

NASDAQ: KOD

KODIAK.COM

KODIAK

THE OPHTHALMOLOGY MEDICINES COMPANY

CLINICAL INVESTIGATOR MEETING

**Victor Perloth, M.D.
Chief Executive Officer**

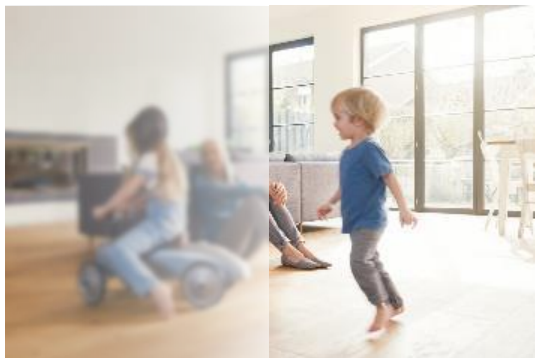
November 2020

SPECIAL NOTE REGARDING

FORWARD-LOOKING STATEMENTS

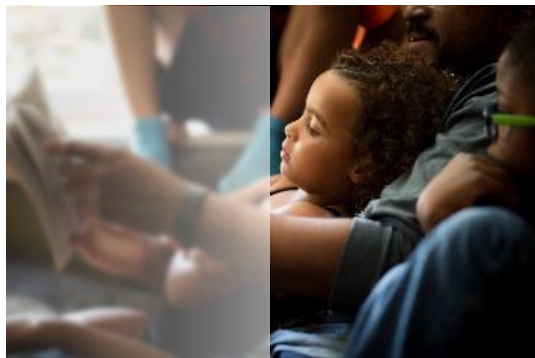
These slides contain forward-looking statements and information. The use of words such as “may,” “might,” “will,” “should,” “could,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “project,” “intend,” “future,” “potential,” or “continue,” and other similar expressions are intended to identify 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 to entail 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-Q, 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.

OUR MISSION



1 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

OUR 2022 VISION

WET AMD

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



RETINAL VEIN OCCLUSION

2022 BEACON Phase 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 (TBD)
2023 BLA filing (TBD)



KSI-601 Triplet Inhibitor for dry AMD

2022 IND submitted



3

Indications submitted in
BLA (wAMD, DME, RVO,
potentially DR)

3

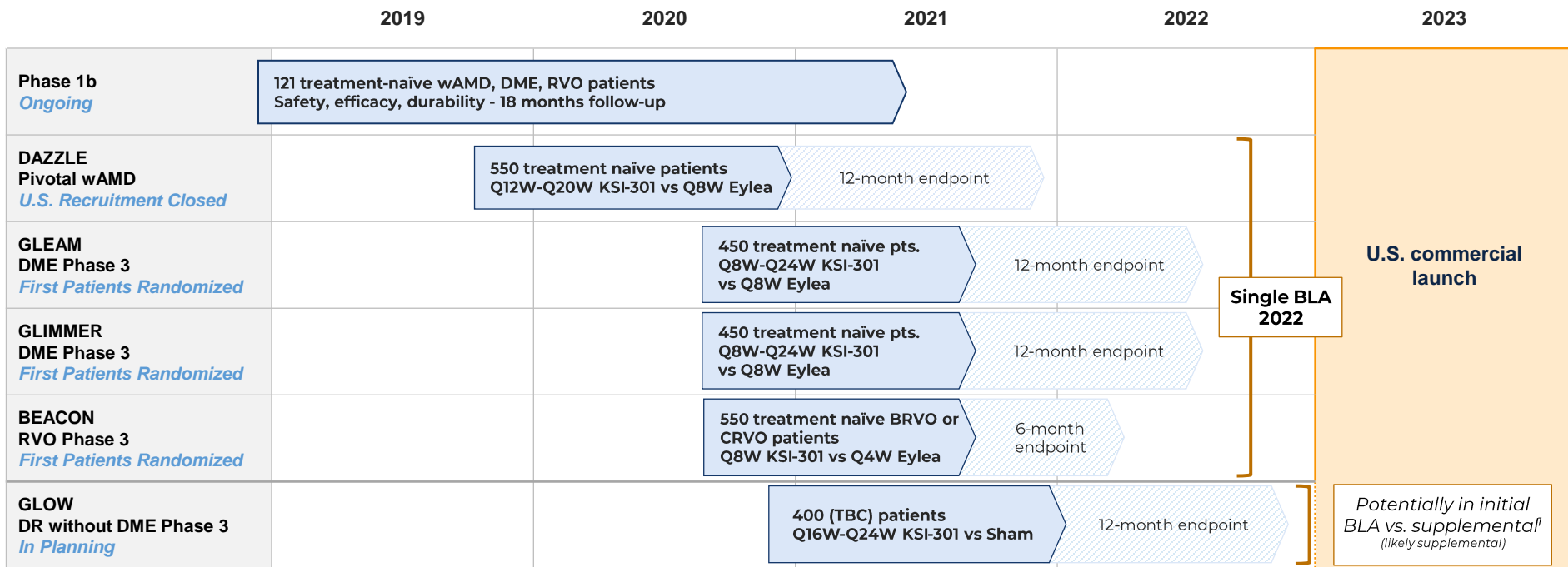
Clinical molecules

1

IND per year beginning 2021

KSI-301 Accelerated Development Strategy

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



BLA: biologics license application; RVO: retinal vein occlusion; BRVO: branch RVO; CRVO: central RVO; wAMD: wet age-related macular degeneration; DME: diabetic macular edema; DR: diabetic retinopathy

