Bilateral Use of Vabysmo in nAMD and DME

This article responds to your request for information on the bilateral use of Vabysmo® (faricimab). This response was developed according to the principles of evidence-based medicine and presents clinical study information from the Vabysmo clinical development program.

Warning on theoretical risk associated with bilateral use

The safety and efficacy of Vabysmo administered in both eyes concurrently have not been studied in neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME).[1-4]

Bilateral treatment could cause bilateral ocular adverse reactions or potentially lead to an increase in systemic exposure or both, which could increase the risk of systemic adverse reactions. Until data for bilateral use become available, this is a theoretical risk for Vabysmo.[5]

Relevance of batch numbers

Roche has no recommendations related to whether vials from the same or different batches should be used if administering Vabysmo bilaterally. Neither option is expected to have an impact on improving patient safety.

Phase 3 protocol-defined selection of study eye

In the Phase 3 studies, if both eyes were considered eligible for the study, the eye with the worse best corrected visual acuity (BCVA) score, as assessed at screening, was selected as the study eye unless the investigator deemed the other eye to be more appropriate for treatment in the study.[1-4]

Bilateral use in post-marketing setting

Further safety data on bilateral use of Vabysmo will be generated post-approval in countries where Vabysmo is already approved. In the AVONELLE-X (nAMD) and RHONE-X (DME) long-term extension studies, treatment with Vabysmo in the fellow, or non-study, eye is permitted once Vabysmo was available commercially.[6,7]

The AVONELLE-X study is still ongoing and the RHONE-X study results are not yet available.[8,9] The data will be analysed and able to be shared once these results are available.

References

1. Roche Internal Clinical Study Report (RHINE)(Accessed on 1 November 2023).

2. Roche Internal Clinical Study Report (YOSEMITE)(Accessed on 1 November 2023).

3. Roche Internal Clinical Study Report (LUCERNE)(Accessed on 1 November 2023).

4. Roche Internal Clinical Study Report (TENAYA)(Accessed on 1 November 2023).

5. European Medicines Agency (EMA). Vabysmo EPAR - Public assessment report. July 22, 2023. Available at https://www.ema.europa.eu/en/medicines/human/EPAR/vabysmo. Accessed on November 1, 2023.

6. Roche Internal Clinical Study Report (AVONELLE-X)(Accessed 2 November 2023).

7. Roche Internal Clinical Study Report (RHONE-X)(Accessed 2 November 2023).

8. A Study to Evaluate the Long-Term Safety and Tolerability of Faricimab in Participants With Diabetic Macular Edema (Rhone-X). Available at https://clinicaltrials.gov/study/NCT04432831. Accessed on November 2, 2023.

9. A Study to Evaluate the Long-Term Safety and Tolerability of Faricimab in Participants With Neovascular Age-Related Macular Degeneration (AVONELLE-X). Available at https://clinicaltrials.gov/study/NCT04777201. Accessed on November 2, 2023.