# kala.... PHARMACEUTICALS

Innovation In Ophthalmology

**Corporate Overview** January 2021

#### **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 Company's products, EYSUVIS<sup>™</sup>, for the short term (up to two weeks) relief of the signs and symptoms of dry eye disease, INVELTYS<sup>®</sup>, the first and only topical twice-daily ocular corticosteroid for treatment of post-operative inflammation and pain following ocular surgery; the Company's plan to grow its salesforce to 125 sales representatives in 2021, pending the status of the COVID-19 pandemic; the status of insurance coverage and the availability of reimbursements for EYSUVIS and INVELTYS for commercial and Medicare Part D patients; the commercial potential for EYSUVIS and INVELTYS; Kala's plans to advance its preclinical pipeline of programs and the potential benefits of such programs; and the Company's expectations regarding its use of cash, cash runway and projected revenues. All statements, other than statements of historical facts, contained in this presentation, including statements regarding the Company's strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions are intended to identify forward looking statements, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements, and you should not place undue reliance on such 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: the impact of extraordinary external events, such as the current pandemic health event resulting from the novel coronavirus (COVID-19), and their collateral consequences, including disruption of the activities of the Company's sales force and the market for EYSUVIS and INVELTYS; whether the Company will be able to successfully implement its commercialization plans for EYSUVIS and INVELTYS; whether the market opportunity for EYSUVIS and INVELTYS is consistent with the Company's expectations and market research; the Company's ability execute on the commercial launch of EYSUVIS on the timeline expected, or at all, including obtaining Commercial and Medicare Part D payor coverage; whether the Company will be able to generate its projected net product revenue on the timeline expected, or at all; whether the Company's cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements for the Company's expected timeline; other matters that could affect the availability or commercial potential of EYSUVIS and INVELTYS; and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, 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 Annual Report on Form 10-K, most recent 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 11, 2021 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.



#### Kala is a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies for diseases of the eye

#### **Portfolio of Innovative Therapies**



- Two marketed products that utilize Kala's proprietary AMPPLIFY<sup>®</sup> mucus-penetrating particle (MPP) Drug Delivery Technology to address unmet medical needs in Dry Eye Disease and post ocular surgery
- Pipeline with multiple proprietary NCE development programs targeted to address front and back of eye diseases
- Kala holds worldwide rights and IP on all marketed products and pipeline assets

#### **R&D to Commercial**



- Approximately 190 employees
- Recently expanded ophthalmic sales, marketing and market access teams brings proven experience in eye care space
- Deep expertise in discovery, clinical operations and regulatory affairs for both front and back of the eye diseases

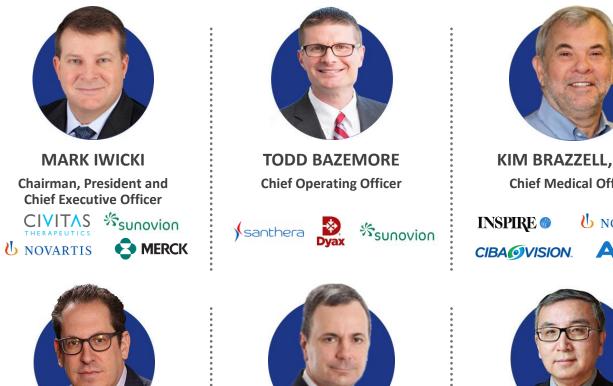
#### **Strong Cash Position**



- Expected to report cash, cash equivalents and short-term investments of \$153.5 million as of December 31, 2020
- Existing cash, cash equivalents and short-term investments, along with sales of INVELTYS, anticipated to enable funding of operations into at least the fourth quarter of 2022
- Revenue generated from sales of EYSUVIS will provide additional cash runway



#### Kala Team





**General Counsel and Chief Compliance Officer** P AUXILIUM enobia Ssunovion Proneering Medicines



Sunovion Astra USA



**KIM BRAZZELL, PHD Chief Medical Officer** 

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MARY REUMUTH, CPA **Chief Financial Officer** 





**KATE KLINE** Senior Vice President, Marketing





#### Kala Holds Worldwide Rights to a Portfolio of Promising Therapies

### Marketed Products

Two innovative therapies utilizing Kala's proprietary AMPPLIFY<sup>®</sup> Drug Delivery Technology to address medical needs for front of the eye



First and only prescription therapy specifically for the shortterm management of the signs and symptoms of dry eye disease

#### INVELTYS®

(loteprednol etabonate ophthalmic suspension) 1%

First and only BID corticosteroid indicated for the treatment of post-operative ocular inflammation and pain



Proprietary NCE development programs targeted to address front and back of the eye diseases

	Discovery	Lead Optimization	Candidate Selection	Formulation Development	IND- Enabling Studies
<b>Tyrosine Kinase Inhibitor</b> Retinal diseases, including wet AMD, DME, and RVO					
Surface Targeting Steroid (STS) Ocular surface diseases					
Selective Glucocorticoid Receptor Modulator (SEGRM) Retinal diseases, including wet AMD, DME, and RVO; ocular surface diseases					





# **AMPPLIFY®** Technology Overview



#### Mucus is an Innate Defense Mechanism That Can Impair Drug Delivery

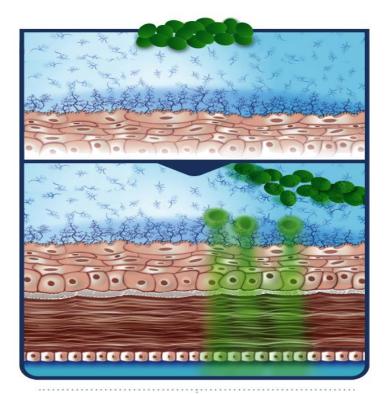
- Heterogeneous mesh of mucin fibers present in tear film and other protective coatings in the body
- Mucus binds drugs and other particulate matter to facilitate elimination via tear turnover:
  - 1. Small particles (<500 nm) penetrate into mucus pores and are bound by charged macromolecules inside the pores
  - 2. Large particles (larger than mucus pores) are bound to the surface of mucus

