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# KODIAK

THE OPHTHALMOLOGY MEDICINES COMPANY

Corporate Presentation February 2021

# FORWARD-LOOKING STATEMENTS

These slides contain forward-looking statements and information. The use of words such as "may," "might," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements regarding our 2022 Vision; our ability to submit a BLA for KSI-301 in wet AMD, DME, RVO and potentially diabetic retinopathy in 2022; the potential licensure of KSI-301 in the U.S. and EU in 2023; our platform technology and potential therapies; future development plans; clinical and regulatory objectives and the timing thereof; the anticipated design of our clinical trials and regulatory submissions; expectations regarding the potential efficacy and commercial prospects of our product candidates; the anticipated presentation of additional data; the results of our research and development efforts; and our ability to advance our product candidates into later stages of development and potential commercialization. All forward-looking statements are based on management's current expectations, and future events are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the safety, efficacy and durability data for our KSI-301 product candidate may not continue or persist; cessation or delay of any of the ongoing clinical studies and/or our development of KSI-301 may occur, including as a result of the ongoing COVID-19 pandemic; future potential regulatory milestones of KSI-301, including those related to current and planned clinical studies may be insufficient to support regulatory submissions or approval; anticipated presentation of data at upcoming conferences may not occur; our research and development, efforts and our ability to advance our product candidates into later stages of development may fail; any one or more of our product candidates may not be successfully developed, approved or commercialized; adverse conditions in the general domestic and global economic markets, including the ongoing COVID-19 pandemic, which may significantly impact our business and operations, including out of our headquarters in the San Francisco Bay Area and our clinical trial sites, as well as the business or operations of our manufacturers, contract research organizations or other third parties with whom we conduct business; as well as the other risks identified in our filings with the Securities and Exchange Commission. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent Form 10-O, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. Any forward-looking statement speaks only as of the date on which it was made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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#### KODIAK SCIENCES

WHERE WE

ARE TODAY



4 ONGOING PIVOTAL TRIALS

### 3 INDICATIONS

**SINGLE** BLA FILING EXPECTED IN 2022

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## KSI-301 CLINICAL EXPERIENCE

Clinical data from ~2,000 injections in ~500 patients representing ~350 patient-years of exposure in representative populations in wAMD, DME and RVO

- Safety: Tracking with current standard of care (Lucentis, Eylea)
- Efficacy: Vision & retinal anatomy improvements in line with current anti-VEGF agents
- Durability: 2 in every 3 patients going 6-months or longer between doses in wet AMD, DME and RVO

### OPTIMIZED PIVOTAL STUDY PROGRAM

Objective to show disruptive durability with same safety and efficacy as Eylea

DAZZLE wet AMD study enrollment complete; BEACON RVO study and GLEAM & GLIMMER DME now enrolling – Data from all studies expected in 2022

Pivotal studies designed from phase 1b data with high dose (5.0 mg), high statistical power, tighter criteria for disease activity assessments, tighter dosing interval ranging, maintaining similar (80%+) U.S. treatment naïve population

### OPERATING WITH CONVICTION

On track for a single BLA filing in the key indications of wAMD, DME, RVO treatment and with NPDR indication in a supplemental

Manufacturing investments aligned to clinical opportunity with commercial supply goal of 2.5M+ Prefilled Syringes in Year 1 of launch

Developing bispecific and triplet ABC Medicines for multi-mechanism diseases, including dry AMD and glaucoma

## POISED COMMERCIAL OPPORTUNITY

Competitive landscape is clearing with competing molecules/technologies demonstrating poor risk-benefit profiles

We believe KSI-301 may be able to capture market share from standard of care agents, future biosimilars, and competing late-stage molecules in development

#### THE OPHTHALMOLOGY MEDICINES COMPANY

## OUR MISSION



TRAILBLAZING SCIENCE

Our creative and thoughtful foundation



### 2 GENERATION 2.0 MEDICINES

Our challenge to the status quo



## **3** SINGULAR FOCUS IN OPHTHALMOLOGY

Our 24 / 7 / 365

#### KODIAK

A PIPELINE OF ABCs FOR RETINA

Kodiak's deepening pipeline of mono-, bi-specific and triplet inhibitors that merge biologics with small molecules to address major causes of vision loss beyond retinal vascular disease

#### MONOSPECIFIC

### 1 Molecule, **1 Target**

Antibody conjugated to phosphorylcholine biopolymer

**KSI-301** inhibits VEGF— In Phase 3 clinical development

### BISPECIFIC

## 1 Molecule, **2 Targets**

Bispecific antibody conjugated to phosphorylcholine biopolymer

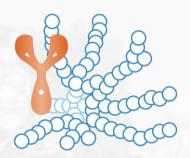
**KSI-501** inhibits VEGF and IL-6 for retinal diseases with inflammatory component - IND planned 2021

### TRIPLET

### 1 Molecule, **3 Targets**

Bispecific antibody conjugated to phosphorylcholine biopolymer embedded with 100's of copies of smallmolecule drug

**KSI-601** for high-prevalence multifactorial diseases, such as dry AMD - IND planned 2022







#### THE OPHTHALMOLOGY MEDICINES COMPANY

## FOCUSED ON DEVELOPING ABC MEDICINES FOR HIGH PREVALENCE RETINAL DISEASES



#### KSI-301 AND KSI-501 FOR RETINAL VASCULAR DISEASES

#### A GROWING \$11B MARKET WITH CLEAR UNMET NEEDS

- · Wet age-related macular degeneration (wet AMD) remains a leading cause of blindness in the elderly
- Diabetes is the leading cause of blindness in working-age adults
- Novel agents such as KSI-301 are needed to provide long treatment-free durability and/or improve response to therapy
- KSI-501 targets both VEGF & Interleukin-6; supplemental targeting of retinal microvascular inflammation through Interleukin-6 may be of additional clinical benefit

#### **KSI-601 TRIPLETS FOR DRY AMD**

#### DRY AMD IS 10 TIMES MORE PREVALENT THAN WET AMD AND HAS NO AVAILABLE THERAPIES

- Dry AMD frequently leads to irreversible vision loss and substantial functional vision limitations
- There are no available therapies for dry AMD; drugs targeting single pathways have repeatedly yielded no / limited efficacy
- Targeting multiple biological pathways both intracellular and extracellular as enabled by our triplet inhibitor technology may be required to achieve meaningful treatment for complex multifactorial diseases such as dry AMD
- Durability of a potential treatment will be key due both to chronic nature of the disease and size of the patient population and will be enabled by ABC Platform based triplets

#### **TRIPLETS FOR THE NEURODEGENERATIVE ASPECTS OF GLAUCOMA**

#### GLAUCOMA IS A LEADING CAUSE OF IRREVERSIBLE BLINDNESS WORLDWIDE

- Many patients experience progression of glaucoma and lose vision over time despite maximum medical therapy
- Available therapies today treat intraocular pressure, not the fundamental biology of retinal neural cell loss which is multifactorial in nature
- Our triplets technology is designed to target multiple intra- and extracellular pathways implicated in the neurobiology of glaucoma
- Durability of potential treatment will be key and will be enabled by ABC Platform based triplets



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## IN THEORY

Intravitreal anti-VEGF agents improve & maintain vision when dosed per label...

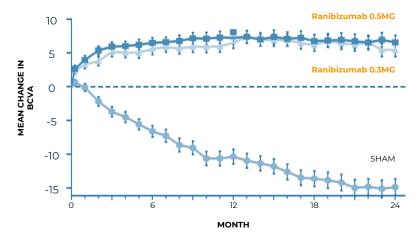
## Recommended dosing in first year:

Ranibizumab 12 monthly

### Aflibercept

bi-monthly after 3 monthly loading doses

#### PHASE III STUDY OF MONTHLY ANTI-VEGF 1



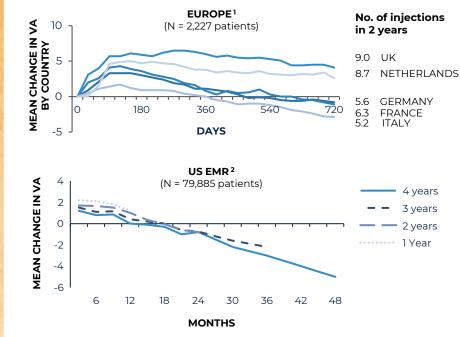
1. Rosenfeld PJ et al; MARINA Study Group. N Engl J Med. 2006;355:1419-14313.

## IN PRACTICE

...yet in the real word, visual gains are minimal and not maintained.

Patients cannot be treated frequently enough and are overextended between doses in the real world. Without continuous high-intensity treatment, vision loss can begin after only 3 months of anti-VEGF therapy.

This pattern is seen globally and with all current medicines.



1. The AURA Study, adapted from Holz FG et al. Br J Ophthalmol 2015; 99 (2): 220-226.

2. Adapted from SIERRA-AMD, Khanani A, et al. Ophthal. Retina 2020 Feb; 4(2):122-123. EMR= Electronic Medical Records

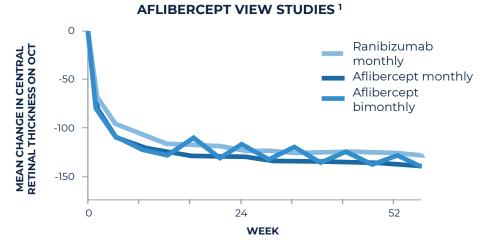
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## WHY?

Current, Generation 1.0 agents do not provide disease control for long enough between doses.

Undertreatment leads to disease progression and permanent retinal damage. Bimonthly anti-VEGF therapy results in disease activity between doses due to insufficient durability.



