KALA BIO

Innovation in Ophthalmology

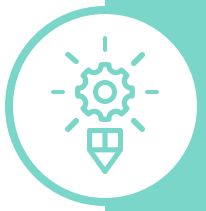
Corporate Overview
January 2025

Disclaimers and Notices

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. Any statements in this presentation about KALA's future expectations, plans and prospects, including but not limited to KALA's expectations with respect to potential advantages of KPI-012 and its MSC-S platform; anticipated timelines to report topline data for the CHASE Phase 2b clinical trial of KPI-012; the design of the CHASE Phase 2b clinical trial; KALA's belief that the Chase Phase 2b trial could serve as the first of two pivotal trials required to support the submission of a BLA to the FDA; the clinical utility of KPI-012 for PCED; KALA's plans to pursue research and development of KPI-012 and its MSC-S platform for other indications; KALA's ability to realize potential milestones payments under the transaction with Alcon and the risk that KALA may not realize the expected benefits of the transaction; the sufficiency of KALA's existing cash resources and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: KALA's ability to comply with the requirements under the CIRM award; uncertainties inherent in the initiation and conduct of preclinical studies and clinical trials; uncertainties regarding availability and timing of data from clinical trials; whether results of early clinical trials or trials in different disease indications will be indicative of the results of ongoing or future trials; whether results of the Phase 1b clinical trial of KPI-012 will be indicative of results for any future clinical trials and studies of KPI-012, including the CHASE Phase 2b clinical trial; whether interim data from a clinical trial will be predictive of the results of the trial; uncertainties associated with regulatory review of clinical trials and applications for marketing approvals; KALA's ability to retain and hire key personnel; the impact of extraordinary external events, such as the pandemic health event resulting from the coronavirus (COVID-19), and their collateral consequences; the sufficiency of cash resources and need for additional financing and other important factors, any of which could cause KALA's actual results to differ from those contained in the forward-looking statements, discussed in the "Risk Factors" section of KALA's Annual Report on Form 10-K, most recently filed Quarterly Report on Form 10-Q and other filings KALA makes with the Securities and Exchange Commission.

All information in this presentation is as of January 13, 2025 and should not be considered current after such date. KALA does not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

KALA BIO Clinical Readout Q2 2025 in High Value PCED Market



Late-Stage Lead Program with "Pipeline-in-a-Product" Potential

- **MSC-S Platform** enables products for multiple potential orphan indications
- **Lead MSC-S Product KPI-012 is "Pipeline in a Product" for Rare Ocular Surface Diseases**
  - Enrolling patients in CHASE (**C**orneal **H**ealing **A**fter **SE**cretome therapy) Phase 2b for Persistent Corneal Epithelial Defect (PCED), a potential $1B+ market opportunity in the US alone
  - Evaluating program for limbal stem cell deficiency (LSCD) & other rare corneal diseases
- **KPI-014** – MSC-S pre-clinical program for rare inherited retinal diseases

Meaningful Upcoming Milestones

- **4Q 2022:** KPI-012 PCED IND filed and accepted ✓
- **2Q 2023:** CHASE Phase 2b trial in PCED cohort 2 (randomized, double-masked efficacy portion of trial) initiated ✓
- **Q2 2025:** CHASE Phase 2b top-line data in PCED – CHASE could serve as the first of two pivotal trials to support the submission of a Biologics License Agreement (BLA) to the FDA

Strong Corporate Position

- **Experienced team:** Developed & secured FDA approval for two ophthalmology products, EYSUVIS for dry eye disease and INVELTYS for post ocular surgery - Acquired by Alcon
- **April 2023:** Announced award by California Institute for Regenerative Medicine (CIRM) to support ongoing KPI-012 program for the treatment of PCED
- Cash, equivalents and investments of $49.2 million as of 9/30/24
- Completed $12.5M PIPE in June 2024 led by SR One and $10.75M PIPE in Dec 2024 including SR One and new investors Cormorant Asset Management and Woodline Partners
- Projected cash runway into Q1 2026
- Current outstanding shares include 6,091,182 common and preferred shares convertible into 7,775,400 common shares.

