

Eyevenys is a clinical stage biotechnology company focused on the treatment of ophthalmic diseases.

The Eyevenys Technology is a non-viral gene therapy ocular drug delivery platform that turns the eye into a biofactory for the production of therapeutic proteins.

In August 2019, Eyevenys received FDA approval of its IND application for its lead product EYS606, a major milestone.

The upcoming phase 2 ELECTRO study to be conducted in the US will explore the efficacy of EYS606 in patients active chronic non-infectious uveitis.



About Eyeevensys

Eyeevensys is developing innovative non-viral gene therapies for the treatment of ocular diseases. Our mission is to address critical unmet ophthalmic needs using our first-in-class sustained drug delivery system to overcome the limitations of current treatment options, including intravitreal injections, subretinal surgery, intravitreal implants, and biodegradable formulations. Our current pipeline targets

include chronic non-infectious uveitis (EYS606); retinitis pigmentosa, glaucoma, and dry AMD (EYS611); and wet AMD, DME, and CRVO (EYS609).

We have developed a proprietary ocular device and electrical pulse generator called the Electrotransfection System. It is designed exclusively to deliver our plasmids encoding therapeutic proteins into the ciliary muscle with a simple,

minimally-invasive, outpatient procedure.

Eyeevensys is currently conducting a phase 1/2 first-in-human study (EYS606-CT1) in the EU for our lead clinical candidate EYS606 and will soon be launching the ELECTRO Study (EYS606-CT2), a phase 2 clinical trial designed to demonstrate the efficacy of EYS606 in patients with active chronic non-infectious uveitis.



ELECTRO will enroll patients with active, chronic non-infectious uveitis of any anatomic subtype in 20 sites distributed throughout the US

Advantages of the Eyeevensys Technology over existing ocular drug delivery approaches:

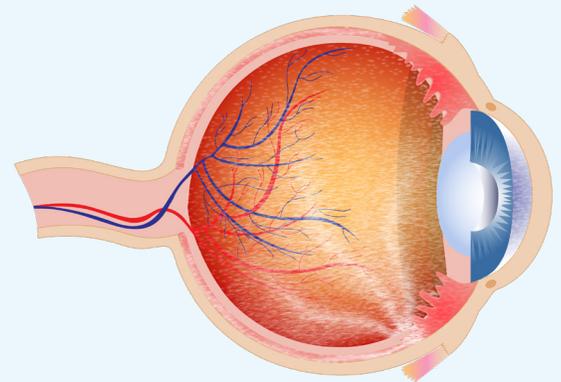
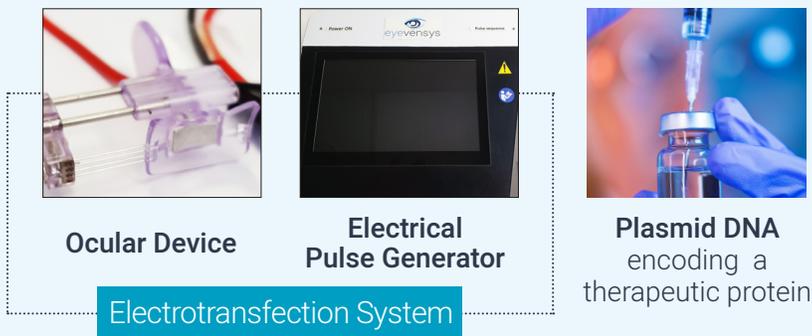
- 1** Our technology platform expands the diversity of therapeutic proteins that can be delivered to the eye.
- 2** Long duration of intraocular therapeutic protein expression, minimizes the need for frequent repeat administrations.
- 3** Delivering therapeutic proteins using the minimally-invasive Electrotransfection System eliminates the risk of ocular complications associated with more-invasive sustained delivery options.
- 4** Low cost, non-viral vector plasmids can encode a variety of therapeutic proteins with no cargo limitation and low risk of immunogenicity.

Our Technology

How it works:

- 1 Eyevensys develops DNA plasmids encoding therapeutic proteins that target specific extracellular retinal disease pathways.
- 2 The Electrotransfection System delivers the plasmids encoding a therapeutic protein into the ciliary muscle.
- 3 The ciliary muscle then produces the therapeutic protein encoded by the plasmid.
- 4 The expressed protein is then primarily secreted into the vitreous and choroid, reaching the back of the eye.

