UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): **November 9, 2023**

KIORA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-36672	**98-0443284**
(Commission File Number)	(IRS Employer Identification No.)

332 Encinitas Blvd.
Suite 102
Encinitas, CA 92024

(858) 224-9600
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	**Trading Symbol(s)**	**Name of each exchange on which registered:**
Common Stock, $0.01 par value	KPRX	NASDAQ

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

Kiora Pharmaceuticals, Inc. (the "Company") hereby furnishes the updated investor presentation attached as Exhibit 99.1 to this Current Report on Form 8-K, which the Company may use in presentations to investors from time to time.

The information furnished pursuant to Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

The information furnished in this report, including Exhibit 99.1, shall not be deemed to constitute an admission that such information or exhibit is required to be furnished pursuant to Regulation FD or that such information or exhibit contains material information that is not otherwise publicly available. In addition, the Company does not assume any obligation to update such information or exhibit in the future.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Title
99.1	Company Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

*Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish copies of any of the omitted schedules and exhibits upon request by the U.S. Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KIORA PHARMACEUTICALS, INC.

By: /s/ Melissa Tosca
Melissa Tosca
Executive Vice President of Finance
(Principal financial and accounting officer)

Date: November 9, 2023

Kiora Pharmaceuticals, Inc.

NASDAQ: KPRX

Q4 2023 | Corporate Overview

Forward Looking Statements

Some of the statements in this presentation are "forward-looking" and are made pursuant to the safe harbor provision of the Private Securities Litigation Reform Act of 1995. These "forward-looking" statements include statements relating to, among other things, the development and commercialization efforts and other regulatory or marketing approval efforts pertaining to Kiora's development-stage products, including KIO-301 and KIO-104, as well as the success thereof, with such approvals or success may not be obtained or achieved on a timely basis or at all, the potential ability of KIO-301 to restore vision in patients with RP, the expecting timing of enrollment, dosing and topline results for the ABACUS study, the ability to develop KIO-301 for Choroideremia and Stargardt Disease and KIO-104 for posterior non-infectious uveitis, the ability to utilize strategic relationships to develop certain product candidates, Kiora's ability to draw on its equity line of credit, and Kiora's ability to achieve the specific milestones described herein. These statements involve risks and uncertainties that may cause results to differ materially from the statements set forth in this presentation, including, among other things, the ability to conduct clinical trials on a timely basis, the ability to obtain any required regulatory approvals, market and other conditions and certain risk factors described under the heading "Risk Factors" contained in Kiora's Annual Report on Form 10-K filed with the SEC on March 23, 2023, or described in Kiora's other public filings. Kiora's results may also be affected by factors of which Kiora is not currently aware. The forward-looking statements in this presentation speak only as of the date of this presentation. Kiora expressly disclaims any obligation or undertaking to release publicly any updates or revisions to such statements to reflect any change in its expectations with regard thereto or any changes in the events, conditions, or circumstances on which any such statement is based, except as required by law.

Sharpened Focus on Orphan Retinal Diseases

Kiora is developing retinal therapeutics to improve sight in patients with severe vision loss due to inherited or age-related diseases

Patient Perspective
Individual's burden of disease

Physicians Perspective
Efficient, cost-effective treatments

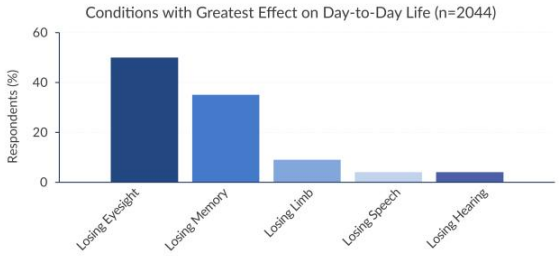
Societal Perspective
Pharma industry obligation to help

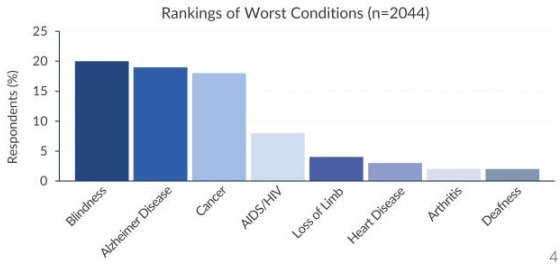
Why Retinal Diseases?

"...the last light sensations faded and the dark discs had finally overwhelmed me. I had fought them bravely, as it seemed to me, for thirty-six years, but to no avail. It was then I began to sink into the deep ocean, and finally learn how to touch the rock on the far side of despair."