Leadership Team with Extensive Ophthalmology Innovation Experience

TODD BAZEMORE
President and
Chief Operating Officer

santhera · Dyax · sunovion

KIM BRAZZELL, PhD
Head of R&D and
Chief Medical Officer

INSPIRE · NOVARTIS · CIBAVISION · Alcon

MARK IWICKI
Chair and
Chief Executive Officer

CIVITAS THERAPEUTICS · sunovion · NOVARTIS · MERCK

DARIUS KHARABI
Chief Business Officer

COMBANGIO · KEDALION THERAPEUTICS · LAGUNITA BIOSCIENCES · WSGR

MARY REUMUTH, CPA
Chief Financial Officer

enobia pharma · genzyme · EY

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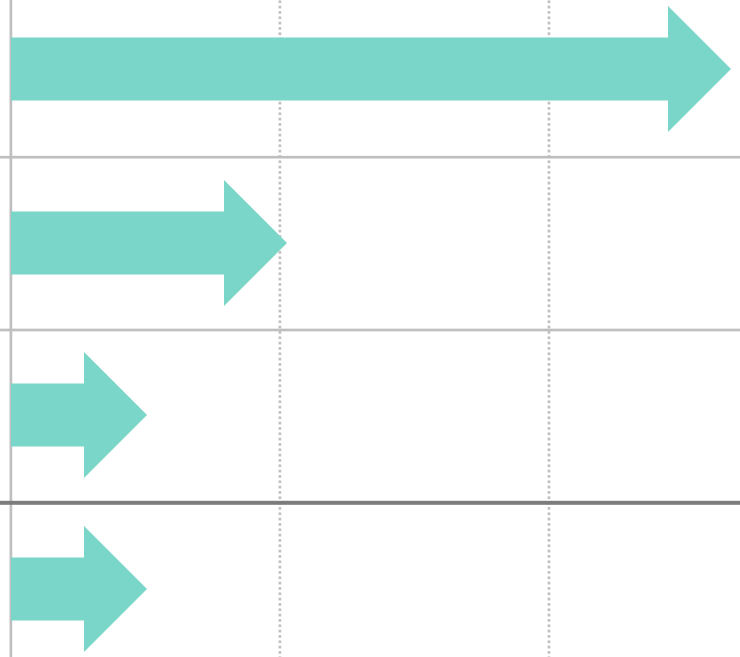
KALA BIO is Advancing an Innovative Pipeline Based on Its Proprietary Mesenchymal Stem Cell Secretome (MSC-S) Platform for the Treatment of Rare Front and Back of the Eye Diseases

Product Candidate*	Indication	Route of Administration	Pre-Clinical	Phase 1	Phase 2	Phase 3
KPI-012 for Rare Ocular Surface Disease	Persistent Corneal Epithelial Defect (PCED)	Topical				
	Limbal Stem Cell Deficiency (LSCD)	Topical				
	Other rare corneal diseases	Topical				
KPI-014 Program for Rare Inherited Retinal Disease		Intravitreal Injection				

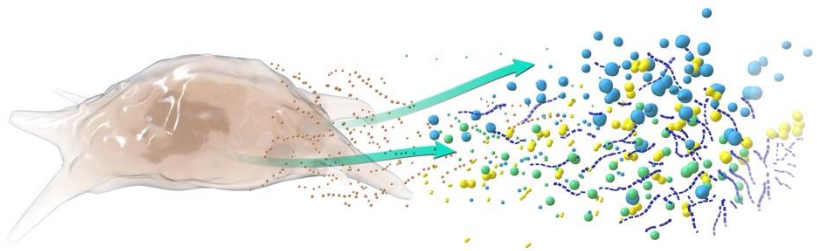


* Product candidates are investigational and have not been approved by any regulatory authority.

KALA BIO is a Leader in the Emerging Field of Mesenchymal Stem Cell Secretome (MSC-S) Therapy

Proprietary MSC-S Platform is a Cell-Free, Regenerative Approach to Disease Management

- Secretomes produced by collecting the biomolecules that are secreted by cells into the extracellular space to support their health and viability
  - KALA secretome manufactured from a master cell bank of human bone-marrow derived MSCs
  - Well-defined GMP CMC processes enable consistent lot-to-lot biopotency, safety and stability
- Offer many of the benefits of cell therapy without administering cells
- Avoids many of the safety and logistic concerns associated with current cell therapy approaches



