Avedro Completes Enrollment in Pivotal U.S. Phase 3 Epi-On Corneal Cross-Linking Clinical Trial for Progressive Keratoconus

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Clinical Trial Evaluates Novel Non-Invasive Procedure Designed to Treat Debilitating Eye Disease

WALTHAM, Mass., May 01, 2019 (GLOBE NEWSWIRE) -- Avedro, Inc. (Nasdaq: AVDR) (Avedro), today announced that the company has completed patient enrollment in a pivotal Phase 3 clinical trial to evaluate the safety and efficacy of an epithelium-on (Epi-On) corneal cross-linking procedure for the treatment of progressive keratoconus. Keratoconus is a debilitating eye disease that, if left untreated, can lead to loss of vision and even blindness and is the leading cause of corneal transplant (penetrating keratoplasty) in the United States[1]. If approved, the company anticipates that its product offering would be the first FDA approved non-invasive corneal cross-linking procedure that does not require removal of the epithelium, the outermost layer of the eye.

The pivotal Phase 3 clinical trial, ACP-KXL-308, is a multicenter, randomized, sham-controlled study of a novel corneal cross-linking procedure that includes Avedro's latest-generation UV light source, supplemental oxygen designed to enhance cross-linking and a new drug formulation designed to penetrate the epithelial layer of the cornea. The study has enrolled patients across 14 centers in the United States with more than 275 eyes included.

"Completion of patient recruitment in the Avedro Epi-On trial marks an important clinical milestone in our development pipeline and illustrates continued progress towards one of our goals—bringing innovativeFDA-approved cross-linking treatment options to patients living with progressive keratoconus," said Rajesh K. Rajpal, MD, Chief Medical Officer for Avedro and Founder of See Clearly Vision Group, Mclean, VA. "In the three years since Avedro's Epi-Off cross-linking treatment was FDA approved, thousands of patients have benefitted from the procedure. We are hopeful that this Phase 3 Epi-On trial will ultimately lead to another treatment option for this sight-threatening disease."

"Avedro's Epi-Off cross-linking procedure has become the standard of care in my practice for patients with progressive keratoconus. This new, investigative procedure, which is designed to reduce post-op discomfort and enhance recovery time, has the potential to provide added benefits to both patients and ophthalmology practices," said George O. Waring IV, MD FACS, Medical Monitor of the trial and Founder and Medical Director, Waring Vision Institute, Mt. Pleasant, SC.

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 is designed to strengthen, stabilize and reshape 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.

IMPORTANT SAFETY INFORMATION

APPROVED USES

Photrexa Viscous® (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) and Photrexa ® (riboflavin 5'-phosphate ophthalmic solution) are used with the KXL® System in corneal cross-linking to treat eyes in which the cornea, the clear dome shaped surface that covers the front of the eye, has been weakened from the progression of the disease keratoconus or following refractive surgery, a method for correcting or improving your vision.

Tell your healthcare provider if you are pregnant or plan to become pregnant.

IMPORTANT SAFETY INFORMATION

Ulcerative keratitis, a potentially serious eye infection, can occur. Your doctor should monitor defects in the outermost corneal layer of the eye for resolution.

The most common ocular side effect is haze. Other ocular side effects include inflammation, fine white lines, dry eye, disruption of surface cells, eye pain, light sensitivity, reduced sharpness of vision, and blurred vision. The risk information provided here is not comprehensive. To learn more, talk to your healthcare provider.

Go to www.livingwithkeratoconus.com to obtain the FDA-approved product labeling.
You are encouraged to report all side effects to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but are not limited to, statements about the market opportunity for the Avedro Corneal Remodeling Platform and the rate of adoption of FDA approved cross-linking procedures. Words such as "anticipates," "believes," "expects," "intends," "projects," "anticipates," and "future" or similar expressions are intended to identify forward-looking statements. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. For a discussion of risks and uncertainties and other important factors, any of which could cause Avedro's actual results to differ from those contained in the forward-looking statements, see the section titled "Risk Factors" in Avedro's prospectus dated February 13, 2019 filed pursuant to Rule 424(b)(4) as well as discussions of potential risks, uncertainties and other important factors in Avedro's

subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Avedro undertakes no duty to update this information unless required by law.

References:

1. Borderie VM, Boelle PY, Touzeau O, et al. Predicted long-term Outcome of corneal transplantation. Ophthalmology 2009;2354-2360 Eye Bank Association of America Statistical Report, 2016

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