FARICIMAB IN DIABETIC MACULAR EDEMA: PRIMARY EFFICACY, SAFETY, AND DURABILITY RESULTS FROM THE PHASE 3 YOSEMITE AND RHINE TRIALS

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Purpose: YOSEMITE (NCT03622580) and RHINE (NCT03622593) are randomized, double-masked, 100-week, active comparator–controlled phase 3 trials investigating the efficacy, safety, and durability of faricimab versus aflibercept in patients with center-involving DME.

Methods: Patients were randomized 1:1:1 to faricimab 6.0 mg Q8W after 6 Q4W doses, faricimab 6.0 mg per personalized treatment interval (PTI) after 4 Q4W doses, or aflibercept 2.0 mg Q8W after 5 Q4W doses. The protocol-driven PTI algorithm adjusted treatment intervals (Q4W to Q16W) based on CST and BCVA criteria at active dosing visits. Primary endpoint was mean change in BCVA from baseline at 1 year, averaged over weeks 48, 52, and 56. Safety, efficacy and durability outcomes will be assessed through week 100.

Results: 1891 patients were enrolled in YOSEMITE (N = 940) and RHINE (N = 951). The primary endpoint was met; mean 1-year BCVA gains with faricimab Q8W (10.7 and 11.8 letters in YOSEMITE and RHINE, respectively) or faricimab PTI (11.6 and 10.8 letters) were noninferior to aflibercept Q8W (10.9 and 10.3 letters). Change in CST, absence of DME, and absence of intraretinal fluid over 1 year favored faricimab. In both trials, 50% of the faricimab PTI arm achieved Q16W dosing at week 52; 70% achieved Q12W or Q16W dosing. Faricimab was well tolerated; no cases of vasculitis or occlusive retinitis were reported.

Conclusions: Faricimab Q8W or per PTI up to Q16W offered noninferior vision gains versus aflibercept Q8W, anatomic improvements, and the potential for extended dosing at 1 year.

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