## WHAT PROFILE MAY BE REQUIRED TO MEANINGFULLY CHANGE THE CURRENT PARADIGM?

	Durability -		7		
Profile	Maintenance Phase	Loading Phase	Efficacy Profile	Safety Profile	
5 to 6 months predominant	<b>wAMD:</b> >50% reach Q20W			Safety profile is in line	
	<b>DME:</b> >50% reach Q20W		wAMD, DME, and RVO: Non- inferior to comparator		
	RVO: Non-inferior with Q8W	≤ 3 loading doses	NPDR: 2 step change and / or ranibizumab lower event rate	with aflibercept and ranibizumab	
	<b>NPDR:</b> Compelling efficacy at 2x / year				
4 to 5 months predominant	wAMD: >50% reach Q16W or better		WAND DME and DVO: Non		
	DME: >50% reach Q16W or better	< 7 loading docos	wAMD, DME, and RVO: Non- inferior to comparator	Safety profile is in line with aflibercept and ranibizumab	
	<b>RVO:</b> Non-inferior with Q8W	≤ 3 loading doses	<b>NPDR:</b> 2 step change and / or lower event rate		
	<b>NPDR:</b> Compelling efficacy at 3x / year		lower event rate		
3 to 4 months predominant	<b>wAMD:</b> 33% Q8W, 33% Q12W, 33% Q16W				
	DME: >50% better than Q12W	≥ 3 loading doses	wAMD, DME, and RVO: Non- inferior to comparator	Safety profile may be	
	<b>RVO:</b> Non-inferior with Q8W	≥ s loading doses	NPDR: 2 step improvement	worse than aflibercept and ranibizumab	
	<b>NPDR:</b> Compelling efficacy at 4x / year				

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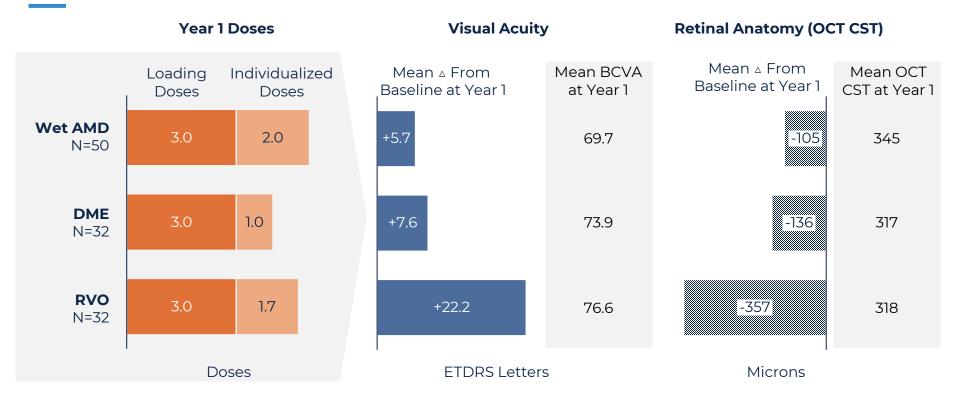
## **DISRUPTIVE DURABILITY WITH AN INTRAVITREAL BIOLOGIC:**

2/3 OF PATIENTS ON A ≥6-MONTH TREATMENT-FREE INTERVAL AT YEAR 1 IN WET AMD, DME AND RVO

	Interval at Year 1	<b>Wet AMD</b> <i>N = 50</i>	<b>DME</b> N = 32	<b>RVO</b> N = 32
	1 month	2%	3%	3%
	2 months	14%	3%	9%
	3 months	6%	9%	13%
	4 months	4%	6%	6%
	5 months	8%	9%	3%
2 in every 3 patients are on a	≥6 months	66%	69%	66%
6-month or longer treatment- free interval at Year 1, after only 3 loading doses	Mean # Injections during Year 1	<b>5.0</b> (3 loading + 2.0 individualized)	<b>4.0</b> (3 loading + 1.0 individualized)	<b>4.7</b> (3 loading + 1.7 individualized)
arter only 5 loading doses	Safety and e	fficacy data in line w	/ith today's first-line	medicines

Phase 1b interim data. 2.5 & 5 mg doses pooled. Includes only patients that received all (3) loading doses and either a) received a dose before Week 52 or b) did not receive a dose and were followed for at least six months after the last loading dose (Week 32 visit). Interval at Year 1 reflects the treatment interval ongoing at the Week 52 visit (where available) or the last interval before Week 52.

## YEAR 1 DATA: EFFICACY ALIGNED WITH TODAY'S MEDICINES WITH MEANINGFULLY FEWER INJECTIONS

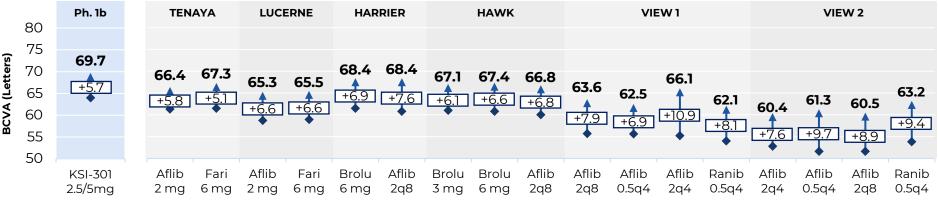


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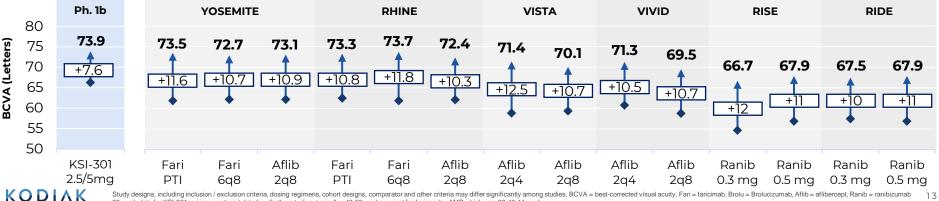
Interim data; 2.5 & 5 mg doses pooled. Observed data, includes only patients that received all (3) loading doses and reached Week 12 or later. Individualized doses reflect the number of injections received per patient between Week 12 and 48 inclusive. OCT CST site reported and includes the PED height for wet AMD. CST= central subfield thickness.

#### TA: VISION IMPROVEMENTS SEEN IN ANTI-VEGF STUDIES ARE YFA DEPENDENT ON BASELINE VISION

#### WET AMD $\sim Y E A R$ BCVA



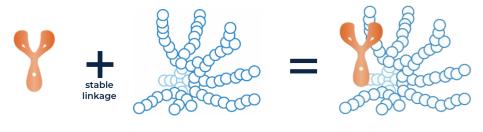
#### DME YEAR BCVA Т.



Study designs, including inclusion / exclusion criteria, dosing regimens, cohort designs, comparator and other criteria may differ significantly among studies, BCVA = best-corrected visual acuity, Fari = faricimab, Brolu = Brolucizumab, Aflib = aflibercept, Ranib = ranibizumab 13 52 week data for KSI-301: primary

## ANTIBODY BIOPOLYMER CONJUGATE ABC PLATFORM

Biologics precision-engineered for increased durability and efficacy



#### ANTIBODY

laG1 with inert immune effector function

#### BIOPOLYMER

Optically clear, high molecular weight phosphorylcholine polymer CONJUGATE

Antibody and biopolymer covalently bound via single site-specific linkage



micro-environment









Zero-friction



## docking



Stereospecific

### SAME WHERE IT MATTERS

- Clinically proven targets
- Antibody-based biologic
- Intravitreal: 25M+ injections annually
- Optically clear, no residues
- Fast and potent clinical responses

### **DIFFERENT WHERE IT COUNTS**

- Designed-in ocular durability
- Designed-in rapid systemic clearance
- Improved bioavailability
- Improved biocompatibility
- Improved stability

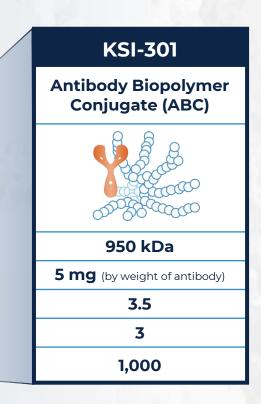
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#### KSI-301: AN ANTI-VEGF ABC

## GENERATION 2.0 ANTI-VEGF

KSI-301's high molecular weight & formulation strength can provide an important dosing advantage

Drug:	RANIBIZUMAB (Lucentis)	AFLIBERCEPT (Eylea)	BEVACIZUMAB (Avastin)
Molecule type	Antibody fragment	Recombinant fusion protein	Antibody
Molecular structure	٩	8	Y
Molecular weight	48 kDa	115 kDa	149 kDa
Clinical dose	0.3-0.5 mg	2 mg	1.25 mg
Equivalent molar dose	0.5	1	0.9
Equivalent ocular PK	0.7	1	1
Equivalent ocular concentration at 3 months	0.001	1	NA <sup>1</sup>



Equivalent values are showed as fold changes relative to aflibercept. kDa= kilodalton 1. Lower affinity of bevacizumab precludes a useful comparison

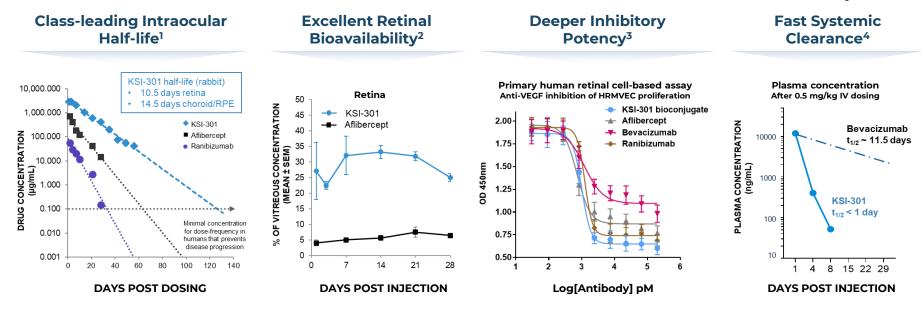
## **KSI-301 ANTIBODY BIOPOLYMER CONJUGATE** "MORE THAN THE SUM OF ITS PARTS"





Artistic representation of KSI-301

Electron microscope image of KSI-301



1. Data from rabbit model. Ranibizumab data: Gaudreault et al (2007) IOVS 46(2) 726 Gaudreault et al (2007) Retina 27(9) 1260 Bakri et al (2007) Ophthalmol 114(12) 2179 || Aflibercept data: EVER Congress Portoroz Slovenia (2008) Struble (Covance) Koehler-Stec (Regeneron). Aflibercept data adjusted arithmetically to reflect 2,000 µg dose administered (based on rabbit in vivo dosing of 500 µg) || KSI-301 data on file, adjusted arithmetically to reflect 5,000 µg dose administered (based on rabbit in vivo dosing of 725 µg). Error bars reflects standard error of the mean

2. Covance rabbit ADME (absorption, distribution, metabolism, elimination) model: Aflibercept data (2008): EVER Congress Portoroz Slovenia Struble (Covance), Koehler-Stec (Regeneron). KSI-301 data (2017): Covance study, data on file. Error bars reflects standard error of the mean

KSI-301 data: data on file; Bevacizumab data: Yeung et al 2010 Cancer Research.

