Intravitreal Aflibercept Injection in Patients With Myopic Choroidal Neovascularization: The MYRROR Study

Ikuno Y, Ohno-Matsui K, Wong TY, et al. *Ophthalmology.* 2015;122:1220-1227. doi: 10.1016/j.ophtha.2015.01.025

In the MYRROR study, the researchers evaluated intravitreal aflibercept 2 mg in adult patients with myopic choroidal neovascularization (CNV); eligible particpants had high myopia of \leq -6.0 diopters or axial length of \geq 26.5 mm, with active subfoveal or juxtafoveal CNV on fluorescein angiography, and best-corrected visual acuity (BCVA) of 73-35 letters in the study eye at 4 meters. This study was conducted at 20 sites across 5 countries or regions of Asia, including Hong Kong, Japan, Republic of Korea, Singapore, and Taiwan.



This was an international, phase 3, multicenter, randomized, double-masked, sham-controlled study.

Screening Primary and **Exploratory** secondary end points Day 21 end points measured measured Baseline Intravitreal aflibercept 2 mg Patients with 28 32 36 12 16 20 24 40 4 8 44 48 myopic CNV Weeks randomized ratio: 3:1 Control/ intravitreal aflibercept 28 32 16 20 24 40 44 48 2 mg Weeks Additional intravitreal aflibercept treatment could be administered Intravitreal aflibercept 2 mg At Week 24, after assessment of from Week 28 to Week 44 (at a Sham the primary efficacy end point, maximum frequency of once Sham/intravitreal aflibercept 2 mg* control patients received the every 4 weeks) if CNV persisted first mandatory intravitreal No treatment or recurred on the basis of the

aflibercept 2.0 mg injection.

assessment of the aforementioned

retreatment criteria.

Retreatment was allowed in patients who met 1 or more of the following criteria: (1) reduction in visual acuity by 5 letters from the previous Early Treatment Diabetic Retinopathy

*If retreatment criteria were fullfilled

- Study examination;
 (2) increase in central retinal thickness (CRT) >50 µm from the time of the previous examination,
- new or persistent cystic retinal changes, subretinal fluid, or pigment epithelial detachment, and new or persistent CNV or bleeding; or

 (3) deemed necessary by the investigator based on their clinical impression or diagnostics performed
- in the context of standard medical care.

 In the control group, patients were given 1 sham injection followed by repeated sham injections every

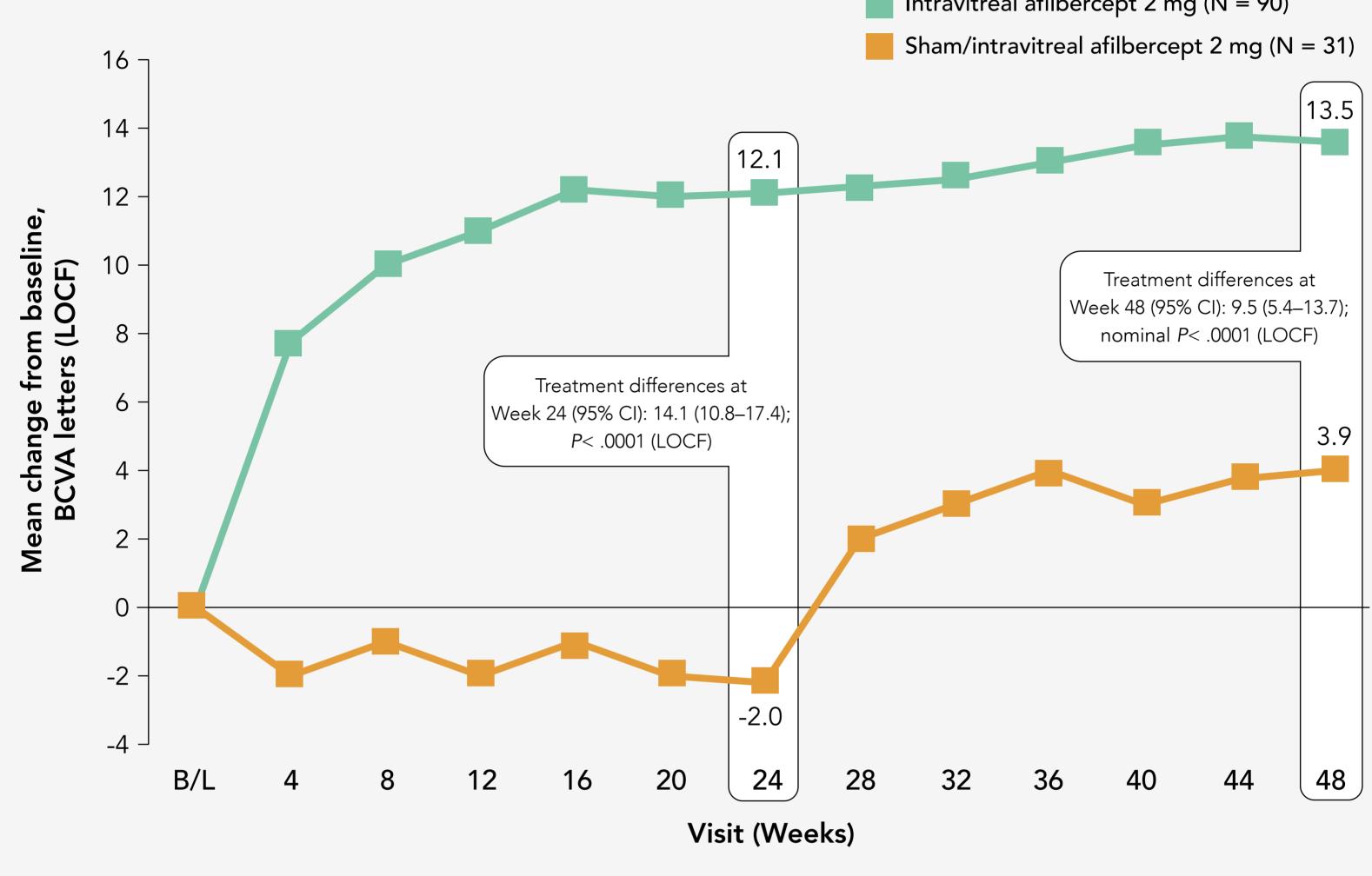
4 weeks through Week 20 regardless of whether retreatment criteria were fulfilled or not.