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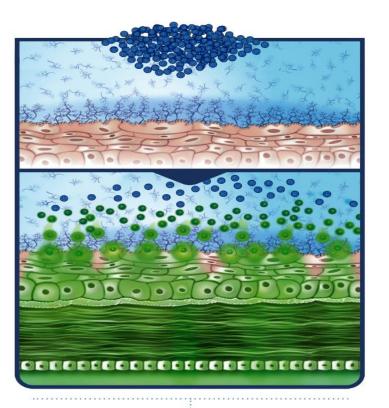
Sources: Olmstead et al. Biophys J 2001; Sigurdsson, Kirch & LehrInt J Pharm 2013

AMPPLIFY utilizes nanoparticles (~300 nm on average) engineered via surface modification to penetrate through mucus pores to the ocular surface without being bound up and eliminated by the tear film

#### AMPPLIFY Technology Increases LE Penetration to Corneal and Aqueous Humor by More Than 3x



Traditional suspension eye drops adhere to mucins and can be rapidly cleared through blinking



#### Drug particles formulated with AMPPLIFY™ Drug Delivery Technology

are designed to enhance penetration through the mucus barrier and deliver increased concentrations of drug to the target ocular tissues



KPI-121 0.5%

- LE Suspension 0.5%

#### Leveraging LE MPP to Enhance Delivery to Target Ocular Tissues

centration

Son 500

1500

1000

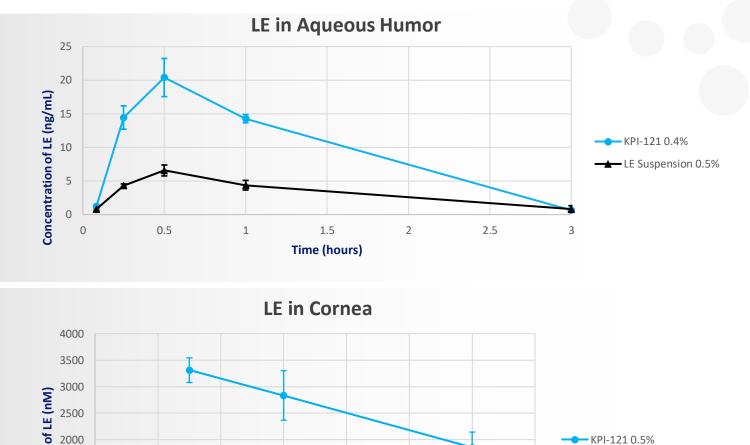
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- KPI-121: MPP loteprednol etabonate (LE)
  - INVELTYS<sup>®</sup> (KPI-121 1%): Approved **Product for Post-Surgical Pain &** Inflammation with BID Dosing
  - EYSUVIS<sup>™</sup> (KPI-121 0.25%): Approved Product for the Short-term Treatment of the Signs and Symptoms of Dry Eye Disease
- AMPPLIFY technology increases LE ٠ 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



Time (min)

40

50

60

70

30





## **Short-Term Treatment of Dry Eye Disease**

#### EYSUVIS: Potential to Be the Preferred Prescription Therapy for Dry Eye Disease Flares

First and only prescription therapy specifically for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease



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3

75-90% of dry eye patients routinely experience dry eye flares

Opportunity to capture a large significant unmet need in dry eye with deep experience in eye care across the organization

Strong IP position (2033) and proprietary manufacturing process

### Approved October 2020 with U.S. promotional launch in January 2021



#### **Market Overview**

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U.S. prevalence of dry eye, of which **17.2M** have been diagnosed and are under the care of an Eye Care Professional<sup>1</sup>

of dry eye patients have never tried prescription therapy<sup>2</sup>



**Only ~10%** of dry eye patients are currently on an Rx Chronic therapy<sup>3</sup>

Only 2.9% of dry eye patients receive Rx for off- label steroids<sup>3</sup>



L.5B Combined Net Revenue for Restasis,

Cequa and Xiidra annually<sup>5</sup>

80% of patients discontinue their chronic Rx medication by 4 months<sup>6</sup>

75–90% of dry eye patients routinely experience dry eye flares<sup>7,8,9</sup>

1. 2019 Dry Eye Products Market Report, Market Scope, 2. Dry Eye Sufferers 2020 Multi-sponsor Survey, 3. Symphony Rx Data divided by DED Prevalence Study and validated with Market Scope data, 4. Symphony Health National Level Total Pack Unit Data – 52 weeks ending 8/14/2020, 5. Symphony Health Gross Dollar Data - 52 weeks ending 8/14/2020, 6. NPA Market Dynamics IQVIA data, June 2019, as reported in October 2019, Restasis (N=24,340) and Xiidra (N=13,037) 7. Based on a survey of 297 patients commissioned by Kala and performed by a third party. 8. Based on a survey of 500 patients diagnosed with dry eve disease commissioned by Kala and performed by a third party. 9. Based on a survey of 774 patients performed by a third party.



#### Majority of DED Patients Suffer from Episodic Flares, Not Continual Symptoms

#### **Dry Eye Disease (DED) Flare Definition<sup>1</sup>:**

Rapid-onset, inflammation-driven response to a variety of triggers that typically cannot be adequately managed with patient's current therapy (e.g., artificial tears, chronic Rx therapies)

~75-90%

of all DED patients report they suffer from flares <sup>2,3,4</sup>

~81%

of patients on artificial tears report they **suffer from flares**<sup>4</sup>

~91%

of patients on prescription medications report they **suffer from flares**<sup>4</sup>

1. ASCRS EyeWorld. https://www.eyeworld.org/download/file/fid/453. Published May 2019. Accessed May 24, 2019. 2. Based on a survey of 297 patients commissioned by Kala and performed by a third party.

3. Based on a survey of 500 patients diagnosed with dry eye disease commissioned by Kala and performed by a third party.

13 4. Based on a survey of 774 patients performed by a third party.

