



## Ocular Therapeutix Completes Proof of Principle Study with Moxifloxacin-Loaded Punctum Plugs

*Plugs achieved 100% retention and demonstrated sustained levels of moxifloxacin throughout the 10-day treatment period.*

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Ocular Therapeutix, Inc. announced today the completion of a successful Proof of Principle clinical study with their novel sustained drug delivery moxifloxacin punctum plug.

The study was a single-site, single-armed, single-dose study in which ten patients received the punctum plug immediately following cataract surgery and were evaluated over a 10-day period. Primary outcome measures were plug retention and moxifloxacin levels above the minimum inhibitory concentration (MIC) to stop growth in various strains of bacterial conjunctivitis.

The moxifloxacin punctum plug achieved 100% retention in all 10 patients as proven via tear fluid testing. Pharmacokinetic data demonstrated that tear sample drug levels were maintained between 2,000 and 3,000 ng/ml over a 7 day period. These levels were well above MIC<sub>90</sub>, the concentration necessary to inhibit bacterial growth of *staphylococcus aureus*, *staphylococcus epidermidis*, and *streptococcus pneumonia* ( $\leq$  MIC<sub>90</sub> = 250 ng/ml). No adverse events were reported, and there were no ocular complaints outside of normal post-cataract symptoms.

Principal Investigator for the study, Dr. Soon Phaik Chee of the Singapore National Eye Centre in Singapore, commented that "Ocular Therapeutix's moxifloxacin punctum plugs were easy to use and insert. In addition to the fact that the plugs were retained and released favorable and sustained levels of moxifloxacin, I was impressed at the patients' level of comfort— not one of the patients complained of foreign body sensation or discomfort in relation to the plugs following surgery."

The innovative platform technology uses Ocular Therapeutix's proprietary and patented polyethylene glycol (PEG) hydrogel to encase drug-loaded polylactide-co-glycolide (PLGA) microspheres. After insertion, the plugs gently expand upon contact with moisture providing a universal fit, and release therapeutic levels of drugs to the ocular surface over a specified period of time. The plug depot gradually absorbs and is eliminated from the site, so removal is not necessary after therapy is complete.

"The platform is extremely versatile and compatible with a variety of prescription medications for numerous ophthalmic diseases. Additionally, we can tailor the material for different treatment periods - from days to months - dependent on the disease," stated Amar Sawhney, PhD, President and CEO of Ocular Therapeutix. "The success of this trial is a validation of our technology platform, and we are moving forward with this technology for other applications including glaucoma, allergies, and dry eye."

Current ocular drug delivery methods are plagued with disadvantages, including limited penetration and rapid washout. One of the biggest issues, however, is patient non-compliance, as it has been reported that up to 60% of patients do not administer ophthalmic drops as directed. "Compliance with topical drop treatment regimens is a growing problem as our population ages. We need safe and effective sustained drug delivery methods to manage this issue, as in many surgical and medical clinical cases poor compliance can lead to permanent visual loss or blindness," stated Dr. Richard Lindstrom, founder and attending surgeon of Minnesota Eye Consultants and internationally recognized leader in ophthalmology. "Ocular Therapeutix's sustained drug delivery technology has the potential to solve these issues."

Ocular Therapeutix plans to initiate Phase II clinical trials in 2011 for several indications using the punctum plug technology. For more information about Ocular Therapeutix and their sustained ocular drug delivery program, please visit [www.ocutx.com](http://www.ocutx.com).

**About Ocular Therapeutix, Inc:**

Founded in November 2006, Ocular Therapeutix, Inc. is a privately held company based in Bedford, MA focused on the development and commercialization of ophthalmic therapeutic products using its proprietary hydrogel technology. Ocular Therapeutix's first product, the ReSure™ Adherent Ocular Bandage, is CE Mark Approved and under clinical investigation in the United States. Ocular Therapeutix has also developed sustained ocular drug delivery depots using its hydrogel punctum plug technology.

**Corporate Communications:**

Scott Corning  
Director of Global Marketing  
Ocular Therapeutix, Inc.  
36 Crosby Drive, Ste 101  
Bedford, MA 01730  
<http://www.ocutx.com>  
[info@ocutx.com](mailto:info@ocutx.com)

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