in BCVA of +12.1 letters compared with a 2.0 letter loss in the sham group.

Intravitreal afilbercept 2 mg (N = 90)

Patients in the intravitreal aflibercept group had a mean change



A greater proportion of intravitreal aflibercept-treated patients gained

performed for Week 24. Treatment different is least squares (LS) mean change. CI = confidence interval.

Primary end point: mean change in best-corrected visual acuity (BCVA) (last observation carried forward

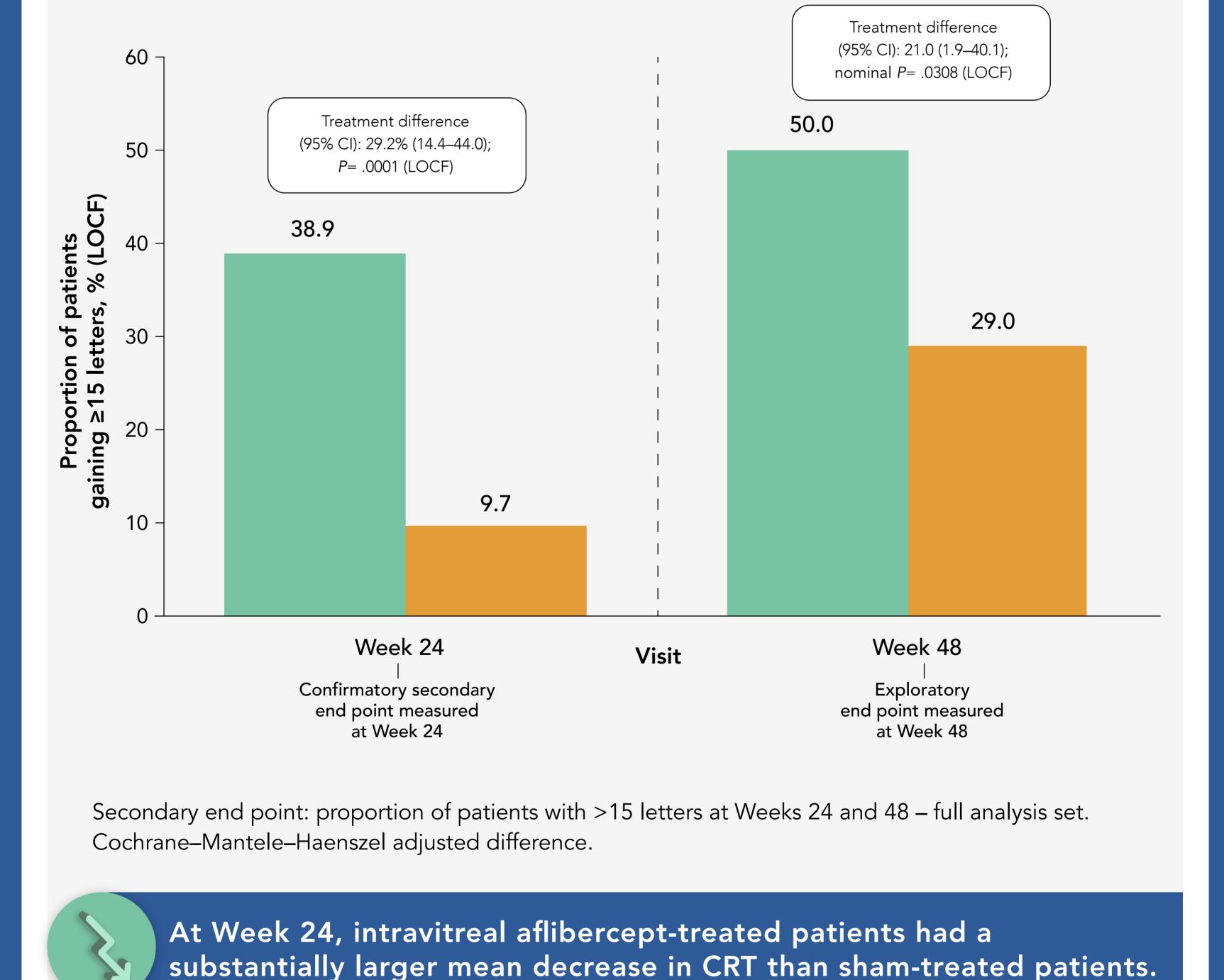
[LOCF]) from baseline to Week 48 – full analysis set. A confirmatory analysis of the primary end point was

