**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, D.C. 20549**

# FORM 8-K
# CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the**
**Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): August 22, 2011 (August 22, 2011)

**REGENERON PHARMACEUTICALS, INC.**
(Exact Name of Registrant as Specified in Charter)

| **New York** | **000-19034** | **13-3444607** |
|---|---|---|
| (State or other jurisdiction of Incorporation) | (Commission File No.) | (IRS Employer Identification No.) |

**777 Old Saw Mill River Road, Tarrytown, New York 10591-6707**
(Address of principal executive offices, including zip code)

**(914) 347-7000**
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 7.01 Regulation FD Disclosure.**

On August 22, 2011, at the American Society of Retina Specialists meeting in Boston, Massachusetts, data from the Phase 3 COPERNICUS Study of the safety, efficacy, and tolerability of repeated intravitreal administration of VEGF Trap-Eye in patients with macular edema secondary to central retinal vein occlusion will be presented by W. Lloyd Clark, M.D. A copy of the slides that will be presented is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

99.1 Presentation entitled VEGF Trap-Eye in CRVO: 1-year Results of the Phase 3 COPERNICUS Study

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 22, 2011

REGENERON PHARMACEUTICALS, INC.

By: /s/ Murray A. Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance and Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Exhibit Index

| Number | Description |
| --- | --- |
| 99.1 | Presentation entitled VEGF Trap-Eye in CRVO: 1-year Results of the Phase 3 COPERNICUS Study |


COPERNICUS
VEGF Trap-Eye for Central Retinal Vein Occlusion
A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of VEGF Trap-Eye in Subjects with Macular Edema Secondary to Central Retinal Vein Occlusion (CRVO)

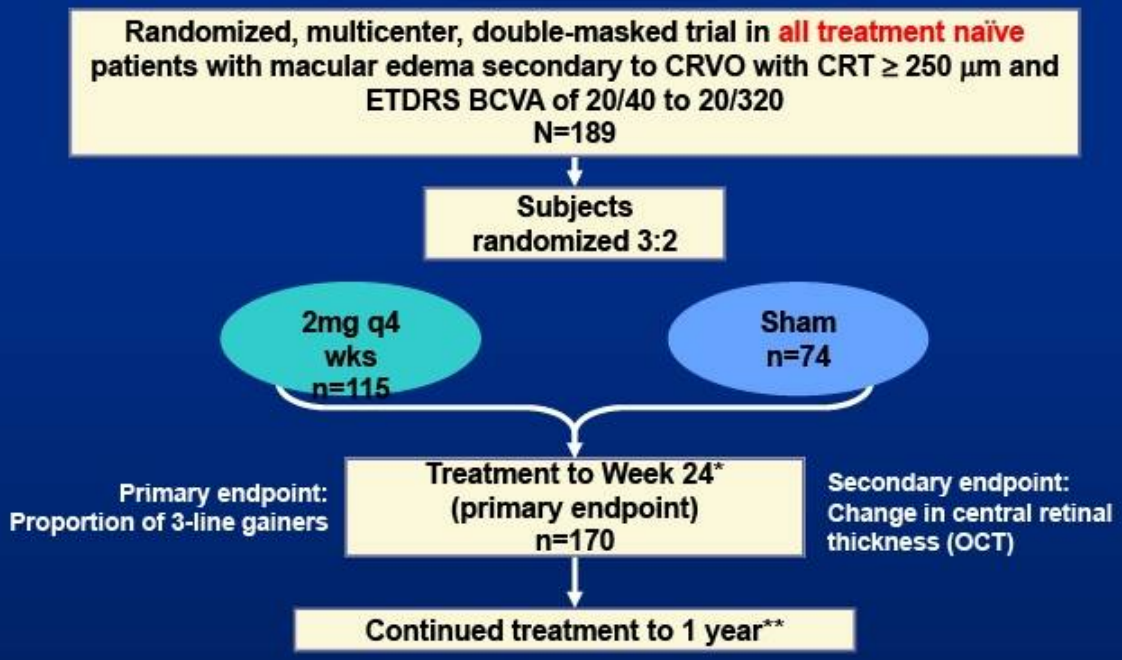
# Introduction

- CRVO is an obstruction of the retinal venous system due to thrombus formation
- Prevalence currently of all RVO 0.7–1.6% and increases with age
  - BRVO 3 to 4 times greater incidence versus CRVO

| Nonischemic |
| --- |
| Up to 50% have visual acuity decrease to ≤ 20/200 |
| < 10% recover normal visual acuity[1,2] |
| 34% progress to ischemic by 3 years;<br>15% convert in first 4 months[2] |
| **Ischemic** |
| Up to > 90% have final visual acuity 20/200 or worse[1] |
| 37% progress to rubeosis by 4 months[2] |

1.Morley et al. Chapter 6.17. In: *Ophthalmology*. 2009.
2.Denniston et al. *Oxford Handbook of Ophthalmology*. 2006.

# COPERNICUS
## CRVO Phase 3 Study Design




*Beginning at Wk 24, patients will be dosed on a PRN (as needed) basis
PRP available for all subjects

# COPERNICUS
## Key Exclusion Criteria

- Treatment naïve patients
- Previous use of intraocular or periocular corticosteroids in the study eye
- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months

# COPERNICUS
## Patient Disposition

| | Sham | VTE 2q4 |
|---|---|---|
| Randomized | 74 | 115 |
| Received Study Medication | 74 (100%) | 114 (99.1%)* |
| Completed Week 24 | 60 (81.1%) | 110 (95.7%) |
| Discontinuation Before Wk 24 | 14 (18.9%) | 5 (4.3%) |
| Withdrawal Of Consent% | 1 (1.4%) | 3 (2.6%) |
| Protocol Deviation& | 1 (1.4%) | 0 |
| Adverse Event# | 3 (4.1%) | 0 |
| Death^ | 2 (2.7%) | 0 |
| Lost To Follow-Up | 2 (2.7%) | 1 (0.9%) |
| Treatment Failure | 4 (5.4%) | 0 |
| Other† | 1 (1.4%) | 1 (0.9%) |

*One patient was randomize but not treated after a retinal tear was identified at Visit 2.
% Sham: VA Reduced 2q4: Lung cancer, unknown x2
& Sham: Bilateral CRVO
# Sham: Neovascular glaucoma, retinal tear, vitreous hemorrhage/NVG
^ Sham: MI and arrhythmia
† Sham: Lack of efficacy 2q4: patient never treated

