



Avedro Receives Additional Indication for Photrexa[®] Viscous, Photrexa[®] and the KXL[®] System for the Treatment of Corneal Ectasia Following Refractive Surgery

Photrexa Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146%, Photrexa (riboflavin 5'-phosphate ophthalmic solution) 0.146%, and the KXL System comprise the first and only FDA-approved collagen cross-linking therapy

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WALTHAM, Mass.--(BUSINESS WIRE)--Avedro, Inc., an ophthalmic pharmaceutical and medical device company, has received approval from the U.S. Food and Drug Administration (FDA) for Photrexa Viscous, Photrexa and the KXL System used in corneal collagen cross-linking for the treatment of corneal ectasia following refractive surgery, the products' second indication. Avedro's photoenhancers, Photrexa Viscous and Photrexa, used in conjunction with the KXL System, received an initial indication for the treatment of progressive keratoconus in April 2016, and remains the first and only corneal collagen cross-linking therapy approved in the United States.

"We are pleased to be able to expand the clinical utility of our first-in-class corneal collagen cross-linking technology to another indication," said Rajesh Rajpal, MD, Chief Medical Officer for Avedro. "The American Academy of Ophthalmology's Preferred Practice Pattern for corneal ectasia endorses this approach and emphasizes the importance of treating the condition in its early stages. Since our initial launch in April, we've enjoyed an enthusiastic reception from the ophthalmic community and have been busy filling orders for the KXL System. With the availability of our Photrexa products in early Fall, clinicians will be able to begin treating their patients with either of these forms of corneal ectasia."

Corneal ectasia, a non-inflammatory condition marked by progressive corneal steepening and thinning, is a rare but serious complication of vision correction procedures. The condition can begin within a week of surgery or after several years and is associated with worsening best uncorrected visual acuity, an increase in ocular aberrations, and decreasing best-corrected distance visual acuity. **The incidence of corneal ectasia following refractive surgery is estimated to affect approximately 160,000 patients in the United States, qualifying it as an orphan disease.**

"It is significant that Avedro has received this additional indication for corneal collagen cross-linking," said Peter Hersh, MD of The Cornea and Laser Eye Institute – CLEI Center for Keratoconus, and the Avedro medical monitor. "This much anticipated availability of an FDA-approved corneal collagen cross-linking therapy fills an unmet need in our ability to best treat our patients. This new approval will help to ensure that this important therapy is available to patients who need it."

Patients should consult their ophthalmologist to determine if corneal cross-linking is right for them. The Photrexa formulations and the KXL System are expected to be available for qualifying patients through their ophthalmologists before the end of this year. Patients can find a listing of ophthalmologists who are familiar with the treatment of these ectatic diseases by [clicking here](#).

Clinical Study Background and Results

The approval of Photrexa Viscous and Photrexa used with the KXL System in corneal collagen cross-linking (CXL) for the treatment of corneal ectasia following refractive surgery was based on Avedro's NDA submission which encompasses data from three prospective, randomized, parallel-group, open-label, placebo-controlled, 12-month trials conducted in the United States. These trials were sham-controlled for the first 3 months and had a total duration of 12 months for safety and efficacy evaluations. Study 1 enrolled 58 patients with progressive keratoconus and 49 patients with corneal ectasia following refractive surgery. Study 2 enrolled 147 patients with progressive keratoconus, and Study 3 enrolled 130 patients with corneal ectasia following refractive surgery.

At Month 12, the CXL-treated eyes in corneal ectasia patients had an average K_{\max} reduction of 1.0 diopter in Study 1 and 0.5 diopter in Study 3, while the sham eyes had an average increase of 1.0 diopter in Study 1 and 0.5 diopter in Study 3; the treatment difference between the CXL and sham groups was: -2.0 (-3.0, -1.1) diopters in Study 1 and -1.1 (-1.9, -0.3) diopters in Study 3.

In corneal ectasia patients enrolled in the clinical studies, the most common ocular adverse reactions were corneal opacity (haze), corneal epithelium defect, corneal striae, dry eye, eye pain, punctate keratitis, photophobia, reduced visual acuity, and vision blurred. These events are expected sequelae following epithelial corneal debridement and occurred at a higher incidence than observed in control patients, who did not undergo debridement or exposure to UVA light. In 6% of corneal ectasia patients, corneal opacity continued to be observed at 12 months.

What are Photrexa Viscous and Photrexa?

PHOTREXA VISCOUS and PHOTREXA are photoenhancers indicated for use with the KXL System in corneal collagen cross-linking for the treatment of progressive keratoconus and corneal ectasia following refractive surgery.

Important Safety Information

In progressive keratoconus patients, the most common ocular adverse reactions were corneal opacity (haze), punctate keratitis, corneal striae, corneal epithelium defect, eye pain, reduced visual acuity, and blurred vision.

In corneal ectasia patients, the most common ocular adverse reactions were corneal opacity (haze), corneal epithelium defect, corneal striae, dry eye, eye pain, punctate keratitis, photophobia, reduced visual acuity, and blurred vision.

Ulcerative keratitis can occur, and patients should be monitored for resolution of epithelial defects.

It is not known if CXL is safe and effective in pediatric patients below the age of 14.

Please see full Prescribing Information by clicking here: http://avedro.com/wp-content/uploads/dlm_uploads/13597/

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <http://www.fda.gov/medwatch> or call 1-800-FDA-1088.

About Avedro, Inc.

Avedro is a privately held pharmaceutical and medical device company advancing the science and technology of corneal cross-linking and refractive correction.

Avedro's Photrexa Viscous, Photrexa and KXL products are approved for sale in the United States for the treatment of progressive keratoconus and corneal ectasia following refractive surgery. Avedro's products sold outside of the United States include capital equipment such as the UV-X devices, the KXL[®] and Mosaic[™] Systems, and related proprietary

pharmaceuticals such as the VibeX[®] and MedioCROSS[®] formulations. Avedro distributes its products in countries outside of the United States through a network of ophthalmic medical device distributors.

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