Patients Suffer a Median of 5.5 Flares a year<sup>4</sup>

#### Eye Care Professional (ECP) Key Insights



ECPs believe there is an **opportunity to better manage many mild-to-moderate DED** patients that currently go untreated with Rx therapy because current therapies take too long to work, and often have significant tolerability issues



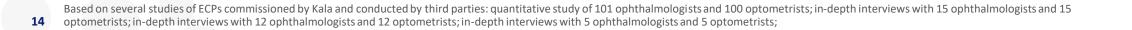
ECPs have a **large proportion of patients that suffer from flares**, and intend to discuss the topic of flares more proactively with patients now that there is an FDA-approved, short-term treatment option



ECPs cited rapid relief and safety/tolerability profile of EYSUVIS as top advantages vs. other DED therapies



ECPs intend to use **EYSUVIS 1<sup>st</sup> line for the treatment of DED flares** and adjunctive to chronic Rx to treat breakthrough symptoms, induction to chronic Rx therapy and for short-term DED treatment prior to ocular surgery





#### **Key Patient Insights**



Once diagnosed, patients are typically first recommended to try an OTC artificial tear, but **continue to suffer** with symptoms from episodic DED flares



**Continuous source of frustration** – Artificial tears provide minimal palliative relief, but do not address inflammation – Patients on current Rx therapy often report limited satisfaction due to unwanted side effects and the time it takes to work (slow onset of weeks to months)



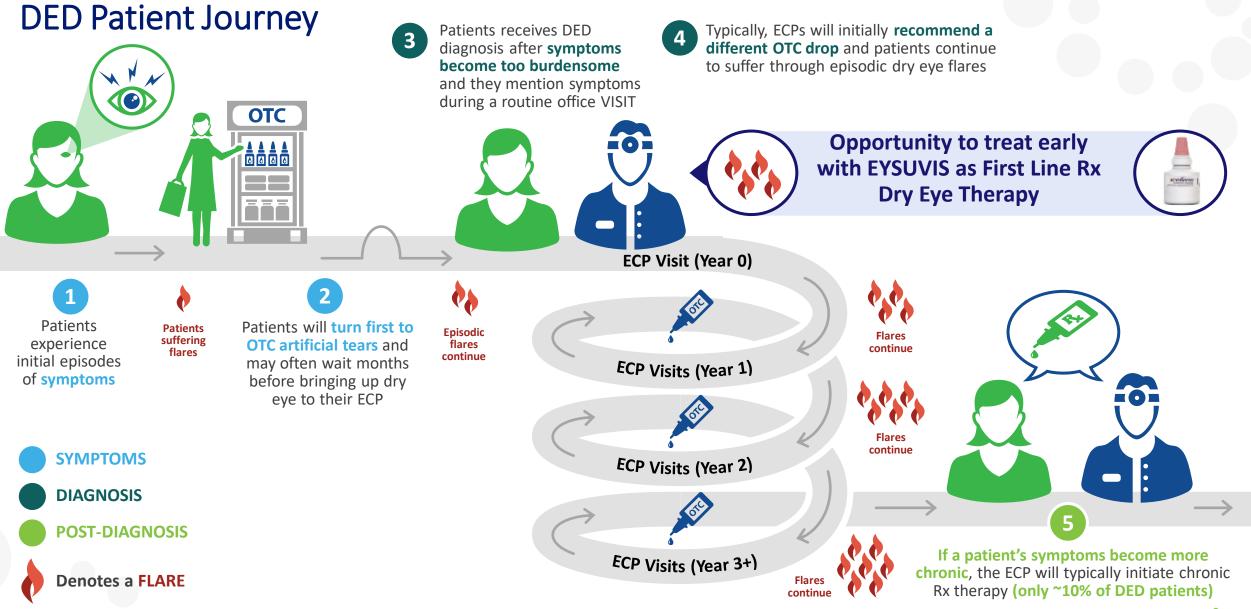
Regardless of DED severity, majority of patients say they suffer from flares and **desire a fast-acting treatment they can use short term**, during times when they are experiencing symptoms



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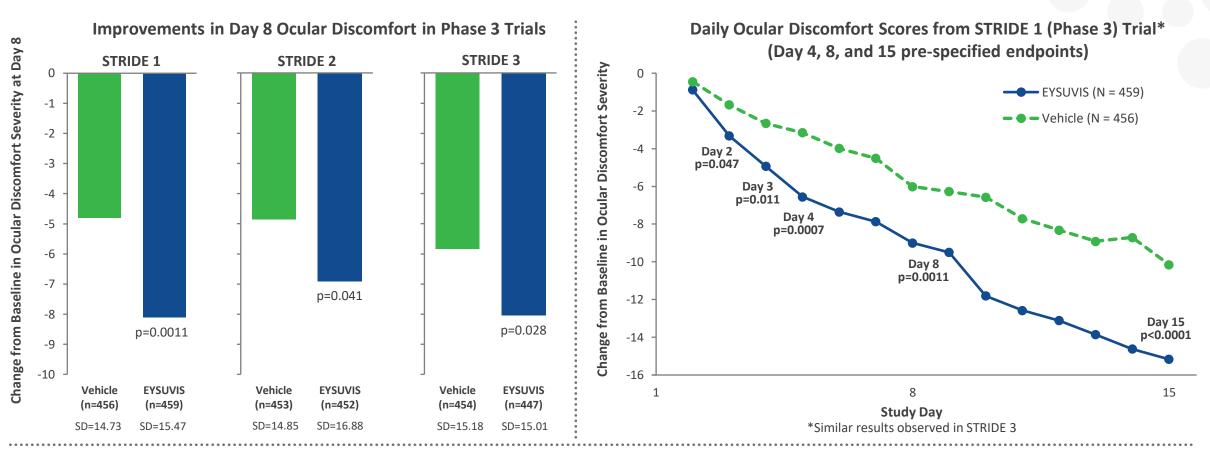
Patients see EYSUVIS as a breakthrough therapy because it provides rapid relief and is used short term vs chronically – **90% of respondents report they intend to ask their ECP about EYSUVIS** 







