A0087

Outcomes in Patients with Neovascular Age-related Macular Degeneration Based on Dosing Intervals in the Second Year of the VIEW Studies

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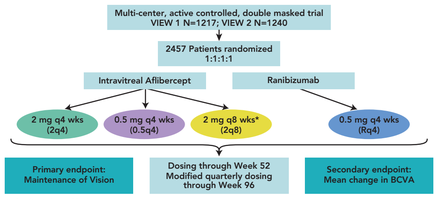
BACKGROUND

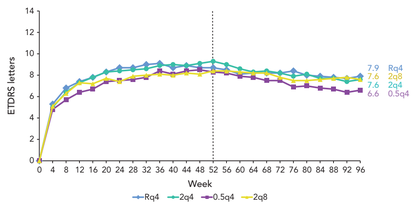
- The VIEW 1 and VIEW 2 studies evaluated efficacy and safety of intravitreal aflibercept injection (IAI) compared with ranibizumab for treatment of neovascular AMD



*After 3 initial monthly doses

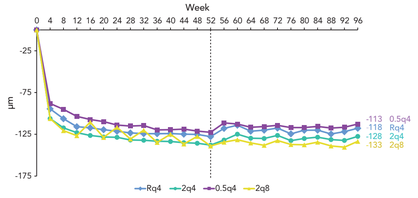
- In the integrated VIEW 1 and VIEW 2 studies at week 52, all IAI groups demonstrated similar improvements in all visual acuity endpoints compared to Rq4
- Incidences of Antiplatelet Trialists' Collaboration defined arterial thromboembolic events were similar across treatment groups (2.4% to 3.8%) from baseline to week 96
- From weeks 52 through 96, patients received their original dosing assignment using a modified quarterly dosing regimen with defined retreatment criteria and mandatory dosing at least every 12 weeks
  - Retreatment criteria
    - 12 weeks since previous injection
    - New or persistent fluid on optical coherence tomography (OCT)
    - Increase in central retinal thickness (CRT) of ≥100 µm compared to the lowest previous value
    - Loss of ≥5 Early Treatment Diabetic Retinopathy Study (ETDRS) letters from the best previous score in conjunction with recurrent fluid on OCT
    - New onset classic neovascularization
    - New or persistent leak on fluorescein angiography (FA)
    - New macular hemorrhage
- At week 96, all IAI and Rq4 groups were equally effective in improving best-corrected visual acuity (BCVA).

Figure 1. Mean Change in BCVA from Baseline Through Week 96



LOCF; Full analysis set. Rq4 n=595; 2q4 n=613; 0.5q4 n=597; 2q8 n=607

Figure 2. Mean Change in CRT from Baseline Through Week 96



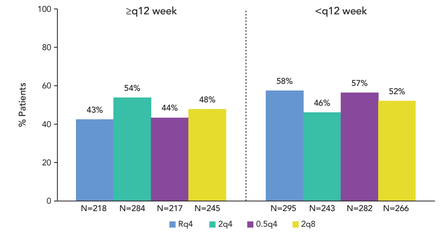
LOCF; Full analysis set. Rq4 n=595, 2q4 n= 613, 0.5q4 n=597, and 2q8 n= 607

METHODS

- During weeks 52-96 of treatment in the VIEW studies, two subgroups of patients were defined who received treatment with 0.5 mg ranibizumab or 2 mg IAI at the following frequencies:
  - Always received injections at ≥12 weeks intervals (≥q12 week)
  - Received, at least once, an injection at a 4- or 8-week interval (<q12 week)
- For each subgroup, the following were evaluated in the integrated data:
  - Key disease characteristics at baseline and week 52
  - Visual outcomes at week 96
  - Anatomic outcomes at week 96

RESULTS

Figure 3. Proportion of Patients Who Received Injections at ≥q12 weeks or <q12 Weeks Intervals



