

OC-10X Drug Development Summary

April 2011

Animal Ocular Efficacy: Rat AMD Model

- Antiangiogenic and angiolytic studies with topical eye drops
- Statistically significant results

Primate Studies (monkeys)

- Efficacy demonstrated in a laser induced CNV model
- Penetration to retina demonstrated: Clinically relevant concentration

Animal Ocular Toxicity: No Toxicity Observed

- 14-day study with topical administration
- Long term studies with topical administration: 6 weeks and 16 months
- Genetic toxicity studies

Pharmacokinetic Study: Rabbit Study

- Bioanalytical methods developed
- OC-10X measured in aqueous humor, retina, and plasma

API Synthesis

- Synthesized with 99+% purity

Formulation of Final Product

- Suspension formulation completed
- 9 mo stability study completed: Both API and final product

FDA Regulatory Status

- Pre-IND meeting with FDA conducted
- Clarity on the development plan for regulatory requirements