#### Rapid Onset of Relief for Ocular Discomfort



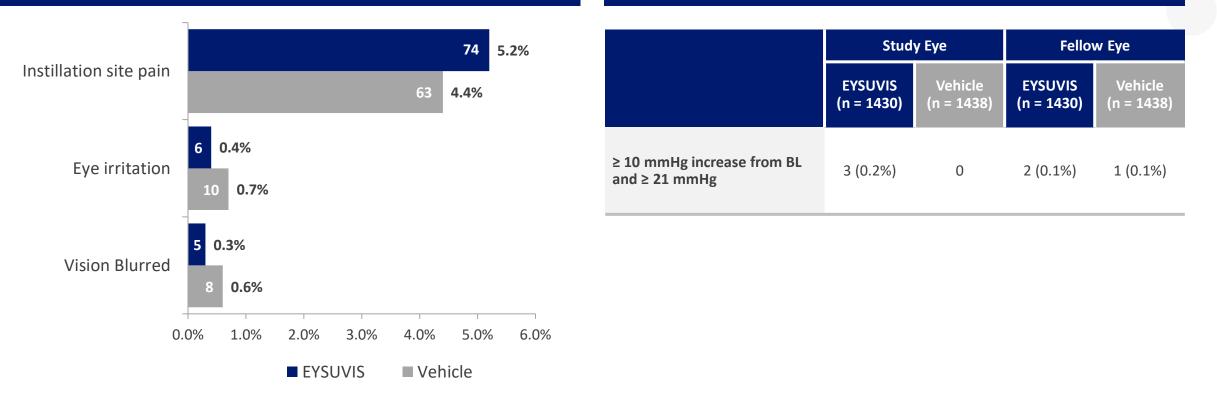
• Day 8 and 15 were pre-specified efficacy endpoints in STRIDE 1, STRIDE 2 and STRIDE 3

- Day 4, Day 8 and Day 15 were pre-specified efficacy endpoints in STRIDE 1
- Day 2 and day 3 are exploratory efficacy endpoints in STRIDE 1
- p values for the Day 8 and day 15 results in each study were analyzed on the days following Day 7 and 14 using the 3 day mean prior to Day 8 (Days 5, 6 and 7) and the 3 day mean prior to Day 15 (days 12, 13 and 14) compared to the 3 day mean prior to Day 1 (Baseline)
- The daily ocular discomfort change from baseline data presented in the graph on the right are derived comparing the single day data from each time point to the 3 day mean prior to Day 1 (baseline)



#### Pooled Safety Findings from Over 2,800 Patients Across Four Clinical Trials

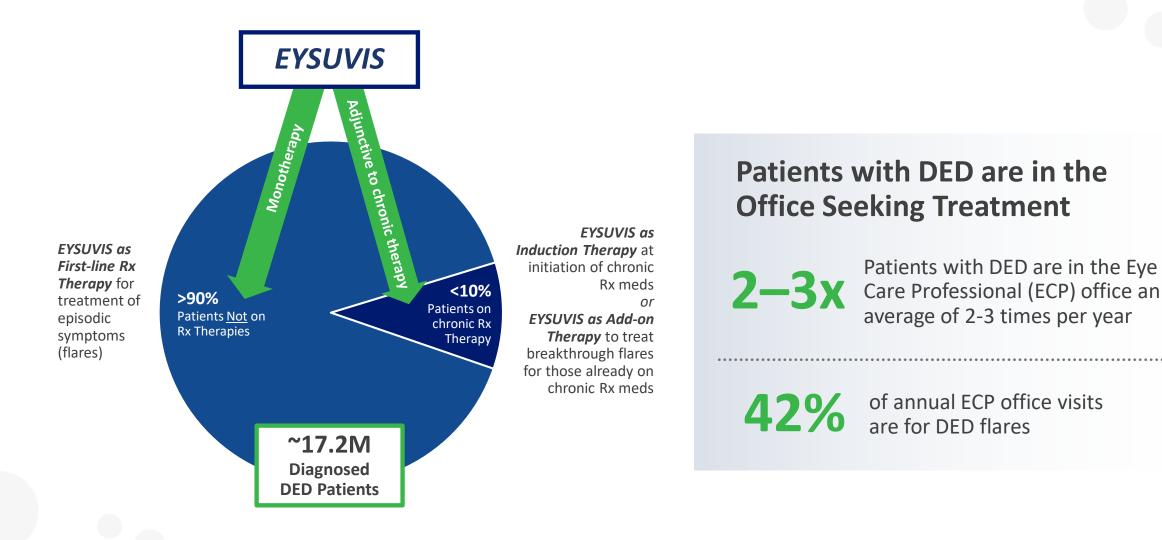
Percentage of Subjects Reporting Treatment-related Adverse Event by >0.3% of Subjects Number (%) of Subjects with Increased Intraocular Pressure Compared with Baseline at any Postbaseline Visit



The most frequently reported treatment-related AE was instillation site pain, reported by 5.2% of subjects in the EYSUVIS group and 4.4% of subjects in the vehicle group



#### EYSUVIS May Be Suitable for the Vast Majority of Patients with Dry Eye Disease





MarketScope 2018 report – Diagnosed Dry Eye patients in the US; Symphony Prescription data, November 2018; NPA Market Dynamics IQVIA data, October 2018; Epidemiology research commissioned by Kala and performed by a third party; Schaumberg et al, 2013, Prevalence of diagnosed dry eye in the US; Survey of 73 ophthalmologists commissioned by Kala and performed by a third party

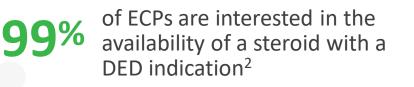
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#### EYSUVIS is Poised to Answer Unmet Needs in DED

- Broad anti-inflammatory activity addresses key driver of DED
- In clinical trials, EYSUVIS provided rapid onset of relief of signs and symptoms of DED
- In clinical trials, **EYSUVIS** was **well tolerated** with low incidence of IOP elevations (similar to vehicle)
- EYSUVIS is the first and only ocular corticosteroid indicated for dry eye disease

# Eye Care Professionals (ECPs) Prefer an On-label Steroid for DED:<sup>1</sup>

- Off-label steroids have varied safety profiles
- Risk of IOP elevation when prescribing steroids off-label
- The DED indication provides patient comfort and confidence
- Efficacy and safety reviewed by the FDA



Third Party Qualitative Physician Market Research with 70 ECPs (34 OPH and 36 OPT).
 Quantitative Market Research with 201 ECPs (101 OPH and 100 OPT).