# COPERNICUS
## Baseline Demographics

| | Sham | VTE 2q4 |
|---|---|---|
| n (full analysis set) | 73 | 114 |
| Age years (SD) | 67.5 (14.29) | 65.5 (13.57) |
| Gender | | |
| Women (%) | 35 (48%) | 45 (39%) |
| Men (%) | 38 (52%) | 69 (61%) |
| Race (%) | | |
| White | 59 (80.8%) | 88 (77.2%) |
| Black | 5 (6.8%) | 5 (4.4%) |
| Asian | 2 (2.7%) | 7 (6.1%) |
| American Indian/Alaska Native | 0 | 2 (1.8%) |
| Native Hawaiian/Pacific Islander | 1 (1.4%) | 0 |
| Not Reported/Multi racial | 6 (8.2%) | 12 (10.5%) |

# COPERNICUS
## Baseline Disease Characteristics

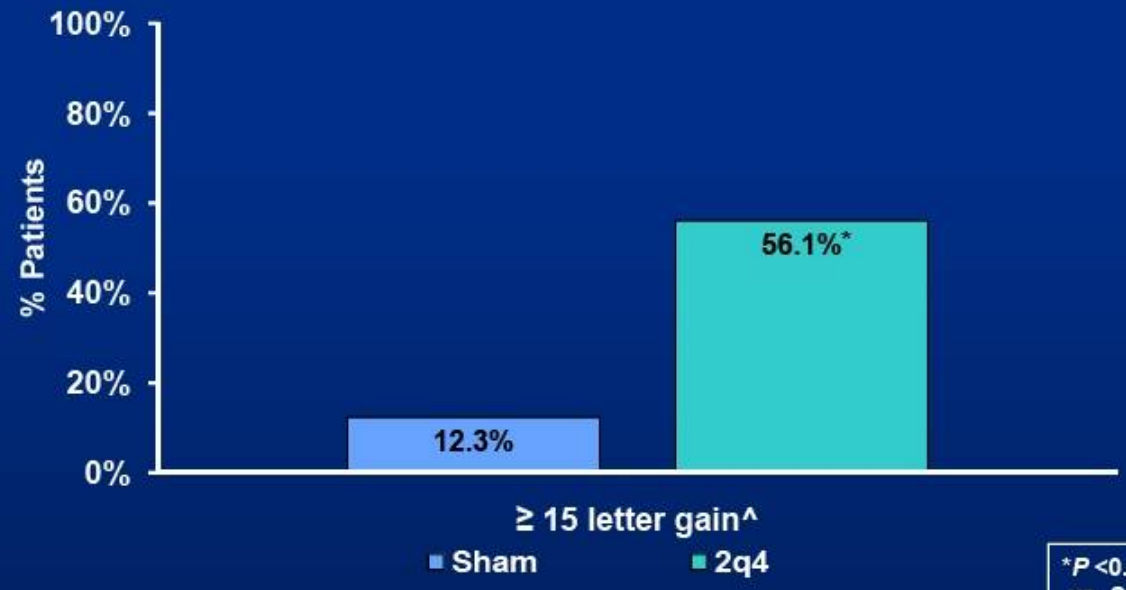
| | Sham | VTE 2q4 |
|---|---|---|
| n (full analysis set) | 73 | 114 |
| ETDRS BCVA letter score (SD)<br>Snellen Equivalent | 48.9 (14.4)<br>20/126 | 50.7 (13.9)<br>20/100 |
| BCVA > 20/200 (%) | 55 (75.3) | 86 (75.4) |
| BCVA ≤ 20/200 (%) | 18 (24.7) | 28 (24.6) |
| Central Retinal Thickness µm (SD) | 672.4 (245.3) | 661.7 (237.4) |
| Baseline perfusion status n (%) | | |
| Perfused* | 50 ( 68.5%) | 80 ( 70.2%) |
| Non-perfused | 12 ( 16.4%) | 14 ( 12.3%) |
| Indeterminate | 10 ( 13.7%) | 18 ( 15.8%) |
| Missing | 1 ( 1.4%) | 2 ( 1.8%) |

*Less than 10 DA of non perfusion


EFFICACY

# COPERNICUS

## % Patients Who Gain ≥ 15 letters at Week 24

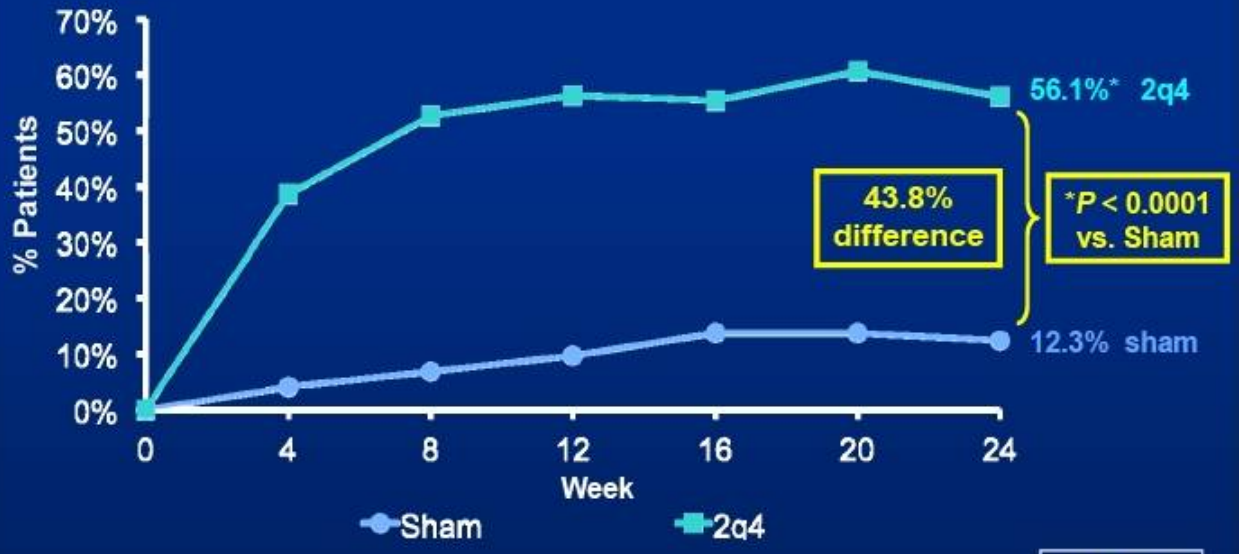



*P <0.0001 vs. Sham

^Compared to baseline; LOCF; full analysis set; sham n=73; 2q4 n=114;

