Avedro Receives FDA Approval for Photrexa® Viscous, Photrexa® and the KXL® System for Corneal Cross-Linking

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Photrexa Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146%, Photrexa (riboflavin 5'-phosphate ophthalmic solution) 0.146%, and the KXL system are the first and only FDA-approved therapeutic treatment for progressive keratoconus

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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. Photrexa Viscous and Photrexa are photoenhancers indicated for use with the KXL System in corneal collagen cross-linking for the treatment of progressive keratoconus. Avedro's Photrexa Viscous, Photrexa and the KXL System represent a first-in-class therapeutic treatment for this sight threatening indication.

"This approval marks a tremendous milestone for the treatment of progressive keratoconus," said Brian Roberts, Chief Operating and Financial Officer for Avedro. "We're excited to provide ophthalmologists in the United States with these tools to treat this orphan disease. We thank the FDA for their diligent efforts as we worked towards approval. We plan to begin taking orders for the KXL System immediately, and plan to begin shipping our Photrexa products in the next few months as we ramp up our drug manufacturing."

Keratoconus is a progressive thinning and distortion of the cornea. It is the most common corneal dystrophy in the US, affecting approximately one in every 2,000 Americans[1] or approximately 170,000 people in the US. Keratoconus causes the cornea to bulge from its normal symmetric domelike smooth optical shape, creating an abnormal curvature that changes the cornea's optics, producing blurred and distorted vision that is difficult to correct with spectacle lenses. This progressive thinning and weakening can result in significant visual loss and may lead to corneal transplants.

"This FDA approval has been highly anticipated by the keratoconus community," said Mary Prudden, Executive Director for the National Keratoconus Foundation. "Corneal cross-linking provides patients a much-needed option to treat this debilitating disease. Patients suffering from progressive keratoconus can now receive a therapeutic treatment that has been rigorously tested and approved."

"I applaud Avedro's efforts to make this clinically important treatment available to US patients," said Peter Hersh, MD of The Cornea and Laser Eye Institute – CLEI Center for Keratoconus, and the clinical study medical monitor. Dr. Hersh continued, "In the studies, treated eyes showed improvement in K_{max} at 12 months, while in untreated eyes K_{max} continued to worsen. The Photrexa formulations and the KXL system represent an invaluable new treatment option for corneal surgeons in the treatment of keratoconus patients."

Rajesh Rajpal, MD, Chief Medical Officer for Avedro added, "Avedro and I look forward to working with US ophthalmologists to raise awareness of our new FDA-approved treatment for progressive keratoconus. Avedro is hosting an evening event during the ASCRS meeting in New Orleans in early May. This will be an opportunity for US ophthalmologists to learn what approval of Photrexa Viscous, Photrexa and the KXL System means to their keratoconic patients."

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 treatment of progressive keratoconus here.

Clinical Study Background and Results

The approval 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 to determine the safety and effectiveness of Photrexa Viscous and Photrexa when used for performing corneal cross-linking in eyes with progressive keratoconus. These studies included Study 1, which enrolled 58 patients with progressive keratoconus, and Study 2, which enrolled 147 patients with progressive keratoconus. In each study, patients had one eye designated as the study eye and were randomized to receive one of two study treatments (CXL or sham) in their study eye.

The cross-linked eyes showed increasing improvement in K_{max} from Month 3 through Month 12. K_{max} is defined as the maximum corneal curvature and measured in diopters (D). Progressive keratoconus patients had an average K_{max} reduction of 1.4 D in Study 1 and 1.7 D in Study 2 at Month 12 in the cross-linked eyes, while the untreated eyes had an average increase of 0.5 D in Study 1 and 0.6 D in Study 2 at Month 12; the difference (95% CI) between the cross-linked and untreated groups in the mean change from baseline K_{max} was -1.9 (-3.4, -0.3) D in Study 1 and -2.3 (-3.5, -1.0) D in Study 2.

- Ulcerative keratitis can occur, and patients should be monitored for resolution of epithelial defects.
- In clinical studies, the most common ocular adverse reactions in any cross-linked eye were corneal opacity (haze), punctate keratitis, corneal striae, corneal epithelium defect, eye pain, reduced visual acuity, and blurred vision.

Indication and Important Safety Information for Photrexa Viscous, Photrexa, and the KXL System

INDICATION AND USAGE

Photrexa Viscous and Photrexa are photoenhancers indicated for use with the KXL System in corneal collagen cross-linking for the treatment of progressive keratoconus.

Important Safety Information

CONTRAINDICATIONS

None

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Ulcerative keratitis can occur. Monitor for resolution of epithelial defects.

ADVERSE REACTIONS

The most common ocular adverse reactions in any CXL-treated eye were corneal opacity (haze), punctate keratitis, corneal striae, corneal epithelium defect, eye pain, reduced visual acuity, and blurred vision.

Please see full Prescribing Information here.

[1] National Eye Institute (NEI). Facts About The Cornea and Corneal Disease. http://www.nei.nih.gov/health/cornealdisease/#12

About Avedro, Inc.

Avedro is a leading commercial-stage ophthalmic medical technology company focused on treating corneal ectatic disorders and improving vision to reduce dependency on eyeglasses or contact lenses. Avedro's proprietary Avedro Corneal Remodeling Platform strengthens, stabilizes and reshapes the cornea utilizing corneal cross-linking in minimally invasive and non-invasive outpatient procedures to treat corneal ectatic disorders and correct refractive conditions. The Avedro Corneal Remodeling Platform is comprised of Avedro's KXL and Mosaic systems, each of which delivers ultraviolet A light, and a suite of proprietary single-use riboflavin drug formulations, which, when applied together to the cornea, induce a biochemical reaction called corneal collagen cross-linking.

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