- John M. Hull, *Touching the Rock*

JAMA Ophthalmol Oct 2016; 134(10)



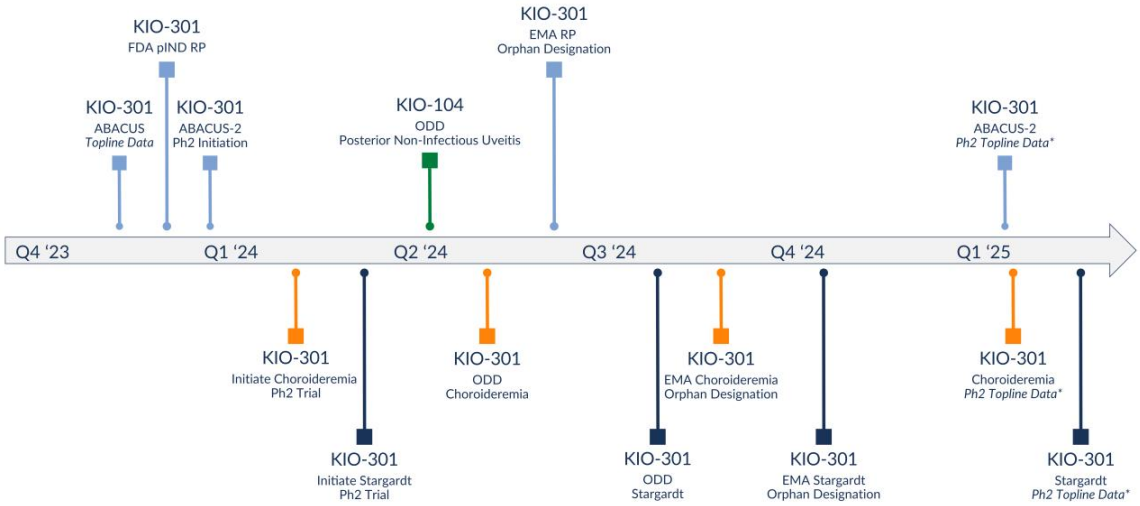


Pipeline

Product Route of Delivery	Indication	Development Stage				Prevalence*
		Pre-clinical	Phase 1	Phase 2	Phase 3	(US, EU5, JP)
KIO-301 Intravitreal	Retinitis Pigmentosa (Mutation Agnostic)	*Granted Orphan Drug Designation (USA) – Mar 2022*				250,000
	Choroideremia					16,000
	Stargardt Disease					99,000
KIO-104 Intravitreal	Posterior Non-Infectious Uveitis	*Granted Orphan Drug Designation (EU) – May 2015*				180,000

* Approximate 2023 populations.
Orpha.net, NORD, Ophthalmol Ther 2021 Sep; 10(3)

Upcoming Clinical/Regulatory Milestones



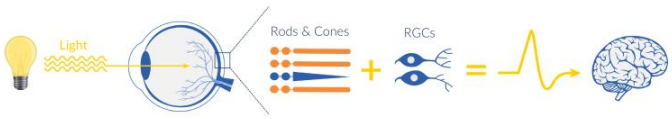
* Excludes open label extension
RP – Retinitis Pigmentosa, ODD – Orphan Drug Designation (USA), EMA – European Medicines Agency

KIO-301

Small Molecule Targeting Vision Restoration

Retinitis Pigmentosa, Choroideremia, Stargardt Disease

Inherited Retinal Diseases Lead to Loss of Vision



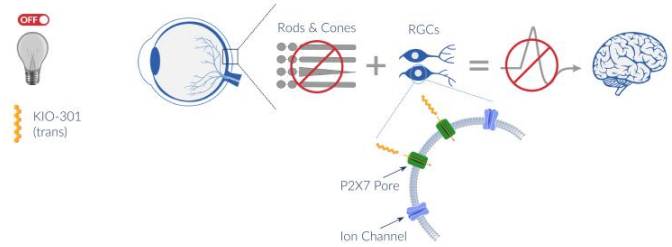
Healthy Vision

- Rods and cones, the photoreceptors of the retina, process light and relay an electrical signal to downstream cells.
- One of these cell types, retinal ganglion cells (RGCs), transmit the signal to the visual cortex.
- The visual cortex is the part of the brain where vision is perceived.