FAS, Year 2 medication completer

KEY DISEASE CHARACTERISTICS

Table 1. Baseline Disease Characteristics

A) ≥q12 week

	Rq4	2q4	0.5q4	2q8
n (%)	218/513 (42.5)	284/527 (53.9)	217/499 (43.5)	245/511 (47.9)
BCVA, letters (SD)	52.6 (13.4)	54.0 (13.4)	52.0 (14.4)	53.5 (13.7)
CRT, µm	317.5 (105.5)	322.2 (111.5)	314.3 (107.6)	331.3 (120.6)
CNV Area, mm²	6.7 (5.4)	7.4 (5.3)	7.1 (4.9)	7.0 (5.3)
Total lesion size, mm²	7.0 (5.8)	7.8 (5.8)	7.5 (5.1)	7.4 (5.5)
Total lesion size, n (%)				
≤4 DA (10.16 mm²)	162 (74.3)	209 (73.6)	162 (74.7)	175 (71.4)
>4 DA (10.16 mm²)	53 (24.3)	73 (25.7)	54 (24.9)	69 (28.2)
Type of CNV, n (%)				
Occult	69 (31.7)	98 (34.5)	82 (37.8)	88 (35.9)
Minimally Classic	81 (37.2)	122 (43.0)	75 (34.6)	80 (32.7)
Predominantly Classic	65 (29.8)	62 (21.8)	59 (27.2)	76 (31.0)

FAS, Year 2 medication completer

B) <q12 week

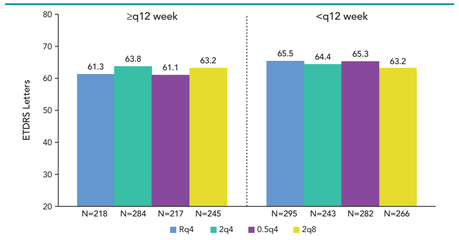
	Rq4	2q4	0.5q4	2q8
n (%)	295/513 (57.5)	243/527 (46.1)	282/499 (56.5)	266/511 (52.1)
BCVA, letters (SD)	55.2 (13.1)	54.7 (13.6)	54.7 (13.3)	54.3 (13.0)
CRT, µm	322.3 (109.5)	327.2 (119.4)	327.3 (113.1)	333.6 (114.0)
CNV Area, mm²	7.3 (5.4)	7.2 (5.6)	7.0 (5.1)	7.2 (5.3)
Total lesion size, mm²	7.8 (5.8)	7.6 (5.8)	7.4 (5.4)	7.5 (5.5)
Total lesion size, n (%)				
≤4 DA (10.16 mm²)	211 (71.5)	181 (74.5)	209 (74.1)	194 (72.9)
>4 DA (10.16 mm²)	83 (28.1)	61 (25.1)	73 (25.9)	72 (27.1)
Type of CNV, n (%)				
Occult	125 (42.4)	98 (40.3)	112 (39.7)	110 (41.4)
Minimally Classic	95 (32.2)	68 (28.0)	88 (31.2)	97 (36.5)
Predominantly Classic	74 (25.1)	76 (31.3)	82 (29.1)	58 (21.8)

FAS, Year 2 medication completer

RESULTS

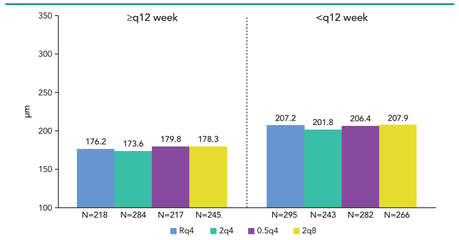
CHARACTERISTICS AT WEEK 52 FOR EACH DOSING SUBGROUP

Figure 4. BCVA



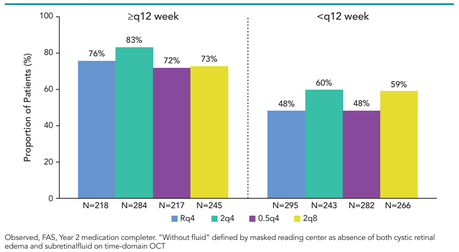
LOCF; Full Analysis Set

Figure 5. CRT



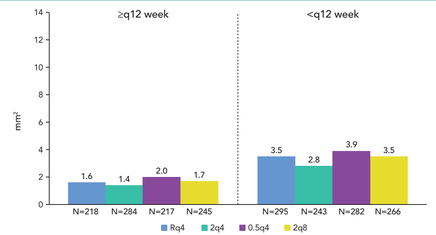
Compared to baseline; LOCF; Full Analysis Set

Figure 6. Proportion of Patients without Fluid



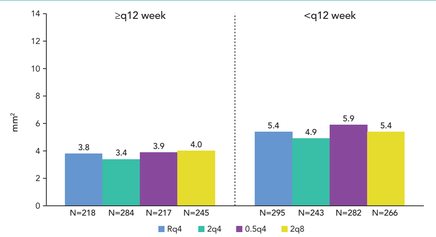
Observed, FAS, Year 2 medication completer. "Without fluid" defined by masked reading center as absence of both cystic retinal edema and subretinalfluid on time-domain OCT