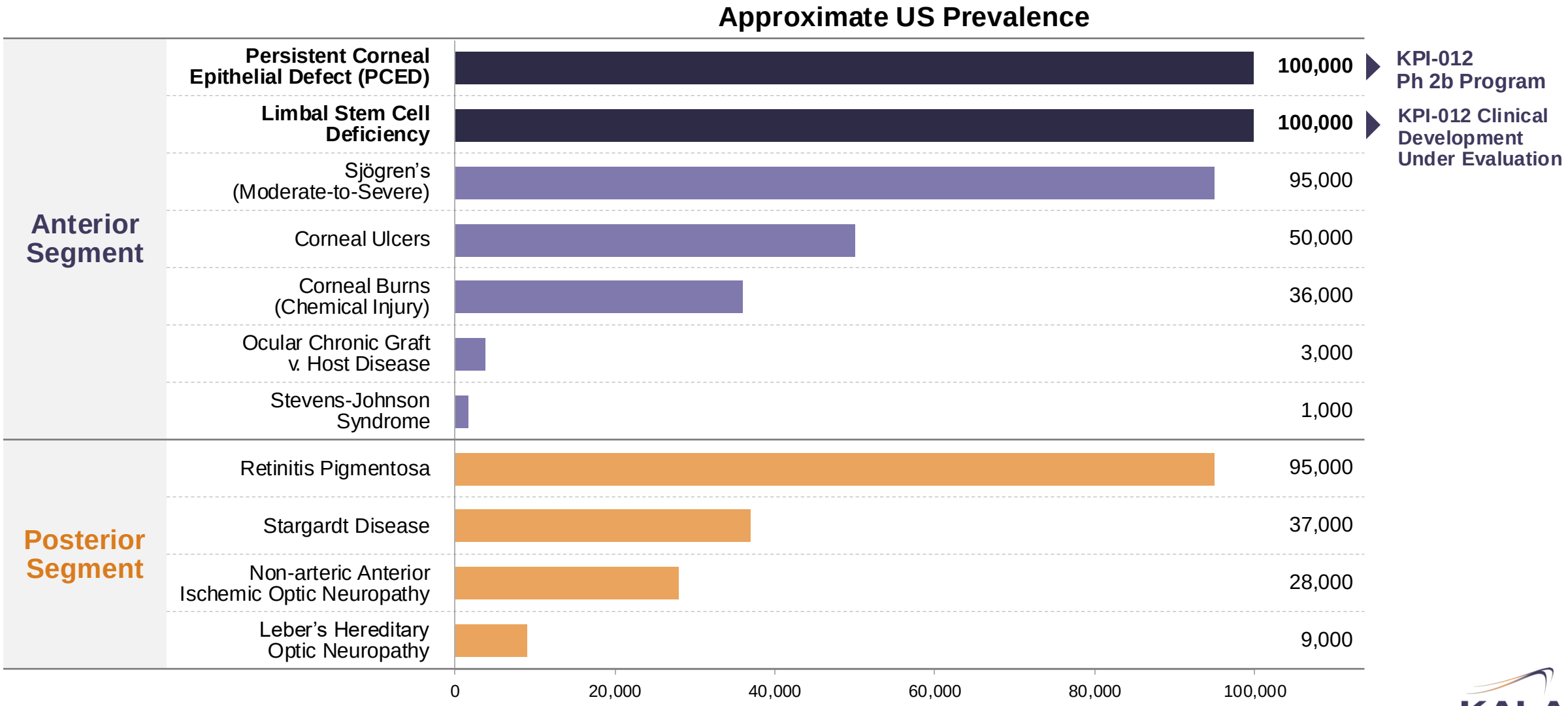
Secretomes Have Shown Benefits in Ocular Diseases, Including:

- Corneal injury
- Retinal degeneration
- Glaucoma
- Dry eye disease

MSC-S Mechanisms of Action Include:

- Wound Healing/Tissue Repair
- Anti-inflammatory/Immunomodulatory
- Neurotrophic/Neuroprotective

MSC-S Has Potential Applications in Multiple Rare Ocular Disease Segments



Sources: ClearView Analysis; PEDMarketInsights, Epidemiology, and Market Forecast—2030 Delveinsight, 2020; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4498999/. Accessed4Feb2021.

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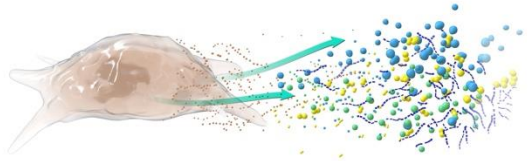
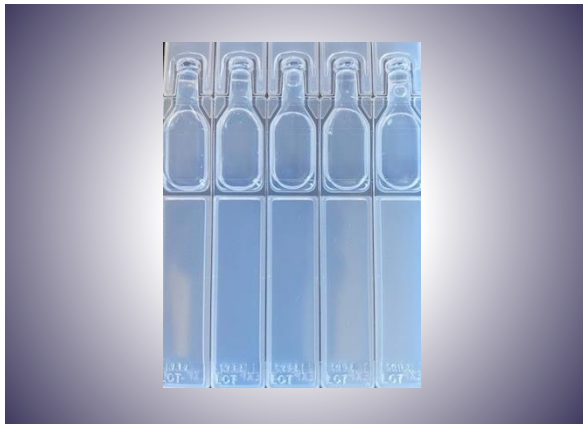
KPI-012 – Regenerative Therapy for Rare Ocular Surface Diseases

KPI-012 – Human Bone Marrow-Derived MSC-S Therapy in Development for Persistent Corneal Epithelial Defect (PCED)

KPI-012 Cell-Free Regenerative Therapy





- Composed of biomolecules produced by human bone marrow-derived MSCs and formulated into topical ocular non-preserved single dose unit formulation
  - The simple convenient topical formulation should improve patient experience
- Contains key classes of biomolecules associated with corneal wound healing (e.g., growth factors, protease inhibitors, matrix proteins, neurotrophic agents) providing a multifactorial approach to addressing impaired corneal healing
- Currently in development for PCED with the goal of complete healing of the PCED
  - Multifactorial mechanism of action could address all underlying etiologies of PCED
- Orphan Drug and Fast Track Designations granted by FDA

