

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): **January 8, 2018**

Kala Pharmaceuticals, Inc.

(Exact Name of Company as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38150
(Commission
File Number)

27-0604595
(IRS Employer
Identification No.)

100 Beaver Street, Suite 201
Waltham, MA 02453
(Address of Principal Executive Offices) (Zip Code)

Company's telephone number, including area code: **(781) 996-5252**

(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 (*see* General Instruction A.2. below):

- 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 x

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. x

Item 7.01. Regulation FD Disclosure.

On January 8, 2018, Kala Pharmaceuticals, Inc. (the "Company") intends to make a slide presentation at the 36th Annual J.P. Morgan Healthcare Conference. A form of the slide presentation is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information responsive to Item 7.01 of this Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1 [Form of Presentation of Kala Pharmaceuticals, Inc., dated January 8, 2018](#)

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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 hereunto duly authorized.

KALA PHARMACEUTICALS, INC.

Date: January 8, 2018

By: /s/ Mary Reumuth

Name: Mary Reumuth

Title: Chief Financial Officer

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Innovation In
Ophthalmology

Corporate Overview
January 2018



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 including statements regarding the development and regulatory status of the company's product candidates, including INVELTYS™ (KPI-121 1.0%) for the treatment of inflammation and pain following ocular surgery and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. All statements, other than statements of historical facts, contained in this presentation, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements as a result of various risks and uncertainties including, but not limited to: whether the data from our Phase 3 clinical trials of KPI-121 0.25% will warrant submission of an NDA on the timeline expected, or at all, whether any additional clinical trials will be required prior to submission of an NDA and whether any such NDA will be approved; that topline data is based on preliminary analysis of key efficacy and safety data, and such data could change following a more comprehensive review and may not accurately reflect the complete results of our clinical trials; whether our NDA for INVELTYS will be approved by its PDUFA date or at all; uncertainties inherent in the availability and timing of data from ongoing clinical trials; expectations for regulatory approvals to conduct trials or to market products; whether the Company's cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; the risk that our audited financial results for the year ended December 31, 2017, including cash on hand, may differ materially from our estimated results for these periods as a result of the completion of year-end closing procedures, other matters that could affect the availability or commercial potential of the Company's product candidates; and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, discussed in the "Risk Factors" section of the Company's most recently filed Quarterly Report on Form 10-Q and other filings the Company makes with the Securities and Exchange Commission.

All information in this presentation is as of January 8th, 2018, and should not be considered current after such date. We do 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.

Experienced Leadership Team



Mark Iwicki: CEO, Chairman of the Board
Previous: CEO Civitas Therapeutics; CEO Blend Therapeutics; CEO Sunovion Pharmaceuticals; Novartis; Merck



Todd Bazemore: Chief Operating Officer
Previous: EVP & COO Santhera Pharmaceuticals; EVP & CCO Dyax Corp; Sunovion



Kim Brazzell, PhD: Chief Medical Officer
Previous: CMO/Head Ophthalmology Business, Inspire Pharmaceuticals; Head R&D, Novartis Ophthalmics



Michele LaRussa: SVP, Regulatory Affairs and Quality Assurance
Previous: Global Head of Regulatory Affairs, Dermatology, GSK; Allergan



Hongming Chen, ScD: Chief Scientific Officer
Previous: TransForm Pharmaceuticals (J&J), AstraZeneca; Merck; MIT ScD



Vin Kosewski: SVP, Manufacturing and Supply Chain
Previous: VP Supply Chain Ops, Sunovion; Sepracor; Astra USA



Mary Reumuth, CPA: Chief Financial Officer
Previous: Corporate Controller, Enobia Pharma; Genzyme; Ernst & Young LLP

Key Highlights

Mucus-penetrating nanoparticle (MPP) technology to enhance delivery to target tissues of the eye

IP protection for MPP technology and products through 2033

INVELTYS™ NDA (Post-surgery product) submitted to FDA in Oct 2017; PDUFA action date of Aug 24, 2018

Retained worldwide commercial rights for our current product candidates

Topline results for Dry Eye Disease Phase 3 trials announced in Jan 2018

Expect to commercialize product candidates in the US with our own focused, specialty sales force

Two Product Candidates in Late Stage Development

INVELTYS™ (KPI-121 1%): For Post-Surgical Inflammation and Pain

- Potential first FDA-approved topical steroid with BID dosing for treatment of inflammation and pain following ocular surgery
- ~7.7M ocular surgeries performed in the U.S. in 2016 with ~9.4M annual ocular surgeries projected for 2021
- Phase 3 complete; statistical significance achieved for both primary endpoints for both Phase 3 trials
- **NDA submitted to FDA in October 2017**
- **PDUFA date: Aug 24, 2018**

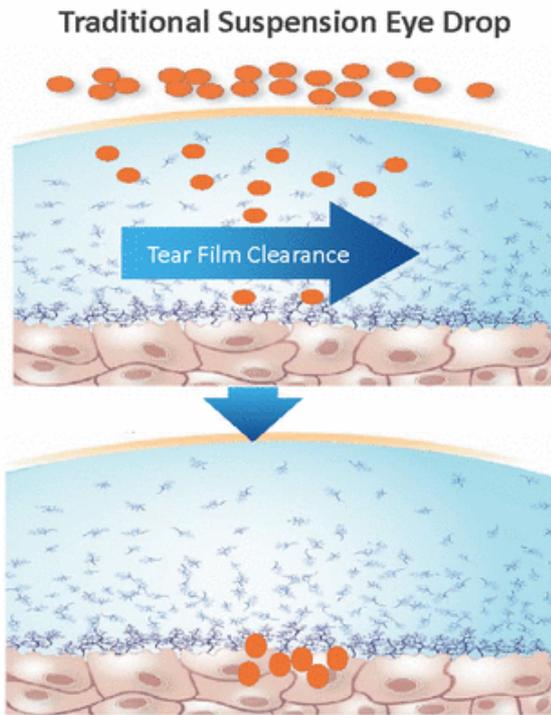
KPI-121 0.25%: For Dry Eye Disease

- ~33M dry eye sufferers in U.S. of which ~16M are diagnosed patients
- Potential first-line Rx therapy in dry eye disease
- May be complementary to chronic maintenance therapies
- **Two Phase 3 trials completed:**
 - **Statistical significance for primary sign and primary symptom endpoint in STRIDE 1**
 - **Statistical significance for primary sign endpoint in STRIDE 2**



