RECOMMENDATION ON

TEBENTAFUSP IN THE TREATMENT OF UVEAL MELANOMA

At its meeting of 15 December 2022, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on tebentafusp in the treatment of uveal melanoma

*According to the recommendation, tebentafusp is included in the national range of services for HLA-A*02:01 positive adult patients with unresectable or metastatic uveal melanoma. Treatment was found to significantly prolong survival. However, the treatment cost calculated at the wholesale list price is unreasonable. COHERE Finland emphasises that this medicinal product can only be adopted if price negotiations lead to a very significant reduction in the price compared to the effectiveness of the treatment. COHERE also requires that the marketing authorisation holder and the national price negotiator agree, as part of the price negotiations, on the collection and reporting of monitoring data on treatment. The information will be used, for example, in assessing the need to update the recommendation.*

There is no established, effective therapy available for the treatment of metastatic uveal melanoma. In accordance with the marketing authorisation granted by the European Commission in April 2022, tebentafusp is intended as therapy for adult patients who are human leukocyte antigen HLAA*02:01 positive with unresectable or metastatic uveal melanoma.

Research evidence is based on a randomised phase III open-label IMCgp100-202 study where tebentafusp (n=252) was compared to the investigator's choice of therapy (n=126, pembrolizumab, ipilimumab or dacarbazine). According to the results, tebentafusp prolonged the median survival of patients with uveal melanoma by 5.7 months compared to

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the patients who received comparator therapy (21.5 vs. 16 months). While the difference is clinically significant, therapy is not remedial. Progression-free survival (PFS) and response rates were more modest; the difference between the median PFS rates was 0.4 months. Additionally, only about one in ten patients who received tebentafusp achieved partial response. In the control group, response was only 5%. A considerable proportion of the patients receiving tebentafusp (43%) continued the therapy after the progression of the disease compared to the patients receiving the control therapy (14%).

Tebentafusp therapy caused significantly more frequent and severe adverse events than the comparator therapy. The most common adverse events associated with tebentafusp therapy were cytokine release syndrome, rash and pruritus.

Tebentafusp leads to an additional cost of nearly EUR 600,000 per patient compared to the comparator therapy. The Finnish Medicines Agency estimates the incremental cost-effectiveness ratio (ICER) to be EUR 541,000/QALY. Although the therapy was found to prolong survival, its benefit-cost ratio is unreasonable.

Uveal melanoma refers to the melanoma of the iris, the ciliary body and the choroid. It is the most common eye cancer among adults. Some 65 new patients are diagnosed in Finland each year, of whom about half develop metastatic melanoma. In Finland, the number of patients eligible for tebentafusp therapy is estimated to be 11 per year.

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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 Recommendations.

The summary of the recommendation is also available in Finnish and Swedish.

The Council for Choices in Health Care in Finland (COHERE Finland) works in conjunction with the Ministry of Social Affairs and Health, and its task is to issue recommendations on services that should be 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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