

IN THE NEWS

Daily Xibrom trial data. ISTA Pharmaceuticals, Inc. reported surprising clinical trial of Xibrom (bromfenac ophthalmic solution) QD 0.18% formulation, a new formulation of ISTA's ocular NSAID. The data showed no difference in efficacy between the once-daily Xibrom QD formulation designed for

use. Results demonstrated equivalence between the new 0.18% formulation and the existing 0.09% formulation of Xibrom QD administered once daily in achieving the primary endpoint of absence of inflammation 15 days following surgery. The data also showed no statistically significant difference between the two formulations in achieving the secondary endpoints of elimination of inflammation and mean reduction of markers of inflammation (inflammatory cells). In addition, the results indicated no difference in the overall incidence of ocular side effects.

ISTA undertook this trial in connection with its Xibrom QD NDA application, which was submitted to the FDA in February 2007. The nearly identical performance of the two concentrations was observed and inconsistent with the available data. The results suggest that the 0.18% formulation is near the top of the response curve," stated Vicente Garcia, Ph.D., president and CEO of ISTA Pharmaceuticals. "Our next steps are to complete the data analysis and speak with the FDA to determine a possible path forward as well as consider other options for new Xibrom products. Part of our strategy will be to review the possibility of a label change for the currently marketed 0.09% formulation of Xibrom so that it can be administered once-daily."

In related news, ISTA announced it has entered into an agreement with Dowen and Company as its financial advisor. For more than a year, ISTA has been in discussions with other companies

and financial sponsors regarding new product opportunities and potential mergers and acquisitions that would allow it to grow the scale of ISTA's business. In addition, ISTA has been approached from time to time regarding business combination opportunities. Cowen will assist the company in evaluating these and other opportunities.

Older corneas OK for transplant.

A new study may be used to widen the age of cornea donation to as much as 75.

Researchers randomly assigned cornea recipients to get either younger or older tissue and found the corneas of both groups performed about equally well as long as 5 years later. The study was published recently in *Ophthalmology*.

"We now have scientific evidence showing that older donors can be used reliably in corneal transplantation," said Edward Holland, M.D., of the University of Cincinnati and lead researcher in the study.

More than 39,000 corneal transplants were performed last year, according to the Eye Bank Association of America. The United States has had an adequate supply of corneas for transplant so far, but the nation's eye banks fear that supplies will tighten as a result of stricter FDA donor-safety rules initiated last year. The new rules have increased interest in older donors.

Cataract surgery with canaloplasty. A recent study of 54 eyes that had combined clear corneal cataract surgery with canaloplasty for the treatment of open-angle glaucoma showed a major improvement in mean IOP. The study, led by Bradford Shingleton, M.D., of Boston, was recently reported in the *Journal of Cataract and Refractive Surgery*.

Mean IOP improved from 24.4 mm Hg at baseline to 13.7 mm Hg at 1 year, with an accompanying significant drop in medication usage. Surgical complications were reported in five eyes, including hyphema in three patients, Descemet tear in one patient and iris prolapse in another patient.

Eleven surgeons at nine sites partici-

pated in this study.

Tecnis 1-Piece IOL launched.

Advanced Medical Optics (AMO) has introduced the Tecnis 1-Piece IOL and announced that the lens has earned the New Technology IOL (NTIOL) designation from the Centers for Medicare and Medicaid Services.

AMO says the Tecnis 1-Piece IOL design combines two groundbreaking design advancements. The innovative ProTec 360-degree edge design has an uninterrupted barrier edge designed to minimize cell migration onto the posterior capsule. Unlike first generation one-piece lenses, the Tecnis 1-Piece IOL has no interruption at the haptic-optic junction. The lens also has a frosted edge designed to minimize edge glare. The Tecnis IOL Tri-Fix design provides three-point fixation for exceptional stability. Refraction stabilizes quickly after the implantation procedure.

100 get free crystalens. In the space of 100 minutes on April 9, 100 ophthalmologists around the country implanted free crystalens presbyopia-correcting IOLs in 100 low-income cataract surgery patients. The event marked the implantation of the 100,000th crystalens. The lenses were donated by Bausch & Lomb, which recently bought eyeonics, the developer of the crystalens.

B&L IOL wins award. Bausch & Lomb said that its Akreos M160 Microincision IOL has won a 2008 Medical Design Excellence Award, one of the premier awards programs for the medical technology community.

In keeping with Bausch & Lomb's drive for smaller cataract incisions and better patient outcomes, the Akreos M160 IOL was designed specifically for implantation through a 1.8 mm incision. It can be inserted through a microincision because of its strong yet flexible acrylic base material. A unique acrylic material that Bausch & Lomb says has a 10-year history of performance and successful implantation in more than two million eyes worldwide. on