Avedro Announces Agreement with the FDA for the First U.S. Pivotal Phase 3 Trial of an Epi-on Cross-Linking Treatment for Patients with Progressive Keratoconus

Procedure Includes New Drug Formulation and Use of Oxygen

Avedro, Inc., an ophthalmic pharmaceutical and medical device company and the world leader in corneal remodeling, today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design of a pivotal Phase 3 clinical trial for an epithelium-on (epi-on) corneal collagen cross-linking procedure to treat patients with progressive keratoconus. The agreement provides that the Phase 3 clinical trial design, which includes clinical endpoints, trial population and statistical analyses, adequately address objectives that, if met, would form the primary basis of a regulatory submission to obtain FDA approval of Avedroâ€™s epi-on cross-linking treatment.

This press release features multimedia. View the full release here: http://www.businesswire.com/news/home/20180315005109/en/

The KXL308 Phase 3 clinical trial is a multicenter, randomized, controlled study comparing a novel, accelerated corneal collagen cross-linking procedure, including the use of oxygen to a control (untreated eyes), in approximately 275 subjects with progressive keratoconus. Subjects will be followed for one year. The study, as is typical for FDA drug trials, will be conducted at no cost for participating patients.

Rajesh K. Rajpal, MD, Chief Medical Officer for Avedro, said, â€œPatients in this orphan population, and practices that treat them, have truly benefited from the availability of Avedroâ€™s FDA approved epi-off cross-linking treatment that was launched in 2016. A new procedure that is designed to eliminate the need to remove the epithelium has the potential to be of great value to patients and practices alike, and I look forward to the start of this first-in-class pivotal Phase 3 study.â€•

â€œCollaborating and reaching agreement with the FDA on the design of our pivotal Phase 3 epi-on corneal cross-linking clinical trial for the treatment of progressive keratoconus has been a priority for Avedro. We are pleased to have reached this milestone as we are fully committed to the development of breakthrough cross-linking procedures that may dramatically improve the lives of patients with this sight-threatening orphan disease,â€• said Reza Zadno, CEO of Avedro.

Dr. Zadno added, â€œAvedro would like to thank the physicians who are helping to evolve the standard of care for keratoconus by working to expand therapeutic treatment options for patients via next generation cross-linking procedures. We now look forward to enrolling the first patients.â€•

Once study enrollment begins, patients can visit clinicaltrials.gov to find a listing of participating locations.

About Avedro, Inc.

Avedro is a privately held pharmaceutical and medical device company and the world leader in corneal remodeling. Avedroâ€™s patented cross-linking technology, consisting of drug formulations and medical devices, are approved for sale in numerous countries around the globe. In the United States the company sells orphan drugs for use in epithelium-off corneal cross-linking procedures, Photrexa ViscousÂ (riboflavin 5â€™-phosphate in 20% dextran ophthalmic solution) and Photrexa (riboflavin 5â€™-phosphate ophthalmic solution), which were FDA approved in 2016. Avedro continues to develop proprietary corneal cross-linking products for the treatment of keratoconus, a sight-threatening disease, and for refractive correction.

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