KODIAK 4. KSI-301 data: Non-human primate toxicology study, data on file; Bevacizumab data: Yeung et al 2010 Cancer Research.

## OUR GOAL WITH KSI-301

Develop KSI-301 as a meaningfully differentiated first-line treatment in each retinal vascular disease Better meet the individual needs of key stakeholders globally



**Retina Practice Owner** 





## We are developing KSI-301 to be first line in the 4 major retinal vascular diseases

Target enrollment exceeded Recruitment closed	<b>Now Re</b> First patients randomized in Gl	<b>cruiting</b> LEAM / GLIMMER and BEACON	Enrollment Start 1H 2021 Planned	
Wet AMD	Diabetic Macular Edema Retinal Vein Occlusion		Non-Proliferative Diabetic Retinopathy	
DAZZLE Study (n~550)	GLEAM and GLIMMER Studies (n~450 each)	BEACON Study (n~550)	GLOW Study (n~240)	
KSI-301 <b>once every 3, 4 or 5 months</b> after 3 monthly doses	KSI-301 <b>once every 2 to 6 months</b> after 3 monthly doses	KSI-301 once every 2 months or longer after 2 monthly doses	KSI-301 <b>once every 6 months</b> After 3 initiating doses	
<b>Comparator</b> Aflibercept <b>Once every 2 months</b> after 3 monthly doses	<b>Comparator</b> Aflibercept <b>Once every 2 months</b> after 5 monthly doses	Comparator Aflibercept Once every month	<b>Comparator</b> Sham	

KSI-301 pivotal studies enroll treatment-naïve patients and incorporate key learnings from our Phase 1b study, supporting a high level of confidence in our KSI-301 development program

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#### **KSI-301 COMMERCIAL MANUFACTURING**

## BUILDING CAPACITY TO SUPPLY RAPID MARKET UPTAKE

Expected Year 1 manufacturing capacity to supply 2.5M+ doses with the ability to flex up to 15M+ doses

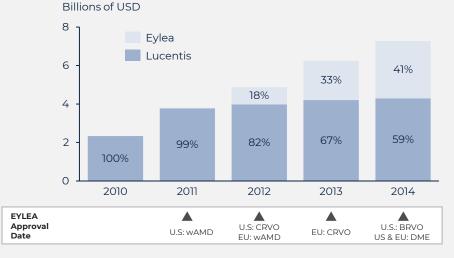
Integrated global pharmaceutical supply chain

Purpose-built Lonza IBEX Dedicate bioconjugation
 facility to support commercial launch

#### Case study on market adoption

Worldwide anti-VEGF revenue

Can Eylea market share growth educate KSI-301 adoption?



Kodiak aims to submit a single BLA for KSI-301 in wet AMD, DME and RVO in calendar year 2022

Company financial disclosures and product labeling

#### KODIVK

## **OUR 2022 VISION**

### **RETINAL VEIN OCCLUSION**

2022 BEACON Phase 3 top-line data 2022 BLA filing

### WET AMD

2022 DAZZLE Phase 2b/3 top-line data 2022 BLA filing

### DIABETIC MACULAR EDEMA

2022 GLEAM / GLIMMER Phase 3 top-line data 2022 BLA filing 2022 THE OPHTHALMOLOGY

MEDICINES COMPANY

## KSI-501 anti-VEGF/IL-6

2021 IND submitted 2022 Phase 1a/1b data

### DIABETIC RETINOPATHY

2023 GLOW Phase 3 top-line data





## KSI-601 Triplet Inhibitor for dry AMD

2022 IND submitted

Indications submitted in
 BLA (wAMD, DME and RVO)



**Clinical molecules** 

IND per year beginning 2021

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## MILESTONES AND KSI-301 DEVELOPMENT ACCELERATION

#### 2019

#### KSI-301

- Safety, efficacy, durability proof-of-concept established
- Initiation of DAZZLE wAMD pivotal study
- FDA EOP2 meeting
- \$225MM royalty financing
- ✓ \$317MM equity financing

### 2020

#### KSI-301

Achieved

- Additional readouts of Phase 1b data
- Maturation of data support pivotal clinical studies
- Manufacturing framework to supply millions of doses in first year of launch
- Initiate two DME Phase 3 trials (GLEAM & GLIMMER)
- Initiate RVO Phase 3 trial (BEACON)
- Complete enrollment in wAMD (DAZZLE)
- **\$645MM equity financing**

### 2021

#### KSI-301

- Presentation of one-year
  Phase 1b results in wet
  AMD, DME and RVO
- Initiate NPDR Phase 3 trial (GLOW)
- Complete enrollment in DME (GLEAM & GLIMMER) and RVO (BEACON) studies
- DAZZLE wet AMD last patient last visit for primary endpoint
- KSI-501 (bispecific ABC)
- Submit IND

## 2022

#### KSI-301

- DAZZLE wAMD pivotal study top-line readout
- RVO pivotal study (BEACON) top-line readout
- DME pivotal studies (GLEAM & GLIMMER) topline readouts
- Submit BLA for wAMD, DME and RVO

#### KSI-501

 Phase 1/2 data in inflammatory retinal diseases

KSI-601 (triplet ABC) for dry AMD

Submit IND

### 2023

#### KSI-301

Potential regulatory approval for wAMD, DME and RVO in US and EU

- Potential commercial launch for wAMD, DME, RVO in US
- DR pivotal study (GLOW) readout
- Submit sBLA for DR pivotal study (GLOW)
- KSI-501
- Additional readouts of Phase 1/2 data
- KSI-601
- Initiate Phase 1/2 study

#### Potential Milestones 2021 - 23

## **KSI-301 Accelerated Development Strategy**

4 Pivotal Studies to support BLA with All 3 Major Anti-VEGF Indications Run Concurrently

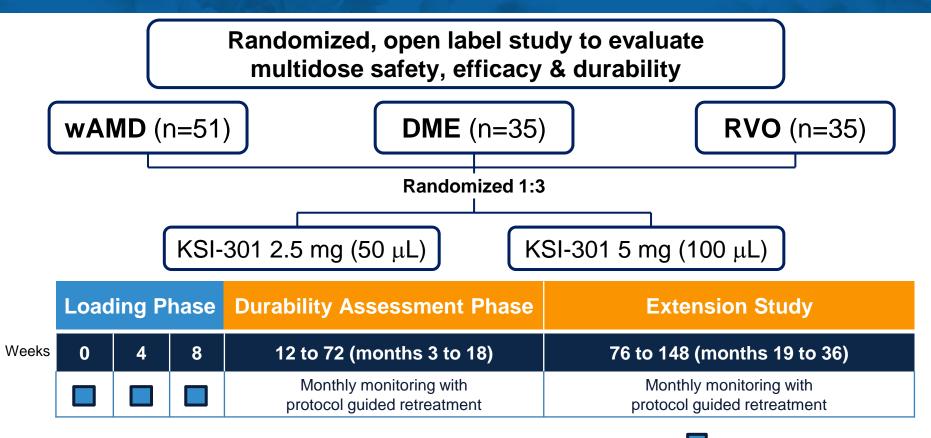
	2019	2020	Today Z021	20	22	2023
Phase 1b Ongoing	121 treatment-naïve wAMD, DMI Safety, efficacy, durability - 18 m					
DAZZLE Pivotal wAMD Target Enrollment Exceeded	012W	treatment naïve patients /-Q20W KSI-301 vs Q8W Eylea	12-month endpoi	nt		
GLEAM DME Phase 3 <i>Recruiting</i>			atment naïve pts. 4W KSI-301 Eylea	) 12-month endpoint	Single BLA	U.S. commercial launch
GLIMMER DME Phase 3 <i>Recruiting</i>			atment naïve pts. 4W KSI-301 Eylea	) 12-month endpoint	2022	
BEACON RVO Phase 3 <i>Recruiting</i>		or CRVO	atment naïve BRVO patients I-301 vs Q4W Eylea	6-month endpoint		
GLOW DR without DME Phase 3 In Planning			~240 patient Q24W KSI-30 injections vs	01 after 3 initiation	12-month end	dpoint sBLA 2023

## **KSI-301**

# **Clinical Data**

130 patients dosed in Phase 1a/1b Program 168+ patient years of clinical experience

## **KSI-301** Phase 1b Study Design



wAMD = wet age-related macular degeneration; DME = diabetic macular edema; RVO = retinal vein occlusion; Clinicaltrials.gov ID: NCT03790852

## **KSI-301** Phase 1b Retreatment Criteria

## wAMD

- − Increase in CST ≥75  $\mu$ m with a decrease in BCVA of ≥ 5 letters compared to Week 12, OR
- Decrease in BCVA of > 5 letters compared to Day 1, due to worsening wAMD activity, OR
- Decrease in BCVA of  $\geq$  10 letters compared to the best prior BCVA, due to worsening wAMD activity, OR
- 6 months have elapsed since the last retreatment

