RECOMMENDATION ON LISOCABTAGENE MARALEUCEL IN THE SECOND-LINE TREATMENT OF LARGE B-CELL LYMPHOMA

At its meeting of 27 March 2025, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on lisocabtagene maraleucel in the second-line treatment of large B-cell lymphoma.

Lisocabtagene maraleucel (liso-cel) is included in the national range of services for the second-line treatment of large B-cell lymphoma in patients with good performance status (ECOG 0–1). Treatment can only be given to patients who have not received any prior CAR T-cell therapy. COHERE Finland requires that the marketing authorisation holder and the buyer agree on a price significantly lower than the public wholesale price. It is also required that they agree, as part of the price negotiations, on the collection and reporting of monitoring data on treatment. In COHERE Finland's opinion, a large proportion of patients achieved a complete response to liso-cel treatment. The evidence is based on a randomised phase III comparative study. The efficacy of treatment has only been demonstrated in patients with good performance status, and there is uncertainty associated with the research evidence as the medians of most endpoints have not yet been reached.

Liso-cel is intended for the treatment of diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma (HGBCL), primary mediastinal large B-cell lymphoma (PMBCL) and follicular lymphoma grade 3B (FL3B) in adult patients who relapsed within 12 months from completion of, or are refractory to, first-line chemoimmunotherapy.

The research evidence of the effects of liso-cel treatment is based on a phase III study. According to the primary analysis of this study, patients receiving liso-cel achieved a complete response to treatment more often than those receiving the comparable standard of care (74% vs. 44%). After a follow-up of three years, the median event-free survival (EFS) for the liso-cel arm was 29.5 months, whereas the medians of other endpoints (progression-free survival PFS, overall survival OS, duration of response) were not yet reached. With regard to the OS results, it should be noted

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that a proportion of patients who received comparator therapy received liso-cel as further treatment.

Liso-cel treatment improved the cancer-related quality-of-life indicators after the first month following infusion. In the comparator arm there were signs of these indicators falling. However, there were no significant differences in the indicators of physical functioning between the treatment arms. No reliable conclusions can be drawn from these results because of the small number of patients involved in the surveys. Based on the results of the subgroup analyses, it cannot be concluded that specific patient groups would benefit from liso-cel treatment more than others. The results of the subgroup analyses should be interpreted with caution, because the number of patients in several subgroups was small. An indirect comparison was made to evaluate the efficacy and safety of liso-cel and another CAR T-cell therapy, axi-cel, as second-line therapies, with the standard of care used as the common comparator. The efficacy comparison showed no statistically significant differences between liso-cel and axi-cel. In the safety comparison, liso-cel had a more favourable safety profile with a lower incidence of grade 3 or higher serious adverse events, cytokine release syndrome and neurotoxicity. All patients experienced at least one treatment-emergent adverse event of varying grade. Serious or life-threatening (grades 3–5) adverse events occurred in nearly all patients and serious adverse events in approximately half of the patients.

Calculated at public list prices, the medicine costs of both liso-cel treatment and axi-cel treatment are EUR 327,000 per patient. Therefore, the introduction of liso-cel would not generate any budget impact compared to axi-cel treatment. It is estimated that each year 149 patients would be eligible for liso-cel treatment. With this number of patients, the annual medicine costs would be approximately EUR 50 million. The annual budget impact of liso-cel treatment would be around EUR 42 million, assuming that liso-cel would fully replace the comparator treatments. According to the Finnish Medicines Agency's (Fimea) a minimum of five patients could receive liso-cel treatment. With this number of patients, the annual medicine costs of liso-cel treatment would amount to approximately EUR 1.7 million. Thus, the budget impact would be EUR 0–1.4 million compared to axi-cel and chemotherapy.

This is a summary of a recommendation adopted by the Council for Choices in Health Care in Finland (COHERE Finland). The actual recommendation and the related background material are available in Finnish on the website of COHERE Finland under Valmiit suositukset.

The summary of the recommendation is also available in Swedish and English on the website.

The Council for Choices in Health Care in Finland (COHERE Finland) is attached to the Ministry of Social Affairs and Health. Its mission is to issue recommendations on services that should be

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included in the range of public health services. Further information about service choices in healthcare is available on the COHERE Finland website.

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