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Our innovative drug delivery platform turns the eye into a biofactory for the sustained production of therapeutic proteins in the eye.
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Proof of concept for the Eyevensys Technology validated in multiple animal models demonstrating safety, efficacy and durability of expression with multiple proteins.

EYS606 for Chronic Non-Infectious Uveitis

Human proof of concept for the Eyeevensys Technology has been demonstrated in an ongoing first-in-human study (EYS606-CT1) investigating our lead clinical candidate EYS606 in patients with non-infectious uveitis¹.

EYS606 encodes a potent TNF- α inhibitor that neutralizes a proinflammatory cytokine that has been shown to play an important role in immune diseases, including uveitis.

The anti-TNF protein expressed following the administration of EYS606 binds TNF with an affinity similar to adalimumab and etanercept.

Following the treatment of 9 patients with advanced-stage uveitis with EYS606 in the dose escalation phase of the EYS606-CT1 study, the Eyeevensys Technology showed promising signals of efficacy and was considered to be safe and well tolerated.



¹ Data on file

No serious adverse events related to the Eyeevensys Technology were reported.

Most adverse events related to the Eyeevensys Technology were mild and resolved spontaneously.

The early safety profile for our technology is similar to that of other intraocularly administered ophthalmic treatments.

A >10 letter gain in visual acuity maintained at the study end in one patient treated at the lowest dose occurred at 2 weeks coincident with the expected peak of anti-TNF protein expression.

In two patients with macular edema treated with the highest EYS606 dose, there was a >20% reduction in macular edema associated with an improvement in visual acuity.

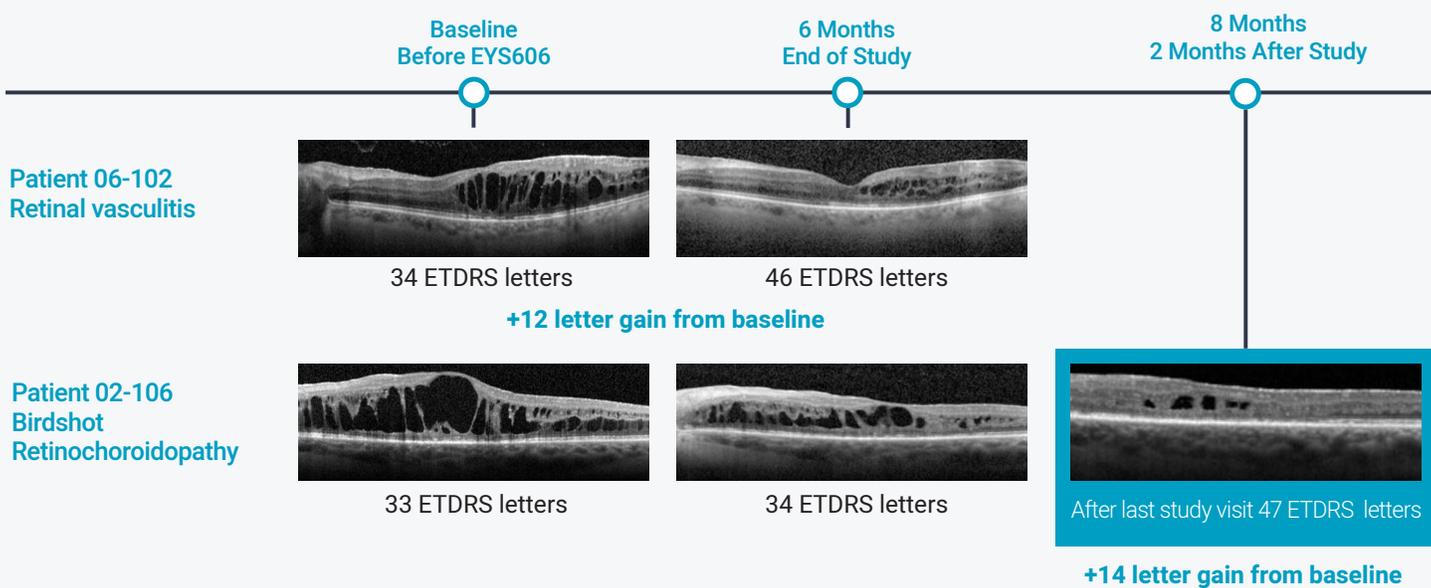
The time course of the improvements in macular edema provide evidence of sustained intraocular protein expression beyond 6 months.