Damage from Retinitis Pigmentosa

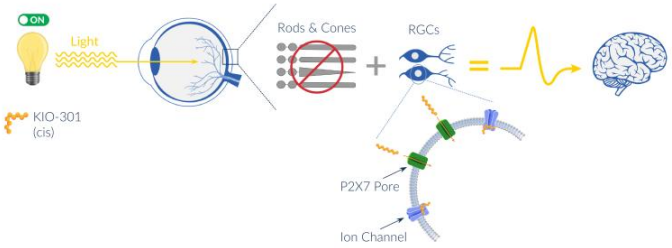
- Retinitis Pigmentosa (RP) results in progressive degeneration and loss of function of rods and cones.
- This causes continuous impairment of vision that often leads to blindness.
- Importantly, in RP and other inherited retinal diseases, the RGCs remain viable.

KIO-301 is a Molecular Photoswitch Designed to Restore Vision



KIO-301 without Light

- When photoreceptors die, RGCs undergo some remodeling, including expressing specific proteins that allow KIO-301 to selectively enter the cell with ion channels.
- Without light, KIO-301 remains in its linear "off" (trans) position.



KIO-301 with Light

- With light, KIO-301 is activated and bends into its "on" (cis) formation.
- This physically blocks ion channels and activates the cell to transmit signals to the visual cortex.

Retinitis Pigmentosa
A Disease with No Available Treatments

Normal Vision

Vision Declines over Time

Clinical Presentation
- Night blindness, reduced visual field range and eventual loss of central vision
- Visual acuity declines
- 50% of patients are not qualified to drive by age 37 and legally blind by 55

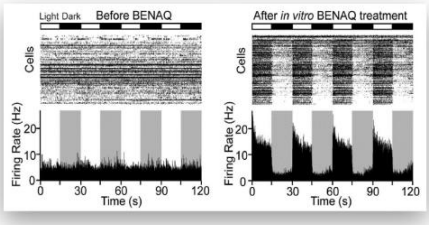
Etiology
- 50+ genetically distinct subtypes from 150+ mutations
- Inherited disease

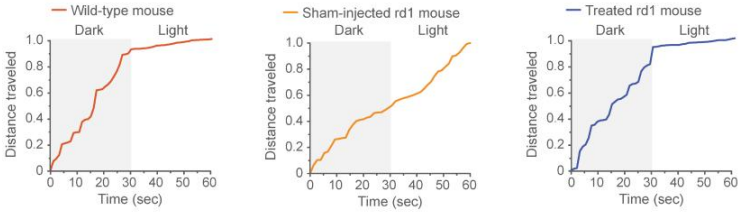
Market Opportunity
- ~100k patients in US (Provider: Retina Specialists [~3k])
- Estimated total cost to US healthcare system in 2019: $3.7B

IOVS: Visual Field Progression in Retinitis Pigmentosa, American Academy of Ophthalmology, Clinical Ophthalmol 2021:15, 2855–2866

KIO-301 Reanimates the Retina & Changes Behaviour

Extensive Validation in Preclinical Models

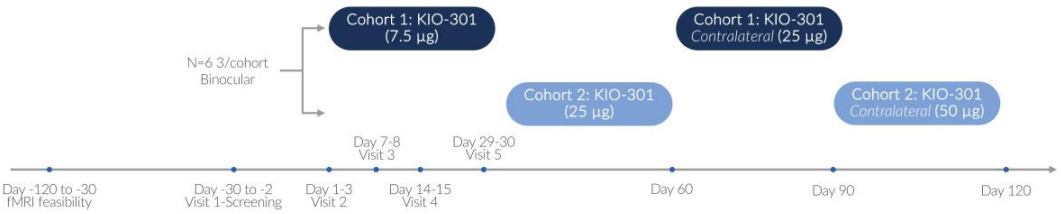




Neuron 2014: 81, 800-813. Behavioural study used a homologue molecule to KIO-301 API

KIO-301-1101: Phase 1b Study Design (ABACUS)

Open Label, Single Ascending Dose Trial – 2 Sites (Australia)



Study Design
- Two cohorts, non-randomized, open-label, single IVT injection per eye
- Cohort 1 – NLP/BLP patients; Cohort 2 – HM/CF patients

Endpoints
- Primary – AEs, PK & labs
- Secondary – Assessment days (shown only for Cohort 1 above) is repeated for each cohort per eye; intensity & contrast assessment, kinetic perimetry, functional MRI, etc.