KPI-012 Has the Potential to Treat Multiple Rare Corneal Diseases

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KPI-012 in Phase 2b for PCED

- PCED – persistent non-healing corneal defect that is refractory to conventional treatments
- Significant symptoms (e.g., pain, photophobia, visual impairment)
- If not healed quickly the risk of infection is high, and further worsening of the lesion can cause stromal thinning/scarring, corneal perforation and vision loss
- Can be caused by a number of underlying etiologies including: trauma, neurotrophic keratitis, diabetic keratopathy, severe ocular surface disease, infectious keratitis, ocular surgery and others
  - Patients often have more than one underlying etiology
- Estimated incidence of approximately 100,000 patients in the US and 238,000 in the US, EU and Japan combined
- In Ph 1b clinical trial, KPI-012 produced clinical improvement in all 8 treated PCED patients with complete healing of the PCED in 6 of 8

PCED is an Underserved Market

- **There are currently no FDA-approved Rx products with a broad PCED indication for all underlying etiologies**
- **Oxervate® (nerve growth factor) has limited indication for Neurotrophic Keratitis (~1/3 PCED cases) and is complex and burdensome for patients to administer.**

PCED is Clinically Burdensome with High Unmet Needs

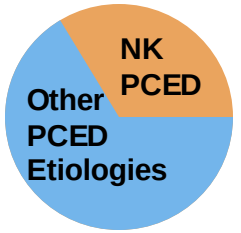
Currently Approved Therapy Only Addresses ~1/3 of PCED Patients and is Complex and Burdensome for Patients to Administer

Unmet Needs in the Treatment of PCED:

- **Single therapy that addresses multiple etiologies**
  - PCED patients often have more than one underlying etiology, all needing to be addressed for effective wound healing
- **Rapid and sustained wound healing**
  - Patients at risk of developing permanent vision loss if defects are not healed quickly enough
  - Need for faster resolution of corneal defects
- **Therapy that is well-tolerated and easily administered**
  - Oxervate requires 6-times a day dosing and a 19-step preparation process
  - 16% of patients treated with Oxervate report eye pain as an Adverse Event, as per the Package Insert (PI); eye disorders - eye irritation, blepharitis and corneal neovascularization also listed as adverse events in PI post-marketing section
  - There is a need for treatments with improved tolerability and that are simpler to administer

PCED is a Potential >$1B Orphan Market Opportunity

- **Currently no FDA-approved prescription therapies with broad PCED indication**
  - Estimated PCED incidence of 100,000 patients in the US and 238,000 in the US, EU and Japan combined
  - Oxervate® (nerve growth factor) limited to Neurotrophic Keratitis (NK) indication - only represents ~1/3 of PCED



  - **Oxervate reported US 2023 annual sales exceeded $828M***
- **KPI-012 could be first approved therapy with broad PCED indication and differentiated product profile**
  - Potential for rapid and sustained healing, improved tolerability, convenient administration and an MOA to address all etiologies
  - ECP target list of ~1800 Cornea Specialists allows for a small rare disease sales force

*Source: Italian Chambers of Commerce, Dompe Farmaceutici S.P.A 2024 filing (https://italianbusinessregister.it/en/)

Key Biomolecules in KPI-012 Can Address the Impaired Corneal Healing Processes in PCED with a Multifactorial Mechanism of Action

PCED: Impaired Corneal Healing Can be Driven by Disruption of One or More Key Biologic Pathways

- Impaired epithelial cell differentiation, proliferation and migration
- Enhanced proteolysis leading to basement membrane matrix degradation
- Impaired basement membrane matrix impacting epithelial cell attachment
- Impaired corneal innervation impacting healing process

KPI-012 Biomolecule Classes Can Address Impaired Healing with a Multifactorial Mechanism of Action

- **Growth Factors (e.g., HGF, PEDF)** – Promote epithelial differentiation/proliferation/migration
- **Protease Inhibitors (e.g., TIMP-1)** – Inhibit proteases that degrade basement membrane
- **Matrix Proteins (e.g., Fibronectin)** – Repair matrix; promote adherence of epithelial cells to basement membrane
- **Neurotrophic Agents (e.g., PEDF**) – Supports reinnervation of cornea

The Key Biomolecules Present in KPI-012 Address Many of the Biologic Pathways Associated with Impaired Cornea Healing

