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Advice document
SMC2685

faricimab solution for injection (Vabysmo®)

Roche

06 September 2024

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutics Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

faricimab (Vabysmo®) is accepted for use within NHSScotland.

Indication under review: treatment of adult patients with visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO).

Faricimab offers an additional treatment choice in the therapeutic class of antineovascularisation agents.

In two phase III studies faricimab was non-inferior to an anti-vascular endothelial growth factor treatment at week 24 for mean change from baseline in best-corrected visual acuity (BCVA) .

This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower.

Chair
Scottish Medicines Consortium

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1. Clinical Context

1.1. Medicine background

Faricimab is a humanised bispecific immunoglobulin G1 (IgG1) monoclonal antibody that inhibits vascular endothelial growth factor (VEGF)-A and angiopoietin-2 (Ang-2).[1] It is licensed for the treatment of adult patients with visual impairment due to macular oedema secondary to branched and central retinal vein occlusion (BRVO and CRVO).

The recommended dose of faricimab is 6 mg (0.05mL solution) by intravitreal injection every 4 weeks; three or more consecutive, monthly injections might be needed.[1] Thereafter, treatment may be extended in increments of up to 4 weeks using a treat -and-extend approach. If anatomic and/or visual outcomes deteriorate, the treatment interval should be reduced. Treatment intervals shorter than 21 days and longer than 4 months between injections have not been studied.

1.2. Relevant comparator(s)

The submitting company has proposed faricimab as an alternative to ranibizumab (Lucentis®, SMC 732/11) and aflibercept (Eylea®, SMC 954/14 and SMC 1074/15), which are accepted for use by SMC for the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion. Aflibercept (a human recombinant fusion protein) and ranibizumab (a humanised recombinant monoclonal antibody fragment) inhibit VEGF-A and, together with faricimab, are classified as antineovascularisation agents.

These comparators are available to NHSScotland under confidential patient access schemes.

2. Summary of Clinical Evidence

2.1. Evidence to support comparable efficacy with relevant comparators

BALATON and COMINO are two randomised, double-blind phase III studies, which compared the efficacy of faricimab versus aflibercept in patients with branch retinal vein occlusion (BRVO) and central retinal vein occlusion (CRVO) or hemi retinal vein occlusion (HRVO) respectively.[2-6] Patients were randomised to receive faricimab 6mg or aflibercept 2mg every 4 weeks from weeks 1 to 24, for a total of 6 injections. From weeks 24 to 72, all patients received faricimab 6mg every 4 to 16 weeks according to a modified treat-and-extend regimen.

The primary endpoint was the mean change from baseline in best-corrected visual acuity (BCVA) at 24 weeks, measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score. Secondary end points included mean change from baseline in BCVA; central subfield thickness (CST); National Eye Institute Visual Function Questionnaire 25 (NEI VFQ-25) composite score; proportion of patients gaining or avoiding loss of ≥15 letters from baseline; proportion of patients achieving a treatment interval of up to 16 weeks at week 68.

Faricimab demonstrated improvement in the primary end point and was non-inferior to aflibercept at week 24 (+16.9 versus +17.5 letters; and, +16.9 versus +17.3 letters for faricimab

versus aflibercept in BALATON and COMINO, respectively). Vision gains were maintained through week 72 when all patients received faricimab up to every 16 weeks.

Mean CST reductions from baseline to week 24 for faricimab (311.4 micrometres and 461.6 micrometres respectively) were comparable to aflibercept (304.4 micrometres and 448.8 micrometres respectively), and were maintained through week 72. Across studies, patients in the faricimab arm showed a comparable improvement from baseline to week 24 in the NEI VFQ-25 composite score versus aflibercept every 4 weeks. These results were maintained through week 72 when all patients received faricimab.[1] At week 24, the proportion of patients who gained and avoided a loss of ≥ 15 letters was similar in the faricimab and aflibercept arms.[5]

In BALATON, 52% and 48% of patients who received faricimab and aflibercept respectively to week 24 followed by faricimab, achieved a 16-week treatment interval at week 68; this compared with 37% and 39% respectively in COMINO.[6]

A network meta-analysis (NMA) was conducted to compare the efficacy and safety of faricimab 6 mg versus aflibercept 2 mg and ranibizumab 0.5 mg. The submitting company concluded that, despite limitations, the results of the NMA suggested that faricimab was similar in efficacy and safety to aflibercept and ranibizumab.

