert consultation is recommended if HLH is suspected.

The New Zealand Data Sheet will be updated accordingly.

The benefit-risk profile of Columvi in the registered indications remains favourable.

Reporting Adverse Events

Roche will continue to monitor the safety of Columvi through established reporting mechanisms and notify regulatory authorities as per current regulations.

Please report any suspected adverse events via email to Roche Patient Safety at nz.drugsafety@roche.com. Alternatively, this information may be reported to the Centre for Adverse Reactions Monitoring (CARM)/Medsafe at https://pophealth.my.site.com/carmreportnz/s/.

Further Information

If you have any questions or require additional information regarding the use of Columvi, to report an adverse event (side effect) or product quality defect or to submit a temperature excursion assessment, please visit MedInfo.roche.com or phone 0800 276 243.

Yours sincerely,

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References

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Wang H, Xiong L, Tang W, Zhou Y, Li F. A systematic review of malignancy-associated hemophagocytic lymphohistiocytosis that needs more attentions. Oncotarget. 2017 Jul 14;8(35):59977-59985. doi: 10.18632/oncotarget.19230. PMID: 28938698; PMCID: PMC5601794.

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