

EFFICACY, SAFETY AND DURABILITY OF FARICIMAB IN nAMD: YEAR 2 RESULTS FROM THE PHASE 3 TENAYA AND LUCERNE TRIALS

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PURPOSE Year 1 data from the TENAYA/LUCERNE (NCT03823287/NCT03823300) trials support the hypothesis that dual angiopoietin-2/vascular endothelial growth factor (VEGF)-A inhibition with faricimab may promote vascular stability/durable efficacy beyond current anti-VEGF therapies for neovascular age-related macular degeneration (nAMD). Year 2 of TENAYA/LUCERNE will evaluate the longer-term efficacy, durability and safety of faricimab in patients with nAMD.

METHODS : TENAYA/LUCERNE were randomised, active comparator-controlled, 112-week trials. Treatment-naïve patients were randomised 1:1 to faricimab 6.0 mg up to every 16 weeks (Q16W), per protocol-defined disease activity assessments at weeks 20 and 24 after 4 initial Q4W doses, or aflibercept 2.0 mg Q8W through week 108 after 3 initial Q4W doses. From week 60, faricimab-treated patients followed a treat-and-extend regimen (personalised treatment interval per protocol).

RESULTS : In total, 1329 patients were enrolled (TENAYA, N = 671; LUCERNE, N = 658). In both trials, mean best-corrected visual acuity for faricimab \leq Q16W was non-inferior to aflibercept Q8W at year 1. Faricimab offered durability, with ~80% of patients on \geq Q12W dosing intervals and ~45% on Q16W dosing intervals at week 48. Despite reduced injection frequency, mean reductions in central subfield thickness (CST) were comparable between treatment arms. Faricimab was well tolerated, with an acceptable safety profile. Year 2 data will be presented and inform longer-term efficacy, durability and safety of faricimab.

CONCLUSION

Year 2 of TENAYA/LUCERNE will explore whether early vision gains, CST reductions and extended dosing with faricimab (\leq Q16W) seen at year 1 are maintained over 2 years in patients with nAMD.

FINANCIAL DISCLOSURE: Yes