# COPERNICUS

## % Patients Who Gained ≥ 15 letters




*P < 0.0001 vs. sham

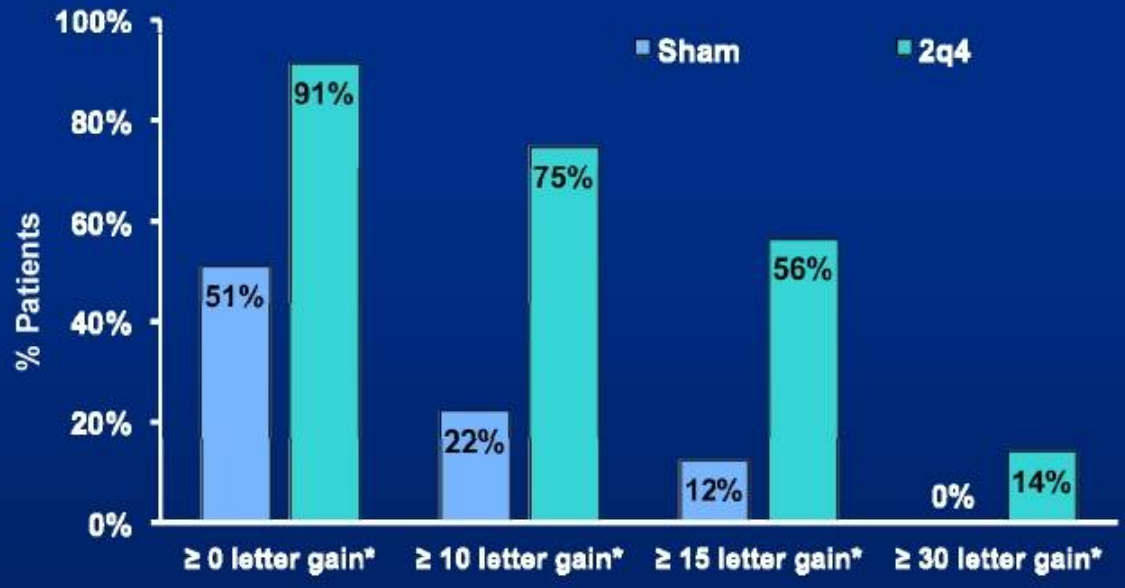
LOCF; full analysis set; sham n=73; 2q4 n=114;

# COPERNICUS
## Mean Change in Visual Acuity

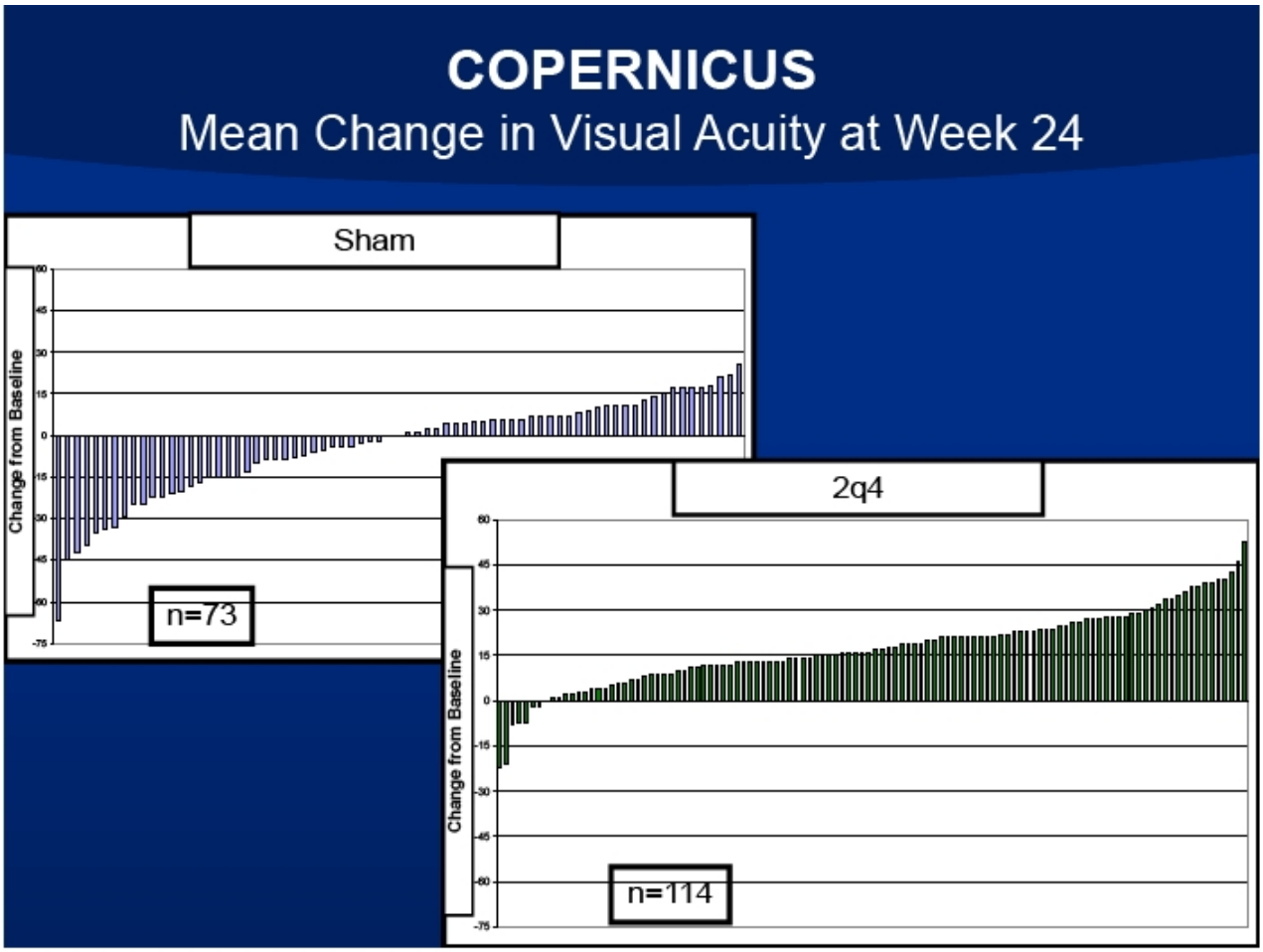

LOCF; full analysis set; sham n=73; 2q4 n=114;

