Poster
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# Iontophoresis Platform Safely and Effectively Delivers Dexamethasone to Manage Post Operative Inflammation and Pain Following Cataract Surgery.

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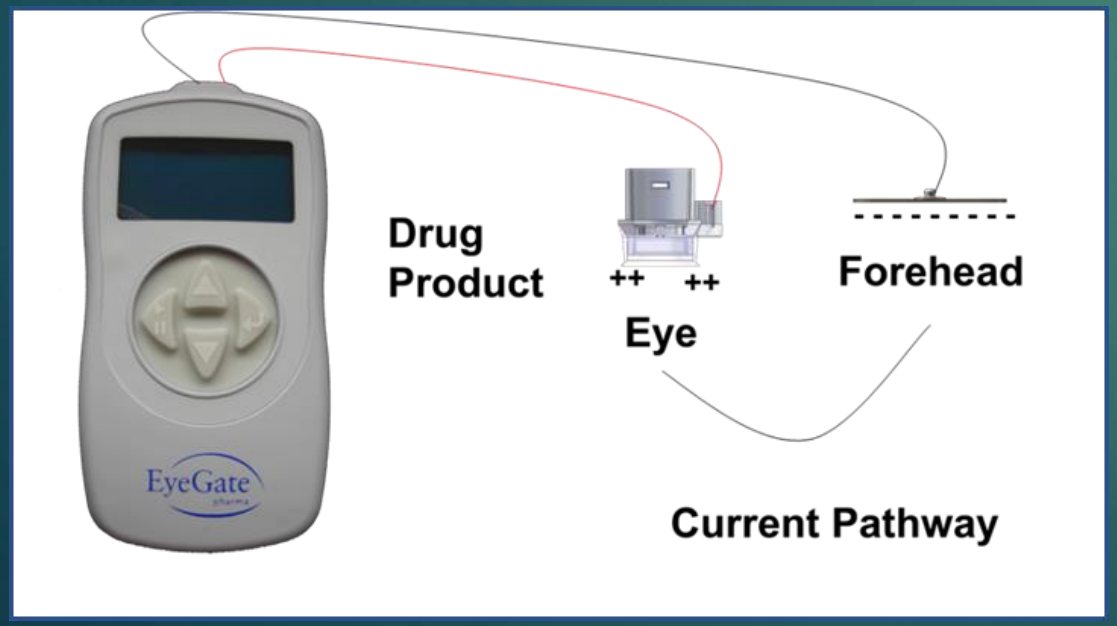
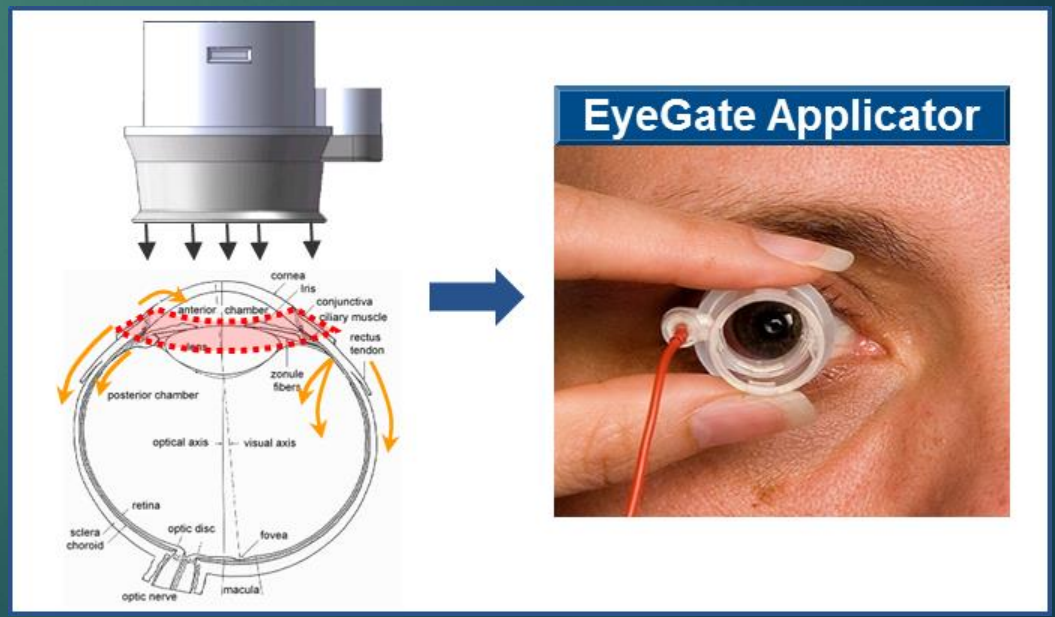
# Purpose:

- To assess the safety and efficacy of a novel and proprietary iontophoretic platform, EGP437, in its ability to deliver dexamethasone to patients following cataract surgery.
- This technology offers the potential to control pain and inflammation after cataract surgery without the need for daily drop therapy.

# Iontophoresis Platform: A Non-Invasive Method of Propelling Charged Active Compounds Into Ocular Tissues

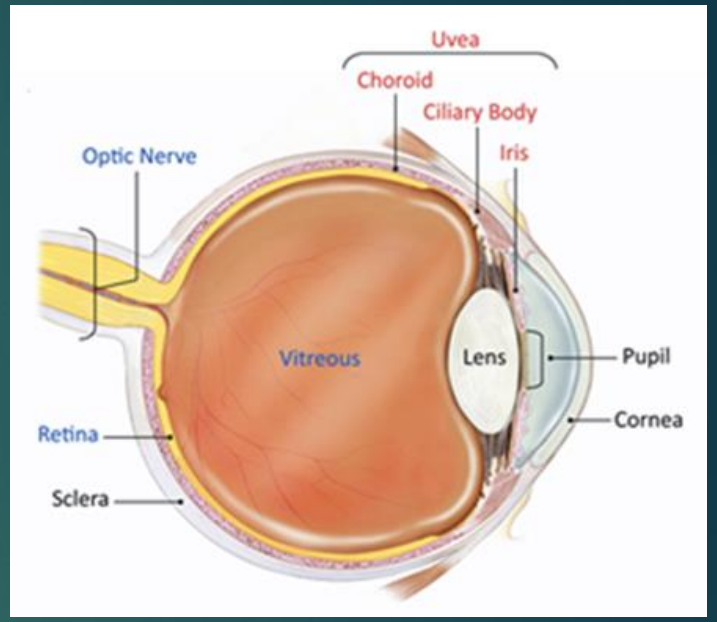
- Small electrical current (constant); current has same charge as active substance (drug)
- Electrode creates repulsive electromotive forces (like charges repel)
- Drug migrates toward return electrode, mobility a function of molecular weight and charge
- Drug dose controlled by 2 variables: Current (mA) x Application time (minutes)
- Software-regulated current and duration ensures proper dosing of compatible compounds
- Easy to use: ophthalmologist or optometrist in <5 minutes
- More than 2,400 treatments performed in office settings



# EGP-437: A Potent Anti-inflammatory Agent *(corticosteroid - dexamethasone phosphate)*

## Cataract Surgery Overview




- Ocular inflammation and pain are common side effects following cataract surgery
  - > 24 million people age 40 and older have cataracts in the US
  - Nearly four million cataract surgeries are performed each year in the US[1]

- Positive outcome from Phase 1b/2a, 80 subject open-label dose ranging trial
  - Subjects enrolled into cohorts (10 subjects/cohort)
  - Primary outcomes:
    - Proportion of subjects with anterior chamber cell (ACC) count of zero and
    - Proportion with pain score of zero

