7.11.2024

STM023:00/2023
VN/8490/2024

RECOMMENDATION ON ELRATANAMAB IN THE TREATMENT OF ADVANCED MULTIPLE MYELOMA

At its meeting of 7 November 2024, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on elratanamab in the treatment of advanced multiple myeloma.

Elranatamab is not included in the national range of services as monotherapy for the treatment of relapsed and refractory multiple myeloma in adult patients who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. In COHERE Finland's opinion, the research evidence involves significant uncertainty. The evidence is insufficient to assess the clinical significance of the therapy.

The evidence on the efficacy and safety of elranatamab is mainly based on open-label, single-arm marketing authorisation studies of Phases I and II. Two years from treatment initiation, the median progression-free survival time of patients in Phase II of the study had not been reached. In the updated analysis, the median OS reached was 24.6 months and the median PFS 17.2 months. Stringent complete response was achieved by 16% of patients and complete response by 21% of patients. Partial response was achieved by 5% of patients. In COHERE Finland's opinion, the research evidence involves significant uncertainty. The evidence is insufficient to assess the clinical significance of the therapy.
In the subgroup analyses, the overall response rate was found to be significantly lower in patients with poor prognostic characteristics. The group sizes are mainly small, which limits the conclusions that can be drawn from the results.
In the marketing authorisation studies, at least one adverse event was observed in all patients, and a serious adverse event in slightly over two-thirds. The treatment was permanently discontinued in approximately one quarter of patients due to adverse events. The most important adverse events monitored relating to elranatamab therapy were cytokine release syndrome, ICANS syndrome and serious infections. Cytokine release syndrome mainly occurred in connection with the first and second dose of elranatamab. It was transient in nature and mostly of grade 1 and 2 in severity, causing only two grade 3 adverse events in the whole safety population.

The Council for Choices in Health Care in Finland
PO BOX 33 (Meritullinkatu 8, Helsinki)
00023 GOVERNMENT, Finland
Tel 358 295 16001
www.palveluvalikoima.fi
e-mail: palveluvalikoima.stm@gov.fi

The assessment of cost-effectiveness is based on a stratified life cycle model in which elranatamab is compared to teclistamab and a comparator therapy formed of several myeloma therapies. The main source of uncertainty in the cost-effectiveness model is related to the assessment of the effects of elranatamab therapy as compared to the comparator therapies and in the long term. The results of the indirect comparison can be considered indicative at most and no reliable conclusions can be drawn on them.

In the marketing authorisation holder's estimate, the total number of patients in the line of treatment in accordance with the marketing authorisation is approximately 15–20 patients per year. The annual costs of the elranatamab therapy as estimated by the marketing authorisation holder would amount to EUR 1.7–2.3 million at public list prices. The marketing authorisation holder estimates that elranatamab will yield annual cost savings of EUR 1.0–1.3 million compared to the comparator therapies, assuming that elranatamab will replace teclistamab (80%) and therapies in accordance with the SoC therapy basket (20%). The principal uncertainty factor in the budget impact analysis is the duration of therapies. With the number of patients estimated by Fimea (10–20 patients), the budget impact of elranatamab therapy would vary annually between additional costs of approximately EUR 165,000 and cost savings of EUR 1.1 million. The magnitude of the budget impact is particularly affected by the duration of therapies and the timing of the transition to every two- or four-weeks dosing, as well as the proportion of transitioning patients.

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) 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.

Ministry of Social Affairs and Health

The Council for Choices in Health Care in Finland
PO BOX 33 (Meritullinkatu 8, Helsinki)
00023 GOVERNMENT, Finland
Tel 358 295 16001
www.palveluvalikoima.fi
e-mail: palveluvalikoima.stm@gov.fi