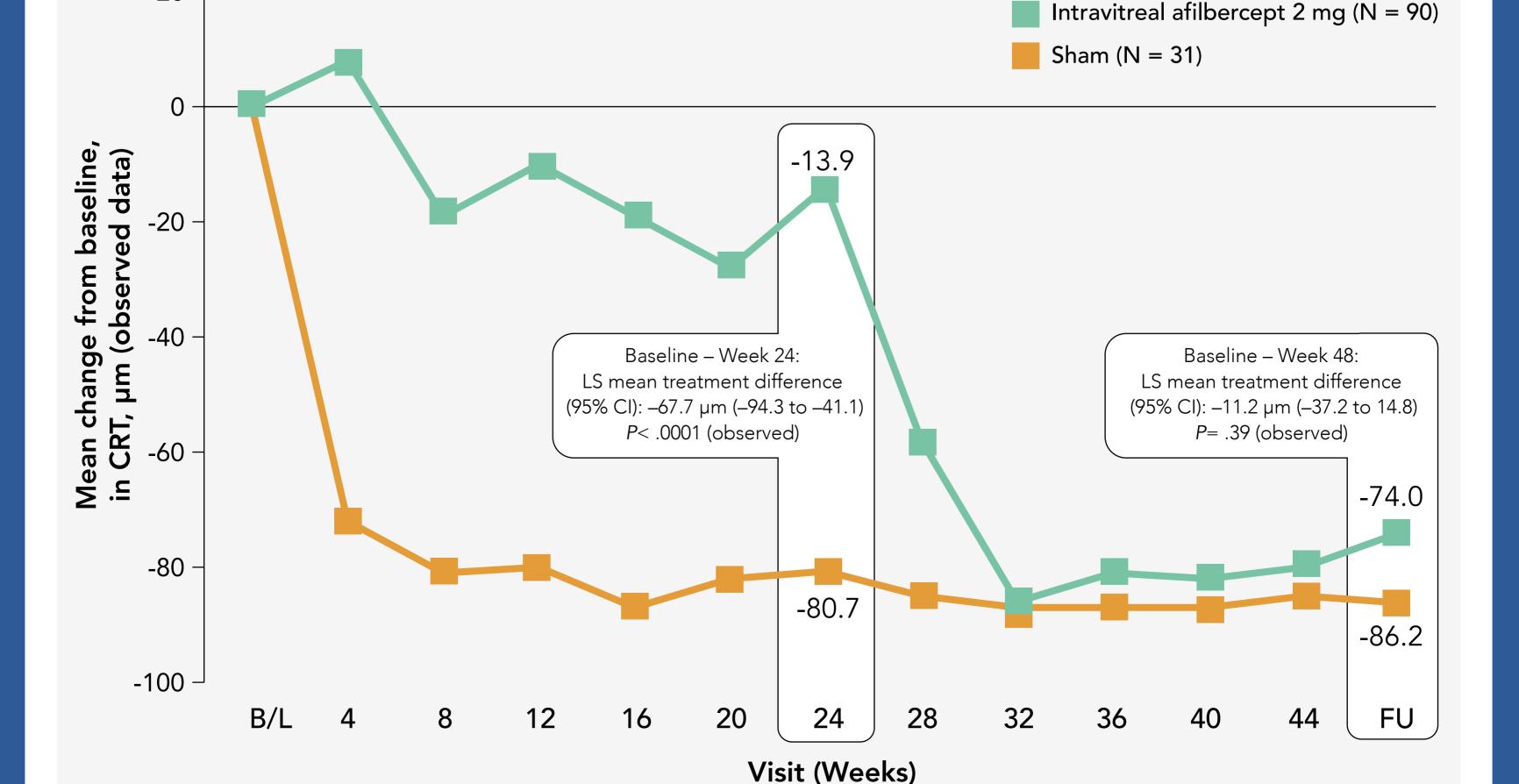


Intravitreal afilbercept 2 mg (N = 90)

Sham/intravitreal afilbercept 2 mg (N = 31)

15 letters compared with sham-treated patients at Weeks 24 and 48.





Conclusions

FU = follow-up.

20

Intravitreal aflibercept 2 mg was effective for treatment of myopic CNV with clinically important visual and anatomic benefits achieved with a limited number of injections given in the first 8 weeks of treatment. No new safety concerns occurred with treatment.

Intravitreal aflibercept should be considered as a treatment option for myopic CNV.

Mean change in central retinal thickness (CRT) from baseline to Week 24 and to Week 48 – full analysis set.