# COPERNICUS

## Proportion of Patients Who Gained Vision at Week 24*

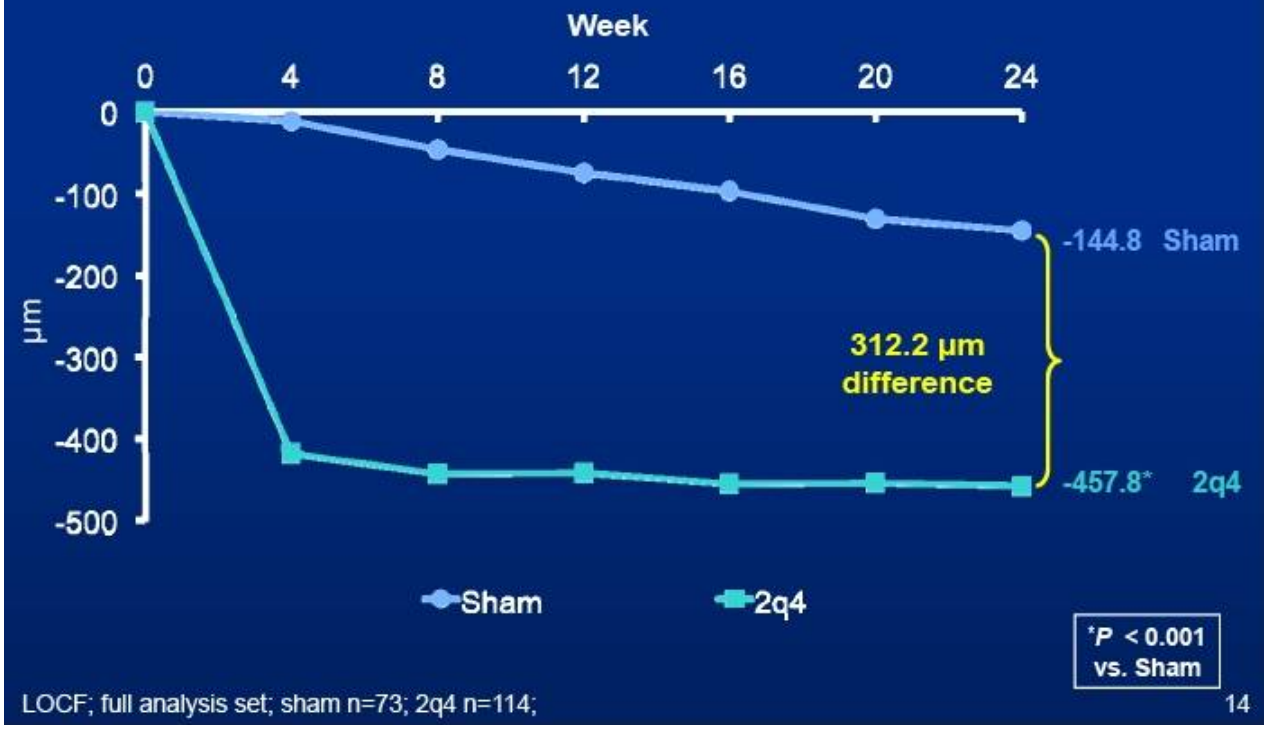



*Compared to baseline; Full analysis set; sham n=73; 2q4 n=114;


COPERNICUS
Mean Change in Visual Acuity at Week 24
Sham
Change from Baseline
n=73
2q4
Change from Baseline
n=114

# COPERNICUS

## Mean Change in Central Retinal Thickness

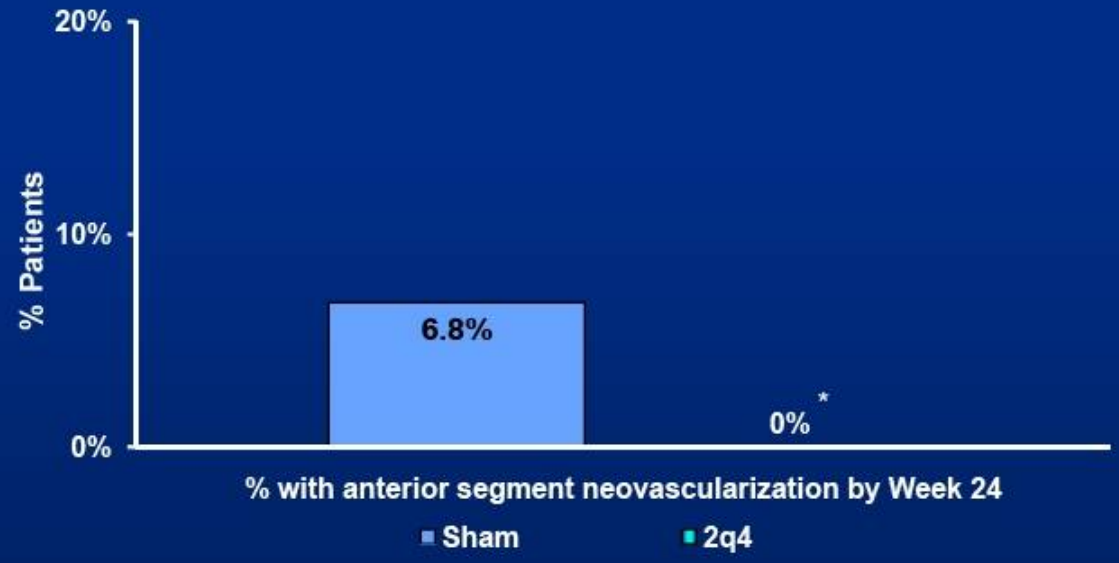



*P < 0.001 vs. Sham

LOCF; full analysis set; sham n=73; 2q4 n=114;