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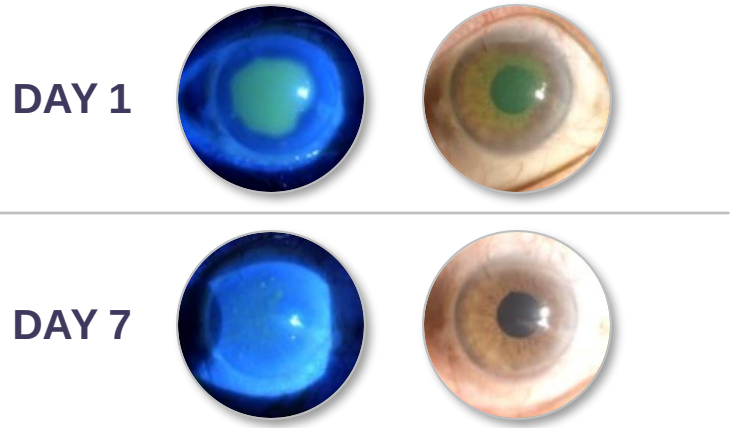
Promising Results in PCED with Twice Daily (BID) Dosing in Phase 1b Clinical Trial

- **Prospective single arm trial**
  - Initial safety cohort of 3 subjects without corneal disease dosed BID for 1 week showed no tolerability or safety issues
  - Efficacy cohort consisted of 8 PCED patients dosed BID for 1 to 8 weeks and followed for up to 19 weeks
  - Key efficacy endpoint – healing of PCED based on corneal staining photographs
- **Top line results in efficacy cohort**
  - 8 of 8 patients showed improvement in PCED
  - 6 of 8 patients had complete healing of PCED
    - 4 of the 6 completely healed after 1 week
    - 1 of the 6 healed after 2 weeks; the other after 4 weeks
  - All healed patients remained healed through end of follow-up
  - KPI-012 well-tolerated with no safety issues observed

6/8 Completely Healed PCED Patients

	Mean	Median
PCED Size at Baseline (mm x mm)	5.1 x 3.5	5.6 x 2.9
PCED Duration at Baseline (Days)	58	32
PCED Healing Time (Days) **KPI-012, 2x/day**	12	7