Review
- Safety review conducted by Investigators between after sentinel subject

NLP – No Light Perception, BLP – Bare Light Perception, HM –Hand Motion, CF – Counting Fingers

Patient Testimonials

Patient 1-02
Baseline VA: NLP
Cohort 1

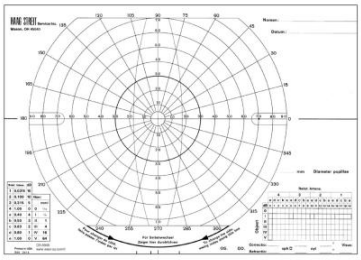
Patient 2-05
Baseline VA: CF
Cohort 2

Patient 1-03
Baseline VA: HM
Cohort 2

Videos also available at: https://kiorapharma.com/technology/kio-301/

VA – Visual Acuity, NLP – No Light Perception, CF – Counting Fingers, HM – Hand Motion

Kinetic Visual Field (Goldmann Perimetry)



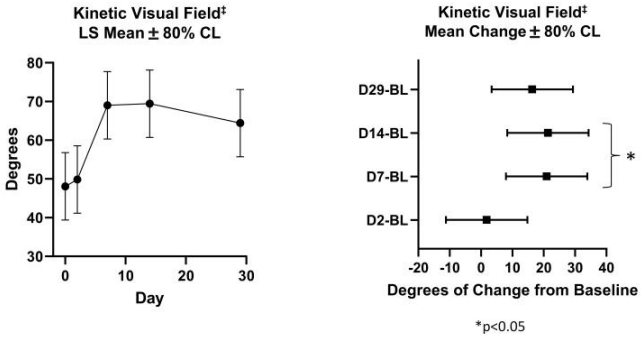
Aim: Evaluate Peripheral Vision at a Basic Level

Assessment & Insights:

- Applicability in this population
- Performed by experienced orthoptists
- Limited to 2-axis
- The patient is asked to acknowledge (using a buzzer) when light stimulus is visualized within the dome
- Method facilitates limitation of fixation
  - > Proof-of-feasibility achieved
  - > Will expand scope of evaluation to capture increased degrees

Kinetic Visual Field

KIO-301 May Improve Visual Field



*p<0.05

Kinetic Visual Field

- Goldmann perimetry
- Performed at baseline (BL), and each study visit
- Performed by same group of orthoptists to reduce variability
- Greater improvement observed in Cohort 2a

‡ Cohort 2 includes 3 patients (6 eyes)

Visual Acuity — Berkeley Rudimentary Vision Test (BRVT)

1040-5488/12/8909-1257/0 VOL. 89, NO. 9, PP. 1257–1264
OPTOMETRY AND VISION SCIENCE
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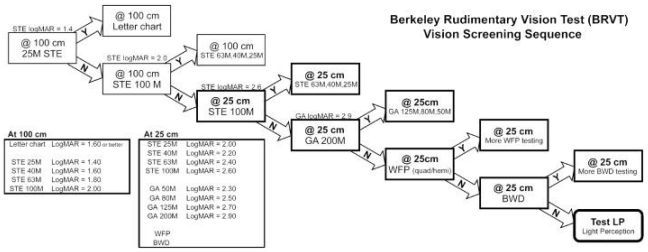
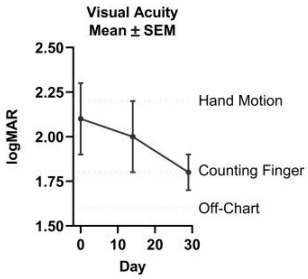
ORIGINAL ARTICLE

The Berkeley Rudimentary Vision Test

Ian L. Bailey*, A. Jonathan Jackson†, Hasan Minto‡, Robert B. Greer‡, and Marlena A. Chu§





Cohort 2 (3 patients, 3 eyes)

Light Perception (Intensity & Contrast Assessment)

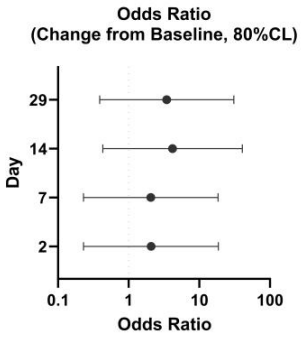
Aim: Evaluate Light Perception at a Basic Level

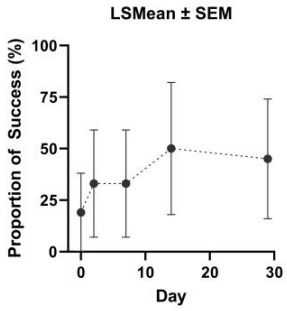
Assessment:

- Series of visual stimuli (a series of letters are presented on a screen to the patient via a rear projector)
- Binary outcome (yes/no)
- The subject is asked to acknowledge (verbally and/or physically) when a change in light is perceived
- Asked to also identify object, if possible

Light Perception – Cohort 1

KIO-301 May Improve Light Perception in the NLP/BLP Population





Light Perception

Insights:

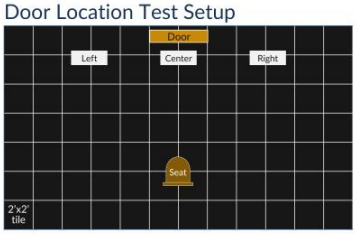
- Cohort 1 subjects demonstrate improved odds ratio on drug
- Odds Ratio – strength of association, OR=2 → 100% increase in the odds of an outcome
  - e.g., duration of diabetes mellitus (> 15 years) with diabetic retinopathy is >9.0*
- Cohort 2 subjects are existing light perception patients; therefore, expect little change

Cohort 1 includes 3 patients (6 eyes), NLP – No Light Perception, BLP – Bare Light Perception

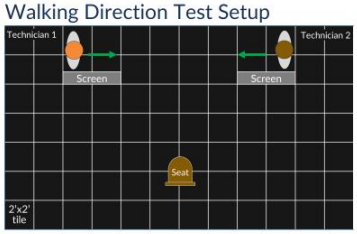
Int J Retin Vitr 2016:2, 21

Functional Vision - Multiluminance Orientation & Mobility (MLOM)

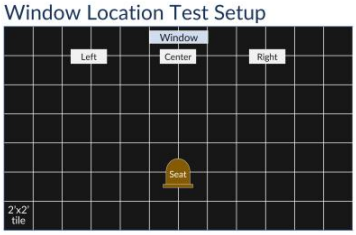
Door Location Test Setup



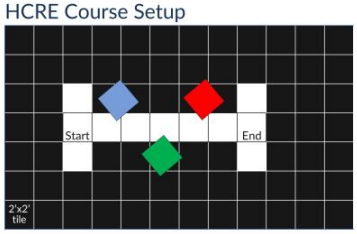
Walking Direction Test Setup



Window Location Test Setup

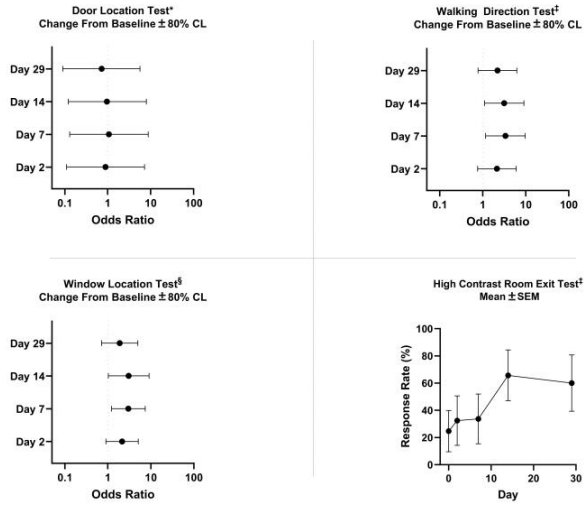


HCRE Course Setup



Functional Vision - Multiluminance Orientation & Mobility (MLOM)

KIO-301 May Improve Functional Vision



* Analysis of 4 patients (7 eyes) ‡ Analysis of 6 patients (10 eyes)
§ Analysis of 3 patients (5 eyes) Ora-MLOM™ Suite of Tests

MLOM

Overview

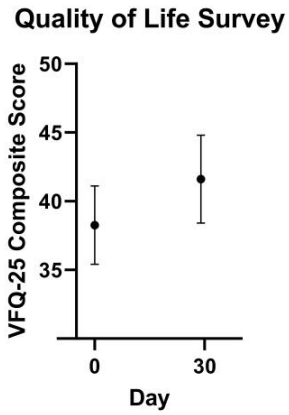
- First time used in ultra-low vision patients
- Question: "Is this test valuable?"

Takeaways:

- Important aspect of documenting vision driven movement
- Not all "functional" tests relevant to the population tested
- One or two clinically meaningful functional tests will remain in Phase II
- Will incorporate light-level changes into Phase II

Visual Function Questionnaire (NEI VFQ-25)