## DME and RVO

- − Increase in CST ≥75 µm with a decrease in BCVA of ≥ 5 letters compared to Week 12 or the prior visit, OR
- Decrease in BCVA of ≥ 10 letters compared to the best prior BCVA, due to worsening DME/RVO disease activity

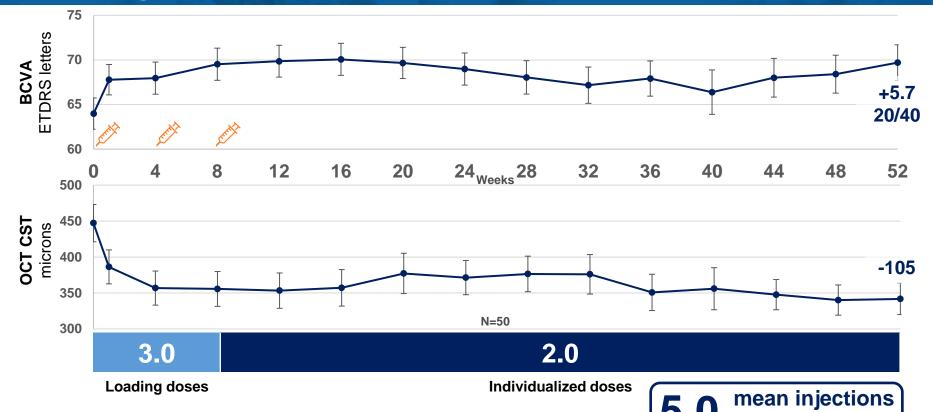
# For all subjects, investigators can retreat at their discretion if significant disease activity is present that does not meet the above criteria

## **Baseline Characteristics**

Variable	wAMD Cohort (n=51)	DME Cohort (n=35)	RVO Cohort (n=35)
Age, mean (SD), years	77.9 (10.5)	59.7 (11.7)	63.6 (12.6)
Gender, n (%), female	32 (62.7)	14 (40.0)	13 (37.1)
Race, n (%), White	48 (94.1)	28 (80.0)	31 (88.6)
BCVA, mean (SD), ETDRS letters	63.3 (13.3)	66.8 (10.2)	54.9 (15.4)
Snellen equivalent	~20/50	~20/50	20/80
Snellen 20/40 or better, n (%)	20 (39.2)	16 (45.7)	6 (17.1)
OCT CST, mean (SD), microns	450 (182)	453 (110)	675 (237)

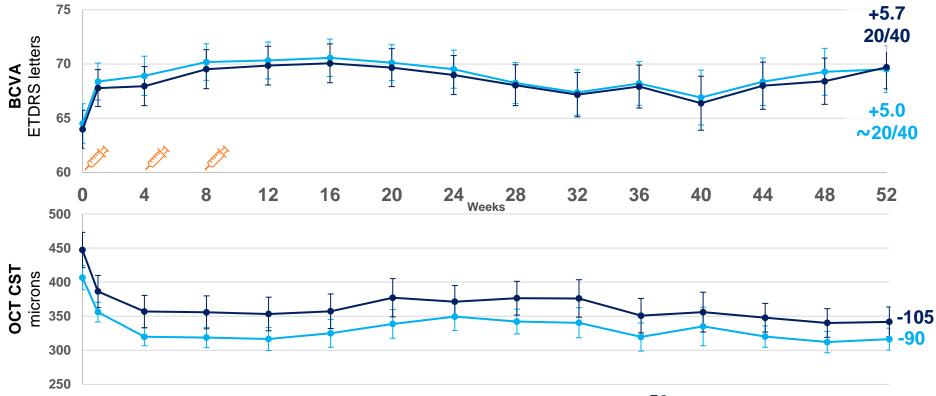
KSI-301 Phase 1b wAMD Year 1 Data

## Efficacy of KSI-301 in Wet AMD Change from baseline to Week 52 in mean BCVA & OCT



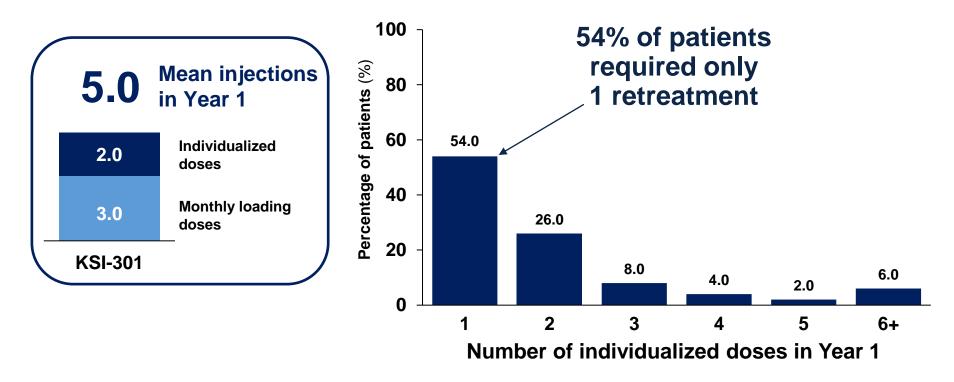
Interim data; 2.5 & 5 mg doses pooled. Observed data, includes only patients that received all (3) loading doses and reached Week 12 or later. Error bars represent standard error of the mean. Individualized doses reflect the number of injections received per patient between Week 12 and 48 inclusive. OCT CST site reported and includes the PED height. CST= central subfield thickness. in Year 1

# Efficacy of KSI-301 in Wet AMD change from baseline to Week 52 by PED status

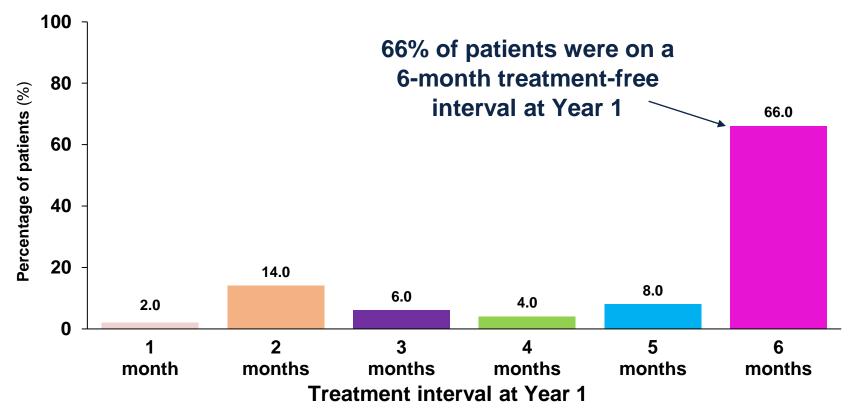


Interim data; 2.5 & 5 mg doses pooled. Observed data, include only patients that received all (3) loading doses and reached Week 12 or later. Error bars represent standard error of the mean. OCT CST site reported and includes the PED height for the overall wAMD cohort. High PED defined as >500 microns of CST in the presence of a PED; CST= central subfield thickness. n= 50 Overall

## **Durability of KSI-301 in Wet AMD** 80% of patients received 2 or fewer retreatments in Year 1

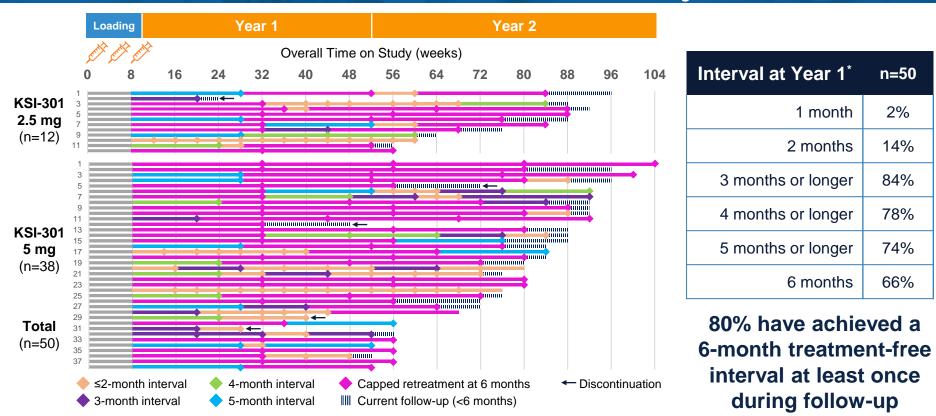


## Durability of KSI-301 in Wet AMD Distribution of retreatment intervals at Year 1



Interim data. 2.5 & 5 mg doses pooled. Includes only patients that received all (3) loading doses and either a) received a dose before Week 52 or b) did not receive a dose and were followed for at least six months after the last loading dose (Week 32 visit). Treatment interval at Year 1 reflects the treatment interval ongoing at the Week 52 visit (where available) or the last interval before Week 52. N=50

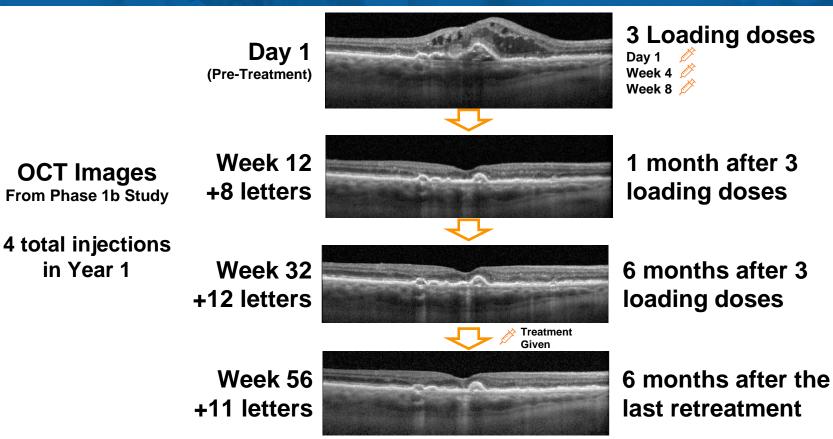
# KSI-301 in wAMD: the majority of patients can achieve 6-month durability



Interim data. Includes only randomized patients that reached the first retreatment opportunity (Week 12 visit). Each bar represents an individual patient.

