Ocular Therapeutix receives FDA approval for the ReSureÂ® Sealant

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Ocular Therapeutix announced today it has received approval from the Food and Drug Administration (FDA) to commercialize the ReSure Sealant in the United States, with an indication for prevention of postoperative fluid egress from incisions with a demonstrated wound leak following cataract surgery. The ReSure Sealant is the first and only sealant that is FDA-approved for ophthalmic use.

The ReSure Sealant was evaluated in a prospective, controlled, randomized, multicenter clinical trial for prevention of fluid egress in clear corneal incisions against sutures, and demonstrated superiority over sutures by successfully preventing wound leaks in 95.9% of cases, compared to sutures in only 65.9% ($p<0.0001$) of cases. The ReSure Sealant also demonstrated significantly fewer device-related adverse events than the control group ($p<0.0001$), at 1.6% versus 30.6% respectively.

â€œEye surgeons have been waiting for an alternative to suture that is easy to apply, comfortable for the patient, and doesnâ€™t require removal following surgery. Beyond those advantages, the ReSure Sealant has shown itself to be even more effective than suture in sealing corneal incisions against the real-world forces that can cause wound leaks after cataract surgery.â€ stated John Hovanesian, MD, of Harvard Eye Associates and a Principal Investigator in the Pivotal Clinical Trial. â€œI foresee this device becoming a staple in ophthalmic practices nationwide.â€

The ReSure Sealant is a patented polyethylene glycol-based (PEG) hydrogel which is applied as a liquid and gels on the surface of the eye in less than 20 seconds. Once the ReSure material gels, it remains localized over the incision to seal the wound and form a lubricious surface barrier. The material is designed to stay on the incision in the immediate post-operative period when wounds are most vulnerable, after which it gently sloughs off in the patientâ€™s tears.

â€œReceiving approval to commercialize this product is a huge milestone for the company,â€ stated Amar Sawhney, PhD, President and CEO of Ocular Therapeutix, Inc. â€œWe expect this novel product will enable surgeons to optimize post-operative care of their patients, and look forward to a successful launch in the United States.â€

About Cataract Surgery:
Cataract surgery is the most commonly performed surgery in the United States, with approximately 3.5 million procedures conducted annually (Market Scope, 2013). Clear corneal cataract wound leaks are widely thought to be a contributing factor to some post-surgical complications. Presently, ophthalmologists use stromal hydration to close these wounds, however, recent reports in the literature suggest this method of wound closure may not be adequate to provide a watertight seal.[1]

About Ocular Therapeutix, Inc.:
Founded in November 2006, Ocular Therapeutix, Inc. is a privately held company based in Bedford, MA, focused on the development and commercialization of ophthalmic therapeutic products using its proprietary hydrogel technology. In addition to the ReSure Sealant, Ocular Therapeutix is developing drug-eluting intracanalicular plugs for treatment of post-operative pain and inflammation and glaucoma, and injectable anti-VEGF drug depots for back-of-the-eye diseases.

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[1] Masket S, Hovanesian JA, et al. Use of a calibrated force gauge in clear corneal cataract surgery to quantify point-pressure manipulation. J Cataract Refract Surg. 2013 Apr; 39(4):511-8.

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