KIO-301 May Improve Patients' Overall Quality of Life



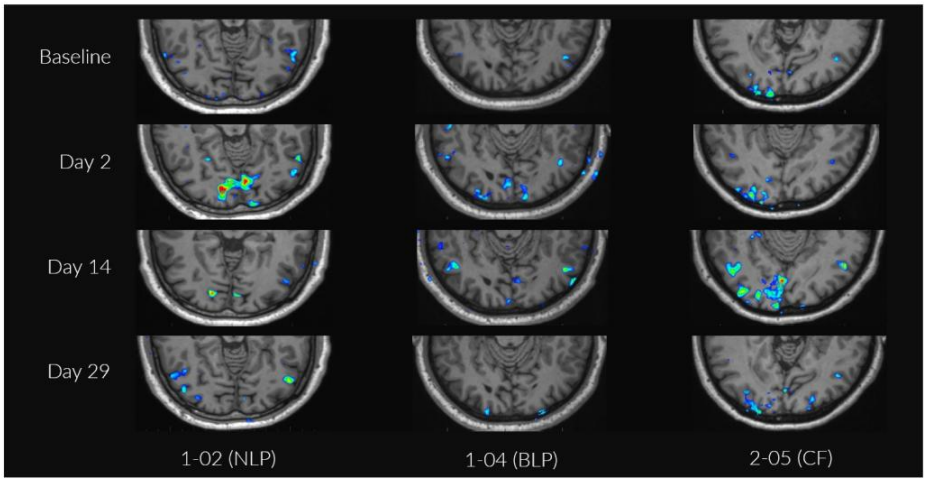
Quality of Life

National Eye Institute generated survey assesses daily functions related to general health & vision, ocular pain, near & distance activities, social functioning, mental health, dependency, driving, color vision, and peripheral vision.

2-4 point increase is considered clinically meaningful*

N=12
* HMSA Medical Policy – Luxturna - 2016

Functional MRI
Supportive of Cortical Activation



NLP – No Light Perception, BLP – Bare Light Perception, CF – Counting Fingers

ABACUS-1 Takeaways

No Safety & Tolerability Concerns

1. KIO-301 appears to reanimate the retina
2. Approvable outcome assessments need to be defined
   - US FDA pIND scheduled for Q4 2023
3. Patients report improvements in vision
   - Consistent with objective clinical assessments
   - Follow-on study will include sham group
4. Pilot study limitations
   - Non-controlled
   - Small sample size

KIO-301-2101: Phase 2 Study Design (ABACUS-2)

Sham Controlled, Masked, Randomized, Multiple Ascending Dose Trial – 4 Sites (Australia)

Key Elements

Study Design ABACUS-2

- Controlled
- N=20 patients
- Includes higher dose* (100µg)
- Multiple injections over 3 months
- Binocular injections
- Open label extension for controls
- Endpoints incorporating US FDA feedback

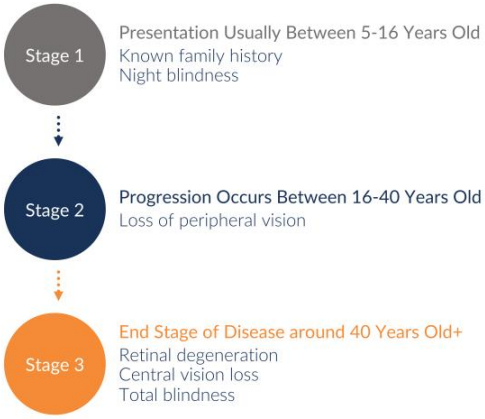
Cohort 1A	5 RP pts with NLP randomized to receive 50µg KIO-301 or sham (3:2) OU monthly for 3 months
Cohort 1B	5 RP pts with LP randomized to receive 50µg KIO-301 or sham (3:2) OU monthly for 3 months
Open Label Extension	Patients randomized to control will be eligible to receive 50µg KIO-301 OU monthly for 3 months

Cohort 2A	5 RP pts with NLP randomized to receive 100µg KIO-301 or sham (3:2) OU monthly for 3 months
Cohort 2B	5 RP pts with LP randomized to receive 100µg KIO-301 or sham (3:2) OU monthly for 3 months
Open Label Extension	Patients randomized to control will be eligible to receive 100µg KIO-301 OU monthly for 3 months

