SESSION: Late Breaking Developments & Updates on Clinical Trials (BBC Style)
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Moderators: Mohamed Moghazy Mahgoub, Mohamed Tawfik

Update on DRCR Clinical Trials, 2023

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Diabetic Retinopathy Clinical Research Network (DRCR) has conducted several pivotal clinical trials in the recent years. This talk will discuss highlights of these trials.

Efficacy, Durability, and Safety of Faricimab in Diabetic Macular Edema: 2-Year Results From the Phase 3 YOSEMITE and RHINE Trials

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Purpose
Year 1 data from YOSEMITE/RHINE suggest that dual angiopoietin-2/vascular endothelial growth factor (VEGF)-A blockade with faricimab may promote vascular stability in diabetic macular edema (DME) and extended durability with up to every-16-week (Q16W) dosing. Year 2 evaluated the longer-term efficacy, durability, and safety of faricimab in patients with DME.

Methods
YOSEMITE/RHINE (NCT03622580/NCT03622593) were double-masked, phase 3 trials. Patients were randomized 1:1:1 to faricimab 6.0 mg Q8W, faricimab 6.0 mg per personalized treatment interval (PTI), or aflibercept 2.0 mg Q8W. The primary endpoint was mean BCVA change from baseline at 1 year (weeks 48/52/56 average). Other efficacy and safety endpoints were assessed through week 100.

Results
Overall, 1891 patients were enrolled in YOSEMITE/RHINE (N = 940/951). Noninferior vision gains achieved at 1 year were maintained through year 2; mean BCVA change from baseline at 2 years (weeks 92/96/100 average) with faricimab Q8W (YOSEMITE/RHINE, +10.7/+10.9 letters) or PTI (+10.7/+10.1 letters) were comparable with aflibercept Q8W (+11.4/+9.4 letters). In the faricimab PTI arms, durable vision gains were maintained with extended dosing, with > 60% of patients on Q16W dosing and almost 80% on >= Q12W dosing at week 96. Mean CST reductions were greater with faricimab versus aflibercept through year 2. More patients achieved absence of DME (CST < 325 µm) and absence of intraretinal fluid with faricimab Q8W or PTI versus aflibercept Q8W through week 100. Faricimab was well tolerated through study end; intraocular inflammation event rates were low across treatment arms (1.1–1.7%). No cases of retinal vasculitis or occlusive retinal vasculitis were reported.
Conclusions
Robust vision gains, anatomic improvements, and extended durability with faricimab up to Q16W were maintained through year 2. Treat-and-extend–based PTI dosing suggests that dual angiopoietin-2/VEGF-A inhibition with faricimab may promote vascular stability and durable efficacy beyond current anti-VEGF therapies for DME.

Efficacy, Safety, and Durability of Faricimab in Neovascular Age-Related Macular Degeneration: Year 2 Results From the Phase 3 TENAYA and LUCERNE Trials

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Purpose
Year 1 data from the TENAYA/LUCERNE trials support the hypothesis that dual inhibition with faricimab may promote vascular stability and durable efficacy beyond current anti-VEGF therapies for neovascular age-related macular degeneration (nAMD). Year 2 of the TENAYA/LUCERNE trials evaluate longer-term efficacy, durability, and safety of faricimab up to every 16 weeks (Q16W) in patients with nAMD.

Methods
TENAYA (NCT03823287)/LUCERNE (NCT03823300) were identical, global, randomized, double-masked, active comparator–controlled, 112-week, phase 3 trials of faricimab in nAMD. Treatment-naïve patients were randomized 1:1 to faricimab 6.0 mg up to Q16W dosing through week 60 after 4 initial Q4W doses or aflibercept 2.0 mg fixed Q8W dosing through week 108 after 3 initial Q4W doses. After week 60, faricimab-treated patients were treated using a treat-and-extend-based personalized treatment interval regimen. The primary efficacy endpoint was mean change in BCVA from baseline at 1 year, averaged over weeks 40, 44, and 48. Other efficacy/safety endpoints were assessed through week 112.

Results
1329 patients were enrolled (TENAYA, N = 671; LUCERNE, N = 658). In both trials, mean BCVA for faricimab up to Q16W was noninferior to aflibercept Q8W at year 1. Faricimab offered durability with ~80% of patients on >= Q12W dosing intervals and ~45% on Q16W dosing intervals at week 48. Despite reduced injection frequency, mean reductions in CST were comparable between treatment arms. Faricimab up to Q16W was well tolerated, with low rates of intraocular inflammation. Year 2 data will be presented and inform longer-term efficacy, durability, and safety of faricimab.

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

Innovation in robotic design for VR surgery - ***Lyndon da Cruz***

Update on Geographic Atrophy

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There has been extensive research on etiology and management of geographic atrophy. This presentation will discuss recent advances including the first FDA approved medication for geographic atrophy.