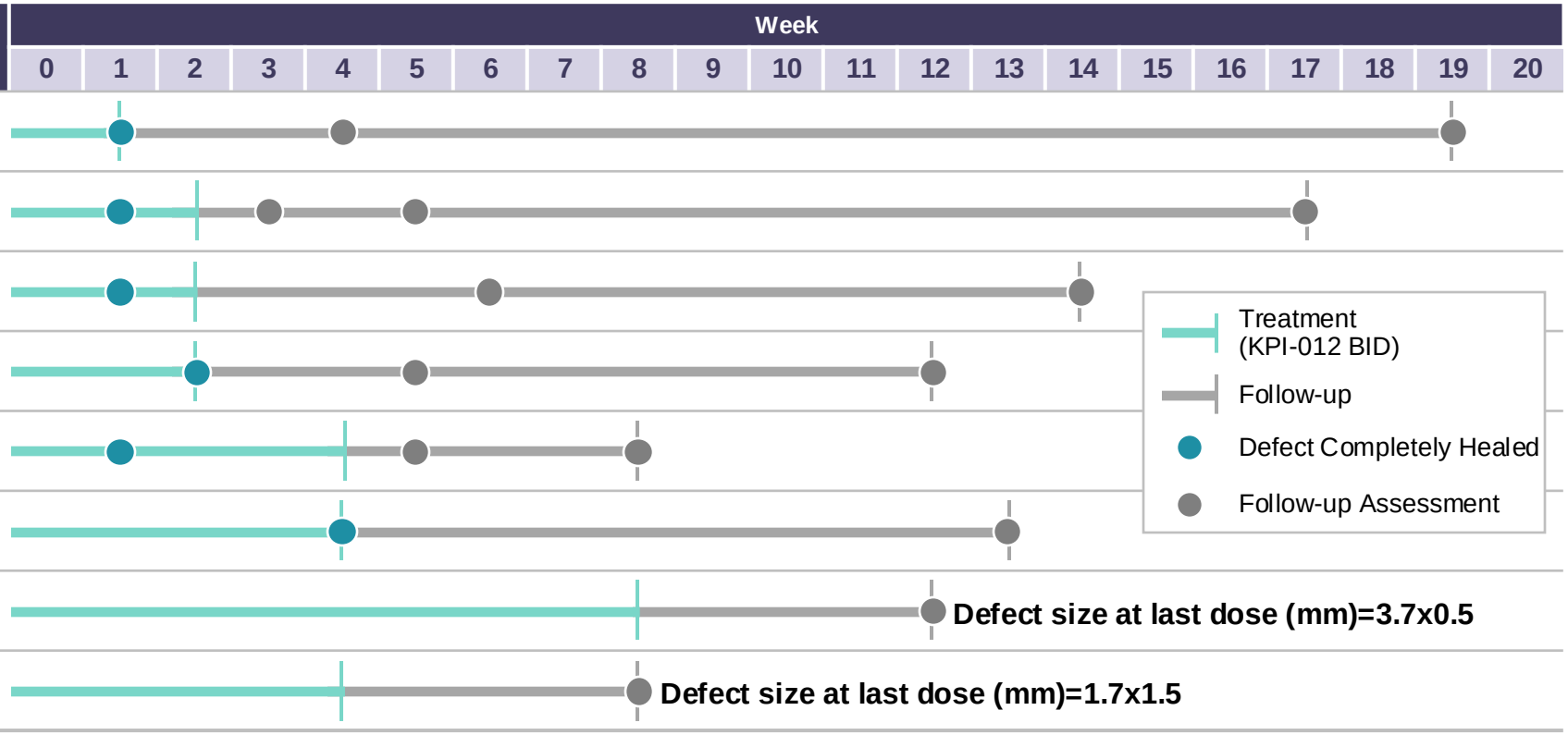


Representative images for a healed patient study eye

Results Support Moving Directly to Phase 2b Clinical Trial

Complete Healing in 6 of 8 PCED Patients After 1–4 Weeks of BID Treatment with KPI-012 in Phase 1b Clinical Trial

Patient ID	PCED Etiology	Baseline Defect Duration (Size, mm)[a]
1-05	Neurotrophic (Diabetic)	17 days (6.5x5.5)
1-06	Neurotrophic (Diabetic)	28 days (6x5.9)
1-07	Neurotrophic (Diabetic)	15 days (5.2x2.5)
1-08	Neurotrophic (Diabetic)	41 days (6.2x3.3)
2-01	Stevens-Johnson/ Dry Eye	213 days (4.7x2)
2-03	Post-Infectious Keratitis	37 days (2.2x1.5)
2-04	Neurotrophic (Diabetic)	35 days (5.7x2.4)
2-05	Neurotrophic/ Dry Eye	871 days (3x2)

