Efficacy and Safety of Biosimilar FYB201 Compared with Ranibizumab in Neovascular Age-Related Macular Degeneration

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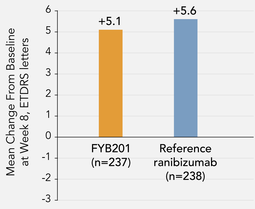
This trial was conducted to investigate the clinical equivalence of the proposed biosimilar FYB201 and reference ranibizumab in patients with treatment-naive, subfoveal choroidal neovascularization caused by neovascular age-related macular degeneration (nAMD). Biosimilars are biologics that are highly similar in their physical, chemical, and biological properties to an already marketed reference drug. They have been available for over 10 years and have helped reduce costs and improve patient access to safe and effective biological medicines.

This was a prospective, multicenter, evaluation-masked, parallel-group, 48-week, phase 3 randomized study on patients with nAMD.

Primary endpoint:

Mean change from baseline in best-corrected visual acuity (BCVA) by Early Treatment Diabetic Retinopathy Study (ETDRS) letters at 8 weeks before the third monthly IVT injection. Biosimilarity of FYB201 to its originator was assessed via a 2-sided equivalence test, with an equivalence margin in BCVA of 3 ETDRS letters.

FYB201 and reference ranibizumab met their primary endpoints of mean BCVA improvements at Week 8, and mean difference between groups within-margin.



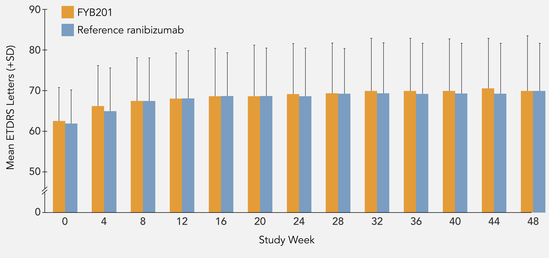
The mean difference[a] between FYB201 - Reference ranibizumab mean changes with [90% CI] was **-0.4 [-1.6 to 0.9]**.

This meets the 90% CI predefined equivalence margin of -3.5 to 3.5.

[a] ANCOVA least squares mean change, adjusted for pooled country and baseline BCVA.

ANCOVA = analysis of covariance; BCVA = best-corrected visual acuity; CI = confidence interval; ETDRS = Early Treatment Diabetic Retinopathy Study.

FYB201 and reference ranibizumab groups demonstrated similar improvements in BCVA throughout the study from the first dose to Week 48.

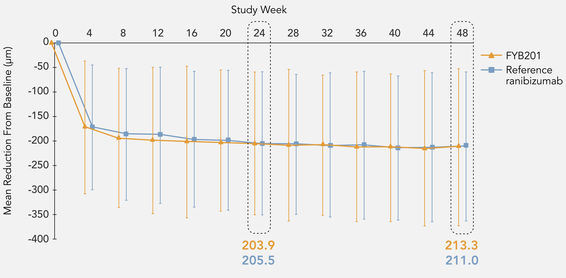


Mean ± SD study eye best-corrected visual acuity during the study (US-relevant population, full analysis set).

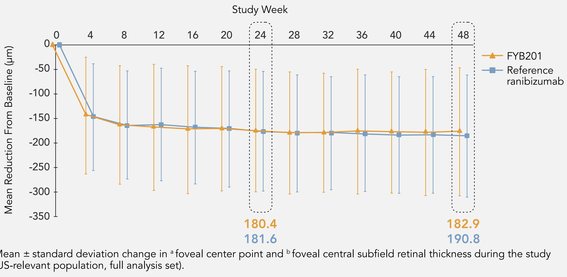
ETDRS = Early Treatment Diabetic Retinopathy Study; SD = standard deviation.

FYB201 showed a mean reduction in FCP and FCS retinal thickness comparable to the mean reduction shown in reference ranibizumab at Weeks 24 and 48.

Mean change in FCP thickness[a]

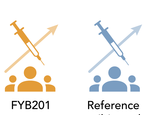


Mean change in FCS thickness[b]



Mean ± standard deviation change in [a] foveal center point and [b] foveal central subfield retinal thickness during the study (US-relevant population, full analysis set).

Conclusions



The present study demonstrates the equivalence of FYB201 and reference ranibizumab in terms of efficacy, safety, and immunogenicity in patients with nAMD. Improvement in BCVA occurred in both treatment groups from the first administration of drug (ie, observed from week 4 onward), with equivalent improvement in BCVA shown for FYB201 versus reference ranibizumab at week 8, the primary study endpoint.