The other 6 treated patients, all legally blind with advanced-stage uveitis complications, did not present any clinical signs at baseline which could be improved with EYS606.

EYS606 for Chronic Non-Infectious Uveitis

OCT improvements associated with increased visual acuity following EYS606 treatment provide evidence of therapeutic anti-TNF- α activity lasting beyond 6 months.

The therapeutic potential of EYS606 for the treatment of patients with chronic non-infectious uveitis will be further evaluated in the ongoing EYS606-CT1 study in Europe and in the upcoming ELECTRO Study (EYS606-CT2 Study) based in the USA.



Macular edema represents a major cause of visual loss patients with chronic non-infectious uveitis.

The primary objective of the study is to determine if one versus two administrations of EYS606 will be more effective for the treatment of patients with active chronic non-infectious uveitis.



Secondary objectives include comparing the efficacy of the two regimens for achieving and maintaining control of CNIU, and for improving visual function and QoL.



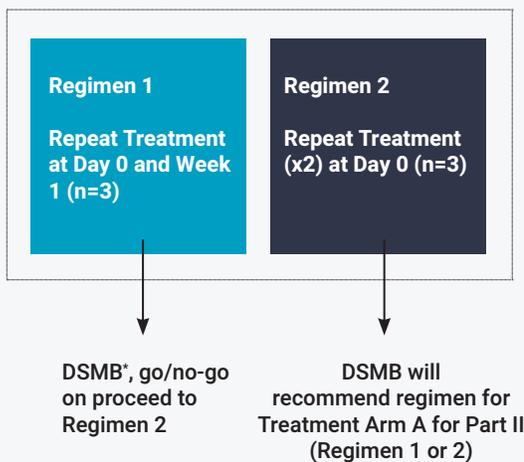
The study will enroll up to 56 patients in up to 20 clinical trial sites distributed across the US.



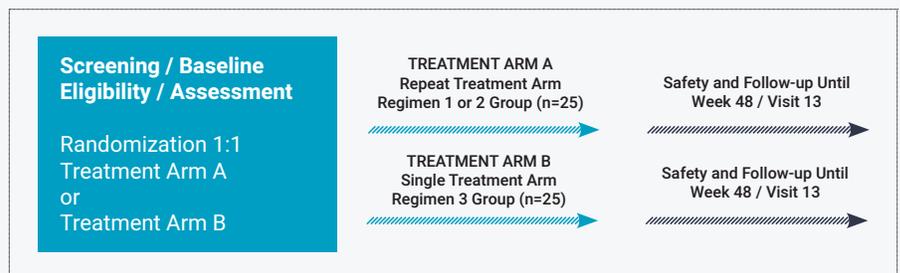
All patients enrolled in the study will receive treatment with EYS606.

ELECTRO Study Design

Part I: Safety Cohort Phase



Part II: Randomized Comparison Phase



*DSMB=Data and safety monitoring board.

THE ELECTRO STUDY WILL RECRUIT PATIENTS THAT MEET THE FOLLOWING KEY INCLUSION CRITERIA



- ★ Adults (≥ 18 years of age) with a diagnosis of chronic non-infectious uveitis of any anatomic subtype

- ★ Have a history of chronic or recurrent non-infectious uveitis requiring treatment with corticosteroids and/or systemic immunosuppressive medication(s) in the 12 months prior to the screening visit.

- ★ Have a best corrected visual acuity of between ≥ 5 and ≤ 77 letters (20/32 to 20/800 Snellen) in the study eye

- ★ Have active chronic non-infectious uveitis as evidenced by at least one or more of the following in the study eye:
 - Active retinal vasculitis (retinal vascular leakage)
 - Vitreous haze grade $\geq 2+$
 - Anterior chamber cell grade $\geq 2+$
 - Persistent macular edema despite treatment with corticosteroids and/or immunosuppressive therapy for at least 4 weeks prior to screening.



**BE A PART OF
THIS NEW
BREAKTHROUGH
TECHNOLOGY**

**If you would like participate
in the ELECTRO study**

GET IN TOUCH

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