¹ Depending on recruitment timing

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

U.S. Enrollment Completed Enrollment expected to complete YE 2020	Now Recruiting First patients randomized in GLEAM / GLIMMER and BEACON		Enrollment Start 1Q 2021
Wet AMD	Diabetic Macular Edema	Retinal Vein Occlusion	Non-Proliferative Diabetic Retinopathy
<p>DAZZLE Study (n~550)</p> <p>KSI-301 once every 3, 4 or 5 months after 3 monthly doses</p> <p>Comparator Aflibercept Once every 2 months after 3 monthly doses</p>	<p>GLEAM and GLIMMER Studies (n~450 each)</p> <p>KSI-301 once every 2 to 6 months after 3 monthly doses</p> <p>Comparator Aflibercept Once every 2 months after 5 monthly doses</p>	<p>BEACON Study (n~550)</p> <p>KSI-301 once every 2 months or longer after 2 monthly doses</p> <p>Comparator Aflibercept Once every month</p>	<p>GLOW Study (n~400)</p> <p>KSI-301 once every 4 or 6 months After 2-3 loading doses Or no loading doses (TBD)</p> <p>Comparator Sham</p>

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

LATE STAGE MOLECULES IN DEVELOPMENT

What will physicians be using
in the near future?

Moderators: Diana V. Do, MD, and Ira Schachar, MD



Stanford

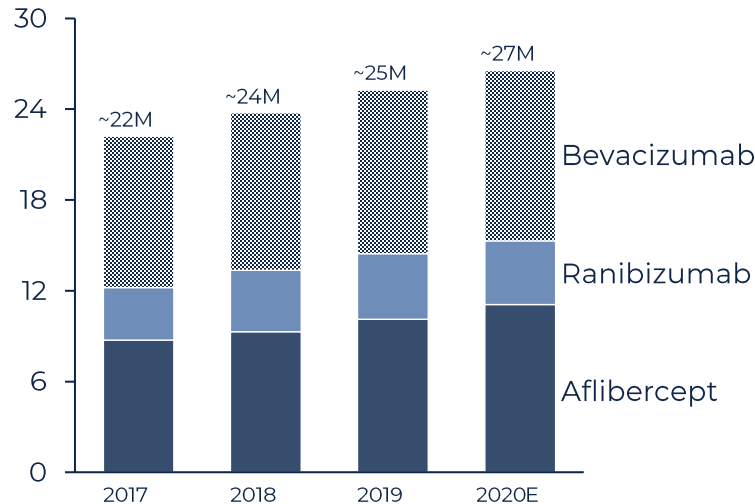
OPHTHALMOLOGY

BYERS EYE INSTITUTE

~27M intravitreal (IVT) anti-VEGF injections will be administered in 2020 to treat retinal diseases

Estimated Global IVT Injections (2017-20E)

Number of injections












Source: Analyst estimates and Retina Times

- Bevacizumab, aflibercept and ranibizumab are the most commonly used agents today
- Of the estimated 27 million IVT injections that will be performed in 2020
 - ~60% are for wet AMD
 - ~30% are for DME
 - ~10% are for RVO
- Non-proliferative diabetic retinopathy is a new indication
- Real-world clinical outcomes are inferior to those seen in clinical trials



Numerous biologics and gene therapies are being developed for retinal indications with a subset in late stage development

	Therapeutic Candidate	Sponsor	Description	Est. U.S. Launch	Stage
Biologics	Abicipar pegol	 	• VEGF DARPIn delivered via IVT injection	Unclear if program will proceed	N / A
	Faricimab		• VEGF & Ang2 bispecific antibody delivered via IVT injection	2022	Late stage
	Ranibizumab biosimilars		• Currently three clinical programs (Coherus, Bioepis, and Stada / Xbrane)	2021-22	Late stage
	ONS-5010		• Ophthalmic formulation of bevacizumab delivered via IVT injection	2022-23	Late stage
	KSI-301		• Extended durability antibody biopolymer conjugate delivered via IVT injection	2023	Late stage
	Conbercept		• VEGF recombinant fusion protein delivered via IVT injection	2023	Late stage
	Aflibercept biosimilars	 Multiple sponsors	• Currently three clinical programs (Amgen, Bioepis / Biogen, Mylan)	2024+	Late stage
Surgical Devices	High dose aflibercept		• 8 mg dose of aflibercept delivered via IVT injection	TBD	Late stage
Gene therapies	Ranibizumab Port Delivery System	 	• Surgical implant in the eye that can be refilled with ranibizumab	2021+	Late stage
	RGX-314		• Gene therapy encoding a VEGF antibody fragment delivered subretinally ¹	2025+	Early stage
	ADVM-022		• Gene therapy encoding aflibercept delivered via IVT injection	2025+	Early stage



WHAT PROFILE IS REQUIRED TO MEANINGFULLY CHANGE THE CURRENT PARADIGM?