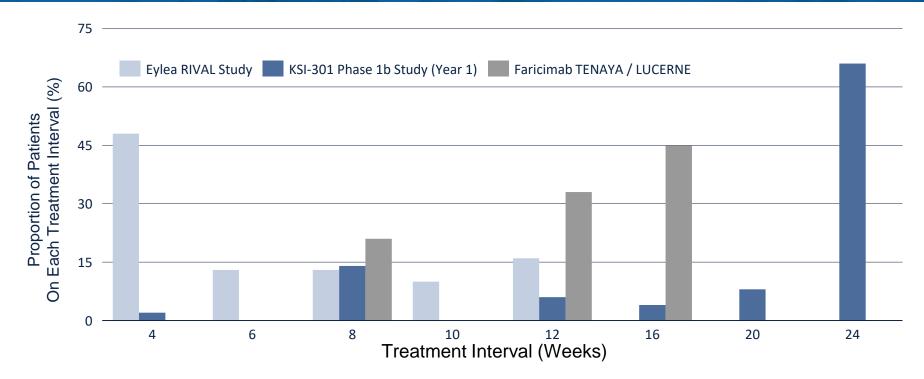
\*Treatment intervals include only patients that received all (3) loading doses and received a dose before Week 52. Interval at Year 1 reflects the treatment interval ongoing at the Week 52 visit (where available) or the last interval before Week 52. Interim data as of 29 Jan 2021

## Case Example: 6-Month Dosing Through 1 Year KSI-301 in wet AMD



## Benchmarking in treatment-naïve wAMD: KSI-301 Phase 1b

"Generation 2.0" durability compared to Eylea long-interval RCT and Faricimab TENAYA/LUCERNE



- Gillies MC, et al. Effect of Ranibizumab and Aflibercept on Best-Corrected Visual Acuity in Treat-and-Extend for Neovascular Age-Related Macular Degeneration: A Randomized Clinical Trial. JAMA 1. Ophthalmol. 2019;137(4):372-379. doi:10.1001/jamaophthalmol.2018.6776
- Angiogenesis 2021 Presentation: Faricimab Phase 3 Topline Results in Exudative AMD Jeffrey S. Heier, MD 2.
- For KSI-301: Treatment intervals include only patients that received all (3) loading doses and received a dose before Week 52. Interval at Year 1 reflects the treatment interval ongoing at the Week 52 visit (where available) 3. or the last interval before Week 52.

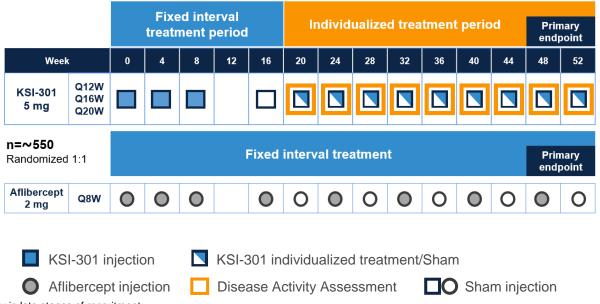
## KSI-301 Phase 2b/3 wAMD DAZZLE Study Dosing with KSI-301 as infrequently as every 20 weeks\*

## Wet AMD – Phase 1b

Interval at Year 1	Percentage (n=50)
1 month	2%
2 months	14%
3 months or longer	84%
4 months or longer	78%
5 months or longer	74%
6 months	66%

### 80% have achieved a 6-month treatment-free interval at least once during follow-up

## DAZZLE pivotal study evaluates individualized dosing of every 12, 16 or 20 weeks



\*After the loading phase. Clinicaltrials.gov ID NCT04049266, currently in late stages of recruitment

Interim data. Includes only randomized patients that reached the first retreatment opportunity (Week 12 visit). Treatment intervals include only patients that received all (3) loading doses and received a dose before Week 52. Interval at Year 1 reflects the treatment interval ongoing at the Week 52 visit (where available) or the last interval before Week 52.

## How do DAZZLE Study Disease Activity Assessment Criteria Compare to Phase 1b?

Parameters	Phase 1b Study <sup>1</sup>	DAZZLE study <sup>2</sup>	Change
Visual <i>and</i> anatomical	Increase in CST ≥75 µm with a decrease in BCVA of ≥ 5 letters compared to Week 12, <i>OR</i>	Increase in CST ≥50 µm with a decrease in BCVA of ≥ 5 letters compared to Week 12, <i>OR</i>	Tighter CST control (25 microns)
Visual only	Decrease in BCVA of ≥ 10 letters compared to the best prior BCVA, due to worsening wAMD activity, <i>OR</i>	Decrease in BCVA of ≥ 10 letters compared to the best prior BCVA, due to worsening wAMD activity, <i>OR</i>	No change
	Decrease in BCVA of > 5 letters compared to Day 1, due to worsening wAMD activity	N/A	Eliminated to reduce subjectivity and unnecessary retreatments
Anatomical only	N/A	Increase of ≥ 75 microns compared to Week 12, <i>OR</i>	Added two anatomical-only
	N/A	New Macular Hemorrhage	criteria

wAMD = wet age-related macular degeneration; CST = central subfield retinal thickness; BCVA = best corrected visual acuity.

<sup>1</sup> Clinicaltrials.gov ID: NCT03790852

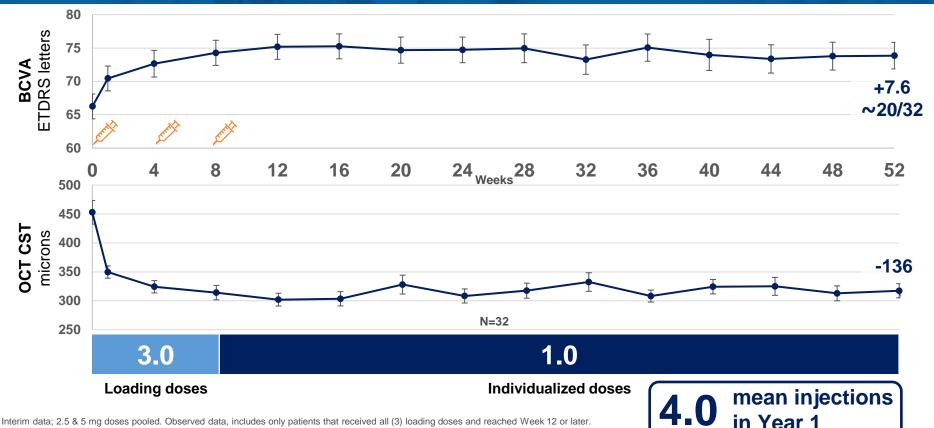
<sup>2</sup> Clinicaltrials.gov ID NCT04049266

## **DAZZLE** protocol optimization

- Building from the exploratory Phase 1b, DAZZLE maintains consistency of key features while further optimizing protocol design
  - 1. Similar patient population treatment naïve wAMD (~80% from USA)
  - 2. Tighter dosing interval ranging from Q4W-Q24W to Q12W-Q20W
  - Tighter disease control tighter disease activity assessments to determine patients' dosing intervals
  - 4. Decreased subjectivity no physician discretion treatment (IRT driven)
  - 5. High statistical power for non-inferiority (>90%)
  - 6. High dose (5.0 mg) selected for pivotal study

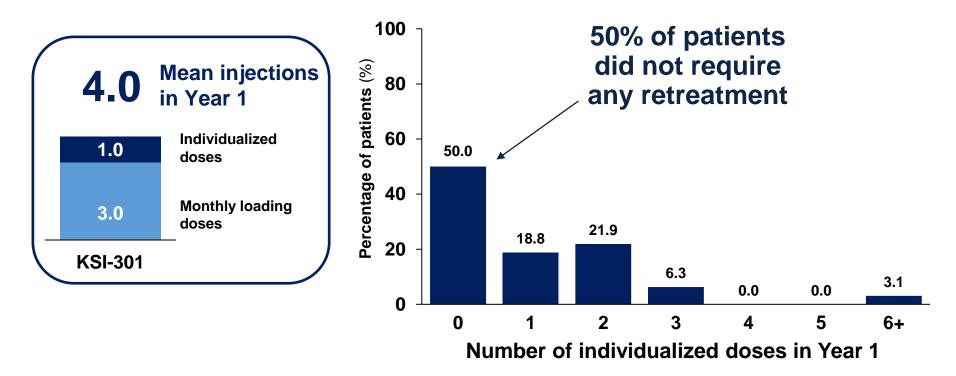
# KSI-301 Phase 1b DME Year 1 Data

### Efficacy of KSI-301 in DME Change from baseline to Week 52 in mean BCVA & OCT



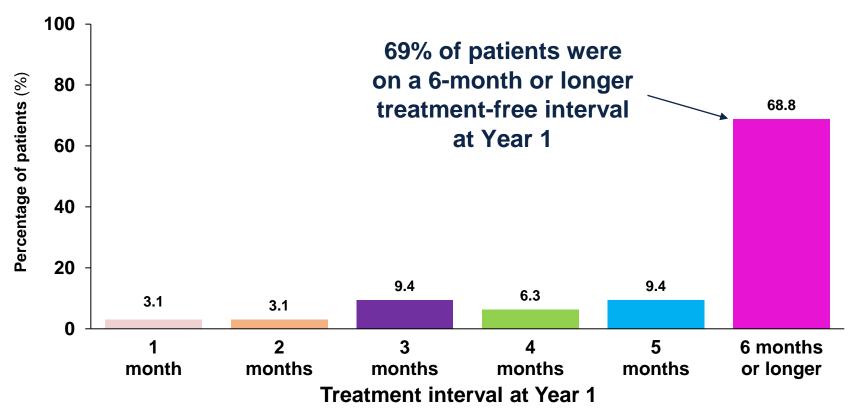
Interim data; 2.5 & 5 mg doses pooled. Observed data, includes only patients that received all (3) loading doses and reached Week 12 or later. Error bars represent standard error of the mean. Individualized doses reflect the number of injections received per patient between Week 12 and 48 inclusive. OCT CST site reported. CST= central subfield thickness.

