EYEPOINT™
PHARMACEUTICALS

Protocol Title:	*DEXYCU (dexamethasone intraocular suspension) 9% retrospective study 001*
Protocol Number:	***DEXYCU Retrospective Study 001***
Sponsor:	*EyePoint Pharmaceuticals* *480 Pleasant Street* *Suite B300* *Watertown, MA 02472* *USA*
Contract Research Organization (CRO):	*Axiom Real-Time Metrics* *1 City View Dr* *Toronto, ON M9W 5A5* *Canada*

Protocol Version/Date: [1.0 /15Oct2019]

PROTOCOL APPROVAL PAGE

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This Protocol has been reviewed and approved by EyePoint Pharmaceuticals.

Approved by	Signature	Date
Dario Paggiarino, MD Senior Vice President, Chief Medical Officer EyePoint Pharmaceuticals		10/21/19
Keyur Patel, PharmD Vice President, Medical Affairs EyePoint Pharmaceuticals	Keyur Patel	10/18/19

INVESTIGATOR STATEMENT

I understand that all documentation provided to me by EyePoint Pharmaceuticals, or its designated representative(s) concerning this study will be kept in the strictest confidence. This documentation includes the study protocol, case report forms, and other scientific data.

This study will not commence without the prior written approval of a properly constituted Institutional Review Board (IRB). No changes will be made to the study protocol without the prior written approval of EyePoint and the IRB.

I have read, understood, and agree to abide by all the conditions and instructions contained in this protocol.

Investigator Signature: _____ Date: _____

Investigator's Printed Name: _____

List of Abbreviations

Abbreviation	Definition
ACC	Anterior Chamber Cells
ACF	Anterior Chamber Flare
BCVA	Best-Corrected Visual Acuity
FDA	Food and Drug Administration
HIPAA	Health Insurance Portability and Accountability Act
IOL	Intraocular Lens
IOP	Intraocular Pressure
IRB	Institutional Review Board
MIGS	Minimally- or micro-Invasive Glaucoma Surgery
NSAID	Non-Steroidal Anti-inflammatory Drug
OD	Oculus Dexter (right eye)
OS	Oculus Sinister (left eye)
POD	Postoperative Day
UCVA	Uncorrected Visual Acuity
VA	Visual Acuity

Study Summary

Title	*DEXYCU (dexamethasone intraocular suspension) 9% retrospective study 001*
Short Title	*DEXYCU Retrospective Study 001*
Protocol Number	*DEXYCU Retrospective Study 001*
Study Design /Methodology	*Retrospective case series*
Study Duration	*From initialization to database lock, approximately 6 months.*
Study Center(s)	*This multicenter retrospective case series will be conducted at approximately 40 sites.*
Objectives	*This study is intended to provide large-scale, real-world data on clinical outcomes with DEXYCU (dexamethasone intraocular suspension) 9%.*
Number of Subjects	*Total of up to 600 subjects across all sites.*
Eligibility Criteria and main objective	*To be eligible, patients must have received a dose of DEXYCU at the close of ocular surgery.*
Study Interventions and Measures	*Review of medical records. Collection of patient characteristics, clinical outcomes, and patient and practitioner satisfaction.*
Statistical Methodology	*Descriptive statistics will be performed for data collected.*

1 Background and Study Rationale

This study is a retrospective case study/chart review. The study will be reviewed and approved by an independent institutional review board and will be conducted in accordance with International Council for Harmonisation/Good Clinical Practice requirements as well as applicable federal and state regulations.

1.1 Study Introduction

DEXYCU (dexamethasone intraocular suspension) 9% was approved by the United States of America Food and Drug Administration (FDA) in 2018 for the treatment of postoperative inflammation. This study was initiated in order to obtain information on the drug's performance in real-world clinical practice.