Durability

Potential Impact	Maintenance Phase	Loading Phase	Efficacy Profile	Safety Profile
Homerun	wAMD: >50% reach Q20W	≤ 3 loading doses	wAMD, DME, and RVO: Non-inferior to comparator NPDR: 2 step change and / or lower event rate	Safety profile is in line with aflibercept and ranibizumab
	DME: >50% reach Q20W			
	RVO: Non-inferior with Q8W			
	NPDR: Compelling efficacy at 2x / year			
Revolutionary	wAMD: >50% reach Q16W or better	≤ 3 loading doses	wAMD, DME, and RVO: Non-inferior to comparator NPDR: 2 step change and / or lower event rate	Safety profile is in line with aflibercept and ranibizumab
	DME: >50% reach Q16W or better			
	RVO: Non-inferior with Q8W			
	NPDR: Compelling efficacy at 3x / year			
Evolutionary	wAMD: 33% Q8W, 33% Q12W, 33% Q16 / 20W	≥ 3 loading doses	wAMD, DME, and RVO: Non-inferior to comparator	Safety profile may be worse than aflibercept
	DME: >50% better than Q12W			
	RVO: Non-inferior with Q8W			

WHAT WILL PHYSICIANS BE USING IN THE NEAR FUTURE?

Scientific Presentations & Panel Discussion



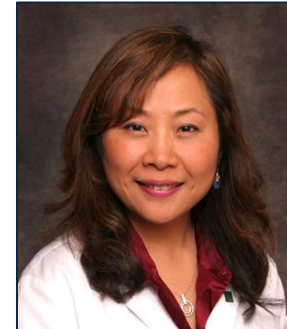
Peter Kaiser, MD



David Brown, MD



Raja Narayanan, MD



Judy Kim, MD





KSI-301 Update

Stanford Innovation Summit 2020

Peter K. Kaiser, MD

Chaney Family Endowed Chair in Ophthalmology Research
Professor of Ophthalmology
Cole Eye Institute, Cleveland Clinic

KSI-301 Phase 1b data in treatment-naïve patients inform the design of our pivotal studies and provide for a high probability of success in the pivotal program

Wet AMD

68% (28/41) have achieved a 6-month interval at least once during follow-up

Time to First Retreatment ¹	Percentage
At or before 2 months	8% (4/49)
3 months or longer	92% (45/49)
4 months or longer	82% (40/49)
5 months or longer	66% (27/41)
6 months	49% (20/41)

Diabetic Macular Edema

45% (15/33) have not yet required a single retreatment

Time to First Retreatment ¹	Percentage
Before 2 months	0% (0/33)
At 2 months	3% (1/33)
3 months or longer	97% (32/33)
4 months or longer	76% (25/33)
5 months or longer	70% (23/33)
6 months or longer	67% (22/33)

Retinal Vein Occlusion

71% (24/34) have achieved ≥4-month treatment interval at least once during follow-up

Time to First Retreatment ¹	Percentage
At 1 month	6% (2/34)
2 months or longer	94% (31/33)
3 months or longer	66% (21/32)
4 months or longer	56% (18/32)

Non-Proliferative Diabetic Retinopathy²

100% (15/15) have improved or maintained their DRSS score at Week 12 after 3 loading doses

Change from Baseline in DRSS at Week 12	Percentage
Maintained	60% (9/15)
1-step improvement	13% (2/15)
≥2-step improvement	27% (4/15)

1. Time to first retreatment per protocol-specified criteria, after 3 initial monthly doses of 2.5 mg or 5 mg KSI-301. Data from Phase 1b KSI-301 presentation at ASRS 2020 Virtual Annual Meeting, complete presentation available at ir.Kodiak.com
 2. Data from Phase 1b KSI-301 presentation at AAO 2019 Annual Meeting, complete presentation available at ir.Kodiak.com

Conclusions !

Therapeutic Candidate

Abicipar

Faricimab

Ranibizumab biosimilars

ONS-5010

Biologics

KSI-301

Conbercept

Aflibercept biosimilars

High dose aflibercept

Devices

Ranibizumab PDS

Gene therapies

RGX-314

ADVM-022

Durability

Potential Impact	Maintenance Phase	KSI-301	Loading Phase
Homerun	wAMD: >50% reach Q20W	66%	None or < 3 loading doses
	DME: >50% reach Q20W	70%	
	RVO: >50% reach Q12W	66%	
	NPDR: Compelling efficacy at 2x / year		
Revolutionary	wAMD: >50% reach Q16W or better	82%	≤ 3 loading doses
	DME: >50% reach Q16W or better	76%	
	RVO: >50% reach Q12W	66%	
	NPDR: Compelling efficacy at 3x / year		

