

## **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