### Durability of KSI-301 in DME 90% of patients received 2 or fewer retreatments in Year 1



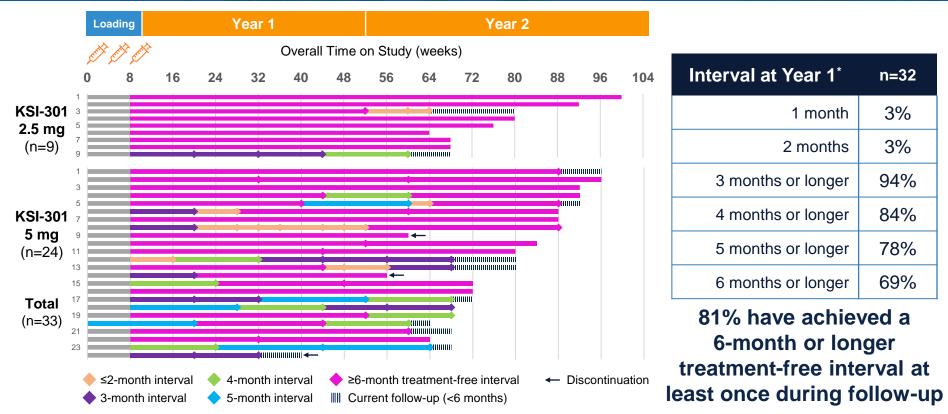
Interim data; 2.5 & 5 mg doses pooled. Includes only patients that received all (3) loading doses and either a) received a dose before Week 52 or b) did not receive a dose and were followed for at least six months after the last loading dose (Week 32 visit). Individualized doses reflect the average number of injections received per patient between Week 12 and 48 inclusive. N=32

### Durability of KSI-301 in DME Distribution of retreatment intervals at Year 1



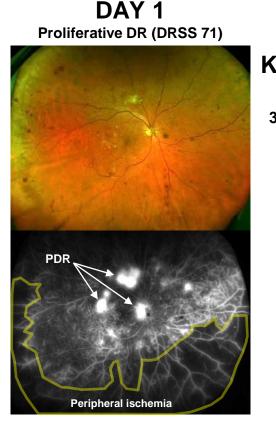
Interim data. 2.5 & 5 mg doses pooled. Includes only patients that received all (3) loading doses and either a) received a dose before Week 52 or b) did not receive a dose and were followed for at least six months after the last loading dose (Week 32 visit). Treatment interval at Year 1 reflects the treatment interval ongoing at the Week 52 visit (where available) or the last interval before Week 52. N=32

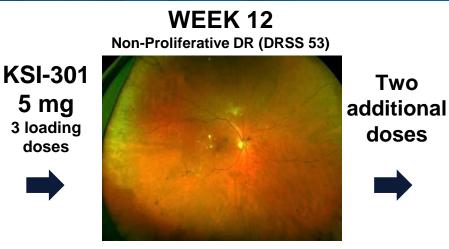
# KSI-301 in DME: 3 loading doses can provide sustained disease control of 3 to 6+ months



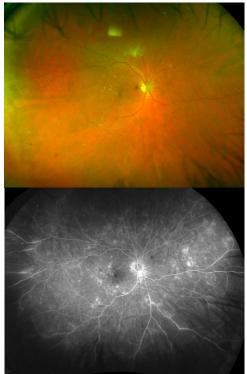
Interim data. Includes only randomized patients that reached the first retreatment opportunity (Week 12 visit). Each bar represents an individual patient. \*Treatment intervals include only patients that received all (3) loading doses and either a) received a dose before Week 52 or b) did not receive a dose and were followed for at least six months after the last loading dose (Week 32 visit). Interval at Year 1 reflects the treatment interval ongoing at the Week 52 visit (where available) or the last interval before Week 52. One patient only received one loading dose and was excluded from the calculation. Interim data as of 29 Jan 2021

# 6-month disease control after only 3 loading doses is also seen in proliferative diabetic retinopathy

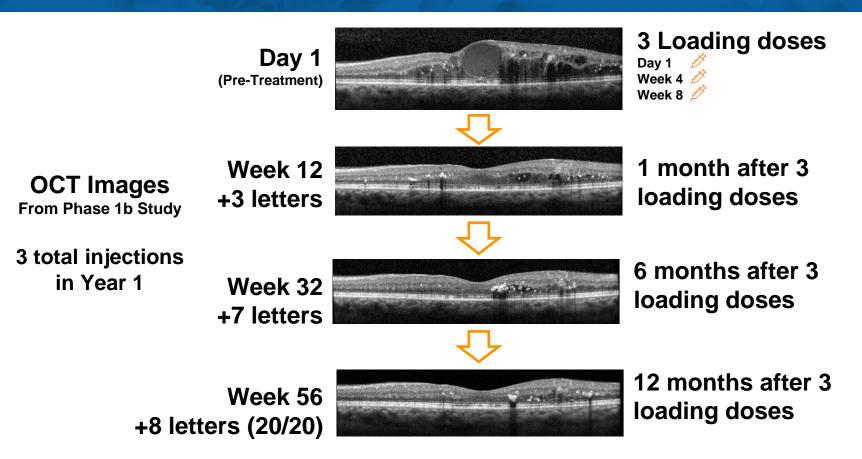




Regression from PDR to NPDR Fast and substantial (3-step) improvement, sustained for 18 months with only 2 additional doses (26-week mean retreatment interval) WEEK 72 Non-Proliferative DR (DRSS 53)

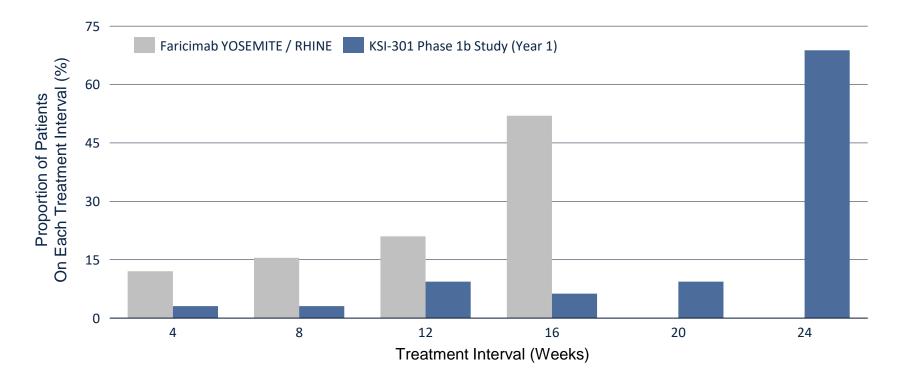


# Case Example: No Retreatments for 12 Months After Loading Phase KSI-301 in DME



### Benchmarking in treatment-naïve DME: KSI-301 Phase 1b

"Generation 2.0" durability compared to Faricimab YOSEMITE / RHINE

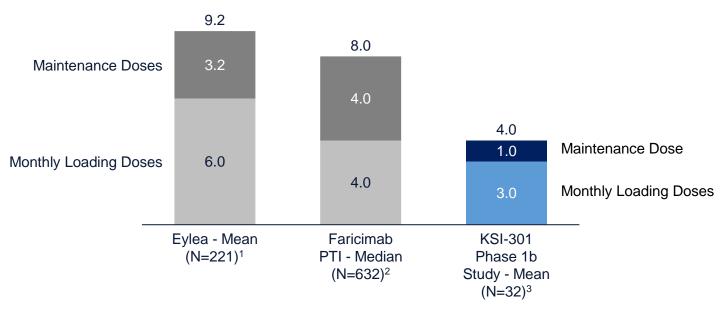


1. Angiogenesis 2021 Presentation: Faricimab Phase 3 (YOSEMITE and RHINE) Topline Results in Diabetic Macular Edema - Charles C. Wykoff, MD, PhD

2. For KSI-301: Treatment intervals include only patients that received all (3) loading doses and received a dose before Week 52. Interval at Year 1 reflects the treatment interval ongoing at the Week 52 visit (where available) or the last interval before Week 52.

#### Benchmarking: KSI-301 Phase 1b DME data "Generation 2.0" durability compared to Eylea

#### Year 1 Average number of injections required



1. Wells JA. Aflibercept, bevacizumab, or ranibizumab for diabetic macular edema (DRCR Protocol T). N Engl J Med. 2015 Mar 26;372(13):1193-203 (supplemental data).