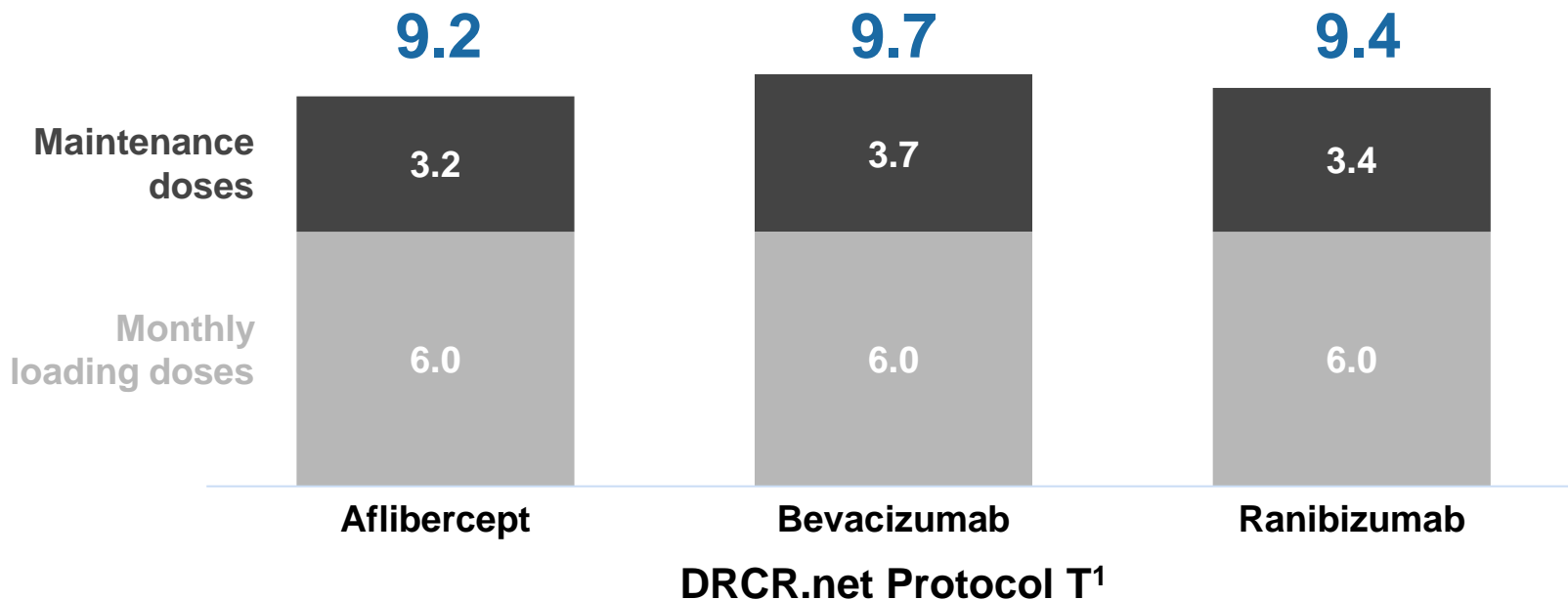
**One Year and Beyond: Long-Term Multiple-Dose
Study of KSI-301, an Anti-VEGF Antibody
Biopolymer Conjugate with Extended Durability,
in wAMD, DME, and RVO**

Arshad M. Khanani, MD, MA

**Director of Clinical Research
Sierra Eye Associates
Reno, NV**

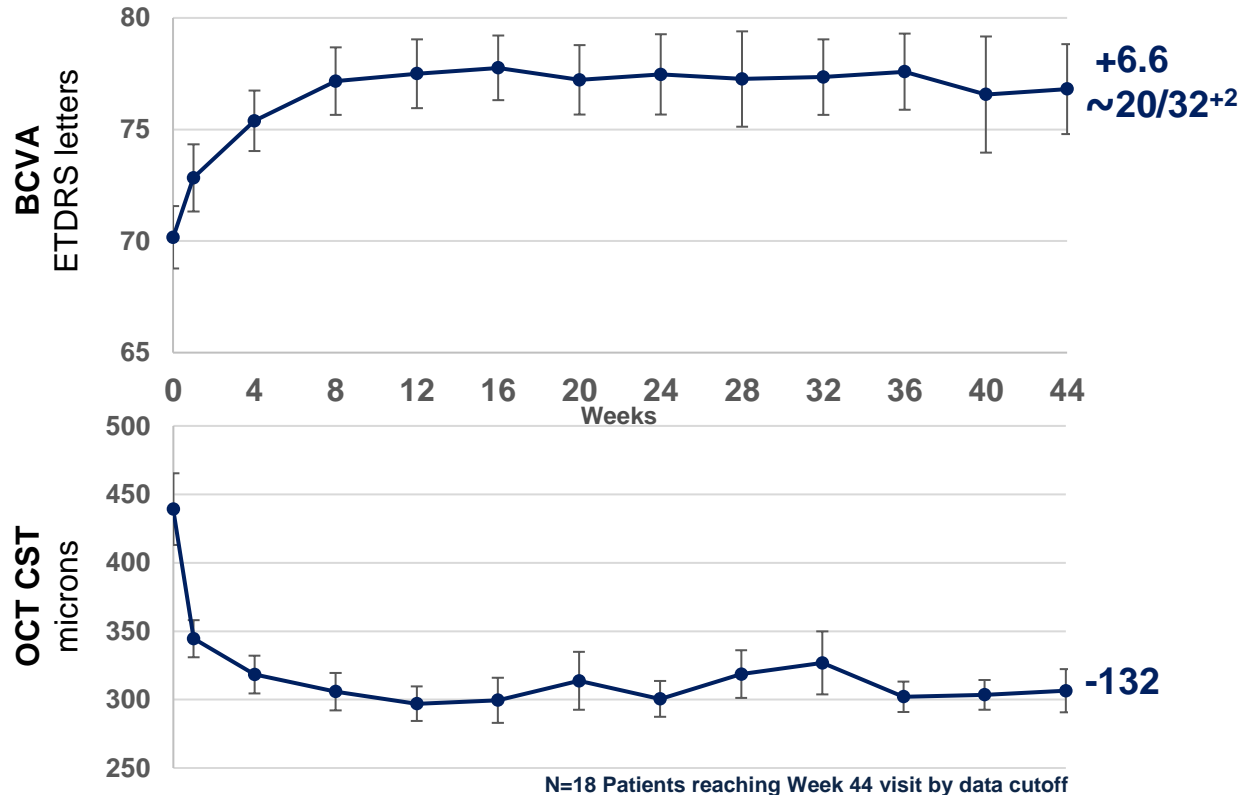
Current anti-VEGF agents require high-frequency treatment to be most efficacious in DMF