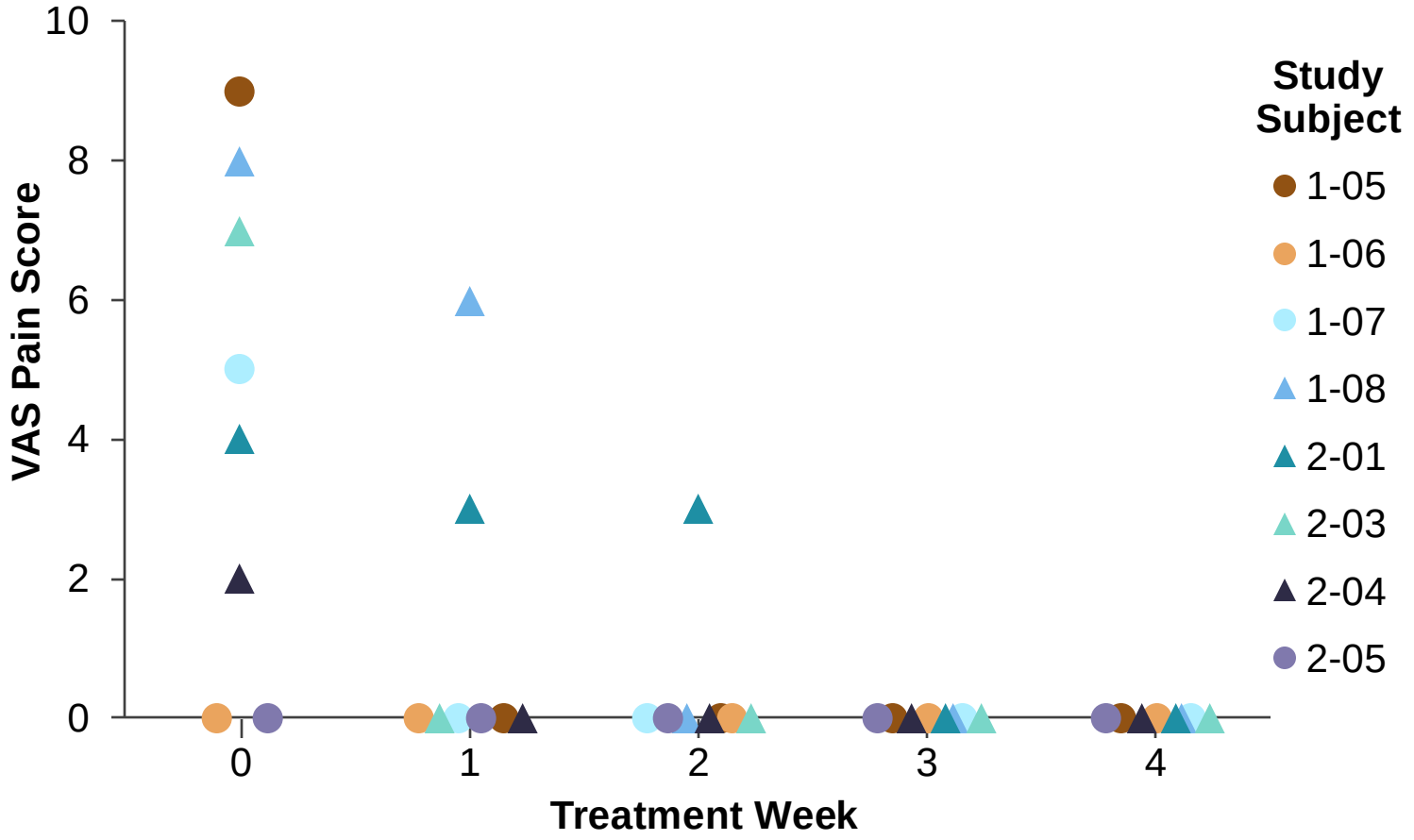


- 6 of 8 of participants completely healed by Week 4 of the trial and remained healed through end of follow-up
- Improvement in PCED lesion size was observed in participants who did not heal completely

Rapid and Sustained Healing in Patients with Varying Etiologies and Duration of Disease Suggests Potential for Broad Efficacy in PCED

[a] Mean PCED size at baseline (mm)=5.1x3.5; Mean PCED Duration at Baseline (Days)=58; Mean PCED Healing time with treatment (Days)=12.

Significant Pain Relief Within 1 Week of Treatment



Of Patients Reporting Pain at Baseline (6 of 8):

100% reported pain reduction at Week 1

67% reported 0 pain score at Week 1

100% reported 0 pain score at Week 3

Rapid Improvement in Pain in PCED Patients Treated with KPI-012

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KPI-012 Development Progressing Towards Key Ph 2b Readout in Q2 2025

- Pre-IND meeting with FDA in 2020
  - FDA open to broad PCED indication
  - Provided guidance on CMC, clinical trial design and endpoints
- Orphan Drug and Fast Track designations granted by FDA for PCED
- US IND accepted Dec 2022; CHASE Phase 2b clinical trial cohort 2 (randomized, double-masked efficacy portion of trial) initiated in late Q2 2023
  - Phase 2b trial ongoing with results targeted in Q2 2025
- Type C meeting with FDA in April 2024: KALA's CMC and potency assay program is aligned with FDA expectations for Phase 3 and a BLA submission
- Expect to leverage KPI-012 PCED CMC program and other IND-enabling activities to support anterior segment follow-on indications for KPI-012

If Phase CHASE 2b Results Positive Could Serve as First of Two Required Trials to Support BLA Submission

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KPI-012 Clinical Update: CHASE Trial Design

- Initial 2-patient open label evaluation to establish safety of 3 U/ml QID dosing completed with no safety findings
  - 1 U/ml dose equivalent to what was tested in Ph 1b trial; 3 U/ml was not tested until ongoing trial
- 90 patient multicenter, randomized, double-masked efficacy trial with 1 U/ml QID, 3 U/ml QID and vehicle QID (30/treatment arm, 1:1:1 randomization) ongoing
- 8-week treatment period plus 2 week and 6-month follow-up
- ~45 investigative sites (mix of academic and independent sites)
- Primary endpoint
  - Proportion of subjects completely staining free at Week 8 in the KPI-012 treatment group vs. vehicle group with no staining at the site of the original lesion at Week 10 and no persistent staining elsewhere in the cornea at Week 10
  - Based on central-reader assessment of photographs of corneal fluorescein staining
- Top line data readout targeted in Q2 2025

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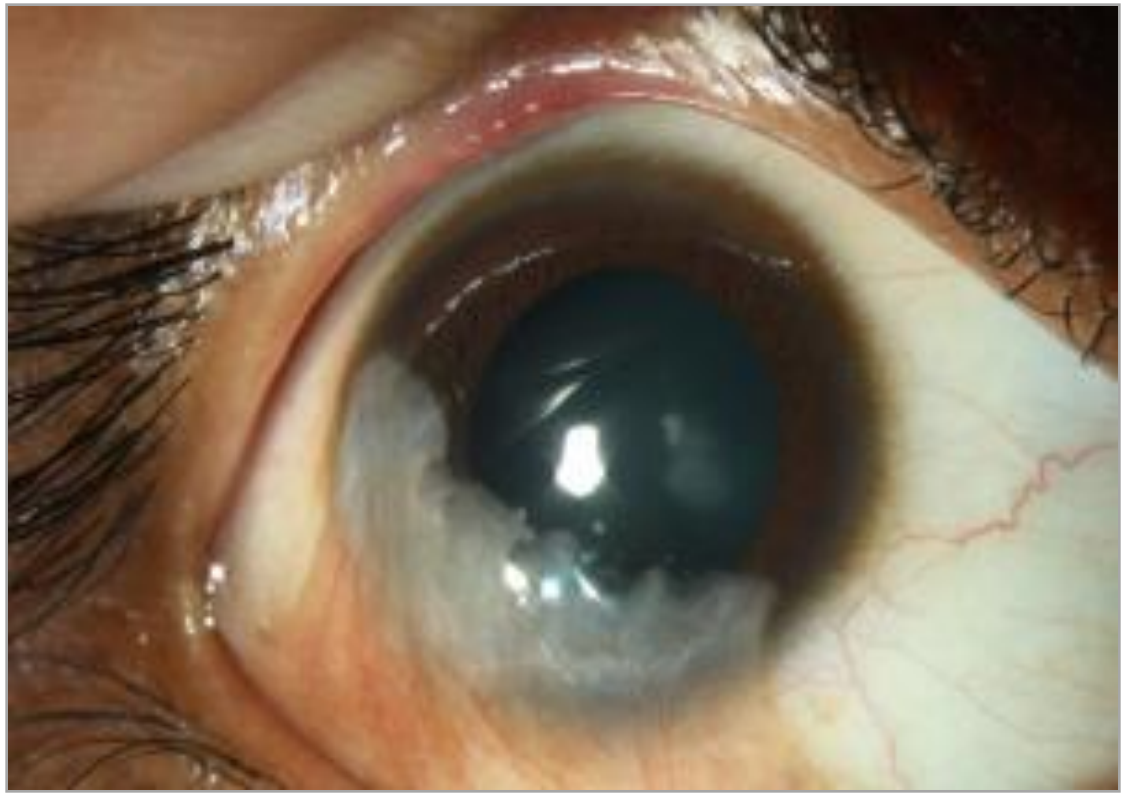
First KPI-012 Follow-on Indication Under Evaluation: Limbal Stem Cell Deficiency (LSCD)