*Other data were also assessed but remain confidential.**

3. Company Estimate of Eligible Population, Uptake and Budget Impact

3.1. Company's number of patients assumed to be eligible for treatment*

The company estimated that there would be 19,956 patients eligible for treatment with faricimab in year 1 rising to 20,359 in year 5. It is estimated that approximately 1,129 patients would receive faricimab in year 1; 3,694 in year 2; 6,498 in year 3; 7,653 in year 4; and, 9,563 in year 5.

3.2. Budget Impact assumption

Medicines reviewed under the abbreviated submissions process are estimated to have a limited net budget impact and resource allocation across NHS Scotland.

References

1. Summary of Product Characteristics https://www.medicines.org.uk/emc/product/13741
2. Clinicaltrials.gov. A Study to Evaluate the Efficacy and Safety of Faricimab in Participants With Macular Edema Secondary to Branch Retinal Vein Occlusion (BALATON) [Accessed on 13/Feb/2024]. 2024. LINK
3. Clinicaltrials.gov. A Study to Evaluate the Efficacy and Safety of Faricimab in Participants With Macular Edema Secondary to Central Retinal or Hemiretinal Vein Occlusion (COMINO) [Accessed on 13/Feb/2024]. 2024. LINK
4. Tadayoni R, Danzig CJ, Abreu F, Khanani AM, Brittain C, Lai TYY, Haskova Z, Sakamoto T, Kotecha A, Schlottmann PG, Liu Y, Seres A, Retiere A-C, Willis JR, Yoon YH, for the BALATON and COMINO Investigators,. Efficacy and Safety of Faricimab for Macular Edema due to Retinal Vein Occlusion: 24-Week Results from the BALATON and COMINO Trials. Opthalmalogy. 2024.
5. Tadayoni R, Abreu F, Arrisi P, Aachal K, Liu Y et al. Faricimab in RVO: 72-Week Results From the BALATON and COMINO Phase 3 Studies. https://medically.gene.com/global/en/unrestricted/ophthalmology/ANGIOGENESIS-2024/angiogenesis-2024-presentation-tadayoni-faricimab-in-rv.html
6. Ghanchi F, Abreu F, Arrisi P et al. Efficacy, Safety, and Durability of Faricimabin Macular Edema Due to Retinal Vein Occlusion: 72-Week Results From the Phase 3 BALATON and COMINO Trials. https://medically.roche.com/global/en/ophthalmology/arvo-2024/medical-material/ARVO-2024-poster-ghanchi-efficacy-safety-and-durability-of-faricimab-pdf.html

This assessment is based on data submitted by the applicant company up to and including 09 August 2024.

**Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the SMC on guidelines for the release of company data into the public domain during a health technology appraisal:*https://www.scottishmedicines.org.uk/about-us/policies-publications/

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

Patient access schemes: A patient access scheme is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. A Patient Access Scheme Assessment Group (PASAG), established under the auspices of NHS National Services Scotland reviews and advises NHSScotland on the feasibility of proposed schemes for implementation. The PASAG operates separately from SMC in order to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHSScotland on the basis of a patient access scheme that has been considered feasible by PASAG, a set of guidance notes on the operation of the scheme will be circulated to Area Drug and Therapeutics Committees and NHS Boards prior to publication of SMC advice.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice is based on the estimation of at least similar comparative efficacy and limited net budget impact compared with other medicinal products, within the same therapeutic class, that are in routine use within NHSScotland.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.