Purpose: TENAYA (NCT03823287) and LUCERNE (NCT03823300) are randomized, active comparator–controlled, 112-week, phase 3 trials, evaluating the efficacy, safety, and durability of faricimab up to every 16 weeks (Q16W) compared with aflibercept Q8W in patients with nAMD.

Methods: Patients were randomized 1:1 to faricimab 6.0 mg up to Q16W (based on protocol-defined disease activity assessments at weeks 20 and 24) or aflibercept 2.0 mg Q8W. The primary endpoint was mean change in BCVA from baseline at week 48, averaged over weeks 40, 44, and 48. Other endpoints included the proportion of patients receiving faricimab Q16W, Q12W, and Q8W; the proportion of patients gaining or avoiding loss of ≥ 15 ETDRS letters from baseline; and the incidence and severity of adverse events.

Results: 1329 patients were enrolled (TENAYA, N = 671; LUCERNE, N = 658). Both trials consistently met their primary endpoint; mean change in BCVA from baseline with faricimab up to Q16W (+5.8 and +6.6 ETDRS letters in TENAYA and LUCERNE, respectively) were noninferior to aflibercept Q8W (+5.1 and +6.6 letters). In both trials, ~45% of faricimab-treated patients were on a Q16W dosing at week 48; ~80% were on ≥ Q12W dosing. Faricimab was well-tolerated; no cases of vasculitis or occlusive retinitis were reported.

Conclusions: Faricimab up to Q16W demonstrated noninferior vision gains to aflibercept Q8W and the potential for up to Q16W fixed dosing intervals at week 48, in patients with nAMD. Faricimab was well-tolerated. Results at week 48 were consistent across both TENAYA and LUCERNE.

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