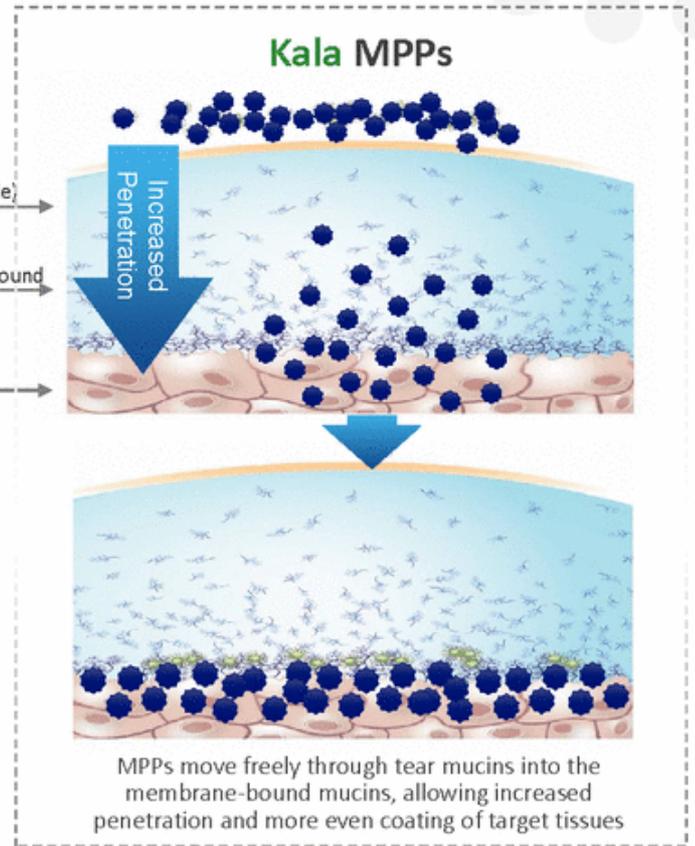
Mucus Penetrating Nanoparticle (MPP) Technology Overview

In the Eye, MPPs Penetrate Through Tear Film Mucins to Enhance Drug Delivery to Target Ocular Tissues



Traditional suspension eye drops adhere to the mucins and are rapidly cleared with the tears via blinking

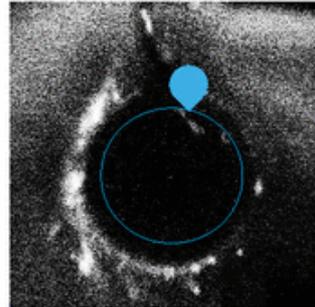
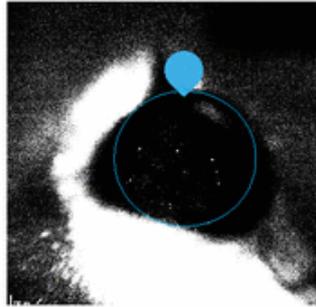
Tear (soluble) mucins
Membrane-bound mucins
Cornea



MPPs move freely through tear mucins into the membrane-bound mucins, allowing increased penetration and more even coating of target tissues

MPPs Enable Corneal Delivery and Duration

Control
Nanoparticles



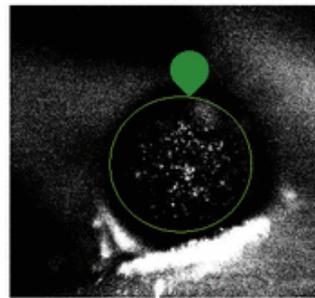
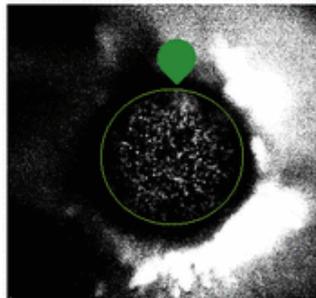
Non-coated nanoparticles are trapped by tear mucins and rapidly eliminated from ocular surface via blinking

1 dose

2 hours

4 hours

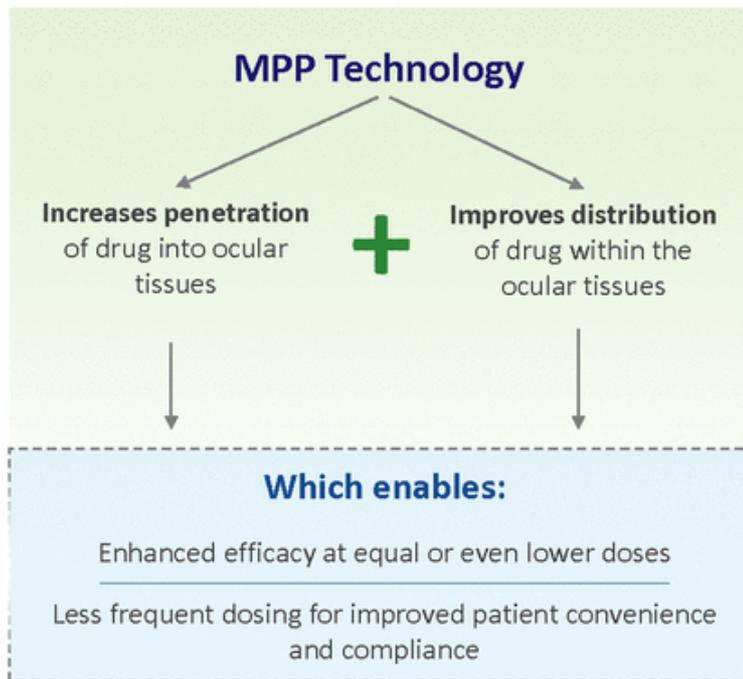
Kala
MPPs



MPP-coated non-dissolving nanoparticles are not trapped by tear mucins. They settle into membrane-bound mucins and penetrate to underlying corneal epithelial tissues

*MPPs – inert nanoparticles with Kala's proprietary coating
Control nanoparticles - same size and composition as the MPPs but without the proprietary coating*

We Believe MPP Technology Can Enhance Drug Delivery and Efficacy



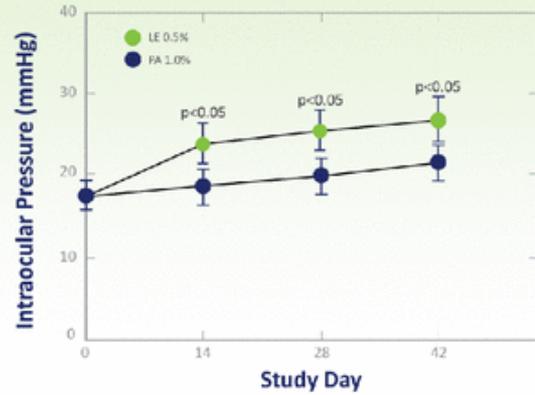
- MPP surface modification avoids mucus clearance → higher target tissue delivery and more uniform coverage → enhanced pharmacokinetics (PK) and efficacy
- MPP's nano-size drives high drug dissolution and thereby enhances tissue penetration
- **Both attributes critical:**
 - Large particles cannot permeate the mucus barrier
 - Conventional nanoparticles without MPP coating have not resulted in enhanced PK

IP Protection for MPP Technology and Products Through 2033

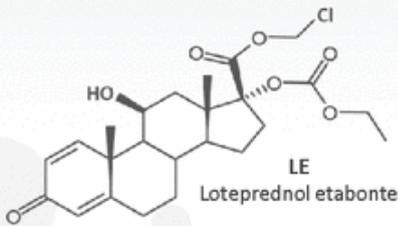
Loteprednol Etabonate (LE) Is A Potent Steroid With Improved Safety Characteristics