Mean number of injections required in Year 1



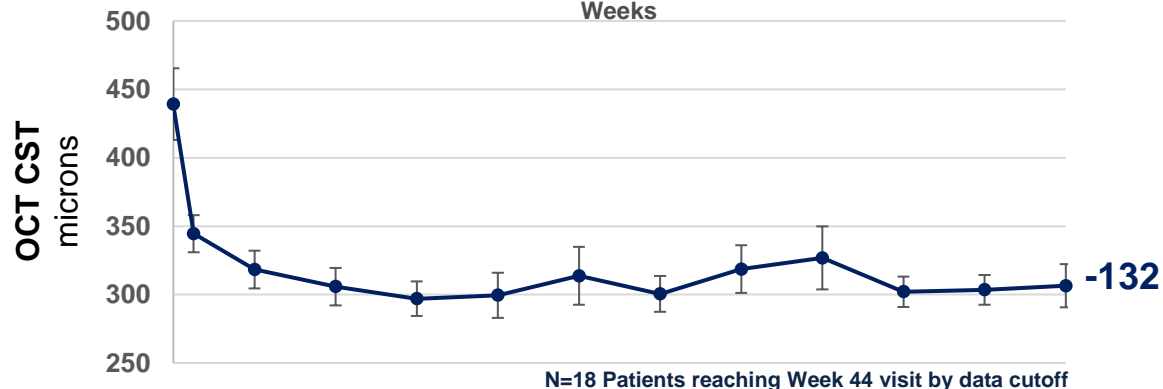
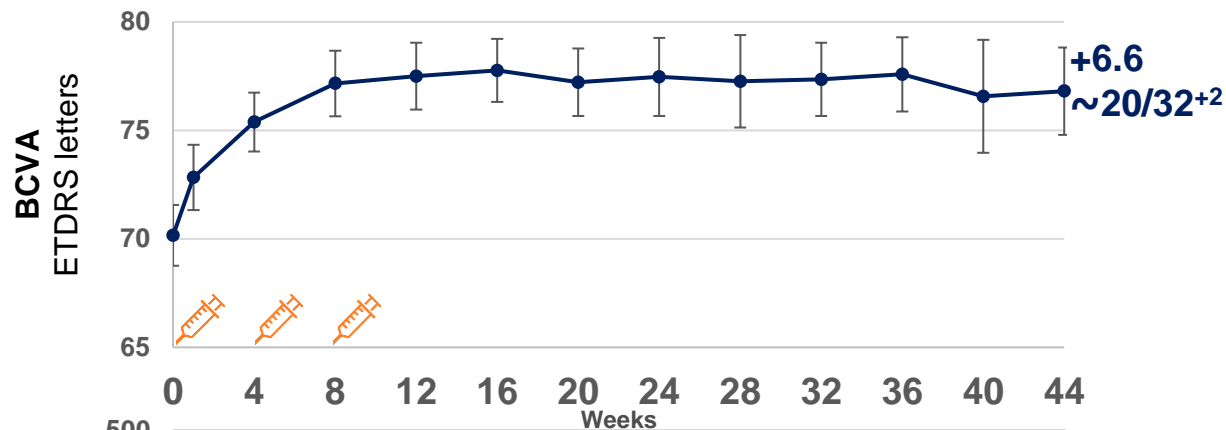
1. Wells JA. Aflibercept, bevacizumab, or ranibizumab for diabetic macular edema (DRCR Protocol T). N Engl J Med. 2015 Mar 26;372(13):1193-203 (supplemental data).

How many KSI-301 injections are needed to achieve these results in DME?



