Contact Lens Drug Delivery Moves Closer to Reality

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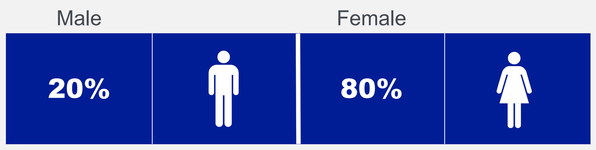
BACKGROUND and PURPOSE

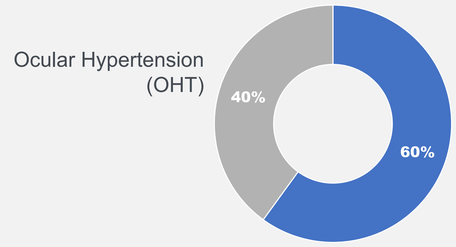
- The use of drug delivery contact lenses is a decades-old idea
- Now, this once-futuristic notion is becoming a reality
- The current standard of care is daily eye drop therapy -- new ocular drug delivery systems are designed to overcome limitations of eye drops with benefits such as:
  - Higher bioavailability, extended residence time, decreased pulsatile delivery, controlled delivery and improved patient compliance
- An example of a promising development is LL-BMT1, a drug-eluting contact lens for glaucoma treatment using the FDA-cleared drug bimatoprost, developed by MediPrint™ Ophthalmics
  - A proprietary process allows for printing of drug and barrier layers on the contact lens surface to control drug diffusion release kinetics
- This poster highlights the SIGHT-1 (Sustained Innovative Glaucoma and Ocular Hypertension Treatment-1) clinical study evaluating LL-BMT1 in humans -- for the first time -- with primary open-angle glaucoma (POAG) or ocular hypertension (OHT)

METHODS

- n = 5
- U.S. adults aged 73 – 84 years old (mean age: 77.4 years)
- All enrolled subjects were contact lens naïve and completed the study
- Subjects received LL-BMT1 in both eyes and wore the LL-BMT-1 contact lenses continuously for one week (seven days and six nights)
- The primary objective of this Phase 2a, open-label clinical study was to evaluate the safety of LL-BMT1 in POAG or OHT patients
  - Additional objectives of this study were to evaluate the tolerability and IOP-lowering effects of LL-BMT1 in patients with POAG or OHT
- All enrolled patients with treated or treatment-naïve POAG or OHT in both eyes successfully passed pre-study screening and all previously treated eyes had a washout period prior to enrollment
- All enrolled subjects received LL-BMT1 (medicated) contact lenses containing bimatoprost at a dose of 26 µg/lens
- Patients were assessed for safety, primarily, and for IOP reduction during the seven-day treatment period
  - Adverse events (AEs) were monitored, along with other safety measures, including best-corrected visual acuity, slit-lamp biomicroscopy and contact lens protein deposition
- CLDEQ-8 was administered at baseline and on day seven
- The study site was the Eye Research Foundation in Newport Beach, CA and the principal investigator was David Wirta, MD

PATIENT DEMOGRAPHICS





Mean Age: 77.4 years old

Subjects' History at Screening

RESULTS

Clear Safety

The study demonstrated strong safety findings with no significant adverse events and lower rates of side effects than typically seen with topical eye drops

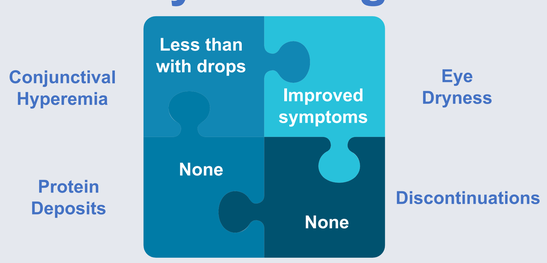
Only minor changes in slit lamp biomicroscopy findings for conjunctival hyperemia, lower than with drops

No contact lens protein deposits were observed

All patients were able to tolerate LL-BMT1 for the treatment duration – no discontinuations

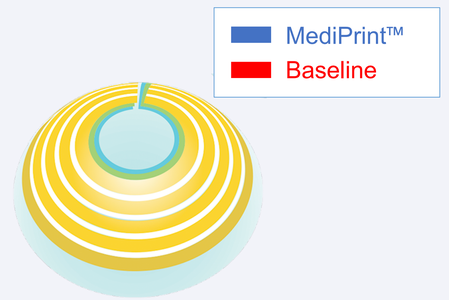
There was a trend toward improved symptoms of eye dryness on Day 7 compared with Day 1

Key Findings



Efficacy Signal

The study demonstrated robust efficacy; all patients showed a decrease in IOP from baseline with LL-BMT1, so a dose optimization study is planned



100%

Of enrolled patients had an IOP ⬇ from baseline

CONCLUSIONS

- The results of SIGHT-1 suggest that use of an LL-BMT1 contact lens imprinted with bimatoprost for one week was well tolerated in a population of five patients with POAG or OHT
- All subjects showed a decrease in IOP from baseline, a robust efficacy signal, so a dose optimization study is planned
- The use of contact lenses as ocular delivery systems is finally emerging as a viable option – the potential for a non-invasive sustained delivery system without the limitations of eye drops offers hope to patients and practitioners that a new treatment paradigm may be forthcoming for ocular diseases such as glaucoma, dry eye and allergy

DISCLOSURE

- This study was funded by MediPrint Ophthalmics
- Dr. Barnett is a paid consultant of MediPrint Ophthalmics