

NASDAQ: KOD

KODIAK.COM

# KODIAK

THE OPHTHALMOLOGY MEDICINES COMPANY

**Corporate Presentation**

August 2022

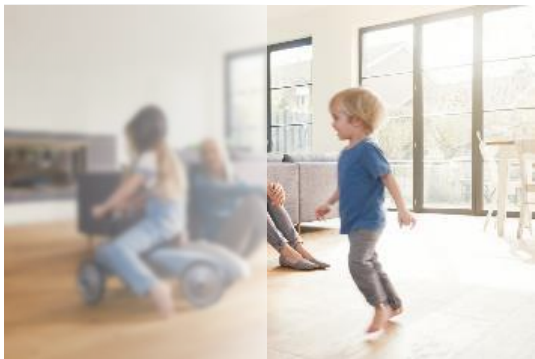
# FORWARD-LOOKING STATEMENTS

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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 ABC Platform enabling durability of tarcocimab tedromer (KSI-301, tarcocimab); dosing advantage due to tarcocimab’s molecular weight and formulation; properties of tarcocimab enabling durability in multiple studies in wet AMD and RVO; patients requiring anti-VEGF will benefit from tarcocimab; the size and growth of patients treated for certain retinal diseases; our ability to submit a BLA for tarcocimab in wet AMD, DME and RVO and NDPR; development plans; clinical and regulatory strategy, including the expected timing of various studies and INDs and potential data regarding efficacy, safety and durability of tarcocimab; our manufacturing capacity, including capacity for pre-filled syringes; our cash position; 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 risk that tarcocimab may not demonstrate safety, efficacy or durability; cessation or delay of any clinical studies and/or development of tarcocimab may occur; future regulatory milestones of tarcocimab, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; 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 economic conditions may significantly impact our business and operations, including our clinical trial sites, and those of our manufacturers, contract research organizations or other 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-K, 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

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## 1 TRAILBLAZING SCIENCE

Our creative and thoughtful foundation



## 2 GENERATION 2.0 MEDICINES

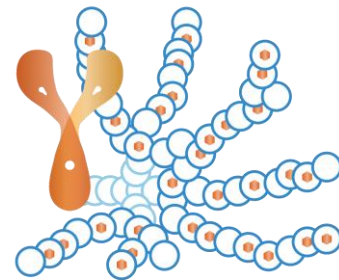
Our challenge to the status quo



## 3 SINGULAR FOCUS IN OPHTHALMOLOGY

Our 24 / 7 / 365

# FOCUSED ON DEVELOPING ABC MEDICINES FOR HIGH PREVALENCE RETINAL DISEASES



## Tarcocimab tedromer (KSI-301) AND KSI-501 FOR RETINAL VASCULAR DISEASES

*A GROWING \$13B+ MARKET WITH CLEAR UNMET NEEDS*

- Wet age-related macular degeneration (wet AMD) remains a leading cause of vision loss in the elderly
- Diabetes is the leading cause of vision loss in working-age adults
- Novel agents such as tarcocimab are needed to provide **extended durability** to reduce treatment burden and improve patient outcome
- KSI-501 targets both VEGF & Interleukin-6; targeting of retinal microvascular inflammation through IL-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 also frequently leads to irreversible vision loss, substantial functional vision limitations and loss of independence
- 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*

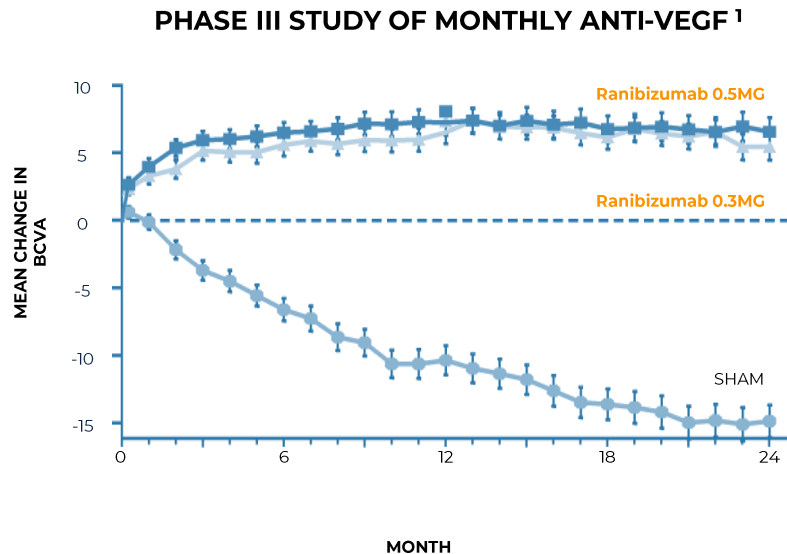
- Many patients experience progression of glaucoma and lose vision over time despite maximum medical therapy
- Available therapies today treat intraocular pressure, not the fundamental biology of retinal neuronal cell loss which is multifactorial in nature
- Our triplets technology is designed to target 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