- Ester steroid differing from traditional ketone-based steroids (such as prednisolone and dexamethasone) by its metabolism to inactive metabolites
- 4.3X greater glucocorticoid receptor (GR) binding affinity versus dexamethasone
- Therapeutic effect followed by predictable single-step deesterification to inactive carboxylic acid metabolites
- Enhanced safety relative to ketone steroids

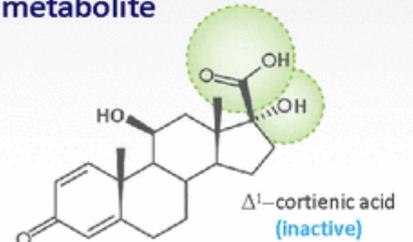
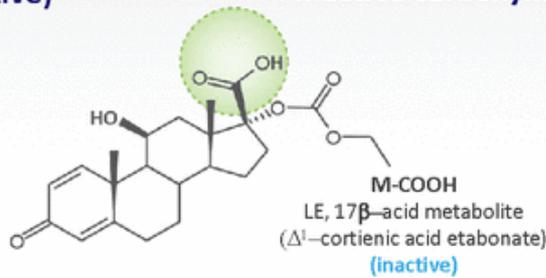
Effect on IOP in steroid responsive patients (LE vs prednisolone (PA))



Loteprednol etabonate (active)



Inactive carboxylic metabolite



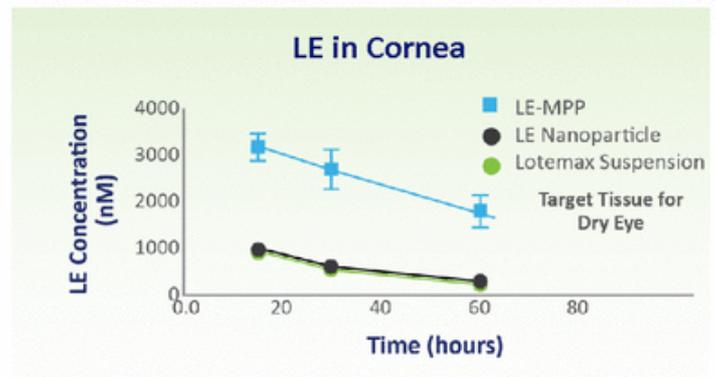
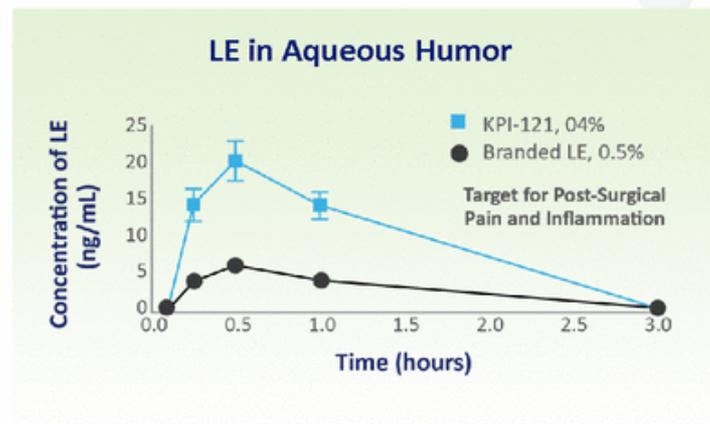
Sources: Comstock and DeCory, *Int J Inflamm* 2011; Bartlett et al, *J Ocul Pharm* 1993

Leveraging LE-MPP to Enhance Delivery to Target Ocular Tissues

- KPI-121: MPP Ioteprednol etabonate (LE)
 - INVELTYS™ (KPI-121 1%): Product Candidate for Post-Surgical Pain and Inflammation
 - KPI-121 0.25%: Product Candidate for Dry Eye Disease
- MPP increases LE penetration to corneal and aqueous humor by more than 3X
- Aqueous Humor concentrations mediate resolution of inflammation following ocular surgery
- Corneal deposition is a key driver for Dry Eye efficacy and resolution of pain following ocular surgery

Preclinical data from rabbit studies

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Kala Late Stage Programs

Late Stage Programs in Dry Eye Disease and Post Surgical Inflammation and Pain

INVELTYS™ (KPI-121 1%): Potential First Approved Product With BID Dosing For Treatment Of Inflammation And Pain Following Ocular Surgery

Positive Phase 3 Trial Completed

Positive Confirmatory Phase 3 Trials Completed

NDA Submitted Oct 2017

KPI-121 0.25%: Potential First Approved Product For The Temporary Relief Of Signs & Symptoms Of Dry Eye Disease – 2 Week Course of Therapy

Positive Phase 2 trial Completed

Two Phase 3 Trials Completed

Topline Results Announced Jan 2018



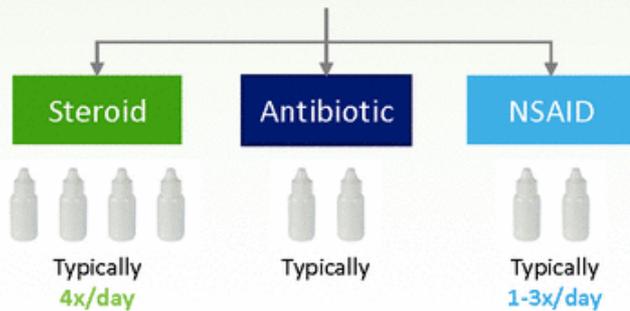
**INVELTYS™ for Post-Surgical
Inflammation and Pain**

