Study of COmparative Treatments in RETinal Vein Occlusion 2 (SCORE2) Month 48 Results

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Disclosures

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SCORE2 Month 48 Results
Summary

• SCORE2 Month 48 results
  – demonstrate long-term effectiveness of anti-VEGF therapy for macular edema due to CRVO or HRVO
  – indicate the chronic nature and variability of disease course in CRVO and HRVO
  – highlight the importance of continued monitoring and individualized treatment

• Patients with macular edema associated with CRVO or HRVO should be followed closely beyond 2 years to determine which patients need treatment
Among patients with macular edema secondary to central or hemiretinal vein occlusion, intravitreal bevacizumab was non-inferior to aflibercept with respect to visual acuity after 6 months of treatment.

One tailed 97.5% Confidence Interval: (-3.1, ∞)
Within non-inferiority margin of -5.0 letters
Month 6-12 Visual Acuity Letter Score
Monthly vs TAE

Aflibercept

Visual acuity letter score leading up to Month 6 randomization

M12

72.7

71.6

1.88*

97.5% CI: -1.07, 4.83
P=0.15

Bevacizumab

Visual acuity letter score leading up to Month 6 randomization

M12

75.2

74.0

1.98*

97.5% CI: -1.08, 5.03
P=0.15

*Estimate of difference between treatment groups (Monthly minus TAE) in mean change in VALS from M6 to M12
SCORE2: 24-Month Summary

- After Month 12, no protocol-defined treatment
  - mean VALS decreased by 5 but mean VALS still significantly improved from baseline (~15 letters)
  - 24 month results show no difference in VALS based on original drug assignment
SCORE2 Long-term Follow-up Study (SCORE2 LTF): Month 24 to 48 Results

• No protocol-defined treatment schedule after Month 12
• Treatment provided as deemed necessary using any commercially available drug (including non-study drug or no drug) based on typical practice and on any schedule
• Outcomes
  – Treatment patterns for the macular edema
  – Visual acuity letter score (VALS)
  – SD-OCT central subfield thickness (CST)
Disposition: Month 24 to Month 48

Enrolled in SCORE2
N=362

Completed M12 and Eligible for LTF
N=330 (100%)

M24 completed visits: N=236 (72%)
M36 completed visits: N=211 (64%)
M48 completed visits: N=163 (49%)
Deaths during LTF: N=30 (9%)
## Baseline Characteristics by Completer Status at 48

<table>
<thead>
<tr>
<th></th>
<th>Completer (N=163)</th>
<th>Non-completer (N=199)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afiblercept treatment arm</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>Mean age (years)</td>
<td>68</td>
<td>69</td>
</tr>
<tr>
<td>Prior anti-VEGF treatment at baseline (M0)</td>
<td>33%</td>
<td>34%</td>
</tr>
<tr>
<td>Mean months of macular edema before M0</td>
<td>7.1</td>
<td>6.1</td>
</tr>
<tr>
<td>Female</td>
<td>42%</td>
<td>45%</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>12%</td>
<td>9%</td>
</tr>
<tr>
<td>Black race</td>
<td>9%</td>
<td>20%</td>
</tr>
<tr>
<td>HRVO</td>
<td>16%</td>
<td>16%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>29%</td>
<td>33%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>74%</td>
<td>79%</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>15%</td>
<td>16%</td>
</tr>
<tr>
<td>Mean visual acuity letter score</td>
<td>50</td>
<td>51</td>
</tr>
<tr>
<td>Mean central subfield thickness (microns)</td>
<td>673</td>
<td>659</td>
</tr>
<tr>
<td>Mean anti-VEGF treatments, M0-M12</td>
<td>10.8</td>
<td>10.0</td>
</tr>
</tbody>
</table>
Treatment Rates

Injections per participant-month (30 days)

<table>
<thead>
<tr>
<th>Interval</th>
<th>Aflibercept</th>
<th>Bevacizumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>M0-M6</td>
<td>1.05</td>
<td>0.95</td>
</tr>
<tr>
<td>M6-M12</td>
<td>0.84</td>
<td>0.38</td>
</tr>
<tr>
<td>M12-M24</td>
<td>0.31</td>
<td>0.41</td>
</tr>
<tr>
<td>M24-M36</td>
<td>0.47</td>
<td>0.45</td>
</tr>
<tr>
<td>M36-M48</td>
<td>0.57</td>
<td></td>
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</tbody>
</table>
Numbers of Treatments Received Between Months 36 and 48

Percent of Month 48 Completers

Original treatment assignment

- Aflibercept (mean=3.2)
- Bevacizumab (mean=4.0)
Treatment Patterns Between Months 36 and 48

Other includes steroid treatment (kenalog or dexamethasone) either alone or in combination with an anti-VEGF agent.
Visual Acuity Letter Score Baseline through Month 48 Among LTF Participants

Visual Acuity Letter Score

Month

Aflibercept

Bevacizumab

M48

67.0

66.5
SD-OCT Central Subfield Thickness Baseline through Month 48 Among LTF Participants

Aflibercept vs Bevacizumab

Month

Baseline through Month 48

SD- OCT Central Subfield Thickness

CST (microns)

0 6 12 24 36 48

Month

M48

291

284

SCORE2
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Take Home Messages

• SCORE2 Month 48 results
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- Study participants
- Investigators, Coordinators, and all SCORE2 clinical site staff
- National Eye Institute
- Data and Safety Monitoring Committee
- Regeneron and Allergan
- Resource Centers (staff at Chair’s office, Data Coordinating Center, Fundus Photograph Reading Center, Penn State Institute for Personalized Medicine)