# COPERNICUS

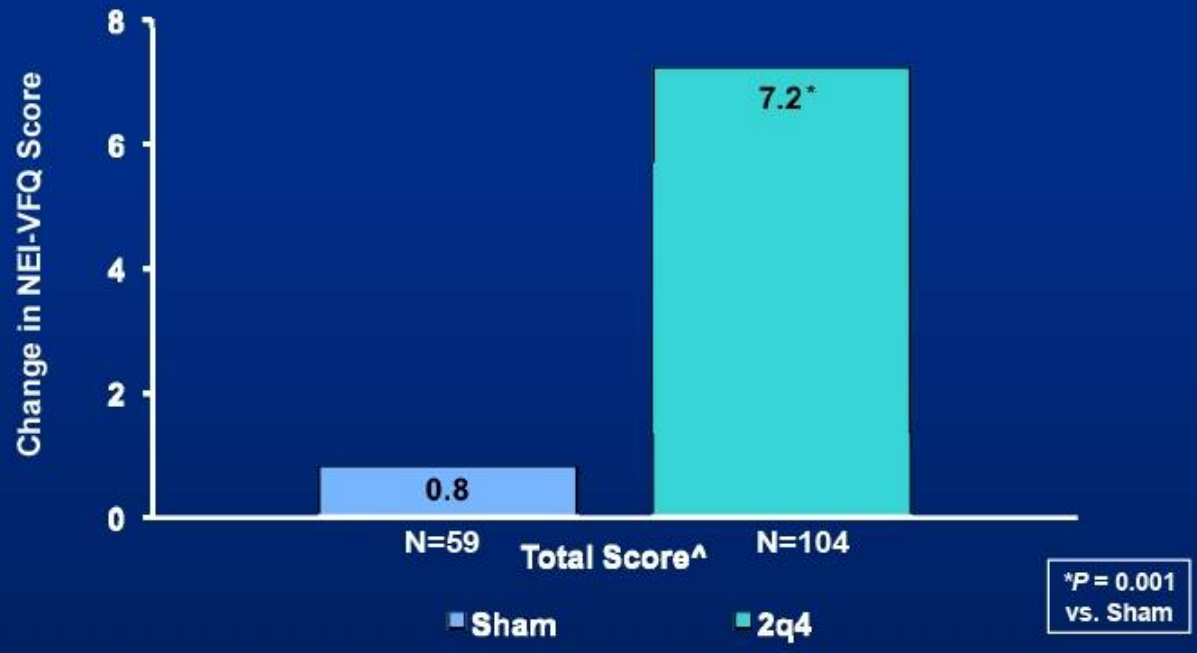
## % with Anterior Segment Neovascularization by Week 24



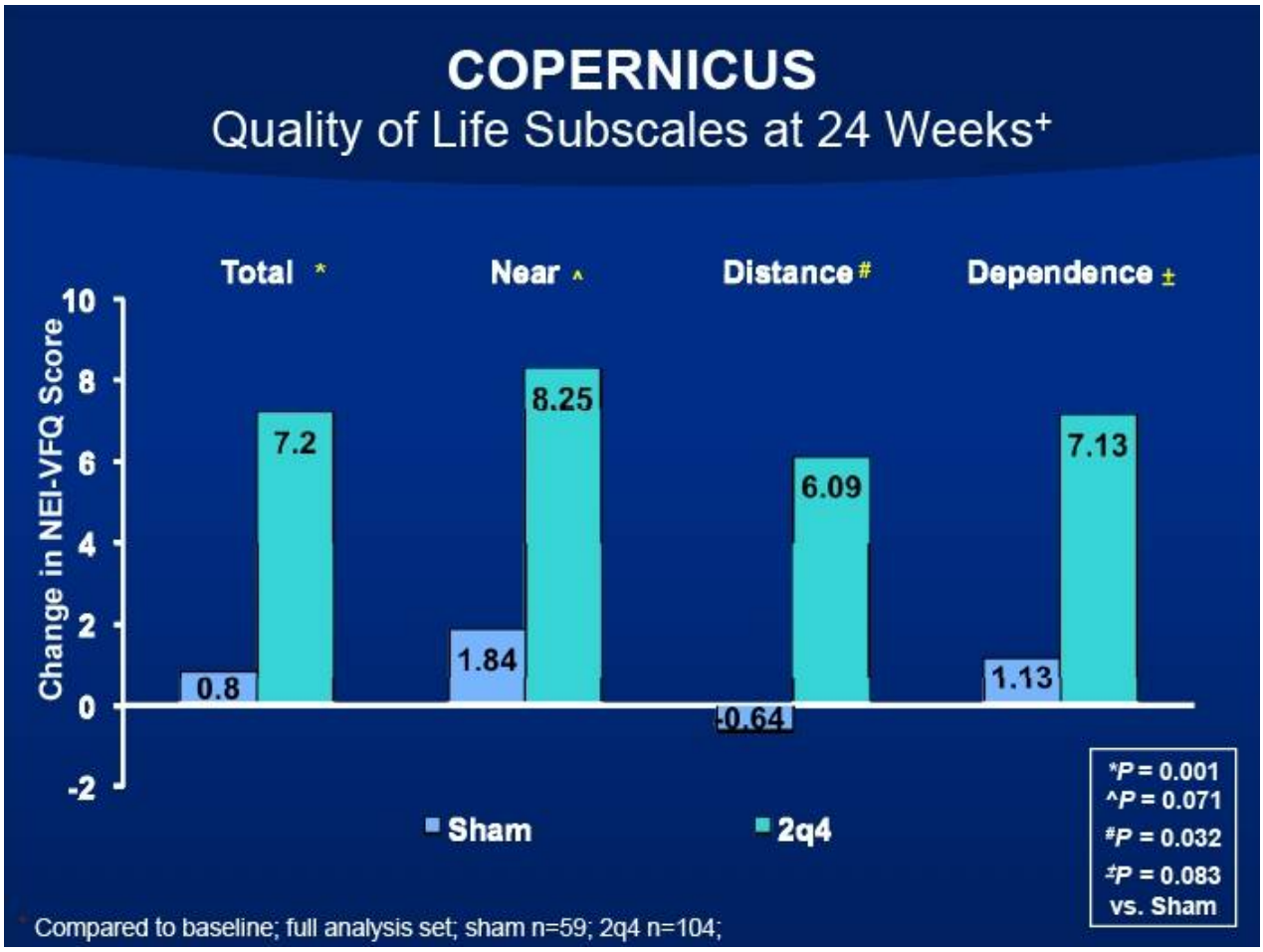

*Compared to baseline; full analysis set; sham n=73; 2q4 n=114;