EYSUVIS Has Potential to Be the Preferred & Therapy for DED Flares



#### **EYSUVIS Launch Status**

#### Trade

- Stocking began in December 2020
- All wholesalers and targeted retail pharmacies stocked by week of January 11

#### **Patient Access**

- Medicare Part-D bids submitted
- Account Directors in active discussions with PBMs and Commercial Plans
- Patient hub in place to assist with access



#### Marketing

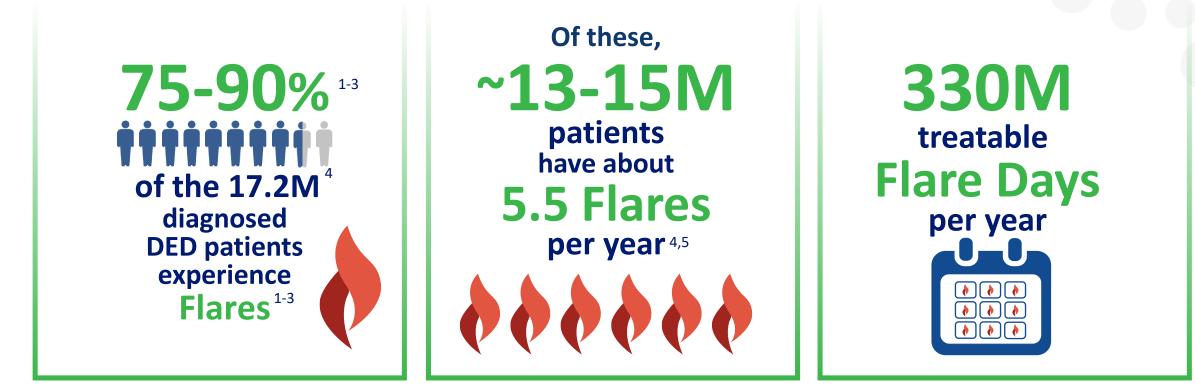
- Patient starter kits distributed in December 2020
- Peer to Peer programs beginning in January
- Full promotional launch is underway

#### **Sales Team**

- Specialty ophthalmic sales team expanded to 91 representatives
- Highly experienced group with an average >7 years of eye care experience and >50% with DED experience
- EYSUVIS sales calls began the week of January 4



#### Annual Total Addressable US Market for Dry Eye Disease Flares



- Only ~15% of diagnosed DED patients are currently on an Rx medication
- 75% of diagnosed DED patients have never tried prescription therapy
- Less than 3% of diagnosed DED patients receive a prescription for an off-label steroid
- U.S. Dry Eye Market expected to exceed \$2.6B in annual revenues by 2026<sup>6</sup>

1. Based on a survey of 297 patients commissioned by Kala and performed by a third party. 2. Based on a survey of 500 patients diagnosed with dry eye disease commissioned by Kala and performed by a third party. 3. Based on a survey of 774 patients performed by a third party. 4. Schaumberg et al, 2013, Prevalence of diagnosed dry eye in the US, MarketScope 2018 report – Diagnosed Dry Eye patients in the US; 5. Based on a survey of 297 patients commissioned by Kala and performed by a third party 6. Evaluatepharma Report: Available USA Sales by Indication (Indications) (Marketed & PII+) 8Jan2021





# INVELTYS<sup>®</sup>: FIRST AND ONLY Approved BID Post-Surgical Steroid



#### INVELTYS: The First & Only Post-Surgical Steroid Approved with BID Dosing



**INVELTYS** launched January 2019

INVELTYS is indicated to treat inflammation and pain following **ALL** ocular surgeries

INVELTYS is the **FIRST AND ONLY** post-surgical steroid shown to be effective and approved with BID dosing

INVELTYS has an excellent safety and tolerability profile, with IOP results similar to placebo

INVELTYS utilizes AMPPLIFY nanoparticle technology that delivers more loteprednol directly to the target ocular tissue while maintaining an excellent safety profile

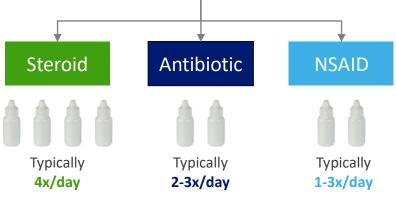


### Steroids Are Standard of Care for Treating Inflammation and Pain Following Ocular Surgery

- Eye care professionals (ECPs) report prescribing steroids in greater than 90% of cataract, glaucoma and refractive surgeries<sup>1</sup>
- Current ocular steroids are approved for TID or QID dosing, which can lead to issues with adherence to the steroid regimen
- An effective and safe topical steroid with BID dosing would be a significant benefit in the management of patients following ocular surgery