*Subject to ongoing nonclinical tox results

Choroideremia: Inherited Disease that Leads to Blindness

No Approved Therapeutics and Only ONE Active Therapeutic Clinical Trial*

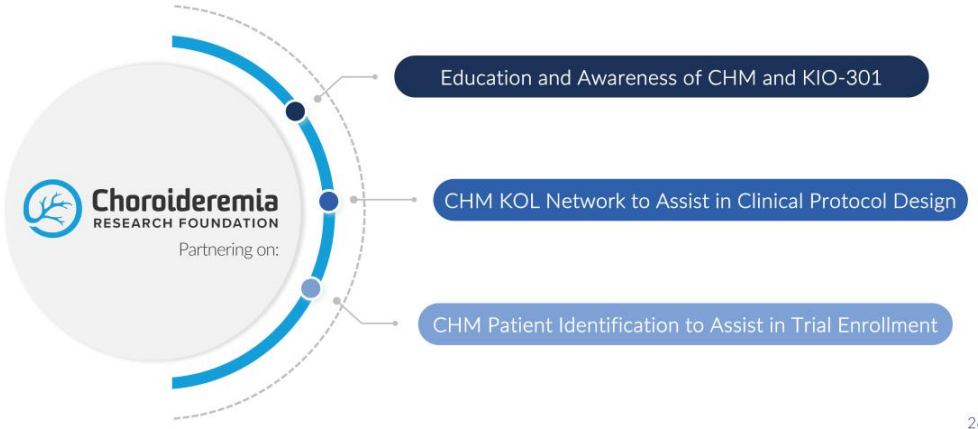


- **Orphan Disease**: prevalence of 1:50,000, ~12,000 patients in US/EU
- **X-linked** recessive disease primarily affecting males
- **Cause**: Inherited mutation in the Choroideremia (CHM) gene encoding Rab escort protein-1 (REP1)
- **REP1** is involved in the regulation of intracellular trafficking of Rab proteins
- **Vision Loss**: Degeneration in the photoreceptors, retinal pigment epithelium (RPE), and choroid. Retinal ganglion cells remain viable.

* Clinicaltrials.gov as of 1 July 2023

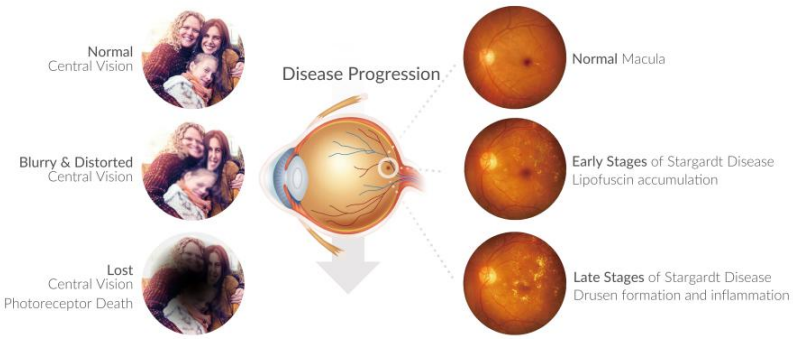
Partnership with the Choroideremia Research Foundation

The Choroideremia Research Foundation (CRF) is the largest global not-for-profit organization focused on the search for a cure for Choroideremia (CHM).



Choroideremia: Inherited Disease that Leads to Blindness

No Approved Therapeutics and Only ONE Active Therapeutic Clinical Trial*

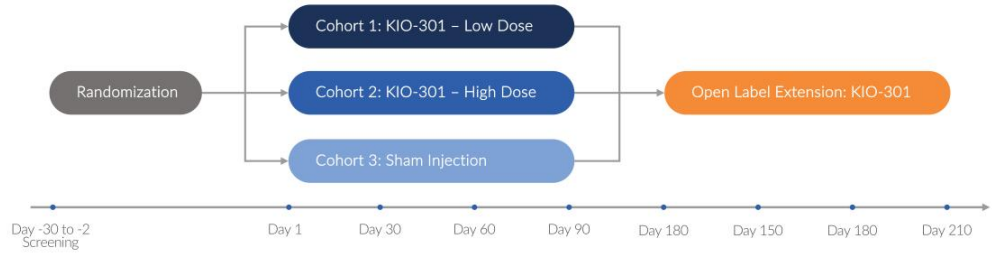


- **Orphan Disease**: prevalence of 1:10,000 ~30,000 patients in US
- **Autosomal** recessive disease inherited from parent carriers, typical onset in 2nd decade of life, vision loss in 4th-5th decade
- **Cause**: Mutation in the ABCA4 or ELOVL4 gene
- **Accumulation** of lipofusion plaques in the retinal pigment epithelium (RPE), leading to inflammation and cell death
- **Vision Loss**: Degeneration of the photoreceptors and RPE. Retinal ganglion cells remain viable. Often, some peripheral vision is retained.

Foundation Fighting Blindness, Makari Wellness

KIO-301-3101: Phase 2 Study Designs (CHM & Stargardt)

Sham Controlled, Randomized Clinical Trial – Australia



Study Design	▪ Three cohorts, randomized, controlled, multiple bilateral IVT injections (days 1, 30, 60)
Endpoints	▪ Primary – AEs, PK & labs ▪ Secondary – Light perception, kinetic perimetry, functional vision, navigation, etc.
Review	▪ Safety review conducted by Investigators after sentinel subject

KIO-104

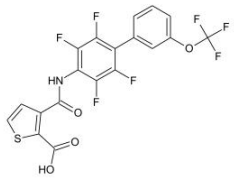
Intravitreal Small Molecule DHODH Inhibitor

