Secondary endpoints

- Mean change in BCVA from baseline to 3, 6, 9, 12, 15, 18, 21, and 24 months
- Mean change in CTR (as measured by OCT) from baseline to 3, 6, 9, 12, 15, 18, 21, and 24 months
- Rate of progression to ischemic CRVO
- Incidence and severity of ocular and nonocular adverse events (AEs)

RESULTS

Study Patients

- Of the 20 patients enrolled, one patient in cohort 1 completed the first year according to protocol and withdrew from the study immediately after the month 12 study visit because she moved to another state.
- These results include 24-month data for cohort 1 and 12-month data for cohort 2.
- Mean number of injections at month 12: 5.7 (range 4-7) for cohort 1 and 6.0 (range 5-8) for cohort 2.

Table 1: Patient Demographics and Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Cohort 1 (N=10)</th>
<th>Cohort 2 (N=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (yrs)</td>
<td>66.8 (40-87)</td>
<td>61.7 (40-86)</td>
</tr>
<tr>
<td>Metabolic risk</td>
<td>9 (90)</td>
<td>5 (50)</td>
</tr>
<tr>
<td>Mean duration of CRVO, weeks</td>
<td>171 (42)</td>
<td>197 (42)</td>
</tr>
<tr>
<td>Mean baseline VA, ETDRS letters:</td>
<td>20/30 (10)</td>
<td>20/25 (10)</td>
</tr>
<tr>
<td>Mean baseline retinal thickness, μm</td>
<td>616.8 (473)</td>
<td>612.6 (303)</td>
</tr>
</tbody>
</table>

Visual Outcomes

- Mean change in BCVA from baseline over time
- Mean change in CTR from baseline over time

Figure 2. Mean change in BCVA from baseline over time.

Figure 3. Percentage of patients gaining ≥15 letters of best-corrected visual acuity from baseline over time.

Figure 5A. Color fundus photograph and OCT images.

Case Studies

Case 1: A 70-year-old female patient from cohort 1 who had received 13 ranibizumab (0.5 mg) injections as of month 24 (Figure 5A, 5B).

Figure 5B. CRT and VA over time.

CONCLUSIONS

- Improvement in visual outcomes
  - Ranibizumab treatment resulted in mean reductions in baseline CRT and VA over time.
  - In cohort 1 patients, the improvement was lost with the switch to quarterly PRN treatment during months 3 to 12 followed by recovery upon resumption of monthly PRN treatment in month 13 to 24.
  - In cohort 2 patients, the initial improvement was sustained until month 12.
  - In cohort 1 and 2, most patients experienced an improvement in retinal vein diameter over the course of 12 months.
  - Intraretinal hemorrhage was more common in cohort 1 than baseline but improved to none or mild after 12 months.
  - Ranibizumab treatment is safe and well tolerated.
  - Follow-up is ongoing and will be continued until month 36 for both cohorts.

- These findings merit further investigation and confirmation in larger ongoing and future studies.

REFERENCES