2. Angiogenesis 2021 Presentation: Faricimab Phase 3 (YOSEMITE and RHINE) Topline Results in Diabetic Macular Edema - Charles C. Wykoff, MD, PhD

3. Interim data; 2.5 & 5 mg doses pooled. Includes only patients that received all (3) loading doses and either a) received a dose before Week 52 or b) did not receive a dose and were followed for at least six months

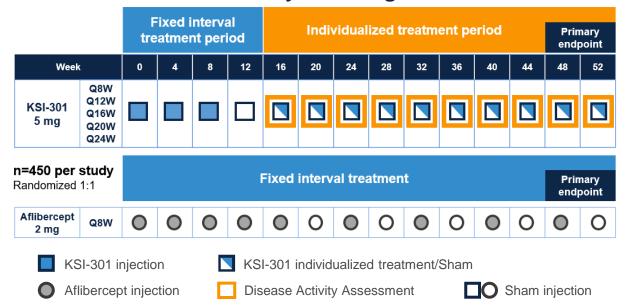
after the last loading dose (Week 32 visit). Individualized doses reflect the average number of injections received per patient between Week 12 and 48 inclusive. N=32

#### KSI-301 Phase 3 DME GLEAM and GLIMMER Studies Dosing with KSI-301 as infrequently as every 24 weeks<sup>1</sup>

#### DME – Phase 1b

Interval at Year 1*	Percentage (n= 32)		
1 month	3%		
2 months	3%		
3 months or longer	94%		
4 months or longer	84%		
5 months or longer	78%		
6 months or longer	69%		
81% have achieved a 6-month or longer treatment- free interval at least once during follow-up			

#### GLEAM-GLIMMER pivotal studies evaluate individualized dosing of every 8, 12, 16, 20 or 24 weeks, after only 3 loading doses



#### 1. After the loading phase

Interim data. Includes only randomized patients that reached the first retreatment opportunity (Week 12 visit). \*Treatment intervals include only patients that received all (3) loading doses and either a) received a dose before Week 52 or b) did not receive a dose and were followed for at least six months after the last loading dose (Week 32 visit). Interval at Year 1 reflects the treatment interval ongoing at the Week 52 visit (where available) or the last interval before Week 52. One patient only received one loading dose and was excluded from the calculation

### How do GLEAM & GLIMMER Studies Disease Activity Assessment Criteria Compare to Phase 1b?

Parameters	Phase 1b Study <sup>1</sup>	GLEAM & GLIMMER Studies	Change
Visual <i>and</i> anatomical	Increase in CST $\geq$ 75 µm with a decrease in BCVA of $\geq$ 5 letters compared to Week 12 or the prior visit, <i>OR</i>	Increase in OCT CST $\geq$ 50 µm <u>compared to</u> <u>lowest previous measurement</u> and a decrease in BCVA of $\geq$ 5 letters <u>compared to</u> <u>the average of the 2 best previous BCVA</u> <u>assessments</u> , due to worsening of DME disease activity, <i>or</i>	Tighter and dynamic control of both vision and anatomy
Visual only	Decrease in BCVA of ≥ 10 letters compared to the best prior BCVA, due to worsening DME activity	N/A	Eliminated to reduce subjectivity and unnecessary retreatments
Anatomical only	N/A	Increase in OCT CST ≥ 75 µm compared to lowest previous measurement due to worsening of DME disease activity; <i>or</i>	Added two anatomical-
	N/A	New or worsening proliferative DR (PDR)	only criteria

DME = diabetic macular edema; OCT = optical coherence tomography; CST = central subfield retinal thickness; BCVA = best corrected visual acuity.

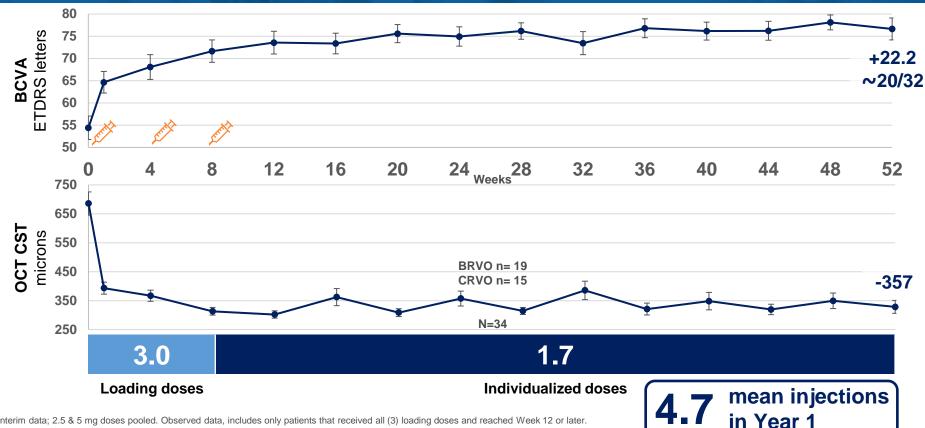
<sup>1</sup> Clinicaltrials.gov ID: NCT03790852

### **GLEAM & GLIMMER Phase 3 protocol optimization**

- Building from the exploratory Phase 1b, GLEAM & GLIMMER maintain consistency of key features while further optimizing protocol designs
  - 1. Similar patient population treatment naïve DME (~80% from USA)
  - 2. Proactive tighter dosing interval ranging from uncapped to Q8W-Q24W
  - Tighter disease control tighter disease activity assessments to patients' determine dosing intervals
  - 4. Decreased subjectivity no physician discretion treatment (IRT driven)
  - 5. High statistical power for non-inferiority (>90%)
  - 6. High dose (5.0 mg) selected for pivotal study

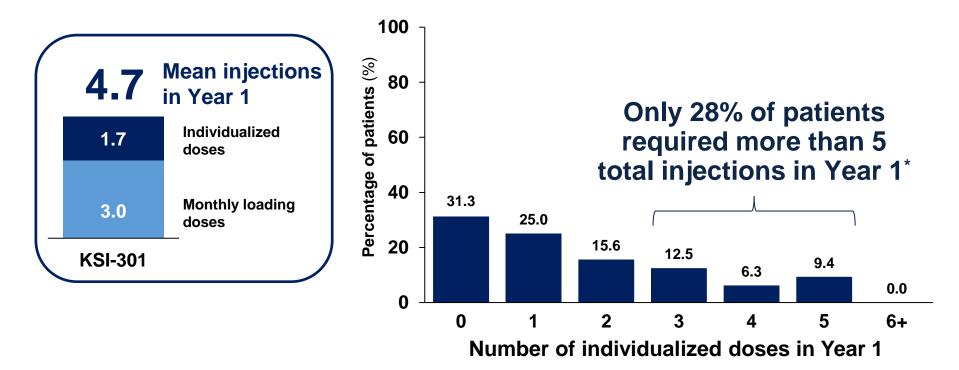
# KSI-301 Phase 1b RVO Year 1 Data

### Efficacy of KSI-301 in RVO Change from baseline to Week 52 in mean BCVA & OCT



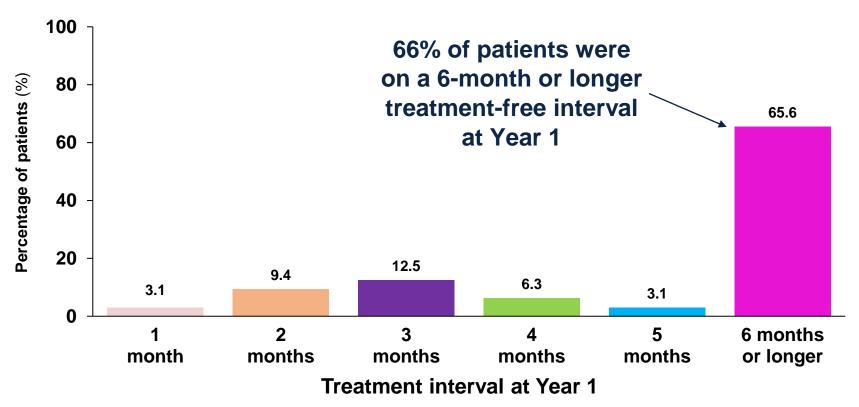
Interim data; 2.5 & 5 mg doses pooled. Observed data, includes only patients that received all (3) loading doses and reached Week 12 or later. Error bars represent standard error of the mean. Individualized doses reflect the number of injections received per patient between Week 12 and 48 inclusive. OCT CST site reported. CST= central subfield thickness.

### Durability of KSI-301 in RVO 72% of patients received 2 or fewer retreatments in Year 1



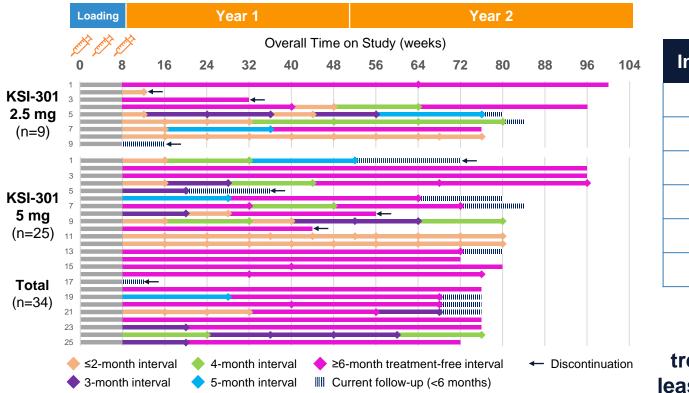
Interim data; 2.5 & 5 mg doses pooled. Includes only patients that received all (3) loading doses and either a) received a dose before Week 52 or b) did not receive a dose and were followed for at least six months after the last loading dose (Week 32 visit). Two patients were not included as they discontinued at the Week 12 and 16 visits, respectively, without receiving a retreatment dose. Individualized doses reflect the average number of injections received per patient between Week 12 and 48 inclusive. N=32 \* 3 loading doses plus more than 2 individualized doses

### Durability of KSI-301 in RVO Distribution of retreatment intervals at Year 1



Interim data. 2.5 & 5 mg doses pooled. Includes only patients that received all (3) loading doses and either a) received a dose before Week 52 or b) did not receive a dose and were followed for at least six months after the last loading dose (Week 32 visit). Two patients were not included as they discontinued at the Week 12 and 16 visits, respectively, without receiving a retreatment dose. Treatment interval at Year 1 reflects the treatment interval ongoing at the Week 52 visit (where available) or the last interval before Week 52. N=32

#### KSI-301 in RVO: 3 loading doses can provide sustained disease control of 2 to 6+ months



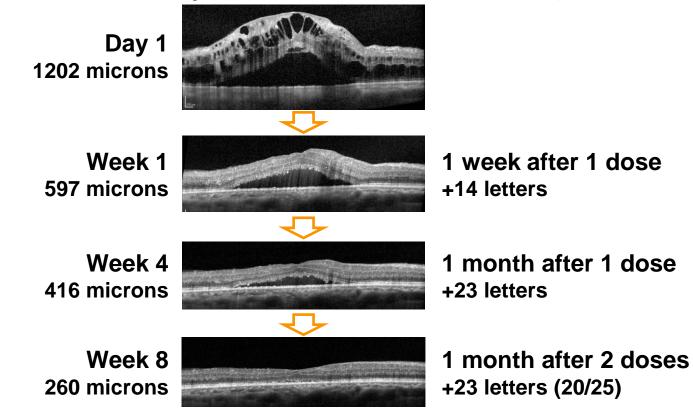
Interval at Year 1*	n=32
1 month	3%
2 months	9%
3 months or longer	87%
4 months or longer	75%
5 months or longer	69%
6 months or longer	66%