Steroid Sparing Approach to Retinal Inflammation

KIO-104 Overview (DHODH Inhibitor)

KIO-104 is an intravitreal, non-steroidal, novel small molecule which mitigates:

- Metabolic activity and proliferation of T-cells
- Secretion of **IL-17, VEGF and IFN-γ**



Existing immunosuppressive agents have a fundamentally different mode of action on T-cells compared to KIO-104

- KIO-104 is best-in-class inhibitor of DHODH (lowest IC_{50})*
- KIO-104 is first-in-class in ophthalmology

**1,000x more potent than Teriflunomide (Aubagio© – Sanofi)*

DHODH - dihydroorotate dehydrogenase

Non-Infectious Uveitis

Uveitis is a group of eye disorders affecting the uvea and characterized by intraocular inflammation that is often chronic, can flare up at any time, and can lead to visual impairment and vision loss.

Clinical Symptoms

- Redness and pain in the eye
- Sensitivity to light
- Blurred vision
- Dark floating spots in the vision
- Vision loss

Statistics

~15% of all cases of legal blindness and visual handicap in the US and EU

~25% of all cases of blindness globally

~20% posterior segment manifestation of uveitis

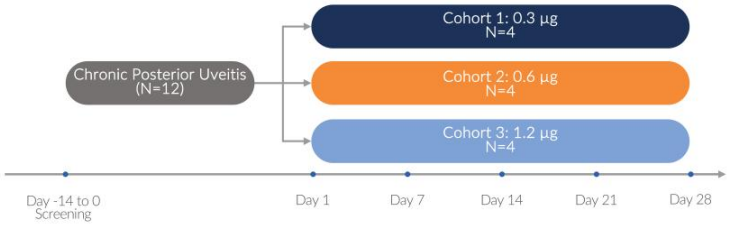
6.9% CAGR 2020-2027

20-50 years old most common age affected in the United States

Significant unmet need for a steroid sparing approach

Br J of Ophthalmol 2004:88(9), 1159-1162. Med Hypothesis Discov Innov Ophthalmol 2013 Winter:2(4), 113-120. Retina Today 2016:47-51. Clin Ophthalmol 2016:10, 1983-2020. JAMA Ophthalmol 2016 Nov 1:134(11), 1237-1245. Uveitis Market Insights, Epidemiology & Market Forecast-2032 DelveInsights

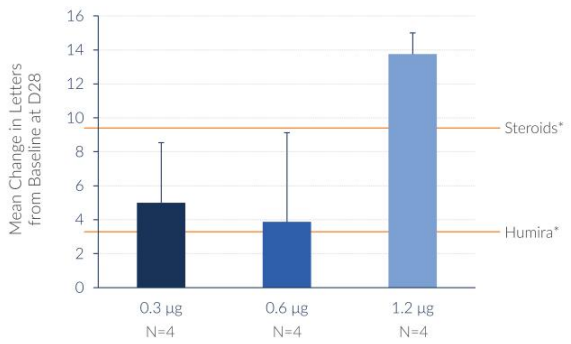
KIO-104-1101: Phase 1 Study Design



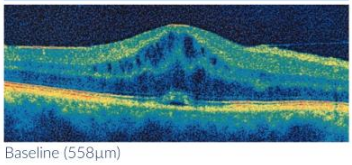
Study Design	▪ Prospective, multi-center, open-label, dose ranging, single IVT injection in worse eye
Endpoints	▪ Primary – Ocular & systemic safety, pK, safety labs ▪ Secondary – Visual acuity, visual field, anterior chamber inflammation, vitreous haze
Key Results	▪ Visual acuity improved in all patients (in all dose groups) ▪ Anterior chamber inflammation and vitreous haze decreased ▪ Evidence of reduced macular edema ▪ No SAEs, excellent tolerability, no peripheral blood detection (at any timepoint)

KIO-104 Improves VA and CME After Single IVT Dose

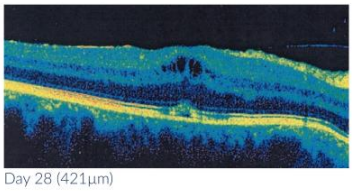
Visual Acuity



Cystoid Macular Edema‡



Baseline (558µm)



Day 28 (421µm)

‡ 40% of eyes with vision threatening cystoid macular edema at baseline had clinically meaningful improvement

** Historical Controls (Yeh et al, Retina 00 2018: 1-9. Suhler et al, Visual III Ophthalmology 2018:125, 7)*
IVT - Intravitreal

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Chief Development Officer

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