

Avedro Announces FDA Orphan Drug Designation for Its Corneal Cross-linking VibeX™ Riboflavin/KXL™ System for the Treatment of Keratoconus

Waltham, Massachusetts, USA, September 12, 2011 Avedro, Inc. announced today that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to the Company's VibeX (0.1% riboflavin ophthalmic solution) for use with its KXL System (UVA irradiation) for Corneal Cross-linking to treat Keratoconus. Keratoconus is a degenerative disease of the eye and is the leading cause of corneal transplants in the United States today.

Dr. Peter Hersh, a leading refractive surgeon and Medical Monitor for Avedro's clinical trials stated, "Avedro's effort to make this clinically important treatment available to US patients will be applauded by all US ophthalmologists who today lack any approved therapeutic treatment to halt the progression of keratoconus, a sight threatening condition."

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. Orphan drug designation may entitle Avedro to seven years of U.S. marketing exclusivity upon regulatory approval.

"This orphan drug designation, along with the encouraging clinical results from our Phase III keratoconus study, is another important step in bringing this technology to patients in the US," said David Muller, CEO of Avedro. "We look forward to working with FDA as we progress towards an NDA submission in the very near future."

Avedro has submitted an additional application for orphan drug designation for cross-linking for the treatment of corneal ectasia following refractive surgery.

About Avedro, Inc.

Avedro, a privately held medical device and pharmaceutical company based in Waltham, MA, developed VibeX Riboflavin and the KXL System for performing Accelerated Cross-linking. Avedro recently completed multi-centered US-based Phase III studies of corneal cross-linking for the treatment of progressive keratoconus and post Lasik ectasia. Additionally, Avedro is developing the science of Thermo-biomechanics for therapeutic medical applications. Keraflex® is the first technology Avedro has developed from its Thermo-biomechanics platform. The Keraflex procedure is a non-invasive, incision-less ophthalmic procedure for flattening the cornea without the removal of tissue, offering the unique ability to induce refractive change without weakening the cornea's biomechanical integrity, as happens with Lasik and other refractive correction procedures. KXL, VibeX, and Keraflex are CE Marked and commercially available outside of the United States.

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