69% have achieved a 6-month or longer treatment-free interval at least once during follow-up

Interim data. Includes only randomized patients that reached the first retreatment opportunity (Week 12 visit). Each bar represents an individual patient. \*Treatment intervals include only patients that received all (3) loading doses and either a) received a dose before Week 52 or b) did not receive a dose and were followed for at least six months after the last loading dose (Week 32 visit). Interval at Year 1 reflects the treatment interval ongoing at the Week 52 visit (where available) or the last interval before Week 52. Two patients discontinued before receiving their first retreatment and less than 6 months of follow-up after the loading phase. Interim data as of 29 Jan 2021 54

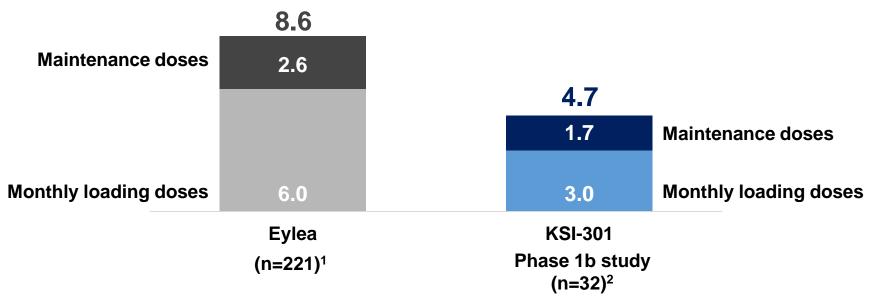
# Is it possible to control the most severe CRVO cases with only 2 loading doses?

Case Example of KSI-301 in the Phase 1b Study



#### Benchmarking: KSI-301 Phase 1b RVO data "Generation 2.0" durability compared to Eylea

#### Year 1 Mean number of injections required



1. Injections averaged between the two pivotal aflibercept trials; n represents the total randomized in the aflibercept groups in both studies. Brown DM. Intravitreal Aflibercept Injection for Macular Edema Secondary to Central Retinal Vein Occlusion: 1-Year Results From the Phase 3 COPERNICUS Study. Am J Ophthalmol 2013;155:429–437.Korobelnik JF, et al. Intravitreal Aflibercept Injection for Macular Edema Resulting from Central Retinal Vein Occlusion. Ophthalmology 2014;121:202-208

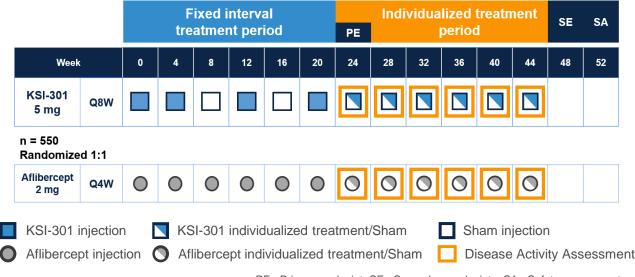
2. Interim data; 2.5 & 5 mg doses pooled. Includes only patients that received all (3) loading doses and either a) received a dose before Week 52 or b) did not receive a dose and were followed for at least six months after the last loading dose (Week 32 visit). Two patients were not included as they discontinued at the Week 12 and 16 visits, respectively, without receiving a retreatment dose. Individualized doses reflect the average number of injections received per patient between Week 12 and 48 inclusive. N=32

### KSI-301 Phase 3 RVO BEACON Study Two loading doses with KSI-301 + every 8 weeks

RVO – Phase 1b			
Interval at Year 1*	Percentage (n= 34)		
1 month	3%		
2 months	9%		
3 months or longer	87%		
4 months or longer	75%		
5 months or longer	69%		
6 months or longer	66%		

69% have achieved a 6-month or longer treatment-free interval at least once during follow-up

## BEACON pivotal study evaluates two loading doses and every 8-week dosing, followed by individualized dosing



PE= Primary endpoint. SE= Secondary endpoints. SA= Safety assessment

#### Clinicaltrials.gov ID NCT04592419, currently recruiting

Interim data. Includes only randomized patients that reached the first retreatment opportunity (Week 12 visit). \*Treatment intervals include only patients that received all (3) loading doses and either a) received a dose before Week 52 or b) did not receive a dose and were followed for at least six months after the last loading dose (Week 32 visit). Interval at Year 1 reflects the treatment interval ongoing at the Week 52 visit (where available) or the last interval before Week 52. Two patients discontinued before receiving their first retreatment and less than 6 months of follow-up after the loading phase.

### How do BEACON Study Disease Activity Assessment Criteria Compare to Phase 1b?

Parameters	Phase 1b Study <sup>1</sup>	BEACON Study <sup>2</sup>	Change
Visual <i>and</i> anatomical	Increase in CST $\geq$ 75 µm with a decrease in BCVA of $\geq$ 5 letters compared to Week 12 or the prior visit, <i>OR</i>	Increase in OCT CST $\geq$ 50 µm <u>compared to</u> <u>lowest previous measurement</u> and a decrease in BCVA of $\geq$ 5 letters <u>compared to</u> <u>the average of the 2 best previous BCVA</u> <u>assessments</u> , due to worsening of RVO disease activity, <i>or</i>	Tighter and dynamic control of both vision and anatomy
Visual only	Decrease in BCVA of ≥ 10 letters compared to the best prior BCVA, due to worsening RVO activity	N/A	Eliminated to reduce subjectivity and unnecessary retreatments
Anatomical only	N/A	Increase in OCT CST ≥ 75 µm compared to lowest previous measurement due to worsening of RVO disease activity; <i>or</i>	Added one anatomical- only criteria

RVO = retinal vein occlusion; OCT = optical coherence tomography; CST = central subfield retinal thickness; BCVA = best corrected visual acuity.

<sup>1</sup> Clinicaltrials.gov ID: NCT03790852

<sup>2</sup> Clinicaltrials.gov ID: NCT04592419

#### **BEACON Phase 3 protocol optimization**

- Building from the exploratory Phase 1b, BEACON maintains consistency of key features while further optimizing study protocol
  - 1. Similar patient population treatment naïve RVO (~80% from USA)
  - 2. Proactive tighter dosing interval from uncapped to fixed q2-month dosing, through 6-month primary endpoint
  - 3. Tighter disease control tighter disease activity assessments to determine dosing interval, in second 6 months of study
  - 4. Decreased subjectivity no physician discretion treatment (IRT driven)
  - 5. High statistical power (>90%)
  - 6. High dose (5.0 mg) selected for pivotal study

# KSI-301 Phase 1b

Safety

## Safety of KSI-301: Excellent safety profile



710 Total doses

Patient-years

168

Across the Phase 1a/1b program

Completed the loading phase in Phase 1b Phase 1b subjects at Week 12 or later that have received all three loading doses plus at least one additional retreatment

- Most AEs were assessed as mild and are consistent with profile of intravitreal anti-VEGFs
- To date, 43 SAEs have been reported in 24 subjects none drug related
- Three ocular SAEs in the study eye, not drug related, all resolved
  - Worsening DME secondary to systemic fluid overload
  - Worsening cataract in a diabetic patient
  - Subretinal hemorrhage in a wAMD patient
- Only two AEs of intraocular inflammation, both trace to 1+ vitreous cells, with complete resolution
  - Rate of 0.28% (2/710 injections)
  - No vasculitis or retinal artery occlusion in either patient

Includes all Phase 1a+1b patients randomized as of 26 Jan 2021, all doses administered across cohorts. Interim safety data as of 26 Jan 2021; AE: adverse event; SAE: serious adverse event Inflammation scored based on the 0 – 4+ standardized vitreous grading scale (Foster 2002)

#### KODIAK SCIENCES

WHERE WE

ARE TODAY



4 ONGOING PIVOTAL TRIALS

#### 3 INDICATIONS

**SINGLE** BLA FILING EXPECTED IN 2022

#### KODIAK

#### 🖉 KSI-301 CLINICAL EXPERIENCE

Clinical data from ~2,000 injections in ~500 patients representing ~350 patient-years of exposure in representative populations in wAMD, DME and RVO

- Safety: Tracking with current standard of care (Lucentis, Eylea)
- Efficacy: Vision & retinal anatomy improvements in line with current anti-VEGF agents
- Durability: 2 in every 3 patients going 6-months or longer between doses in wet AMD, DME and RVO

#### OPTIMIZED PIVOTAL STUDY PROGRAM

Objective to show disruptive durability with same safety and efficacy as Eylea

DAZZLE wet AMD study enrollment complete; BEACON RVO study and GLEAM & GLIMMER DME now enrolling – Data from all studies expected in 2022

Pivotal studies designed from phase 1b data with high dose (5.0 mg), high statistical power, tighter criteria for disease activity assessments, tighter dosing interval ranging, maintaining similar (80%+) U.S. treatment naïve population

#### OPERATING WITH CONVICTION

On track for a single BLA filing in the key indications of wAMD, DME, RVO treatment and with NPDR indication in a supplemental

Manufacturing investments aligned to clinical opportunity with commercial supply goal of 2.5M+ Prefilled Syringes in Year 1 of launch

Developing bispecific and triplet ABC Medicines for multi-mechanism diseases, including dry AMD and glaucoma

#### POISED COMMERCIAL OPPORTUNITY

Competitive landscape is clearing with competing molecules/technologies demonstrating poor risk-benefit profiles

We believe KSI-301 may be able to capture market share from standard of care agents, future biosimilars, and competing late-stage molecules in development



# KODIAK

THE OPHTHALMOLOGY MEDICINES COMPANY