Treatment of Inflammation & Pain Following Ocular Surgery

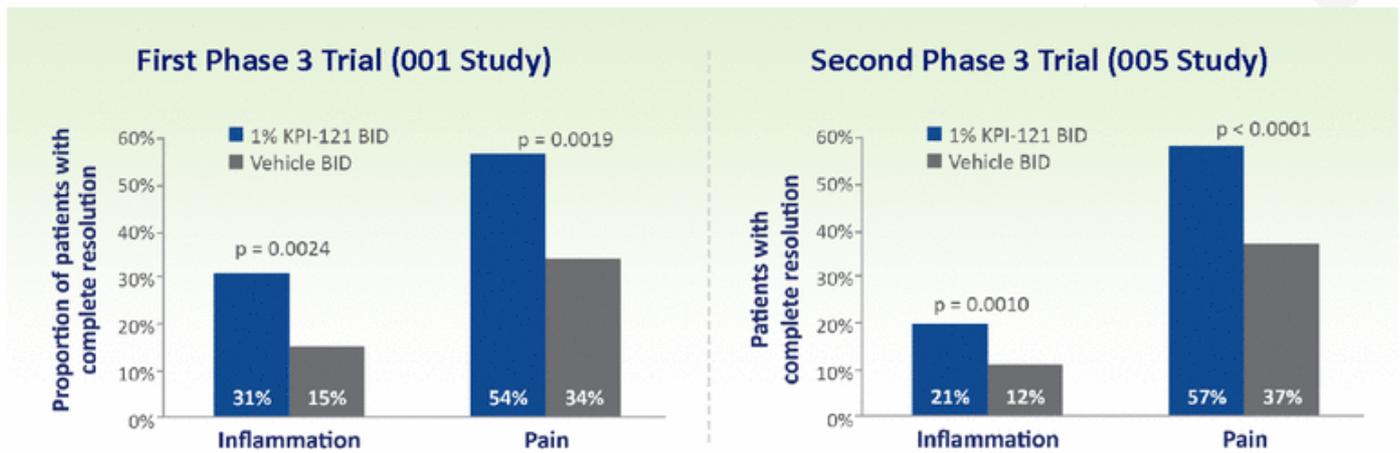
- ~7.7M ocular surgeries performed in the U.S. in 2016 with ~9.4M annual ocular surgeries projected for 2021
 - ~3.9M cataract surgeries in the U.S. in 2016, projected to grow to ~4.6M in 2021
- Topical corticosteroids are the current standard of care for treatment of inflammation & pain after cataract and other ocular surgeries
- Current topical steroids are approved for QID dosing, which can lead to compliance issues for patients
- An effective topical steroid with BID dosing would be a significant benefit in the management of patients following ocular surgery



Typical Current Post-Operative Treatment Regimen



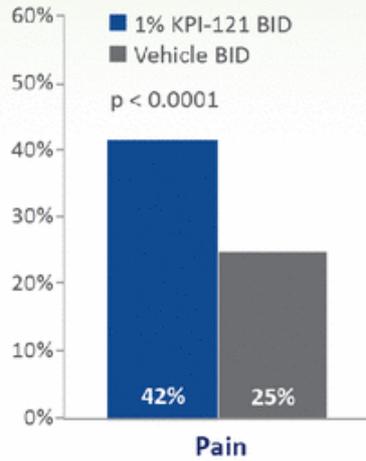
Statistical Significance for Both Primary Endpoints in Phase 3 Trials



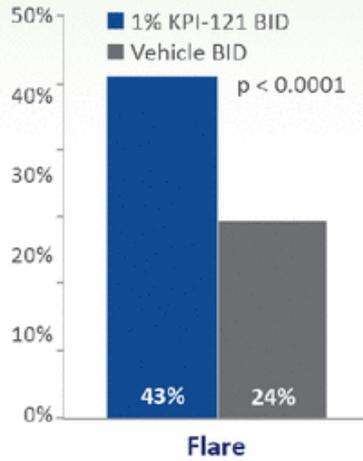
- Standard clinical design utilized for all post-surgical steroids
- Two-week dosing in patients with intraocular inflammation one day after cataract surgery (N=380 in 001 Study, N=520 in 005 Study)
- Primary endpoints:
 - Proportion of patients with complete resolution of anterior chamber cells at post-operative Day 8 maintained through end of study with no need for rescue medication
 - Proportion of patients with complete resolution of pain (grade = 0) at post-operative Day 8 maintained through end of study with no need for rescue medication

Statistical Significance for Secondary Endpoints in Study #005

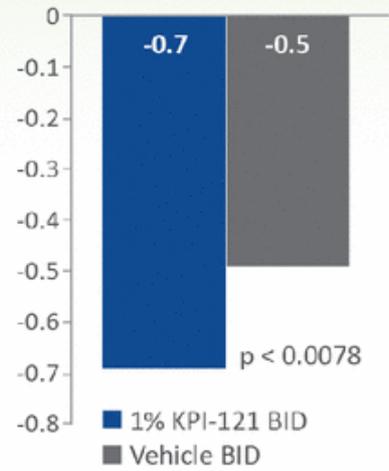
Proportion of Patients with Complete Resolution of Pain at Day 4



Proportion of Patients with Complete Resolution of Flare at Day 4



Mean Change in Cell Count at Day 4



005 Study: Similar Effect on Intraocular Pressure (IOP) for INVELTYS vs Placebo

Mean IOP (Safety Population)

	INVELTYS – BID Mean (SD) in mmHg (n=261)	Vehicle Mean (SD) in mmHg (n=259)
Day 1	15.7 (3.37)	15.6 (2.96)
Day 8	14.3 (3.02)	13.5 (3.10)
Day 15	14.5 (2.77)	14.2 (2.96)

Number of Patients with IOP Increase > 5 mmHg Leading to IOP \geq 21 mmHg (Safety Population)

	INVELTYS – BID	Vehicle
Day 8	0 (0.0%) n=240	1 (0.5%), n=204
Day 15	0 (0.0%) n=212	0 (0.0%), n=159

INVELTYS PDUFA Target Action Date of August 24, 2018

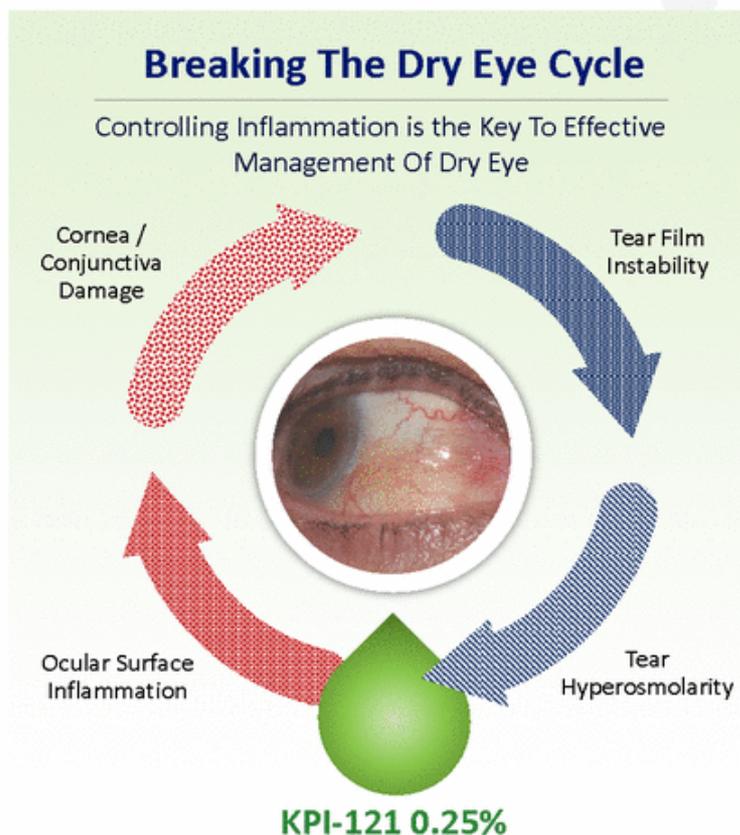
- Statistical significance achieved for all primary endpoints in both Phase 3 trials
- AE profile comparable to placebo
 - Most common AEs in INVELTYS arm only seen in 1.6% and 1.1% of patients in 001 and 005 studies
- Comparable IOP profiles between INVELTYS and placebo
- NDA submitted to FDA in October 2017; PDUFA target date of August 24th, 2018
- Expect to commercialize with sales force of approximately 75 representatives