1. Market Scope, 2015 Comprehensive Report on The Global IOL Market, June 2015

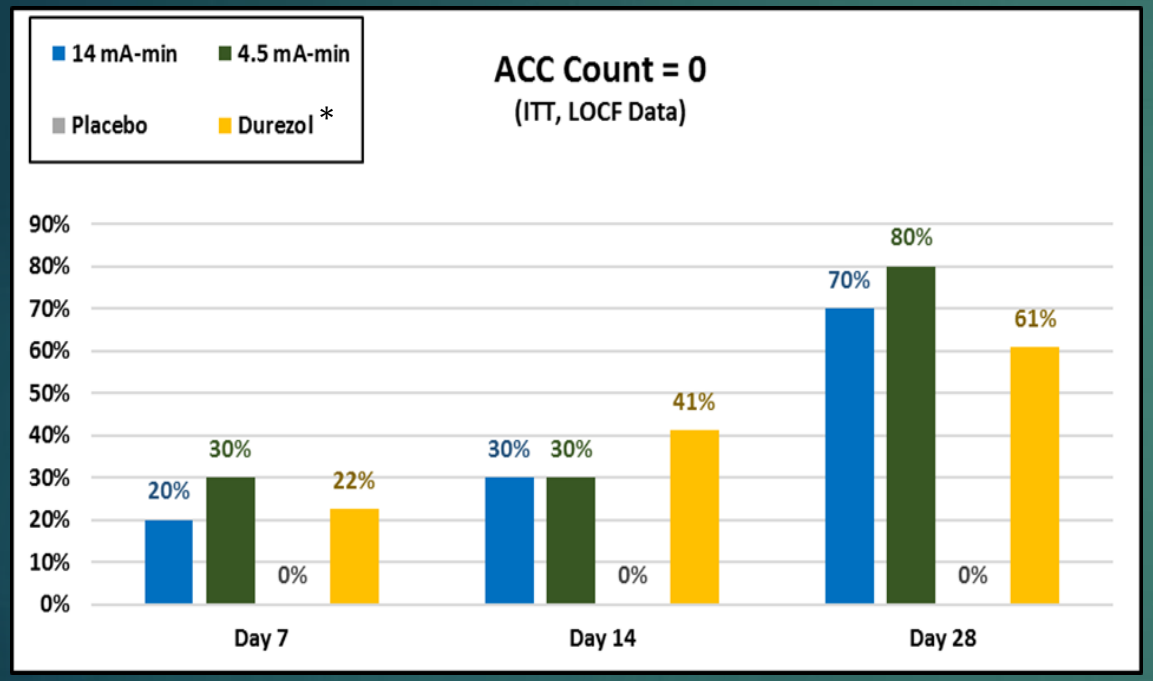
# Methods:

