Drug Eluting Contact Lens

Organization
Mercy Research
Division of Product Development & Informatics (PD&I)

Industry:
Healthcare/medical

Researchers:
Shachar Tauber, MD – Inventor
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Cody Stringer, PhD – Commercialization Manager, PD&I

Status of Intellectual Property:
Issued US Patent No. 7,563,396
Issued US Patent No. 7,579,442
Issued US Patent No. 7,563,396 B2
Issued US Patent No. 8,083,347 B2
Issued US Patent No. 8,361,492
Issued CANADA Patent No. CA2767044C
PCT US2014/043239
EU Patent Application No. 14814276.3
US Patent Application No. 14/309,437
CANADA Patent Application No. 2,916,425

Next Steps:
Transition from laboratory-scale manufacturing to pilot-scale manufacturing
QA/QC development for new production process
In vitro dissolution studies under pilot-scale manufacturing process
In vivo cytotoxicity and ocular irritation confirmatory studies
In vivo pharmacokinetic trials under pilot-scale manufacturing process
Clinical trials per FDA requirements

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Wanted

Experienced leader to develop and commercialization in coordination with the Mercy Research Product Development team

Customer Problem

Eye drops are a poor method of delivering ophthalmic medication to the eye. Patient compliance tends to be very poor. Among compliant patients, accurate administration of eye drops is rare, with the incorrect number of drops often being instilled to the eye. Tear turnover and poor bioavailability are also responsible for loss of drug when eye drops are administered appropriately. It is estimated that typically less than 5% of a topically applied drug permeates the cornea and reaches intraocular tissues. Delivery of ophthalmic medication using a drug eluting contact lens would drastically reduce patient non-compliance, enhance the appropriate administration of drug, and enhance bioavailability of drug by increasing residence time with ocular tissue.

Potential Market Uses

This technology is intended to be the first product released on the market capable of sustained drug release of one or more drugs simultaneously for seven days in a non-implantable form factor of a contact lens. The product may contain one or more active pharmaceutical ingredients (APIs) and release each API independent of one another to achieve the release profile optimal for the pharmaceutical. Virtually any drug can be custom fit for an extended release profile within this technology platform.

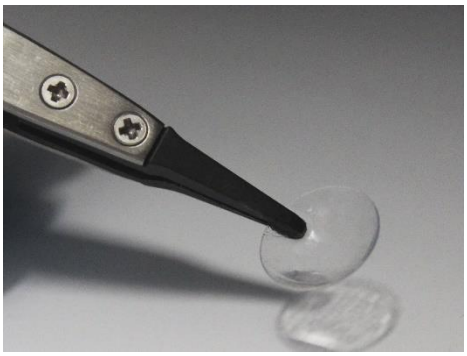
The product has commercial applications for virtually all ophthalmic pharmaceuticals. The extended release drug delivery lens provides simultaneous release of multiple drugs for 7 days in a well-known easy to use base platform of a contact lens. This product is designed to provide increased compliance, elimination of the variation of drug concentration in the corneal tissue throughout the day and the reduction of medication errors. The contact lens can be used for refractive correction surgeries, corneal transplants, long-term therapeutics (glaucoma, chronic inflammation and infections), post-operative inflammation, chemical injuries, and corneal abrasions.

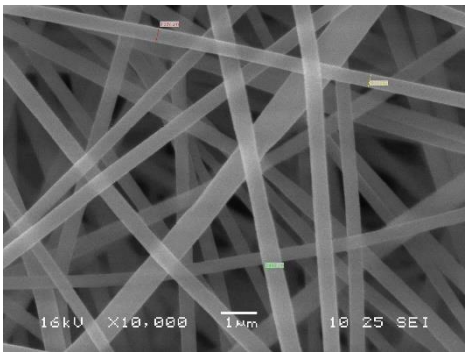
Market Size

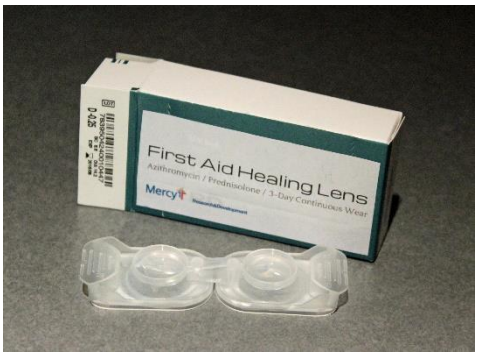
The global market for drug delivery systems was estimated at $178.8 billion in 2015, and is expected to rise at a compound annual growth rate (CAGR) of 4.9%, reaching nearly $227.3 billion by 2020. The U.S. makes up 42% of the total drug delivery market and is estimated at $75.7 billion. It is expected to grow to $93.4 billion in 2020. The global ophthalmologic drug and devices market is experiencing sustained growth due to increased prevalence of eye diseases that are common among an aging population, such as macular degeneration and diabetic retinopathy. This market is expected to reach $52.6 billion by the end of 2017.

Innovation

The drug delivery contact lens utilizes a proprietary technology for extended drug release. The API(s) of interest are loaded into a nanofiber matrix. The nanofibrous mesh with loaded drug is then integrated into a hydrogel contact lens. The contact lens is manufactured using established techniques. It is expected that the drug delivery contact lenses will be packaged and stored dry, and rehydrated by the physician immediately prior to use. Preliminary development of a packaging system has also been carried out that will allow the rehydration process to be accomplished quickly and easily by the physician.







Stage of Development

Development of the drug eluding contact lenses has been conducted using the two most common methods of lens fabrication – molded and lathe cut. The base lens formulation is a high-water content hydrogel. This, in combination with the electrospun materials, yields a near-zero order drug release following an initial burst of release within the first 1-8 hours.

A library of optimal electrospun material/API combinations has been generated using a selection of known biocompatible polymers with focus on anti-inflammatory and anti-microbial molecules based on work for the military. These materials have then been incorporated into the lens formulation and contact lenses fabricated for laboratory testing and dissolution testing using contact lens specific equipment and methods. In vitro cytotoxicity testing has been conducted on the electrospun materials - with and without drug.

Drug release data indicates that the lathe-cut drug-eluting contact lens is capable of simultaneous release of both Azithromycin and Prednisolone 21-acetate for 7 days. Sustained therapeutic delivery is evidenced by the drug concentrations for both APIs remaining above the minimum inhibitory concentration (MIC) for Azithromycin and the minimum effective dose (MED) for Prednisolone 21-acetate over the course of 7 days.

A third party cGLP laboratory was hired to conduct *in vitro* cytotoxicity testing, *in vivo* Irritation/Intracutaneous Reactivity testing, and *in vivo* Acute Systemic Toxicity testing. Results of all third-party testing has been positive.

Competitive Advantages

Currently there are no drug delivery contact lenses on the market. Only 5% of drugs administered by eye drops are bioavailable and drops account for more than 90% of all ophthalmic formulations. Furthermore, patient eye drop compliance is estimated to be around 24% and the form factor of a contact lens will be highly attractive to health systems as they continue to face new disease management reimbursement models and stronger pressure on best outcomes and removing risk of patient error.

The drug delivery contact lens is an innovative and unique approach that can enhance competitive positioning for new drug introductions, accelerate product adoption through enhanced patient compliance and convenience of use. This delivery system can provide product life extension of proprietary drugs coming off patent and competitive differentiation for generic or branded drugs using this unique drug delivery system.