KPI-121 0.25% for Dry Eye Disease

Dry Eye Is An Inflammation Driven Disease

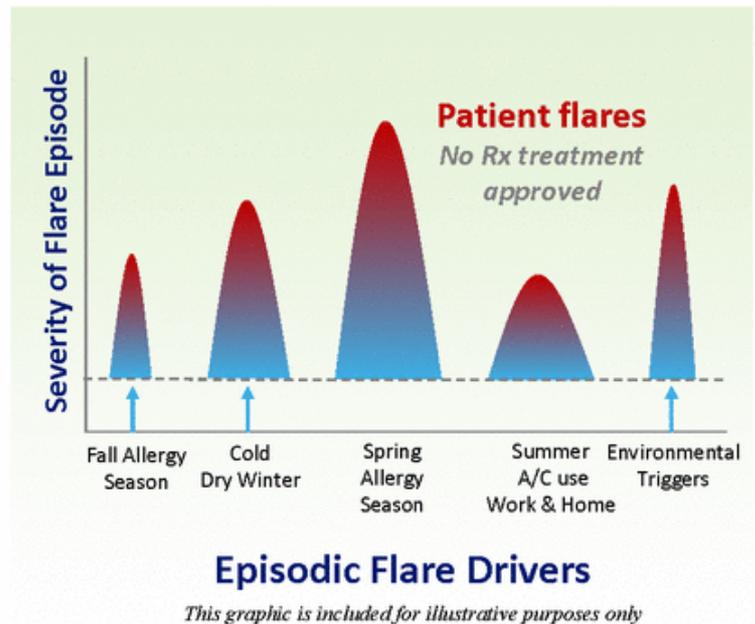
- Dry eye disease is a chronic, episodic disease of ocular inflammation
- ~33 million people in the US with dry eye disease of which ~16M are diagnosed patients
- For most patients, dry eye symptoms are episodic, not continual
 - For these patients, chronic therapy may not be necessary or appropriate
- Currently there is no approved product for the short-term rapid relief of episodic symptoms
 - Restasis and Xiidra are typically used as maintenance therapy for patients who have continuous symptoms
 - These products have relatively long onset of action and therefore are generally not used for the short-term treatment of episodic flares



Dry Eye Is A Chronic...Yet Episodic Disease

~90% of surveyed dry eye patients experience flares and the majority have multi-day episodes

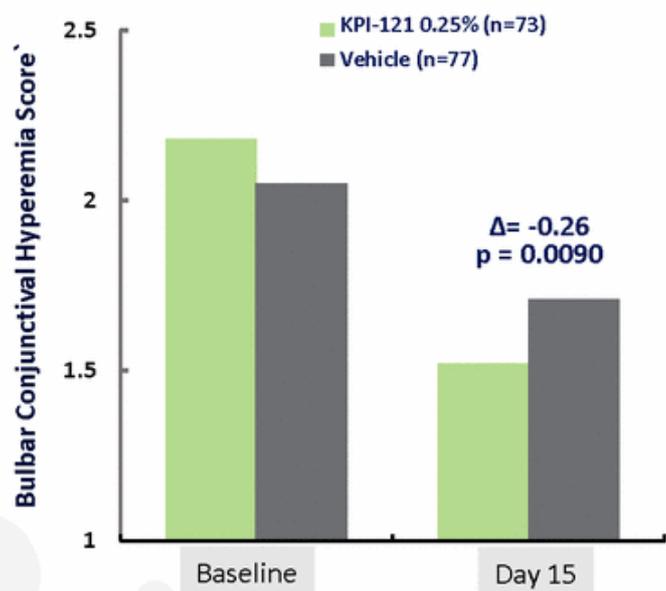
- Patients have symptom “flares” that wax and wane in response to environmental triggers
- Flares are seen across the spectrum of severity levels
- Flares can become more frequent and problematic as the disease progresses
- KPI-121 0.25% can be used as a two-week course in combination with baseline therapies



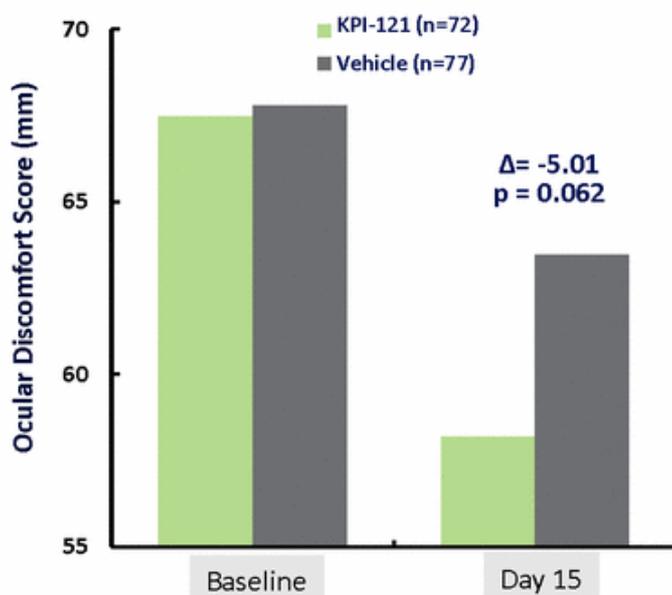
Based on a survey of 30 patients diagnosed with dry eye disease commissioned by Kala and performed by a third party.

Robust Improvement in Primary Sign Endpoint and Strong Trend in Symptom Endpoint in Phase 2

Conjunctival Hyperemia - ITT



Ocular Discomfort - ITT



Phase 2 Results: Effect of KPI-121 0.25% on IOP

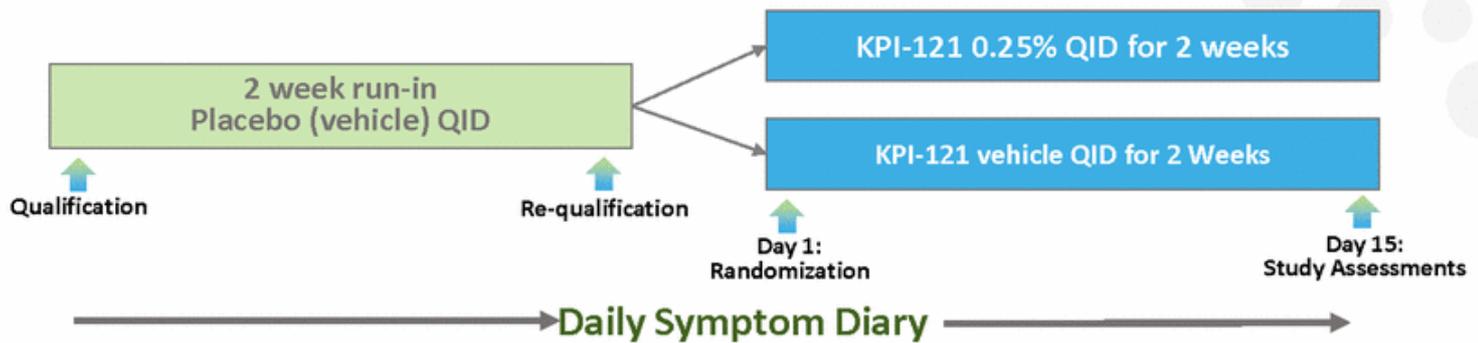
Mean IOP (Safety Population)