# Today patients with retinal vascular diseases do not achieve the same therapeutic benefit in the real world as in published clinical studies, because monthly dosing is not sustainable

## In theory –

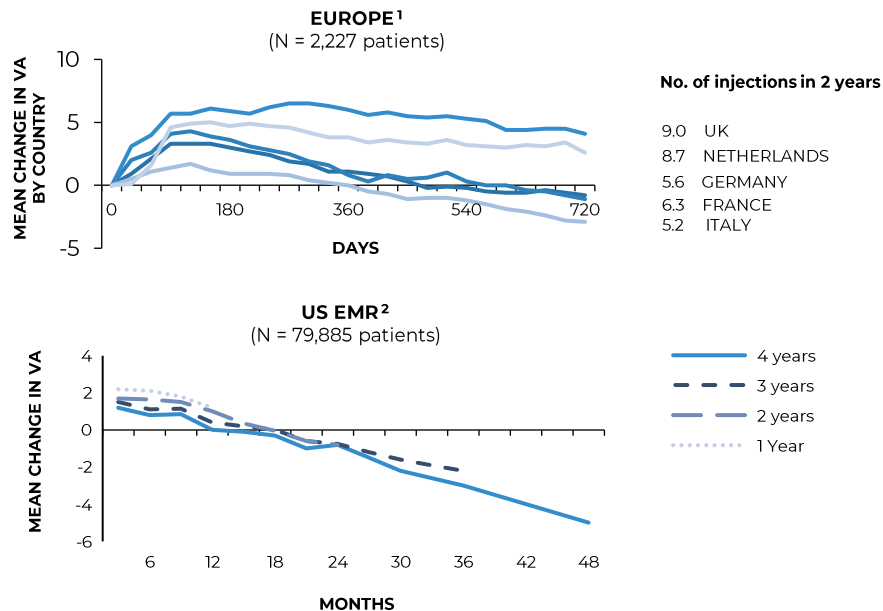
Intravitreal anti-VEGF agents improve & maintain vision when **dosed per label**...



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

## In real-world practice –

...Visual gains are minimal and not maintained. Patients are **over-extended** between doses in the real world



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. Ophthalm. Retina 2020 Feb; 4(2):122-123. EMR= Electronic Medical Records 5

# ANTIBODY BIOPOLYMER CONJUGATE ABC PLATFORM™

Biologics precision-engineered for *increased durability and efficacy*



## ANTIBODY

IgG1 with inert immune effector function

## BIOPOLYMER

Optically clear, high molecular weight phosphorylcholine polymer

## CONJUGATE

Antibody and biopolymer covalently bound via single site-specific linkage

Nature's zwitterion



Structured water micro-environment



Non-adsorption



Zero-friction



Stereospecific docking



## SAME WHERE IT MATTERS

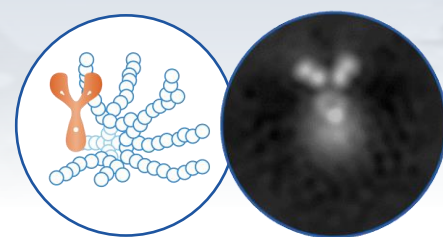
- Clinically proven targets
- Antibody-based biologic
- Intravitreal: 25M+ injections annually
- Optically clear, no residues
- Fast and potent clinical responses