Interim data. Includes only randomized patients that reached Week 44 visit by the data cutoff date of 09 Jun 2020; 2.5 & 5 mg doses pooled. Observed data. Error bars represent standard error of the mean. OCT CST values are site reported. BCVA= best corrected visual acuity; OCT= optical coherence tomography; CST= central subfield thickness. Mean injections reflect the average number of injections received per patient between Week 12 and 40 (afibercept per label mean number of injections 5.0).

Only 3 loading doses and 0.6 mean individualized doses of KSI-301 demonstrate strong efficacy



N=18 Patients reaching Week 44 visit by data cutoff

3.6

Injections over 44 weeks

	0.6	Individualized doses
	3.0	Monthly loading doses

KSI-301

67% of patients did not require retreatment

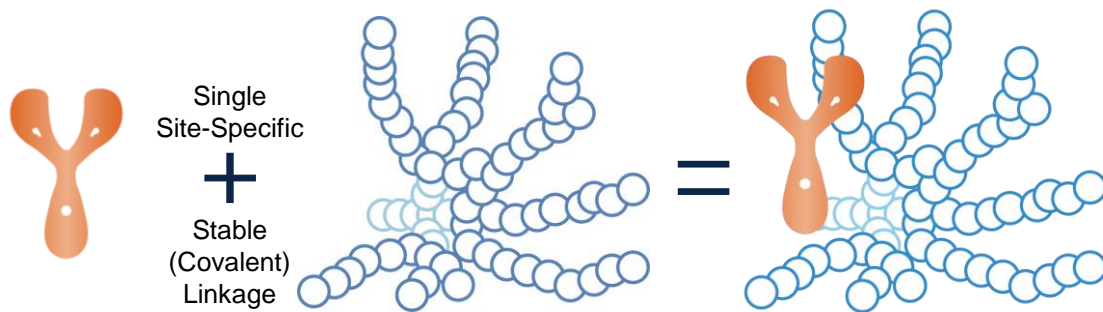
Interim data. Includes only randomized patients that reached Week 44 visit by the data cutoff date of 09 Jun 2020; 2.5 & 5 mg doses pooled. Observed data. Error bars represent standard error of the mean. OCT CST values are site reported. BCVA= best corrected visual acuity; OCT= optical coherence tomography; CST= central subfield thickness. Mean injections reflect the average number of injections received per patient between Week 12 and 40 (aflibercept per label mean number of injections 5.0).



**How can KSI-301 achieve
strong efficacy and remarkable
durability?**

Antibody Biopolymer Conjugates (ABC)

Biologics precision-engineered for increased durability and efficacy



ANTIBODY

IgG1 Antibody
Immunologically inert

BIOPOLYMER

Branched, High Molecular Weight, Optically Clear Phosphorylcholine Polymer.

CONJUGATE

A new set of integrated properties – more than the sum of its parts –

Nature's zwitterion



Structured water micro-environment



Non-adsorption



Zero-friction



Stereospecific docking



SAME WHERE IT MATTERS




- Clinically proven targets
- Antibody-based biologic
- Intravitreal: safest method of administration
- Optically clear, no residues
- Fast and potent clinical responses

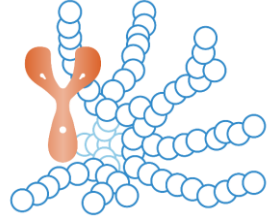
DIFFERENT WHERE IT COUNTS

- Designed-in ocular durability
- Designed-in rapid systemic clearance
- Improved bioavailability
- Improved biocompatibility
- Deeper potency

KSI-301: Next-Generation anti-VEGF

ABC Platform and higher dose for longer treatment duration

	Ranibizumab	Bevacizumab	Aflibercept
Molecule type	Antibody fragment	Antibody	Recombinant fusion protein
Molecular structure			
Molecular weight	48 kDa	149 kDa	115 kDa
Clinical dose	0.3-0.5 mg	1.25 mg	2 mg
Equivalent molar dose	0.5	0.9	1
Equivalent ocular PK	0.7	1	1
Equivalent ocular concentration at 3 months	0.001	NA ¹	1

KSI-301
Antibody Biopolymer Conjugate (ABC)

950 kDa
5 mg (by weight of antibody)
3.5
3
1,000

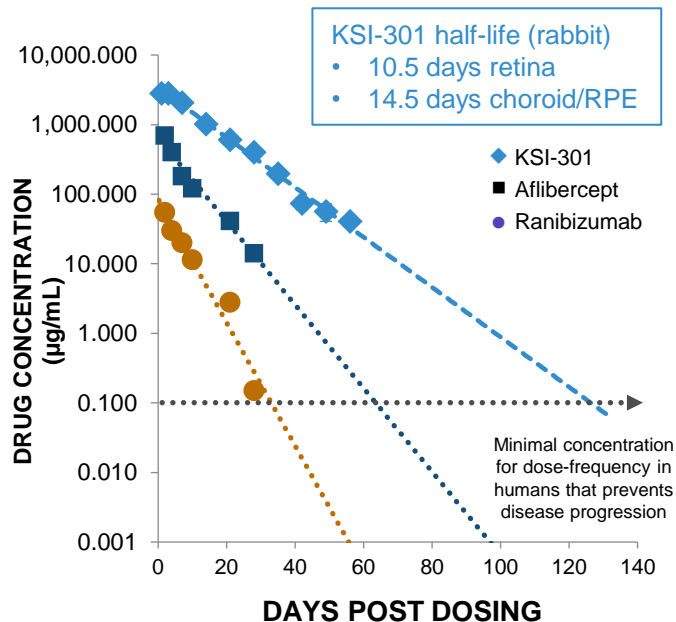
Equivalent values are shown as (approximate) fold difference relative to aflibercept. kDa= kilodalton