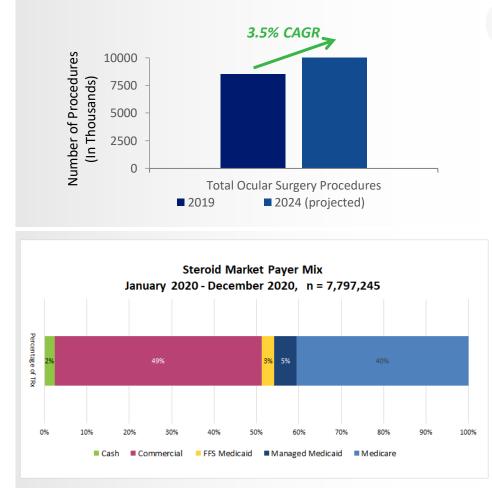




#### The Ocular Surgery Market is Large and Expected to Continue to Grow

- ~8.6M ocular surgery procedures in 2019 in the U.S.; projected to grow at a CAGR of 3.5% through 2024<sup>1</sup>
- Branded products currently account for ~17% of prescriptions and ~41% of gross sales<sup>2</sup>
- At current branded prices, the market is estimated to be valued at ~\$1.9B<sup>2</sup>
- ~6,600 Eye Care Professionals (ECPs) account for 74% of the target surgical business and over 99% of INVELTYS business<sup>3</sup>
- Steroid market payer mix was 51% Commercial/Cash and 40% Medicare<sup>4</sup>

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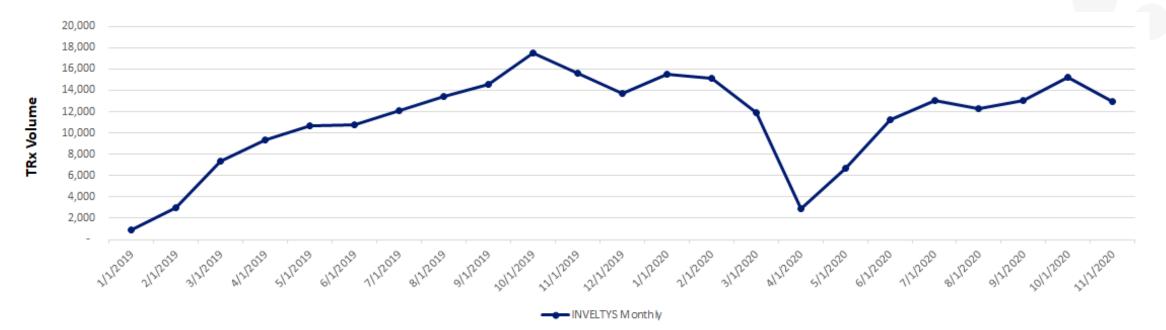


US Ocular Surgery Procedures, 2019-2024

1. Ocular Surgery Procedures: Market Scope US Procedures 2019, impact on growth rate expected in 2020 due to COVID-19; 2. Symphony PHAST December 2019-November 2020; 3. Symphony METYS and Symphony Prescriber December 2019-November 2020; 4. Payer Mix based on BusinessOne claims data January 2020-December 2020; Prescriber-level data:Symphony PHAST January 2020-December 2020; Ocular Steroid Market includes INVELTYS, Prednisolone Acetate, Pred Forte, Lotemax, Durezol, FML, Alrex, Flarex, Flourometholone, Loteprednol Etabonate and Dexamethasone. Note: Commercial includes: TriCare, VA, PBM,Coupon,and Other third party.



#### Strong INVELTYS Recovery Post 2Q-20 COVID-19 Impact



- Q1 INVELTYS TRxs were trending to grow 4% quarter over quarter (Jan/Feb) prior to COVID-19 impact
  - During this time the overall ocular steroid market was trending down ~2% and branded steroid eye drops down 14.1%
- Q2 INVELTYS decreased 53% (NRx) and 51% (TRx) vs Q1 due to deferral of ocular surgeries caused by the COVID-19 pandemic
  - Beginning in late April ocular surgeries recommenced in many parts of the country
- Q3 INVELTYS exceed Q2 by 91% (NRx) and 84% (TRx) with strong recovery from COVID-19 impact





# **Development-Stage Programs**



#### Significant Unmet Need Remains for Effective Therapies to Treat Retinal Disorders



#### Age-related Macular Degeneration

A leading cause of irreversible blindness and visual impairment worldwide



# **288M**



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Number of people living with macular degeneration is expected to reach **288 million** worldwide by **2040**<sup>1</sup>

# **22M**

**By 2050**, an estimated **22 million Americans** are expected to have some form of macular degeneration<sup>1</sup>

Diabetic Retinopathy and Diabetic Macular Edema (DME)

The leading cause of vision loss in working adults



#### **93M** Approximately **93 million**

**people worldwide** have diabetic retinopathy<sup>2</sup>

# **16M**

Number of **Americans** with diabetic retinopathy is expected to grow to **16 million by 2050**<sup>2</sup> Retinal Vein Occlusion (RVO)

Second most common cause of vision loss due to retinal vascular disease



# **16.4M**

**Globally**, an estimated **16.4 million** adults are affected by RVO<sup>3</sup>

# **1.26M**

Estimated number of patients with retinal vein occlusion in the US<sup>4,5</sup>



American Diabetes Association. https://care.diabetesjournals.org/content/35/3/556. Published March 2012. Accessed January 4, 2021.
 National Institutes of Health. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5178091/. Published December 2016. Accessed January 4, 2021.
 National Library of Medicine. https://pubmed.ncbi.nlm.nih.gov/20022117/. Published February 2010. Accessed January 6, 2021.

