SUMMARY OF COHERE FINLAND'S RECOMMENDATION FOR THE USE OF BROLUCIZUMAB IN THE TREATMENT OF NEOVASCULAR AGE-RELATED MACULAR DEGENERATION

The Council for Choices in Health Care in Finland (COHERE Finland) adopted the recommendation at its meeting on 1 September 2021.

According to the recommendation, brolucizumab is included in the national service choices in the treatment of neovascular (wet) age-related macular degeneration (AMD) provided that the sales licence holder and buyer agree upon a price decrease, considering the impact and safety of the medicine. The justification states that there are no clinically significant differences in the impact of various VEGF inhibitors but, considering safety perspectives, the use of brolucizumab should be limited to situations where no other optional treatment is applicable.

Brolucizumab is intended for the treatment of neovascular (wet) AMD in adults. Brolucizumab is injected inside the chamber of the eye. It reduces abnormal neovascularisation and vascular permeability. Brolucizumab is an inhibitor of vascular endothelial growth factor A (VEGF-A). Other VEGF inhibitors used for the same purpose include bevacizumab, aflibercept, and ranibizumab.

Scientific evidence of the effectiveness and safety of brolucizumab is primarily based on two randomised double-blind phase III studies (HAWK and HARRIER), in which aflibercept formed the control group. No significant differences were found in the medical impact between brolucizumab and aflibercept in the treatment of neovascular AMD. Those patients included in the HAWK and HARRIER studies had not received any prior VEGF treatment. At present, there is little knowledge of the effectiveness of brolucizumab in situations

where no other VEGF treatment has been used previously. The cost effectiveness of brolucizumab treatments is unknown.

While serious treatment-related side effects were rare in the studies, those patients who received brolucizumab had more eye infections and retinal vein occlusions than patients treated with aflibercept. Cases of eye infections, related blood clots in the retina and other vascular infections have also been reported in the clinical use of brolucizumab. The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) evaluated the sales licence holder's fixed-term safety review in May 2021. According to its evaluation, no new alarming information about the side effects of brolucizumab was discovered on the basis of the updated safety information, and its risk–benefit ratio will remain unchanged.

AMD is the most common cause of vision loss in the developed countries. At the end of 2018, roughly 7,400 people diagnosed with AMD were included in the Finnish Register of Visual Impairment. Of all AMD patients, 10–20 per cent have the wet form of AMD.

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 COHERE Finland website under Recommendations.

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

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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