1. Lower affinity of bevacizumab precludes a useful comparison

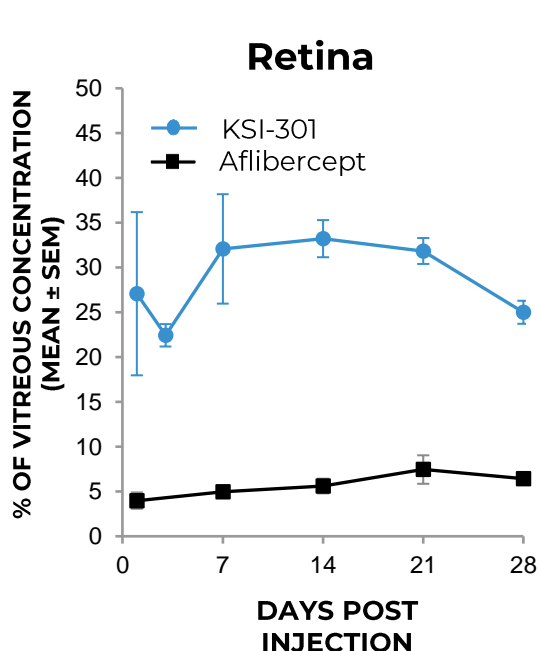
A new set of integrated properties

More than the sum of its parts

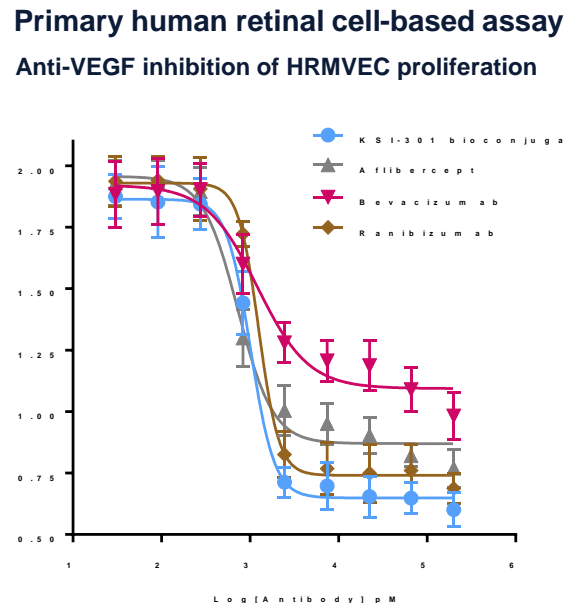
Remarkable Intraocular Half-life¹



Excellent Retinal Bioavailability²



Deeper Inhibitory Potency³



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 2,000µg 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

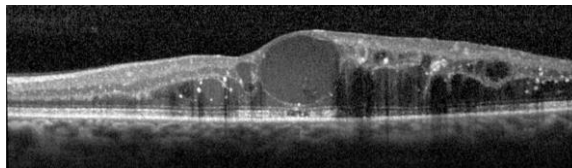
3. KSI-301 data: data on file; Bevacizumab data: Yeung et al 2010 Cancer Research.

Sustained DME control for 12 Months with only 3 loading doses can be achieved with KSI-301

OCT Images
From Phase 1b Study

3 total injections
in Year 1

Day 1
(Pre-Treatment)

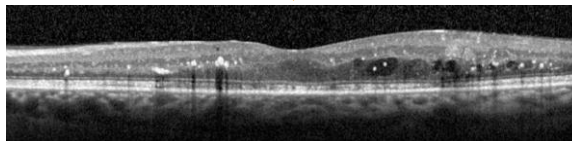


3 Loading doses

Day 1 
Week 4 
Week 8 



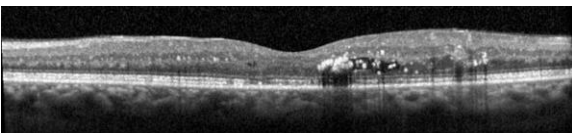
Week 12
+3 letters



1 month after 3
loading doses



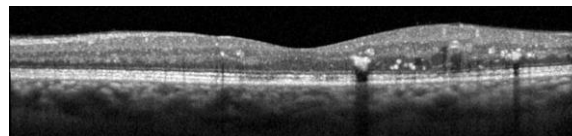
Week 32
+7 letters



6 months after 3
loading doses



Week 56
+8 letters (20/20)