4. Rogers S et al Ophthalmology 2010, 117(2): 313-9.

5. US Census Data 2020 www.census.gov Accessed Jan 9, 2021



Internal Pipeline

Proprietary NCE development programs targeted to address front and back of the eye diseases

	Discovery	Lead Optimization	Candidate Selection	Formulation Development	IND- Enabling Studies
<b>Tyrosine Kinase Inhibitor</b> Retinal diseases, including wet AMD, DME, and RVO					
KPI-285: Topical Formulation					
KPI-286: Depot Formulation					
<b>KPI-333: Surface Targeting Steroid (STS)</b> Ocular surface diseases					
<b>KPI-415: Selective Glucocorticoid Receptor Modulator (SEGRM)</b> Retinal diseases, including wet AMD, DME, and RVO; ocular surface diseases					

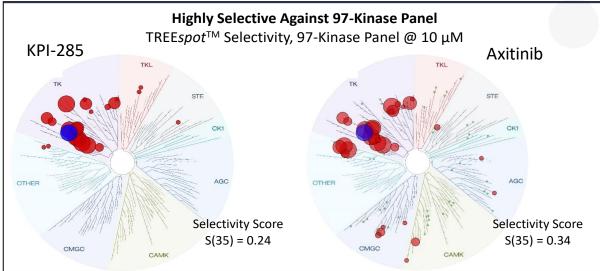


## Potent and Selective NCE Tyrosine Kinase Inhibitor (TKI)



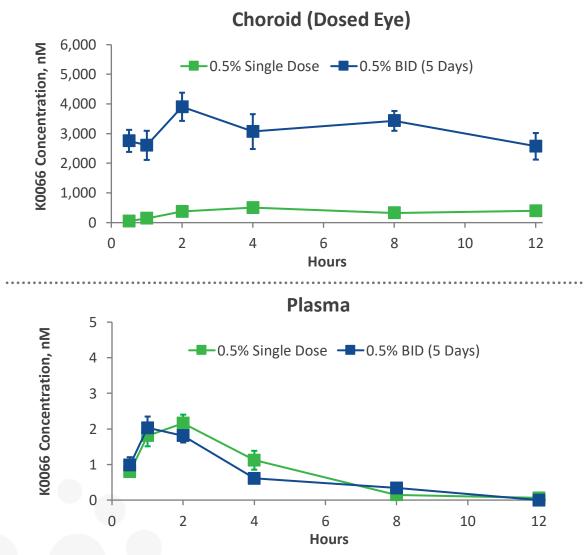
#### Proprietary Potent and Selective NCE Tyrosine Kinase Inhibitor (TKI) for Treatment of Age-Related Macular Degeneration (AMD) and Other Retinal Diseases

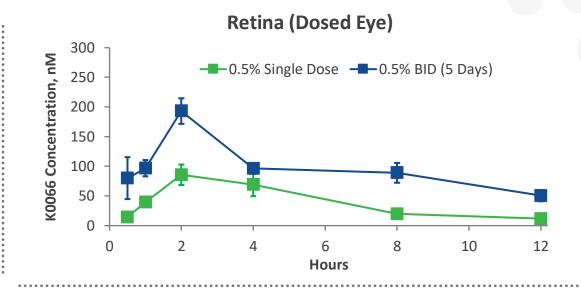
- >100 NCEs synthesized and characterized
- Highly selective and potent lead compound identified
- Compelling preclinical PK and efficacy data generated with topical delivery (KPI-285)
  - Significant drug concentrations achieved in retina and choroid
  - Comparable efficacy to intravitreal Avastin in relevant animal model
  - Topical program (KPI-285) is ready to enter INDenabling studies
- Injectable depot delivery for sustained delivery (KPI-286) currently in formulation development



<b>Potent VEGFR-2 Inhibitor</b> HUVEC IC50: 0.2 ± 0.1 nM (n=6)					
Target	Kd (nM)				
KDR (VEGFR-2)	0.5				
FLT1 (VEGFR-1)	0.8				
FLT4 (VEGFR-3)	6.2				
PDGFRB	1.3				
PDGFRA	0.2				

#### KPI-285 Delivers Significant Levels to the Retina and Choroid in Rabbits

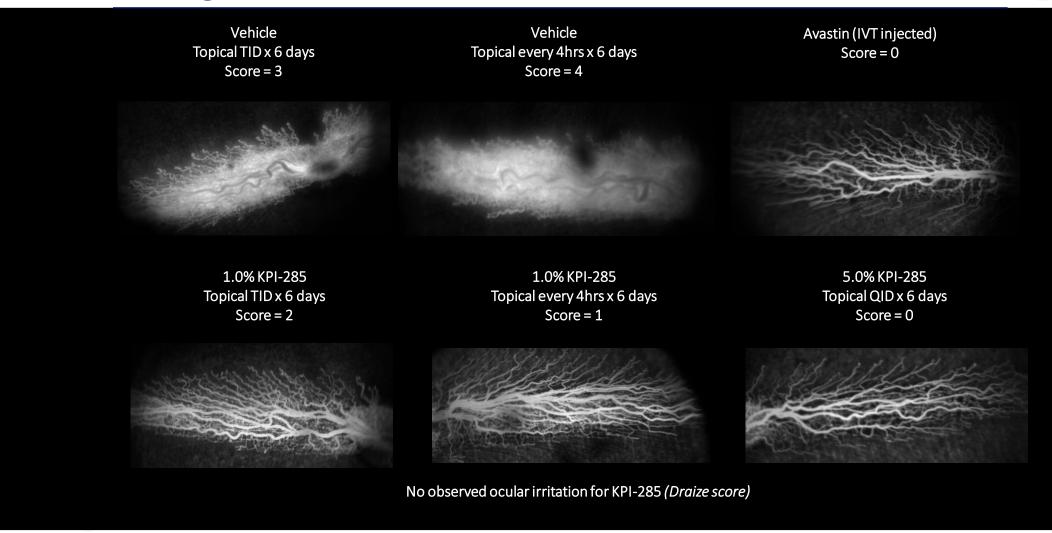




- MPP delivered back-of-eye concentrations well above IC<sub>50</sub>
  - Tissue to plasma ratio ~40–400 fold
  - Multi-day dosing (5 days BID) vs. single dose results in:
    - 8-fold higher choroid levels
    - 2-fold higher retina levels