# COPERNICUS

## Quality of Life at 24 Weeks*




^Compared to baseline; full analysis set; sham n=59; 2q4 n=104;


COPERNICUS
Quality of Life Subscales at 24 Weeks+
Total *
Near ^
Distance #
Dependence ±
Change in NEI-VFQ Score
10
8
6
4
2
0
-2
0.8
7.2
1.84
8.25
-0.64
6.09
1.13
7.13
Sham
2q4
*P = 0.001
^P = 0.071
#P = 0.032
±P = 0.083
vs. Sham
+ Compared to baseline; full analysis set; sham n=59; 2q4 n=104;


SAFETY

# COPERNICUS

## % Patients with Study Eye Ocular SAEs at Week 24

| | Sham | VTE 2q4 |
|---|---|---|
| n (safety analysis set) | 74 | 114 |
| # subjects with at least 1 AE | 10 (13.5%) | 4 (3.5%) |
| | | |
| Vitreous Hemorrhage | 4 (5.4%) | 0 |
| Neovascular Glaucoma | 2 (2.7%) | 0 |
| Iris Neovascularization | 2 (2.7%) | 0 |
| Retinal hemorrhage | 2 (2.7%) | 0 |
| Visual acuity reduced | 1 (1.4%) | 1 (0.9%) |
| Retinal Artery Occlusion | 0 | 1 (0.9%) |
| Retinal Tear | 1 (1.4%) | 0 |
| Retinal Vein Occlusion | 1 (1.4%) | 0 |
| Endophthalmitis | 0 | 1 (0.9%) |
| Corneal Abrasion | 0 | 1 (0.9%) |

# COPERNICUS
## Deaths through Week 24

| Arm | Age/Sex | Day from 1st Injection to Death | Day from Last Injection to Death | Preferred Term with Fatal Outcome |
|---|---|---|---|---|
| Sham | 74 Male | 202 | 54 | Arrhythmia |
| Sham | 64 Female | 32 | 3 | Acute myocardial infarction |

# COPERNICUS

## % Patients with APTC Events through Week 24

| | Sham | VTE 2q4 |
|---|---|---|
| N (safety analysis set) | 74 | 114 |
| Total | 2 (2.7%) | 0 |
| Vascular Deaths | 2 (2.7%) | 0 |
| MI | 1 | 0 |
| Stroke | 0 | 0 |
| Arrhythmia | 1 | 0 |
| Non Fatal MI | 0 | 0 |
| Non Fatal Stroke (ischemic) | 0 | 0 |

# COPERNICUS
## Conclusions

**Safety:**

- VEGF Trap Eye was tolerated without evidence of negative ocular or systemic effects

**Efficacy:**

- Statistically significant difference in proportion of patients who have gained ≥ 3 lines (56.1% vs 12.3%)
- Statistically significant difference in mean BCVA by 21 letters (+17.3 letters vs -4.0)
- Statistically significant difference in retinal thickness (312.2 μm difference)
- Statistically significant difference in total NEI-VFQ score (+7.2 vs +0.8)
- Reduction in formation of iris neovascularization (NVI) (6.8% vs 0%)