	KPI-121 0.25% QID Mean (SD) in mmHg (n=72)	Vehicle Mean (SD) in mmHg (n=78)
Day 1	14.8 (2.33)	14.8 (2.61)
Day 15	15.3 (2.66)	15.3 (2.73)
Day 29	15.6 (3.12)	15.1 (2.80)

Number of Patients with IOP Increase > 5 mmHg Leading to IOP \geq 21 mmHg (Safety Population)

	KPI-121 0.25% QID	Vehicle
Day 15	1 (1.4%), n=72	1 (1.3%) n=78
Day 29	1 (1.4%), n=72	0 (0.0%) n=78

Two Phase 3 Clinical Trials Completed (STRIDE 1 & STRIDE 2)



Study Design (each trial)

Study Population

- 900+ subjects with diagnosed DED (918 randomized in STRIDE 1; 909 randomized in STRIDE 2)

Key inclusion criteria

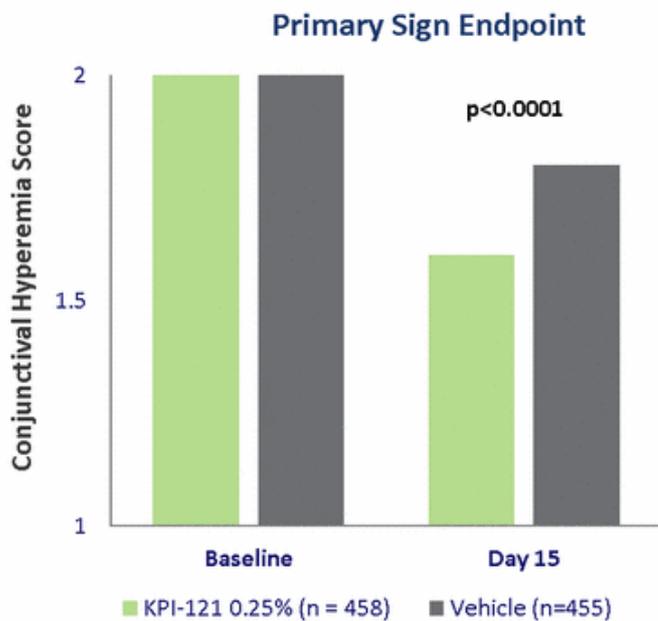
- Investigator-rated bulbar conjunctival hyperemia of ≥ 2 both before and after placebo run-in
- Score of > 50 mm ocular discomfort before placebo run-in AND > 40 mm after run-in
- Corneal fluorescein staining score ≥ 6 (out of possible 15) both before and after placebo run-in
- Schirmer score < 10 mm both before and after placebo run-in

Treatment

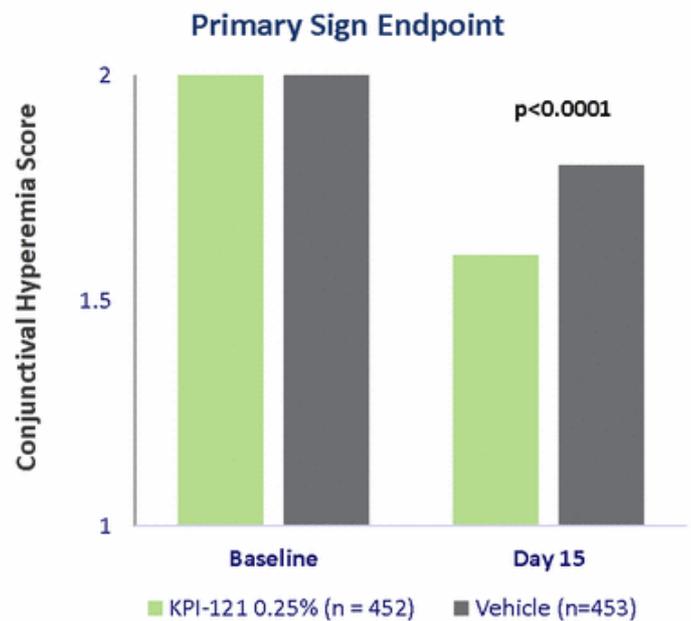
- Two week run-in with placebo QID after qualification
- Two week randomized treatment with KPI-121 0.25% QID vs Placebo QID after re-qualification

Statistically Significant Improvements in Conjunctival Hyperemia in Both Phase 3 Trials