Figure 7. CNV Area



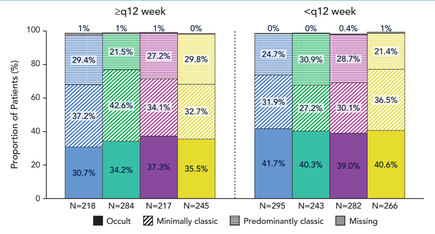
Compared to baseline; LOCF; Full Analysis Set

Figure 8. Total Lesion Area



Compared to baseline; LOCF; Full Analysis Set

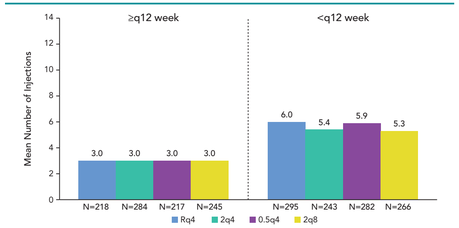
Figure 9. CNV Type



LOCF; Full Analysis Set, Year 2 Medication Completer

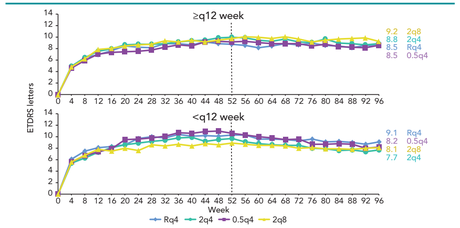
OUTCOMES FROM WEEKS 52–96 (YEAR 2)

Figure 10. Mean Number of Injections



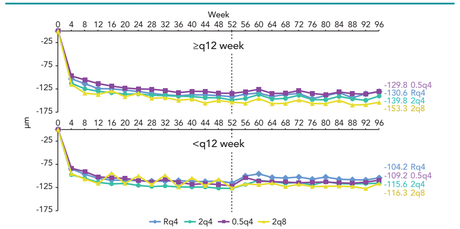
FAS, Year 2 medication completer. A minimum of at least 3 injections required with mandatory quarterly dosing

Figure 11. Mean Change in BCVA from Baseline Through Week 96



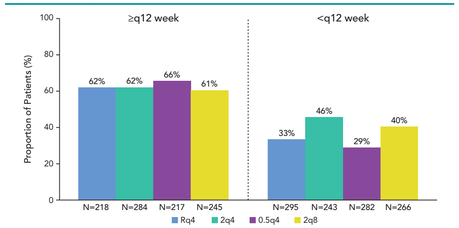
FAS, LOCF; Year 2 medication completer. ≥q12 week: Rq4 n= 218, 2q4 n= 284, 0.5q4 n=217, and 2q8 n=245. <12q week: Rq4 n=295, 2q4 n=243, 0.5 q4 n=282, and 2q8 n=266

Figure 12. Mean Change in CRT from Baseline Through Week 96



FAS, LOCF; Year 2 medication complete. ≥q12 week: Rq4 n= 218, 2q4 n= 284, 0.5q4 n=217, and 2q8 n=245. <12q week: Rq4 n=295, 2q4 n=243, 0.5 q4 n=282, and 2q8 n=266

Figure 13. Proportion of Patients Without Fluid at Week 96



Observed, FAS. "Without fluid" defined by masked reading center as absence of both cystic retinal edema and subretinalfluid on time-domain OCT

CONCLUSIONS

- In a sub-analysis of the VIEW studies, from Weeks 52 to 96:
  - Numerically higher proportion of patients treated with 2 mg IAI received injections at ≥q12 week intervals compared to those treated with Rq4
  - Vision gains and anatomic improvements at week 52 were largely maintained in both ≥q12-week and <12q-week dosing subgroups
- At Week 52 after one year of fixed treatment, patients who received dosing only every 12 weeks compared to those dosed more frequently during year 2 had the following characteristics:
  - Lower CRT
  - Smaller CNV area and lesion size
  - Lower proportion of patients with occult lesions
  - Higher proportion of patients with fluid absent on time-domain OCT
- Some patients may be dosed every 12 weeks with 2 mg IAI based on disease status following a year of fixed treatment

DISCLOSURES: Consultant: Regeneron, Genentech, Allergan, Alimera, Bausch & Lomb/Valeant; Research Grant: Regeneron; Consultant and Equity: Visunex, Versl, OptiSTENT. Presented at The Annual Meeting of the Association for Research in Vision and Ophthalmology, Baltimore, Maryland, May 7–11, 2017