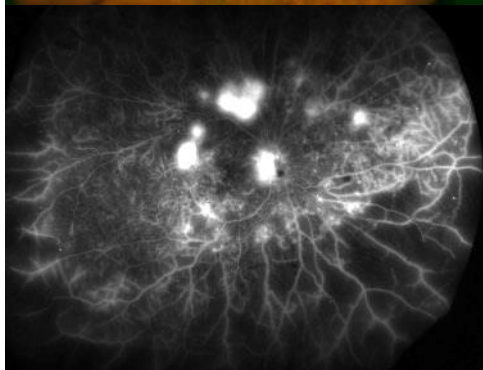
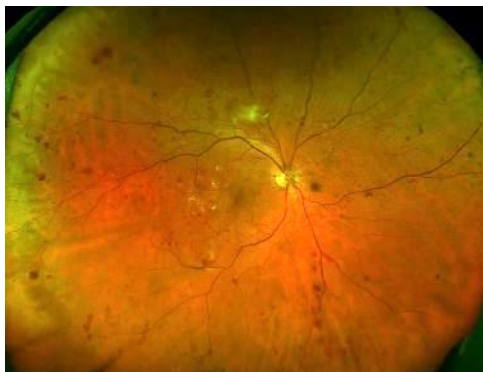


12 months after 3
loading doses

The sustained disease control of only 3 loading doses of KSI-301 is also seen in proliferative diabetic retinopathy

DAY 1

Proliferative DR (DRSS 65)



KSI-301
5 mg
3 loading doses



WEEK 12

Non-Proliferative DR (DRSS 53)

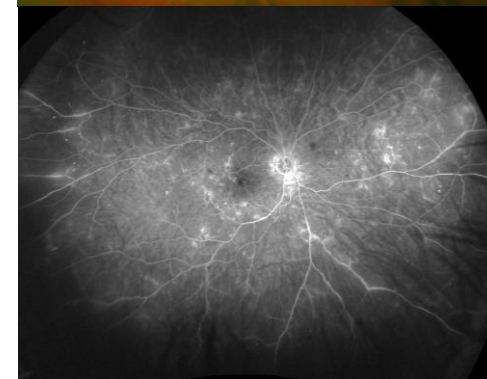
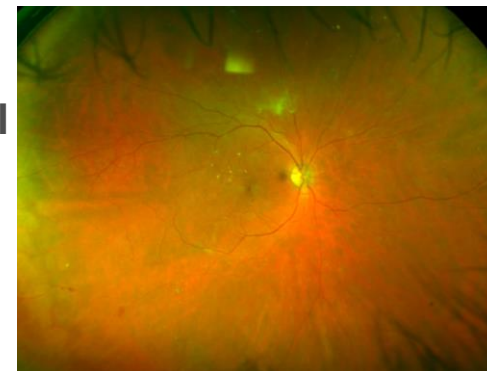


Two additional doses



WEEK 72

Non-Proliferative DR (DRSS 53)



Regression from PDR to NPDR
Fast and substantial (2-step)
improvement, sustained for 18 months
with only 2 additional doses
(26-week mean retreatment interval)

KSI-301+

A PIPELINE OF ABCs FOR RETINA

—

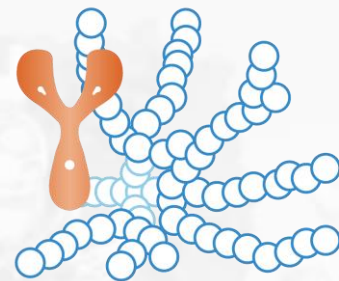
**Kodiak's deepening pipeline
of mono-, bi-specific and triplet
inhibitors that merge biologics with
small molecules to address major
causes of vision loss beyond retinal
vascular disease**

MONOSPECIFIC

1 Molecule, **1 Target**

Antibody conjugated to
phosphorylcholine biopolymer

KSI-301 inhibits VEGF—
In clinical development

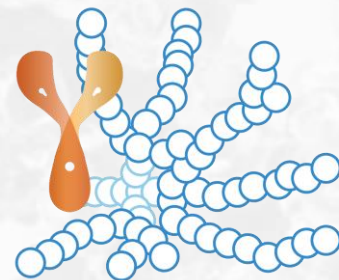


BISPECIFIC

1 Molecule, **2 Targets**

Bispecific antibody conjugated
to phosphorylcholine biopolymer

KSI-501 inhibits VEGF and IL-6 for retinal diseases with
inflammatory component—In GMP manufacturing

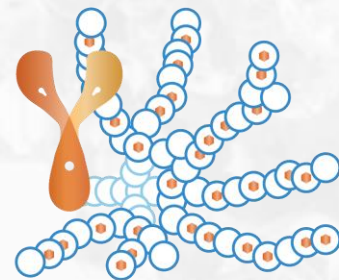


TRIPLET

1 Molecule, **3 Targets**

Bispecific antibody conjugated to
phosphorylcholine biopolymer embedded
with 100's of copies of small-molecule drug

For high-prevalence multifactorial diseases,
such as dry AMD and glaucoma—In research



NASDAQ: KOD

KODIAK.COM



KODIAK

THE OPHTHALMOLOGY MEDICINES COMPANY