STRIDE 1: Mean Conjunctival Hyperemia - ITT

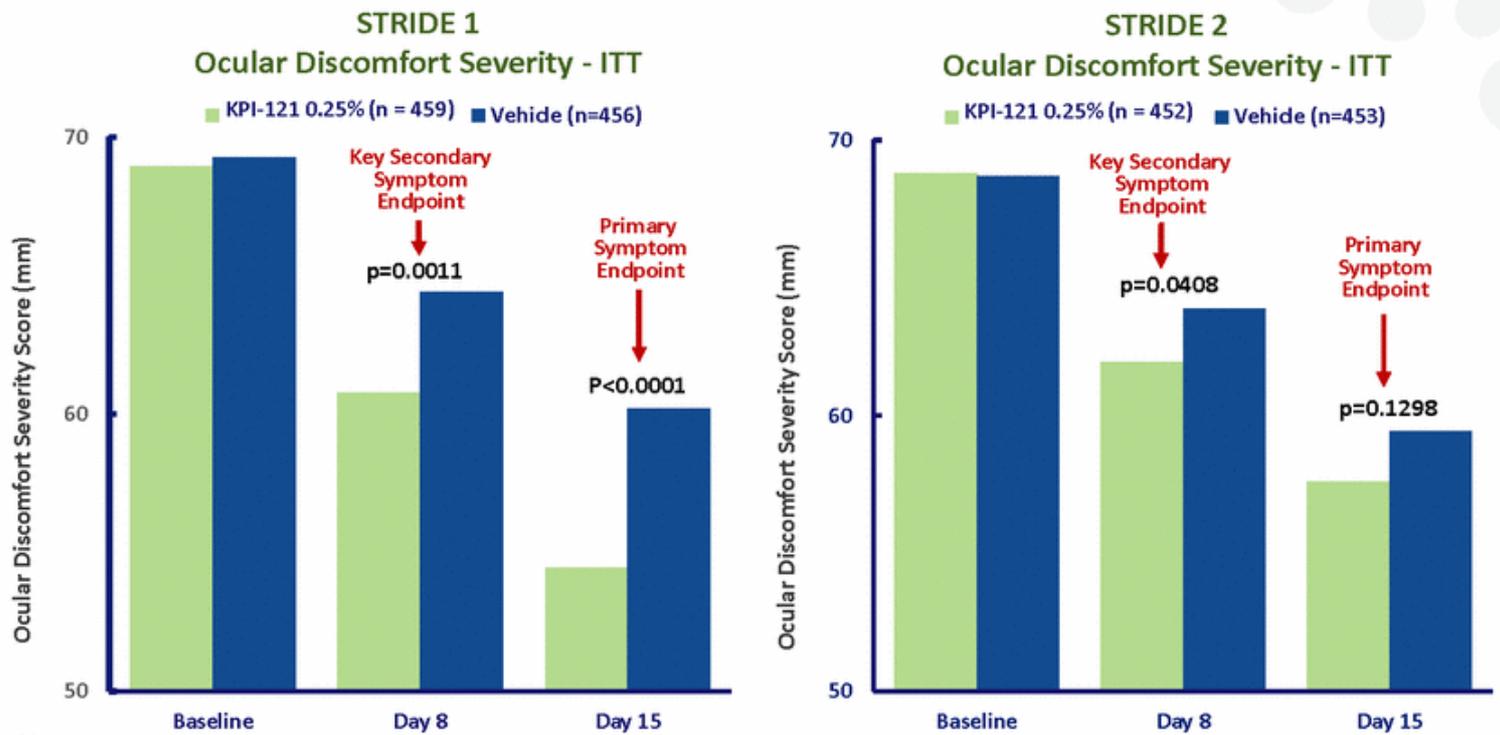


STRIDE 2: Mean Conjunctival Hyperemia - ITT



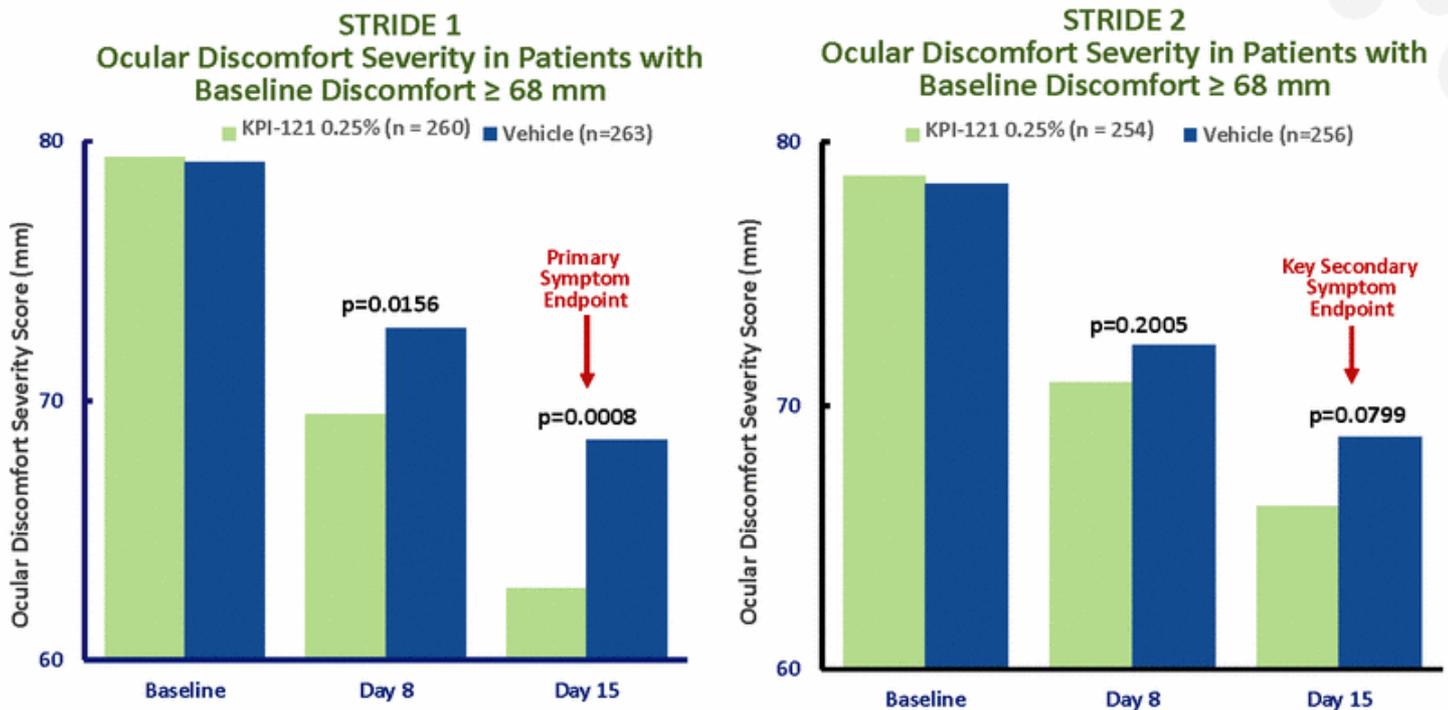
Statistical significance achieved for primary sign endpoint in both STRIDE 1 and STRIDE 2

Statistically Significant Improvements in Ocular Discomfort in STRIDE 1



Statistical significance for primary symptom endpoint achieved in STRIDE 1 but not STRIDE 2

Statistical Significant Improvements in Ocular Discomfort in Patients with More Severe Baseline Discomfort in STRIDE 1



Statistical significance achieved for second predefined primary symptom endpoint in STRIDE 1 but not for key secondary symptom endpoint in STRIDE 2

KPI-121 0.25% Was Well-Tolerated in Both STRIDE 1 and 2

AEs Reported by >1% of patients

STRIDE 1

	KPI-121 0.25%	Vehicle
Instillation site pain	28/459 (6.1%)	28/456 (6.1%)
Eye irritation	5/459 (1.1%)	7/456 (1.5%)

STRIDE 2

	KPI-121 0.25%	Vehicle
Instillation site pain	26/453 (5.7%)	20/452 (4.4%)
Vision blurred	1/453 (0.2%)	6/452 (1.3%)

KPI-121 0.25% Demonstrated Similar IOP Profile to Placebo in Both Trials

Mean IOP

STRIDE 1

	KPI-121 0.25% Mean (SD) in mmHg (n=459)	Vehicle Mean (SD) in mmHg (n=456)
Day 1	14.9 (2.66)	15.0 (2.51)
Day 15	15.1 (2.67)	14.9 (2.68)

STRIDE 2

	KPI-121 0.25% Mean (SD) in mmHg (n=72)	Vehicle Mean (SD) in mmHg (n=78)
Day 1	14.8 (2.42)	14.7 (2.51)
Day 15	15.0 (2.65)	14.6 (2.41)

Number of Patients with IOP Increase > 5 mmHg Leading to IOP \geq 21 mmHg

STRIDE 1

KPI-121 0.25%	Vehicle
2/455 (0.4%)	2/453 (0.4%)