- Little-or-no change in plasma levels

# KPI-285 Demonstrates Similar Efficacy to IVT Avastin in a Rabbit VEGF-induced Vascular Leakage Model





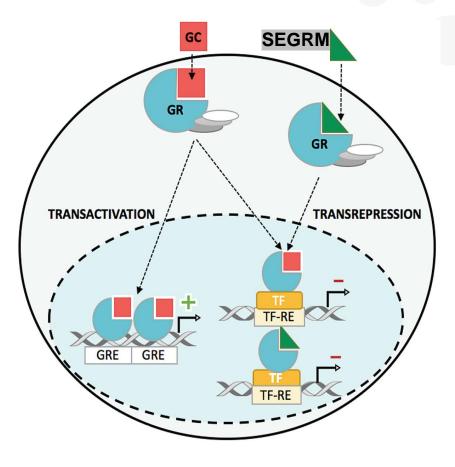
### KPI-415: Selective Glucocorticoid Receptor Modulators (SEGRM)



#### SEGRMs (Selective Glucocorticoid Receptor Modulators)

Novel Anti-inflammatory Compounds to Address Significant Unmet Needs in Ophthalmology and Systemic Diseases

- Activation of glucocorticoid receptor (GR) can result in regulation of gene expression along both the transactivation (TA) and transrepression (TR) pathways
- Considerable evidence that the TR pathway alone is sufficient for anti-inflammatory and immunomodulatory activity
- The TA pathway is thought to be responsible for the untoward effects associated with ocular and systemic administration of corticosteroids
  - Elevated IOP, hypertension, osteoporosis, skin atrophy, etc.
- SEGRMs:
  - Novel class of compounds designed to selectively regulate gene expression through the TR pathway, avoiding the TA pathway
  - Potential for comparable anti-inflammatory activity to the corticosteroid class of therapies without their associated side effects





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#### Kala Advancing Toward Lead SEGRM Candidate

- Kala SEGRM program focused on developing novel NCEs that specifically target the TR pathway of the glucocorticoid receptor
  - Will address key unmet needs in both ophthalmic and systemic disease
- Target profile Novel glucocorticoid receptor modulator with:
  - Potent anti-inflammatory and immunomodulatory effect with favorable therapeutic index
  - Favorable side effect profile, devoid of typical steroid side effects with both ocular and systemic administration
  - Ability to be safely administered long-term
- Good progress on program to date:
  - Promising *in vitro* selectivity data on several NCEs
  - Good separation of transrepression (TR) and transactivation (TA) effects
  - Program currently in Lead Optimization phase
  - Promising candidates moving into in vivo testing in 1Q 2021; targeting a lead compound by year-end 2021
- SEGRM product candidates also have potential to be developed for non-ophthalmic disease
- Kala owns all IP and WW rights



# KPI-333: Surface Targeted Steroid (STS)



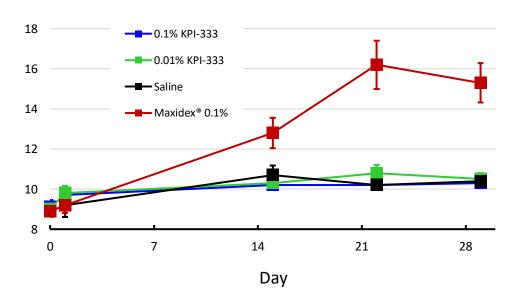
#### The Need for a Surface Targeted Steroid (STS)

- Corticosteroids are potent inhibitors of ocular surface inflammation
  - However long-term use is limited by significant untoward effects such as elevated IOP and cataract formation
  - These adverse events are mediated by absorption of the steroid into the aqueous humor and subsequent penetration into the trabecular meshwork and lens
- A topical steroid that targets the ocular surface without significant absorption into the aqueous humor could overcome the safety issues associated with long-term use of steroids
- A unique combination of potent anti-inflammatory activity, rapid onset of action and absence of impact on IOP and cataract would address a key unmet need for chronic management of ocular surface inflammation
- Kala is developing KPI-333, an NCE which has demonstrated the potential to be an effective STS in preclinical studies
- KPI-333 has the potential to address the significant unmet need for an effective chronic treatment of ocular surface inflammation associated with diseases such as dry eye

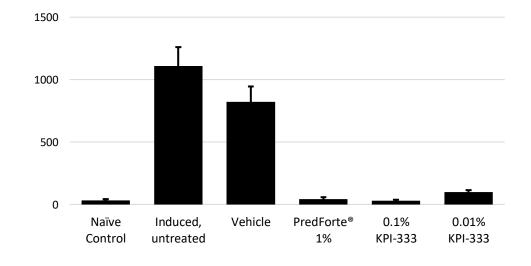


#### Topical Administration of KPI-333 Demonstrates Strong Anti-inflammatory Activity Without Inducing IOP Elevation in Validated Animal Models

- No IOP elevation after repeated topical administrations to rats (BID for 28 days)
- Comparable efficacy to PredForte<sup>®</sup> 1% in an allergic conjunctivitis mouse model despite 10–100×-fold lower doses







Eosinophil Density in Conjunctival Tissues (median cells/mm2)



#### Kala is Positioned to be a Leader in Ophthalmics



- First and only prescription therapy specifically for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease
- 75-90% of dry eye patients suffer from short-term, episodic flares
- Approved by FDA on October 26, 2020 with U.S. promotional launch in January 2021

INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%

Experienced Ophthalmic Team

#### Promising Pipeline Candidates

Strong Financial Position safety profile comparable to vehicle and approved for BID dosing
Approved by FDA in August 2018 with U.S. launch in January 2019

First and only post-surgical steroid with combination of powerful efficacy, a

- Deep experience in clinical development, commercial and medical affairs across multiple ophthalmic brands
- Expanded ophthalmic sales team deepens experience in dry eye and across overall eye care space
- Advancing multiple NCE development programs targeted to address front and back of eye diseases
- Expected to report cash, cash equivalents and short-term investments of \$153.5 million as of December 31, 2020
- Existing cash, cash equivalents and short-term investments, along with sales of INVELTYS, anticipated to enable funding of operations into at least the fourth quarter of 2022
- Revenue generated from sales of EYSUVIS will provide additional cash runway



# kala.... PHARMACEUTICALS

# **Thank You**