- LSCD is a loss or deficiency of limbal epithelial stem cells, which play an essential role in maintaining the integrity of the ocular surface
- Sequalae include recurrent epithelial breakdown/keratopathy, conjunctival overgrowth, neovascularization, chronic inflammation and corneal scarring
- Can lead to loss of corneal clarity and vision impairment
- Also associated with significant symptomology
- There is a significant unmet need in LSCD
  - Currently, there are few treatment options and no pharmacological treatments
- ~100,000 patients in the US have LSCD



Source: ClearView Analysis.

KPI-012 Validated Manufacturing Process

Thaw and Seed Working Cell Bank Vial

Bioreactor Production

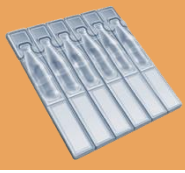
Harvest Secretome

Processing

Drug Substance

Final Drug Product

- Formulation/Fill
- Blow-fill-seal unit dose



Process Control Analytics

KPI-012 manufacturing process is robust and scalable

- Drug Substance currently manufactured at scale to support pivotal clinical studies and early commercialization
- Final Drug Product currently manufactured using industry-standard unit dose blow-fill-seal formulation and filling process

Final Drug Product released based on product potency, consistency and stability methods consistent with FDA Pre-IND meeting feedback, including protein Critical Quality Attributes (CQAs) and a cell-based potency assay

- Validated assays developed for protein CQAs
- Multiple engineering batches assaying CQAs and additional KPI-012 constituents support robust and consistent manufacturing process

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KPI-014 – Pre-Clinical MSC-S Program for Rare Inherited Retinal Diseases

KPI-014: Pre-Clinical MSC-S for Rare Inherited Retinal Disease

- There is a significant need for novel therapies for slowing of disease progression in inherited retinal diseases, including Retinitis Pigmentosa and Stargardt Disease
- Over 75% of clinical pipeline assets for Retinitis Pigmentosa are gene-specific therapies, which greatly limits trial eligibility
- Secretomes have demonstrated a neuroprotective effect in both *in vitro* and *in vivo* models of retinal degeneration
- KPI-014 contains neurotrophic factors, growth factors, anti-inflammatory/immune-modulatory factors and antioxidant inhibitors with the potential to protect and preserve retinal cell function

KPI-014 is a Promising Gene-agnostic Approach for the Treatment of Inherited Retinal Diseases

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Patent and Regulatory Exclusivity

Patent and Regulatory Exclusivity

- Regulatory Exclusivity in the U.S.
  - If approved as a new biologic product under a BLA, KPI-012 should enjoy 12 years market exclusivity during which biosimilars cannot be launched
  - 7-year orphan exclusivity on the treatment of PCED
- Patent Exclusivity
  - A worldwide patent portfolio related to MSC-S and its use for the treatment of an ocular condition, such as PCED and other ocular surface diseases, has a 20-year patent term ending in 2040
  - If approval occurs after 2026, a patent term extension* may be available in the U.S., which can extend the term beyond 2040
- KPI-012 received Fast Track designation

Potential U.S. Regulatory Exclusivity and IP Protection Beyond 2040

* While a maximum of 5 years of patent term extension is available, the total patent life with the patent term extension cannot exceed 14 years from the approval date. If the patent life after approval has 14 or more years, the product would not be eligible for patent term extension.

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Thank You