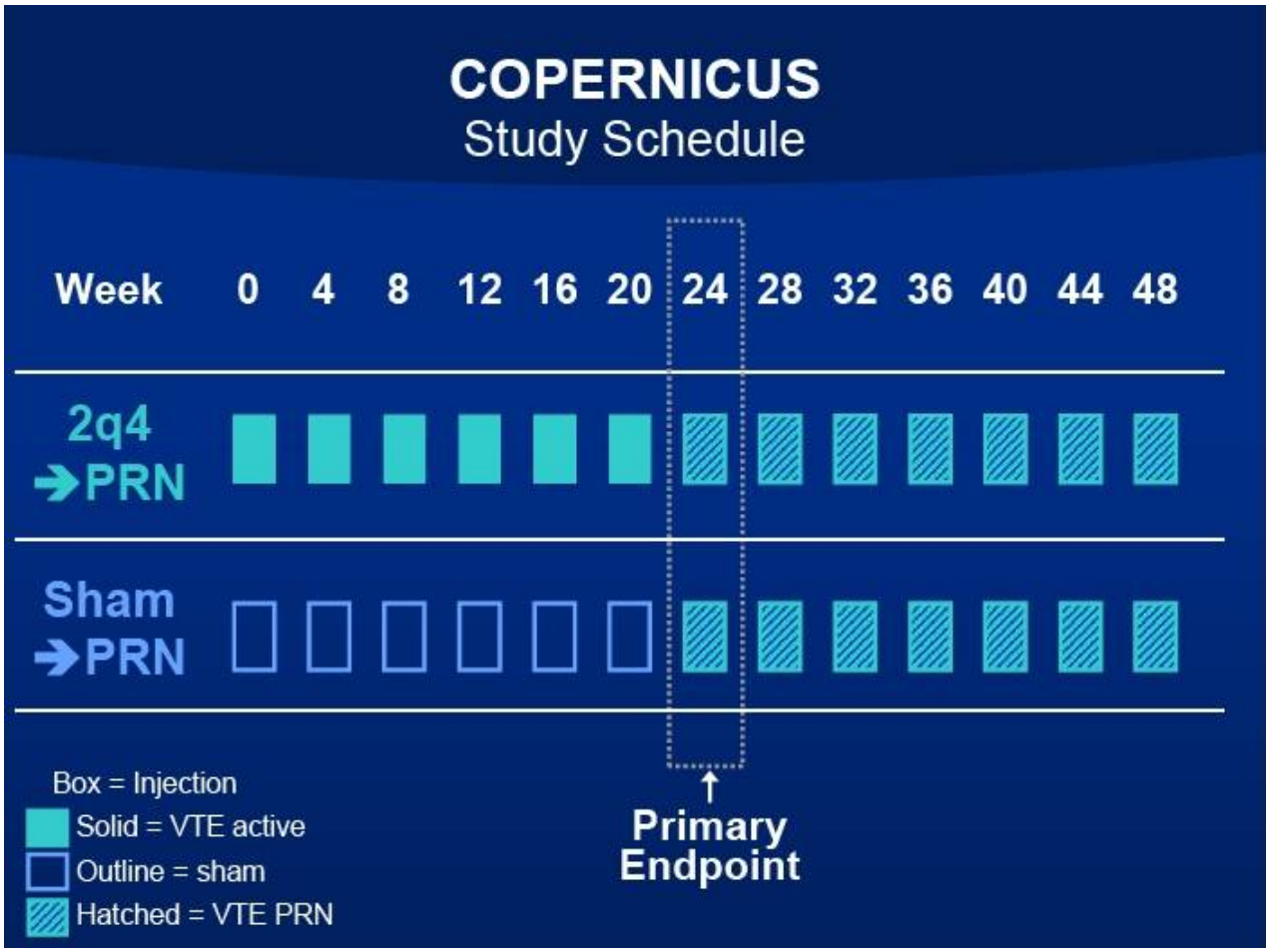
# COPERNICUS
## One Year Analysis

- After the primary endpoint at Week 24, all patients were eligible to receive VEGF Trap-Eye on a PRN basis

**Sham → VTE PRN**

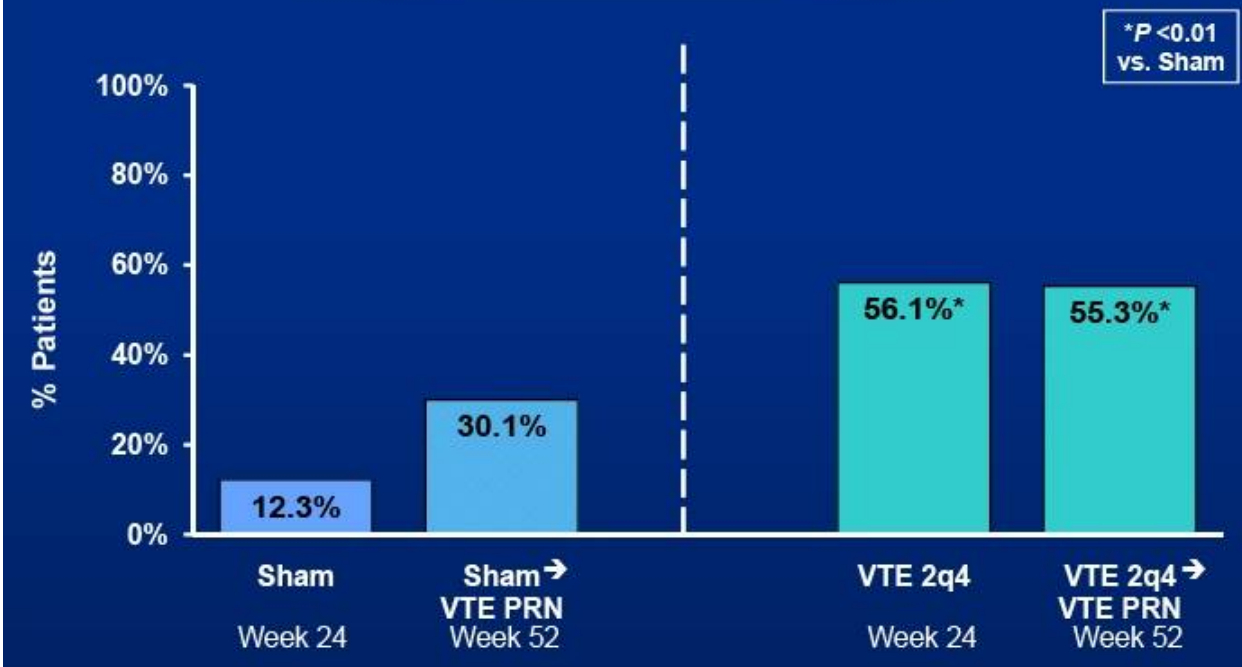
**VTE 2q4 → VTE PRN**

- Therefore, all but 3 patients in the sham arm who continued into the 2nd 6 months of the study received at least one dose of VEGF Trap-Eye