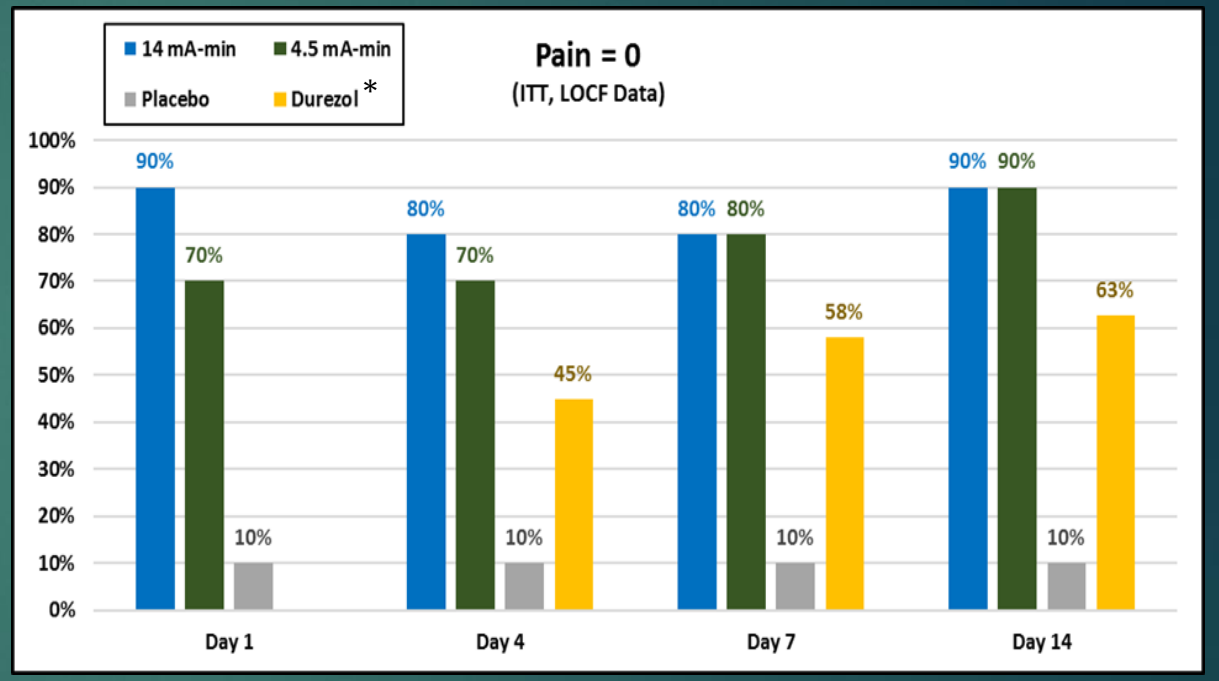
- A  28 day multicenter, open label trial enrolling up to 80 subjects who underwent unilateral cataract extraction with a monofocal intraocular lens.
- The trial design included 8 cohorts whereby 40 mg/ml of dexamethasone in iontophoretic doses of 4.0 mA min, 4.5 mA min, 9.0 mA min and 14.0 mA min were employed versus placebo;
- 9.0 and 14.0 mA min Cohorts included 3 different dosing regimens.
  - Subjects in the 9.0 and 14.0 mA min cohorts had three treatments administered starting day 0 (post surgery), day 1 and day 2 OR day 0 (post surgery), day 1 and day 4 with potential for an additional treatment at Day 7.
- A 9.0 mA min cohort also evaluated 30 – 60 minutes pre surgery day 0 dose followed by day 1, and day 4.
- The primary endpoint for all cohorts was ACC at day 14,
- Secondary endpoints included:
  - measuring pain score
  - Intraocular pressure

# Results:

- A positive response was observed in the majority of the patients. The cohorts receiving the 4.5 mA min and the 14 mA min dose of iontophoretic EGP437 on days 0, 1 and 4 generated the most encouraging results, with an Anterior Chamber Cell count (ACC) of zero in 20-30% of patients at day 7 and 70-80% of patients at day 28.
- Procedure was very well tolerated with minimal pain throughout the duration of the trial.
- 8 of 10 subjects rescued by Day 4 in placebo arm – i.e. control arm for registration trials.
- Percentage of patients in 4.5 and 14 mA-min doses with zero pain on day 1 was 70 and 90% respectively

# Efficacy Results:




*Durezol data from CDER Application Number 22-212: Medical Review for Durezol, studies ST-601A-002a and 002b.
Durezol data shown is based on combined data from both studies. QID dose, ITT, LOCF.
EGP-437 data from 4.5mA-min and 14mA-min dosed on Days 0, 1, and 4 (some subjects received additional dose at Day 7) and is ITT, LOCF.

# Safety Results:

- No increase in IOP due to EGP-437
- In the two dose cohorts selected
  - Mild / moderate AEs included "expected" post operative findings, all of which resolved:
    - Excessive inflammation (30% in 14.0 mA-min & 0% in the 4.5 mA-min)
    - Corneal edema (50% of the 14.0 mA-min & 0% in the 4.5 mA-min)
    - Eye pain / Foreign body sensation (50% in 14.0 mA-min & 30% in 4.5 mA-min cohorts)
    - Mild transient eye or brow discomfort during procedure was noted in a minority of patients
  - On average Moderate inflammation was noted in the majority of the placebo group as expected which resulted in early rescue

# Conclusions:

- EGP-437 is safe and effective in reducing inflammation and preventing pain as early as Day 1 with 2 different iontophoretic doses.
- Best responses observed with 4.5 mA-min and 14.0 mA-min doses
- Percentage of patients with ACC count of zero greater than Durezol historical data at Day 7 and Day 28
- Percentage of patients with zero pain better than Durezol historical data at Day 4, 7, and 14
- Phase 2b trial initiation targeted for 1H 2017

**EGP-437 effectively controls post operative pain and inflammation without the need for drop therapy**