REVIEW ARTICLE

The Use of Faricimab for the Treatment of Wet age Related Macular Degeneration (AMD) and Diabetic Macular Edema (DME)

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The use of intra vitreal anti-vascular endothelial growth factor (anti VEGF) drugs has revolutionized the treatment of retino-choroidal vascular disorders over the past two decades, while earlier anti VEGF agents produced significant improvements in visual acuity (VA) in disorders like wet AMD, DME and retinal vein occlusion (RVO), they left much to be desired regarding there injection schedules, many patients need to receive monthly injections, this comes with its own issues regarding endophthalmitis risks, convenience and costs. Newer anti VEGF agents are constantly being developed to tackle this problem without sacrificing treatment effectiveness.

The FDA has recently approved the use of faricimab for the treatment of wet AMD and DME, on the premise that it allows for up to 4 months between injections after the initial loading of 4 monthly injections, faricimab is a monoclonal antibody composed of two heavy chains and two light chains, one light chain binds to VEGF-A molecule, and the other binds to angiopoietin-2 molecule. The FDA made this approval based on 4 randomized, double masked, multicenter, global, phase 3, non-inferiority clinical trials: TENAYA and LUCERENE for wet AMD and YOSEMITE and RHINE for DME.

TENAYA and LUCERENE were identical, 1329 patients 50 years or older and without previous treatment were randomly assigned across the two trials between faricimab 6.0 mg for up to every 16 weeks, or aflibercept 2.0 mg every 8 weeks, after a loading period of 4 injections every 4 weeks. The results showed that faricimab 6.0 mg was non-inferior to aflibercept 2.0 mg when given at a more flexible regimen with comparable side effects[1].

YOSEMITE and RHINE were also identical, 1891 patients across the 2 studied were randomly assigned in to 3 groups: faricimab 6.0 mg up to every 16 weeks, faricimab 6.0 mg every 8 weeks, or aflibercept every 8 weeks, after a loading dose of 4 injections every 4 weeks. Both studies showed that faricimab 6.0 mg was non-inferior to aflibercept 2.0 mg whether it was given every 8 weeks or in a variable dosing of up to every 16 weeks, which was possible in 50% of patients by the end of the first year with no difference in side effects[2].

For all the 4 trials, the researchers concluded that given the effectiveness of faricimab and the longer interval between injections, it's likely to reduce treatment burden on patients and health institutions.

REFERENCES:

1. Heier JS, Khanani AM, Ruiz CQ, Basu K, Ferrone PJ, Brittain C, Figueroa MS, Lin H, Holz FG, Patel V, Lai TY. Efficacy, durability, and safety of intravitreal faricimab up to every 16 weeks for neovascular age-related macular degeneration (TENAYA and LUCERNE): two randomised, double-masked, phase 3, non-inferiority trials. The Lancet. 2022 ;399:729-40.
2. Wykoff CC, Abreu F, Adamis AP, Basu K, Eichenbaum DA, Haskova Z, Lin H, Loewenstein A, Mohan S, Pearce IA, Sakamoto T. Efficacy, durability, and safety of intravitreal faricimab with extended dosing up to every 16 weeks in patients with diabetic macular oedema (YOSEMITE and RHINE): two randomised, double-masked, phase 3 trials. The Lancet. 2022 ;399:741-55.