Avedro Announces FDA Priority Review Status for Corneal Cross-linking New Drug Application
If Approved, Avedro Could Be Entitled to Seven Years Market Exclusivity

Waltham, Massachusetts, USA, November 25, 2013 – Avedro Inc., a Boston-based ophthalmic medical device and pharmaceutical company announces that it received notification from the U.S. Food and Drug Administration (FDA) stating that their NDA for riboflavin ophthalmic solution/KXL system has been filed, and has been granted priority review status. The priority review status places the application action date (PDUFA) at March 15th, 2014.

The proposed indications of treatment of keratoconus and corneal ectasia following refractive surgery are both orphan indications. Keratoconus is a potentially blinding disease, for which limited therapeutic treatment is available in the US. Corneal ectasia is a rare outcome of refractive surgery (such as Lasik) but is a progressive condition that is difficult to manage. Patients with these sight threatening conditions may require corneal transplant surgery. If approved, riboflavin ophthalmic solution/KXL system would be the first FDA approved therapeutic treatment for these orphan indications.

“US ophthalmic surgeons are thrilled that the FDA is considering this with priority review,” said Peter Hersh, MD, Hersh Vision Group, Teaneck, NJ and Avedro Medical Monitor. “If approved, cross-linking could represent an important new treatment option for patients with keratoconus and ectasia.”

“Avedro is already on the forefront of corneal cross-linking science internationally,” said David Muller, PhD, CEO of Avedro. “Now in the US, we look forward to working with FDA through this stage of the review process.”

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, Avedro would receive seven years of commercial exclusivity in the United States.

About Avedro, Inc.

Avedro is a privately held medical device and pharmaceutical company advancing the science and technology of corneal cross-linking and refractive correction. Avedro’s products include capital equipment and related single dose pharmaceuticals. Those products are currently used in a procedure known as Lasik Xtra®. Over 75,000 surgeries have been successfully performed outside the US using Avedro’s KXL® System. The KXL System’s accelerated cross-linking, in combination with its pharmaceuticals, is also used to treat several important and debilitating ophthalmic pathologies outside the United States.

Avedro distributes its products in 62 countries through 33 ophthalmic distributors with 115 representatives. Avedro products that have received CE Mark include: the KXL II™ System for performing PiXL™, the KXL System for performing Lasik Xtra and Accelerated Cross-linking, and the Avedro family of proprietary single dose pharmaceutical formulations.

Avedro's KXL System and single dose pharmaceutical products are currently being used in three Phase III US clinical trials involving over 100 US clinical sites. Avedro products are not for sale in the US.

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