Avedro Announces FDA Submission for Corneal Cross-linking

The Associated Press

WALTHAM, Mass.--(BUSINESS WIRE)--Mar 8, 2012-- Avedro, Inc. announced today that the Company submitted a New Drug Application (NDA) to the United States Food and Drug Administration (FDA) for its VibeX(TM) (riboflavin ophthalmic solution) /KXL(TM)System for the treatment of keratoconus and corneal ectasia following refractive surgery.

"The ophthalmology community is now looking forward to the possibility of offering cross-linking to keratoconus and corneal ectasia patients in the near future, addressing a significant unmet medical need," said Peter Hersh, MD, Medical Monitor and Director, Cornea and Laser Eye Institute. "Currently, there are limited treatment options for decreasing the natural progression of keratoconus and ectasia.

Cross-linking has the promise of stabilizing these progressive corneal disorders and maintaining patients' visual function over time." In 2011, the VibeX/KXL System was granted orphan designation by the FDA for the treatment of keratoconus and corneal ectasia following refractive surgery. Orphan drug designation is granted by the FDA Office of Orphan Products Development to promote the development of new therapies for rare diseases and disorders affecting fewer than 200,000 individuals in the United States. If approved, orphan drug status will entitle Avedro to seven years of US marketing exclusivity for these indications.

"We are pleased to have submitted our positive results from the first multi-site US clinical studies on corneal collagen cross-linking to the FDA," said David Muller, PhD, CEO of Avedro. "The VibeX/KXL System NDA submission represents an important milestone towards making cross-linking available to patients suffering from keratoconus and post-Lasik ectasia in the US." The VibeX/KXL System for corneal collagen cross-linking received CE Mark in 2010 and has been commercially available internationally since that approval.

About Avedro, Inc.

Avedro is a privately held medical device and pharmaceutical company advancing the science and technology of corneal collagen cross-linking. Avedro recently completed its US-based, multi-centered, Phase III studies of corneal cross-linking for the treatment of progressive keratoconus and corneal ectasia following refractive surgery. Outside the United States, Avedro has commercialized both VibeX(TM) riboflavin and its KXL(TM) System for performing Lasik Xtra(TM) and accelerated cross-linking. Additionally, Avedro is developing the science of Thermo-biomechanics for therapeutic medical applications. The Keraflex(R) refractive correction procedure is the first technology developed from the Thermo-

biomechanics platform and is a non-invasive, incision-less ophthalmic procedure for flattening the cornea without the removal of tissue. Keraflex offers the unique ability to induce refractive change without weakening the cornea's biomechanical integrity, as happens with Lasik and other refractive correction procedures. Keraflex is commercially available outside of the United States.

CONTACT: Avedro, Inc.

Kristen Gleason, 781-768-3400 kgleason@avedro.com KEYWORD: UNITED STATES EUROPE NORTH AMERICA MASSACHUSETTS INDUSTRY KEYWORD: OTHER CONSUMER HEALTH BIOTECHNOLOGY HOSPITALS MEDICAL DEVICES OPTICAL OTHER HEALTH AUTOMOTIVE OTHER AUTOMOTIVE RESEARCH FDA CONSUMER SCIENCE GENERAL HEALTH SOURCE: Avedro, Inc.

Copyright Business Wire 2012 PUB: 03/08/2012 12:28 PM/DISC: 03/08/2012 12:28 PM http://www.businesswire.com/news/home/20120308006108/

Source URL (retrieved on *07/29/2014 - 11:46am*):
http://www.mdtmag.com/news/2012/03/avedro-announces-fda-submission-corneal-cross-linking?qt-video_of_the_day=0