STRIDE 2

KPI-121 0.25%	Vehicle
5/448 (1.1%)	0/448 (0.0%)

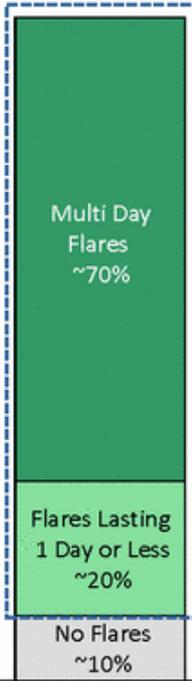
COMBINED

KPI-121 0.25%	Vehicle
7/903 (0.8%)	2/901 (0.0%)

90% of Surveyed Dry Eye Patients Experience Flares

Sufferers On Average Have ~9 Flares Per Year, Each Lasting ~11 Days

Flares in the Dry Eye Disease Population

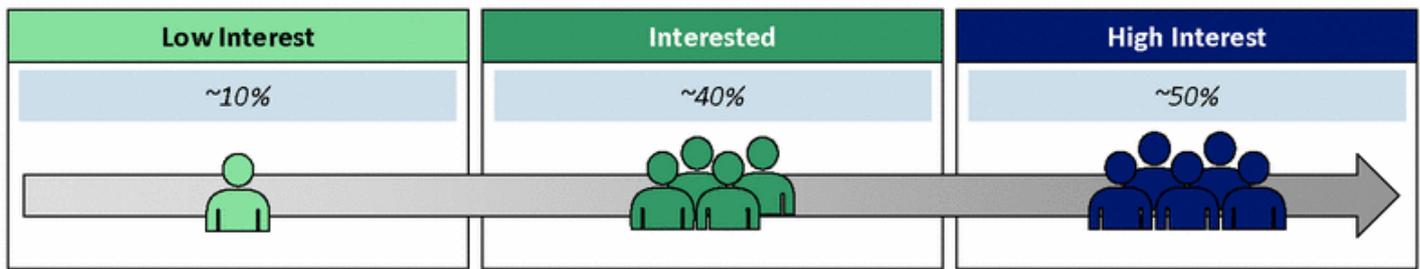


Patients with Flares		
Factor	Comparison to No Flares	Key Takeaway
Average OSDI Score	<p>A horizontal scale with 'Lower' on the left, 'Same' in the middle, and 'Higher' on the right. A vertical tick mark is at 'Same'. A diamond marker is positioned to the right of 'Same', indicating a higher score.</p>	Patients with flares were more likely to have higher OSDI scores than patients without flares
Number of Symptoms	<p>A horizontal scale with 'Lower' on the left, 'Same' in the middle, and 'Higher' on the right. A vertical tick mark is at 'Same'. A diamond marker is positioned to the right of 'Same', indicating a higher number of symptoms.</p>	Patients with flares either experienced or simply noticed more individual symptoms
Time Since Diagnosis	<p>A horizontal scale with 'Shorter' on the left, 'Same' in the middle, and 'Longer' on the right. A vertical tick mark is at 'Same'. A diamond marker is positioned to the right of 'Same', indicating a longer time since diagnosis.</p>	A longer time since diagnosis made patients more likely to experience and identify flare events

Based on a survey of 30 patients diagnosed with dry eye disease commissioned by Kala and performed by a third party.

Patient Market Research Suggests Strong Interest in KPI-121 0.25%

The majority of surveyed patients expressed interest in the KPI-121 0.25% profile

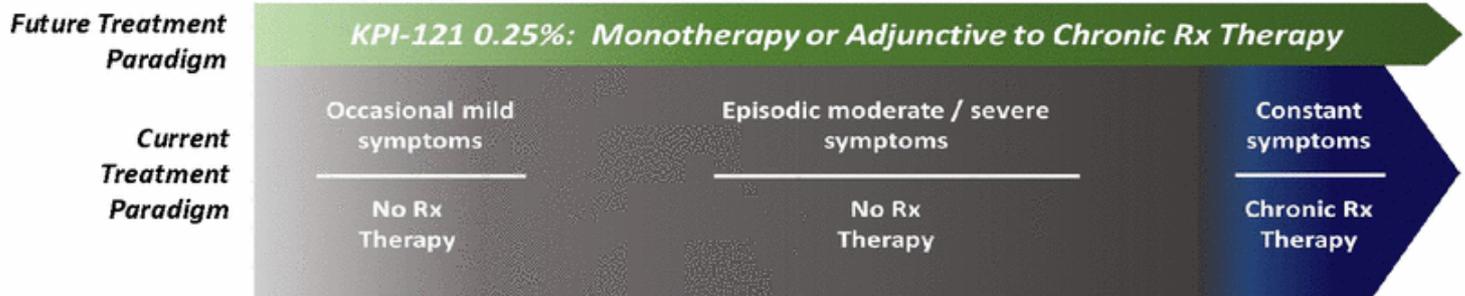


- Patients were very interested in the profile and would ask their physicians for more information about KPI-121 0.25%
- Patients specifically commented they would like an “as-needed” flare treatment vs. a chronic medicine
- The majority of patients indicated they want to try KPI-121 0.25%, expressing high levels of interest
- Patients highlighted they want rapid and strong efficacy with a reduction of “redness”, and short-term and “as-needed” flare treatment

Based on a survey of 30 patients diagnosed with dry eye disease commissioned by Kala and performed by a third party.

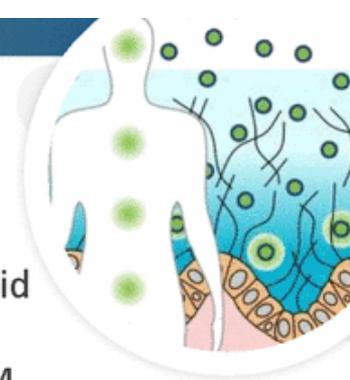
KPI-121 0.25% Is a Potential First Line Rx Therapy in Dry Eye

KPI-121 0.25%: First Line Treatment Option and Suitable for All Stages



- Rapid Onset of Relief
- Broad Mechanism of Action
- Well Tolerated
- Dosing Regimen is Attractive for Treating Episodic Flares
- May Be Complementary to Chronic Maintenance Therapies

Summary



INVELTYS™: Potential First Twice-daily Ocular Steroid

7.7M ocular surgeries in the US in 2016 with ~9.4M annual ocular surgeries projected for 2021

KPI-121 0.25%: Potential First-Line Rx Therapy to Treat Dry Eye Flares

~33M dry eye sufferers in US

MPP Platform Enhances Mobility of Drug Particles Through Mucus Layers

INVELTYS™ PDUFA Target Date of August 24th, 2018

Topline Results for Dry Eye Phase 3 Trials Announced in Jan 2018

Source for ocular surgery market data: Market Scope

Source for dry eye disease market data: Epidemiology research commissioned by Kala and performed by a third party



Thank You

