SUMMARY OF COHERE FINLAND'S RECOMMENDATION FOR COMBINATION THERAPY WITH GLOFITAMAB IN THE TREATMENT OF RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA

At its meeting of 5 February 2026, the Council for Choices in Health Care in Finland (COHERE Finland) adopted the recommendation.

Combination therapy with glofitamab, gemcitabine and oxaliplatin is included in the national range of services for the treatment of relapsed or refractory diffuse large B-cell lymphoma not otherwise specified in adult patients ineligible for autologous stem cell transplantation. COHERE Finland requires that the marketing authorisation holder and the buyer agree on a price significantly lower than the public wholesale price.
In COHERE Finland's view, the phase III comparative marketing authorisation study demonstrated a clinically significantly longer median overall survival with glofitamab combination therapy than with rituximab combination therapy. The study included patients with a performance status of ECOG 0–2. The clinically significant efficacy is uncertain due to the possible undertreatment of the comparator group. Patients receiving glofitamab combination therapy experienced treatment-related serious adverse events more frequently than patients receiving the comparator treatment. These adverse events are typical of bispecific antibodies, and methods for managing them have already been established in clinical practice.

The evidence of the efficacy and safety of glofitamab combination therapy is based on a phase III randomised open-label study comparing glofitamab in combination with gemcitabine and oxaliplatin (glofitamab-GemOx) with rituximab in combination with gemcitabine and oxaliplatin (R-GemOx) in adult patients with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS). The primary endpoint of the

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study was overall survival (OS). In the study's updated analysis, treatment with glofitamab-GemOx resulted in a longer median OS than with treatment with R-GemOx (25.5 months vs 12.9 months). The median values of the secondary endpoint (progression-free survival) were also longer with glofitamab-GemOx than with R-GemOx in the updated analysis (13.8 months vs 3.6 months). The patients in the comparator group may have been undertreated due to the duration of the dosing cycles of the comparator treatment introducing uncertainty regarding the clinical effectiveness of glofitamab-GemOx therapy. Glofitamab combination therapy was compared indirectly with CAR T-cell therapies (axi-cel, tisa-cel, liso-cel) and with Pola-BR therapy. In the indirect comparisons, differences between the studied patient groups were not accounted for, and the results are at most indicative. Glofitamab combination therapy does not appear significantly less effective than CAR T-cell therapies, at least in later lines of treatment. Glofitamab combination therapy could be considered for patients requiring a rapid initiation of treatment.

More treatment-related adverse events of any grade and serious adverse events were observed with glofitamab combination therapy than with R-GemOx therapy. Patients receiving glofitamab combination therapy experienced cytokine release syndrome, anaemia, elevated liver enzymes, fever and hypokalaemia more frequently than patients receiving R-GemOx. These adverse events are typical of bispecific antibodies, and methods for managing them have already been established in clinical practice.

In the marketing authorisation holder's (MAH) baseline analysis, the incremental cost-effectiveness ratio (ICER) of glofitamab-GemOx compared with R-GemOx was EUR 23,600 per QALY. In the scenario analyses conducted by Fimea, the ICER of glofitamab-GemOx was EUR 34,800–36,500 per QALY compared with R-GemOx. According to the MAH estimate, the per-patient drug and administration cost of glofitamab combination therapy was EUR 83,000 at public wholesale prices. If 85 patients were treated annually, the annual budget impact of the treatment would be EUR 4.5 million.

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