1.2 Background and Relevant Literature and Data

The FDA approval of DEXYCU was based on prospective, randomized, controlled clinical trials in patients undergoing cataract surgery.[1,2] After cataract and other ocular surgeries, inflammation is typically controlled with topical corticosteroid and/or non-steroidal anti-inflammatory drug (NSAID) drops.[3] As an intraocular, sustained-release formulation of dexamethasone, DEXYCU may be able to replace routine postoperative topical corticosteroid drops.[1,2]

However, the phase 3 trials evaluating the safety and efficacy of DEXYCU excluded a number of clinical scenarios and aspects of perioperative management likely to be encountered in day-to-day practice. For example, though cataract and glaucoma may often coexist, most patients with glaucoma or ocular hypertension were excluded from clinical trials of DEXYCU, and its use has not been studied in minimally- or micro-invasive glaucoma surgery (MIGS) procedures, which are commonly paired with cataract surgery in patients with glaucoma.[4,5] Similarly, patients experiencing certain intraoperative complications (e.g., posterior capsule rupture) that may not preclude the use of DEXYCU in clinical practice were also excluded from the clinical trials. The concomitant use of postoperative NSAIDs and corticosteroids (topical or intraocular) is routine,[3] but adjunctive NSAIDs constituted a protocol violation in DEXYCU clinical studies unless pre-specified anti-inflammatory rescue criteria had been met.[1,2] Finally, details about the administration of the DEXYCU droplet and its behavior in the eye were limited in the clinical trials and are of interest to collect.

DEXYCU is not only newly available, it is also different in kind from other ophthalmic corticosteroids indicated for treating postoperative inflammation, given that it is the only FDA-approved intraocular formulation. Thus, there is a particular need for data on the performance of DEXYCU in real-world practice, without the restrictions that are necessary for randomized, prospective trials. A retrospective case study allows this data to be obtained relatively rapidly and at scale, so that it may be made available to interested practitioners and published in the medical literature.

2 Study Objectives

This study is intended to provide large-scale, real-world data on clinical outcomes with DEXYCU. The purpose is to collect and summarize data on the clinical performance of DEXYCU in terms of anti-inflammatory efficacy, tolerability, intraocular behavior of the product, and patient satisfaction as reported to the surgeon and surgeon satisfaction.

3 Study Design and Methods

3.1 General Study Design

This is a retrospective chart review study for subjects previously treated with DEXYCU.

3.1.1 Total Number of Subjects

The study will enroll up to 600 subjects at approximately 40 sites.

3.2 Study Population

3.2.1 Inclusion Criteria

- Male and Female subjects at least 18 years of age
- Subjects who underwent cataract surgery from 12Mar2019 to 15Oct2019 and received DEXYCU

3.2.2 Exclusion Criteria

- Subjects who underwent cataract surgery and did not receive DEXYCU

4 Study Procedures

This study will involve the review of existing medical records.

4.1 Date Range of the study

Cases will be included in the study if they underwent cataract surgery and received DEXYCU between 12 March 2019 and 15 October 2019.

4.2 Subject Selection

Subjects will be identified for inclusion in the study by participating investigators/surgeons according to their medical discretion.

4.3 Data Sources

Data will be found in paper or electronic medical records at study sites.

4.4 Variable Abstraction

Patient Characteristics:
Patient ID – Assigned as entered into Fusion (this is not the subject's medical record number)
Patient Demographics including Age at the time of surgery, Gender, Ethnicity, Race
Medical History including risk factors, Diabetes and Glaucoma
Surgery Details:
Affected Eyes, location of cataract and severity
Date of surgery with DEXYCU
Type of surgery

Intraocular lens (IOL) manufacturer, location and model
Viscoelastic usage
DEXYCU placement
Visibility of DEXYCU and Timing of DEXYCU
DEXYCU adherence
Concomitant Medications
Were any preoperative, intraoperative, or postoperative medications taken?
Clinical Outcomes Timepoints (POD 1, 8, 14, 30 and Unscheduled):
DEXYCU visibility
Anterior chamber cells (ACC)
Anterior chamber flare (ACF)
Intraocular pressure (IOP)
BCVA
UCVA
Rank efficacy vs topical steroids
Target Visual Acuity (VA) achieved
Product Tolerated
Patient and Surgeon Satisfaction:
Patient Satisfaction with DEXYCU based on feedback to the Surgeon
Surgeon Satisfaction with DEXYCU
Ease of use
Postoperative regimen
DEXYCU time efficiency for physicians and staff
Other Remarks

5 Statistical Plan

Descriptive statistics will be performed for de-identified demographic data, surgical details, clinical outcomes, and surgeon and patient satisfaction.