Ocular Therapeutix Completes PMA Submission for ReSure® Sealant

The Associated Press

BEDFORD, Mass.--(BUSINESS WIRE)--Feb 25, 2013--Ocular Therapeutix, Inc. announced today that it has submitted its Premarket Approval (PMA) Application to the U.S. Food and Drug Administration (FDA) for ReSure Sealant, a novel ophthalmic medical device that utilizes the company's proprietary hydrogel technology.

ReSure Sealant was evaluated in a prospective, randomized, parallel arm, controlled, subject-masked U.S. Pivotal Clinical Trial in which 488 subjects were enrolled at 24 sites throughout the United States. The study compared the ReSure hydrogel sealant with sutures for safety and effectiveness within the first 7 days following cataract surgery. The proposed indication for ReSure Sealant is intraoperative management of clear corneal incisions with a wound leak as demonstrated by a Seidel test, and for prevention of postoperative fluid egress following cataract or intraocular lens placement surgery.

Clear corneal wounds are often closed by hydrating the stroma of the cornea, which transiently inflates the tissue to more closely oppose the wound edges. However, evidence suggests these incisions may not be, and/or do not remain, watertight. Wound leaks are widely believed to increase the risk of various post-operative complications. "This trial demonstrated that clear corneal incisions may be more vulnerable than previously thought, with zero to minimal touch pressure required to produce a wound leak in 76% of cases," stated Terry Kim, M.D., Professor of Ophthalmology, Duke University Eye Center. "More protection may be necessary to safeguard these incisions, and ReSure Sealant has demonstrated to be a valuable adjunct to clear corneal cataract surgery in this trial." Cataract surgery is the most commonly performed surgery in the United States, with well over 3 million procedures conducted annually. 1 Pending FDA approval, ReSure Sealant would be the first and only sealant approved for ophthalmic use. "We are very pleased with the results of the trial and believe our data set is strong," stated Amar Sawhney, President and CEO of Ocular Therapeutix. "Should FDA view our trial results favorably, we hope to have the opportunity to offer ReSure Sealant to U.S. clinicians later this year." About Ocular Therapeutix, Inc.: 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. Ocular Therapeutix is focusing on development of drug-eluting punctum plugs for treatment of glaucoma and post-operative inflammation and pain, injectable depots for back-of-the-eye diseases, and ReSure Sealant for sealing clear corneal incisions following lens implantation surgery.

1 The Global Cataract Surgery Devices Market is forecast to exceed $3.8 Billion by 2017. ASDR Reports, February 22, 2012. https://www.asdreports.com/news.asp?pr_id=261.

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