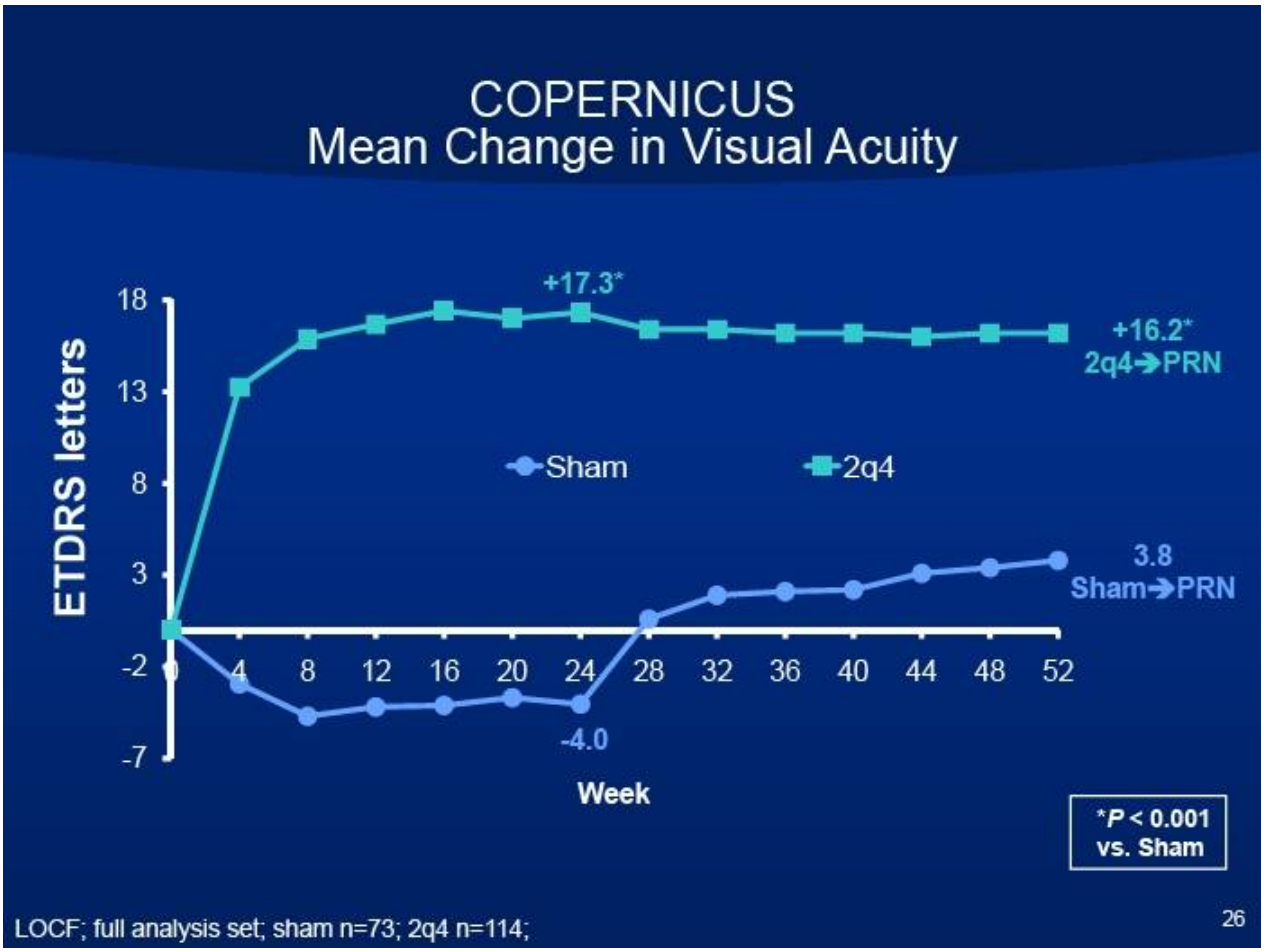

COPERNICUS
Study Schedule
Week 0 4 8 12 16 20 24 28 32 36 40 44 48
2q4 →PRN
Sham →PRN
Box = Injection
Solid = VTE active
Outline = sham
Hatched = VTE PRN
Primary Endpoint

# COPERNICUS

## % Patients Who Gain ≥ 15 letters




Compared to baseline; LOCF; full analysis set; sham n=73; 2q4 n=114;


COPERNICUS
Mean Change in Visual Acuity
ETDRS letters
18
13
8
3
-2
-7
+17.3*
+16.2*
2q4→PRN
Sham
2q4
3.8
Sham→PRN
0
4
8
12
16
20
24
28
32
36
40
44
48
52
-4.0
Week
*P < 0.001
vs. Sham
LOCF; full analysis set; sham n=73; 2q4 n=114;
26

# COPERNICUS
## Retreatment Criteria

- > 50µm increase in CRT on OCT compared to lowest previous measurement
- New or persistent cystic retinal changes or sub-retinal fluid on OCT or persistent diffuse edema ≥ 250 µm in the central subfield on OCT
- Loss of ≥5 letters from the best previous measurement in conjunction with any increase in CRT on OCT
- An increase of ≥ 5 letters in visual acuity between the current and most recent visit

# COPERNICUS
## Treatment Summary

### Total PRN Injections (Week 24 to Week 52)

| | Mean (SD) | Min:Max* | Median | Median time to first PRN injection |
|---|---|---|---|---|
| 2q4 → VTE PRN (n = 110) | 2.7 (1.7) | 0:7 | 3.0 | 68 |
| Sham → VTE PRN+ (n = 60) | 3.9 (2.0) | 0:7 | 4.0 | 29 |

*Maximum of 7 injections possible
+3 Patients in the sham arm did not get treated with VTE during the 2nd 6 months

# COPERNICUS

## % Patients with Study Eye Ocular SAEs

| | Sham BL - Wk 24 | Sham → VTE PRN Wk 24 - 52 | VTE 2q4 BL - Wk 24 | VTE 2q4 → VTE PRN Wk 24 - 52 |
|---|---|---|---|---|
| n (safety analysis set) | 74 | 60 | 114 | 110 |
| # subjects w/ ≥ 1 AE | 10 (13.5%) | 2 ( 3.3%) | 4 (3.5%) | 3 (2.7%) |
| Cataract | 0 | 1 ( 1.7%) | 0 | 1 (0.9%) |
| Retinal Hemorrhage | 2 ( 2.7%) | 0 | 0 | 0 |
| Visual Acuity Reduced | 1 ( 1.4%) | 0 | 1 (0.9%) | 0 |
| Vitreous haemorrhage | 4 ( 5.4%) | 1 ( 1.7%) | 0 | 1 (0.9%) |
| Cystoid macular edema | 0 | 0 | | 1 (0.9%) |
| Glaucoma | 2 ( 2.7%) | 1 ( 1.7%) | 0 | 0 |
| Iris Neovascularization | 2 ( 2.7%) | 0 | 0 | 0 |
| Retinal tear | 1 ( 1.4%) | 1 ( 1.7%) | 0 | 0 |
| Retinal vein occlusion | 1 ( 1.4%) | 0 | 0 | 1 (0.9%) |
| Retinal Artery occlusion | 0 | 0 | 1 (0.9%) | 0 |
| Endophthalmitis | 0 | 0 | 1 (0.9%) | 0 |
| Corneal Abrasion | 0 | 0 | 1 (0.9%) | 0 |

# COPERNICUS

## % Patients with APTC Events

| | Sham BL - Wk 24 | Sham → VTE PRN Wk 24 - 52 | VTE 2q4 BL - Wk 24 | VTE 2q4 → VTE PRN Wk 24 - 52 |
|---|---|---|---|---|
| N (safety analysis set) | 74 | 60 | 114 | 110 |
| Total | 2 (2.7%) | 0 | 0 | 1 (0.5%) |
| Vascular Deaths | 2 (2.7%) | 0 | 0 | 0 |
| MI | 1 | 0 | 0 | 0 |
| Stroke | 0 | 0 | 0 | 0 |
| Arrhythmia | 1 | 0 | 0 | 0 |
| Non Fatal MI | 0 | 0 | 0 | 1 |
| Non Fatal Stroke (ischemic) | 0 | 0 | 0 | 0 |

# COPERNICUS
## One-Year Conclusions

- Efficacy maintained to Week 52 with less frequent dosing
  - 55% of 3 line gainers for VTE/PRN vs. 30% for Sham/PRN
  - Mean change of BCVA at week 52 within 1 letter of week 24 outcome in the original 2q4 group
- Safety
  - VTE was generally well tolerated
  - Most common ocular adverse events were typical of those associated with intravitreal injections
  - Events associated with disease progression more frequent in the sham group