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Interim Analysis of Phase 2 Study of VEGF Trap in AMD patients

Patients treated with 5 different dosing regimens, and compared to their own baseline over the course of three months, using change in retinal thickness at three months as the primary endpoint, with changes in visual acuity as the key secondary endpoint

Patients treated with 0.5 mg, 2.0 mg and 4.0 mg doses, with cohorts in which each patient was treated just once with these doses and evaluated over the ensuing three months, as well as cohorts in the 0.5 and 2.0 doses were given monthly

Study achieved its pre-specified primary endpoint, of decrease in retinal thickness in all treated patients (all cohorts combined) at 12 weeks, with $p < 0.0001$

>>> The average decrease in retinal thickness across all five cohorts was 135 microns

Study also achieved key pre-specified secondary endpoint, of improvement in visual acuity in all treated patients (all cohorts combined) at 12 weeks, with $p < 0.0001$

>>> The average increase in visual acuity across all five cohorts was 6.0 letters at 4 weeks, 5.8 letters at 8 weeks, and 5.9 letters at 12 weeks

Statistical analyses did not show significant differences across the treatment groups, for changes in either retinal thickness or visual acuity, regardless of whether patients were treated with a single dose or received monthly treatments

>>> The improvements in visual acuity in the different cohorts ranged from 3 to 10 letters at 12 weeks

Patients treated with a single dose, at all three dose levels, maintained a decrease in retinal thickness as well as a gain in visual acuity (2.8 to 5.1 letters), at 12 weeks

Only a single patient in the entire study did not at least maintain their vision, as defined by loss of 3 or more lines of vision at three months

Quote:
"In this 12 week study, the VEGF Trap caused statistically significant improvements in both retinal swelling and visual acuity. Moreover, the VEGF Trap may prove unique in that a single dose may be able to maintain a beneficial effect on retinal swelling, as well as improve visual acuity, for at least twelve weeks. We look forward to the required Phase 3 studies to define the doses and intervals that will provide the most benefit and most desirable treatment options for patients."

Key Background Comparisons to Lucentis:

Average Approximate decrease in visual acuity during PIER at each 12w interval following injection (0.5 mg dose): Loss of about 2.5 letters

Mean change in VA at 1m, 3m and 1 year in Lucentis pivotal studies:

		1m	3m	12m
Marina	0.3	~3.5	5.1	6.5
(2m ETDRS)	0.5	~4	5.9	7.2
Anchor	0.3	5.9	6.8	8.5

(2m ETDRS)	0.5	8.4	10	11.3
Pier	0.3	0	2.9	-1.6
(4m ETDRS)	0.5	~3.5	4.3	-0.2