

**ABSTRACT TITLE**

**TITLE:** Suprachoroidal Microinjection of Triamcinolone Acetonide is Well Tolerated in the Albino Rabbit

**PROGRAM # (Final ID)**

**ABSTRACT FINAL ID:** 119 - C0124

**SESSION TYPE:** Poster Session

**POSTER BOARD # (DOI)**

**DIGITAL OBJECT IDENTIFIER (DOI):** C0124

**PRESENTATION START/END**

**SESSION ABSTRACT START TIME:** 8:30 AM

**SESSION ABSTRACT END TIME:** 10:15 AM

**SESSION # (Abbreviation)**

**SESSION ABBREVIATION:** 105

**SESSION TITLE:** Inflammation and Drugs

**SESSION DAY & DATE:** Sunday, May 5, 2013

**SESSION START TIME:** 8:30 AM

**SESSION END TIME:** 10:15 AM

**AUTHORS (LAST NAME, FIRST NAME):** Verhoeven, Rozemarijn S.<sup>1</sup>; Patel, Samirkumar R.<sup>1</sup>; Viaud-Quentric, Karen<sup>2</sup>; Cacciamani, Florian<sup>2</sup>; Amar, Thierry<sup>2</sup>; Yerxa, Benjamin<sup>1</sup>

**INSTITUTIONS (ALL):** 1. Clearside Biomedical, Alpharetta, GA, United States.  
2. Iris Pharma, La Gaude, France.

**Study Group:**

**ABSTRACT BODY:**

**Purpose:** To evaluate ocular tolerability and toxicokinetics of suprachoroidal administration of triamcinolone acetonide (TA) using a Clearside Biomedical proprietary microneedle in a GLP study in the New Zealand White rabbit.

**Methods:** On Day 0, rabbits (5/sex/group) were administered a single bilateral suprachoroidal injection of vehicle, 3.2 mg or 5.2 mg of TA (Triesence®) using a 33g 750µm microneedle. Clinical observations, body weights, food and water consumption, slit lamp biomicroscopy with McDonald-Shadduck scoring, fundus evaluation, intraocular pressure assessment (IOP), electroretinography (ERG), and systemic exposure were assessed up to 17 weeks post-dose. Animals were sacrificed on Day 1 and Week 13 for macroscopic observations, ocular toxicokinetics, and ocular histopathology.

**Results:** There were no adverse effects related to test article or method of administration on clinical observations, body weight, body weight gain, food and water consumption, or ophthalmic examinations. No effect on ERG a- or b-wave amplitude or implicit time was noted in any animal. A mild, transient increase in IOP of 2-3 mmHg was observed in the TA groups on Days 7 and 28, which resolved by Week 13 and was not considered adverse. Inflammatory cells and test article were observed in the suprachoroidal space of TA-treated animals on Day 1 but not Week 13 as assessed by histopathology. Systemic exposure to TA was minimal. TA was observed at high concentrations in the sclera/choroid and retina, to a lesser extent in the iris/ciliary body, and was present only at low concentrations in the aqueous humor, lens, and vitreous.

**Conclusions:** A single bilateral suprachoroidal injection of 3.2 or 5.2 mg TA using a microneedle was well tolerated in the albino rabbit. Systemic exposure to TA was minimal, and absorption of TA into the posterior segment of the eye was observed with minimal TA exposure to the anterior segment of the eye. These data suggest that suprachoroidal drug delivery is well tolerated, results in distribution of TA to the sclera/choroid and retina, structures that are important targets for anti-inflammatories in posterior segment disease, and limits TA exposure in the anterior segment.

(No Image Selected)

**Commercial Relationship(s) Disclosure:**

Rozemarijn Verhoeven: Commercial Relationship(s);Clearside Biomedical:Code E (Employment)

Samirkumar Patel: Commercial Relationship(s);Clearside Biomedical:Code E (Employment);Clearside Biomedical:Code I (Personal Financial Interest);Clearside Biomedical:Code P (Patent)

Karen Viaud-Quentric: Commercial Relationship(s);Iris Pharma:Code E (Employment)

Florian Cacciamani: Commercial Relationship(s);Iris pharma:Code E (Employment)

Thierry Amar: Commercial Relationship: Code N (No Commercial Relationship)

Benjamin Yerxa: Commercial Relationship(s);Clearside Biomedical:Code I (Personal Financial Interest)

**Grant Support:** Yes

**Support Detail:** Georgia Research Alliance

**Clinical Trial Registration:** No

**Other Registry Site:**

**Registration Number:**

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