Rescue Criteria

Rescue therapy will be offered if one or more of the following conditions are met:

- 1. If the study eye shows no response for at least 2 months following the third scheduled injection of sirolimus (i.e., at Month 6).
- Worsening of primary disease in the study eye at least 1 month following the third scheduled injection of sirolimus (i.e., at Month 6) as indicated by at least a 2 point increase in Vitreous Haze or Vitreous Cell Count as compared to Baseline.
- 3. If the fellow eye shows no response for at least 2 months following the last sirolimus injection in the fellow eye despite at least 1 sirolimus injection;
- 4. Worsening of primary disease in the fellow eye at least 1 month following the last sirolimus injection in the fellow eye as indicated by at least a 2 point increase in Vitreous Haze or Vitreous Cell Count and as compared to Baseline despite at least 1 sirolimus injection;
- 5. Severe deterioration of vision in either eye as indicated by at least doubling of the visual angle as compared to Baseline.
- Conditions that can explain the deterioration of vision, other than the primary disease (e.g. cataract), must be excluded before rescue therapy is allowed.
- Rescue therapy will be offered once deterioration of vision or worsening of primary disease has been confirmed at least 1 month following the last sirolimus injection.