## DIFFERENT WHERE IT COUNTS

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

# TARCOCIMAB TEDROMER - ANTIBODY BIOPOLYMER CONJUGATE

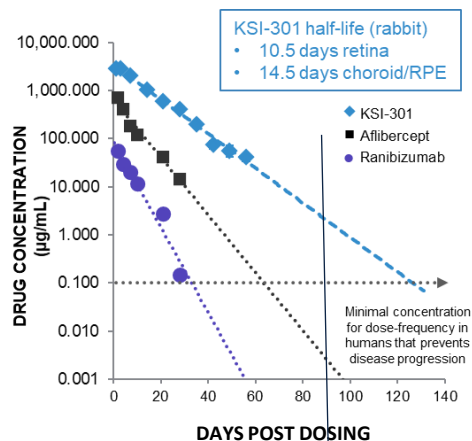
## "MORE THAN THE SUM OF ITS PARTS"



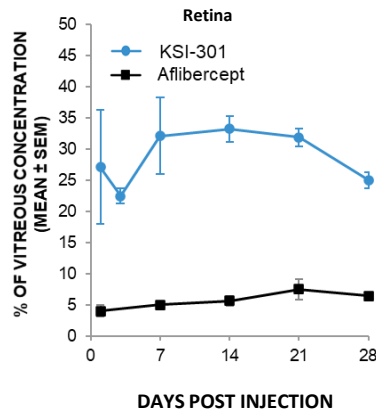
Artistic representation  
of tarcocimab  
tedromer

Electron microscope  
image of tarcocimab  
tedromer

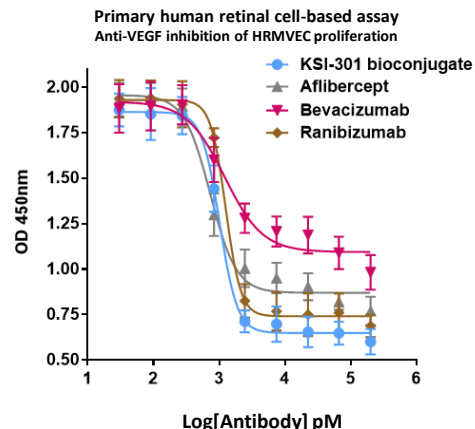
### Class-leading Intraocular Half-life<sup>1</sup>



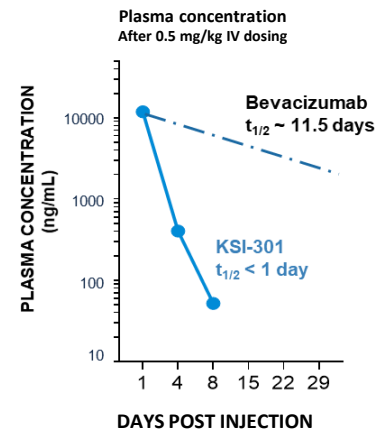
### Excellent Retinal Bioavailability<sup>2</sup>



### Deeper Inhibitory Potency<sup>3</sup>



### Fast Systemic Clearance<sup>4</sup>






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) || tarcocimab tedromer 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). tarcocimab tedromer data (2017): Covance study, data on file. Error bars reflects standard error of the mean
3. tarcocimab tedromer data: data on file; Bevacizumab data: Yeung et al 2010 Cancer Research.
4. tarcocimab tedromer data: Non-human primate toxicology study, data on file; Bevacizumab data: Yeung et al 2010 Cancer Research.

# GENERATION 2.0

## ANTI-VEGF

The high molecular weight & formulation strength of tarcocimab can provide an important dosing advantage

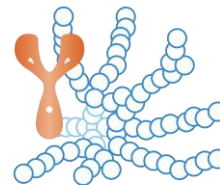
Drug:	RANIBIZUMAB (Lucentis)	AFLIBERCEPT (Eylea)	FARICIMAB (Vabysmo)
Molecule type	Antibody fragment	Recombinant fusion protein	Antibody
Molecular structure			
Molecular weight	48 kDa	115 kDa	149kDa
Clinical dose	0.3-0.5 mg	2 mg	6 mg
Equivalent molar dose	0.5	1	2
Equivalent ocular PK	0.7	1	1
Equivalent ocular concentration at 3 months	0.001	1	2 <sup>†</sup>

Equivalent values are shown as fold changes relative to aflibercept. kDa= kilodalton

<sup>†</sup>Assumes 2x starting anti-VEGF molar dose and similar ocular T<sub>1/2</sub> as Aflibercept

### Tarcocimab tedromer (KSI-301)

#### Antibody Biopolymer Conjugate (ABC)



**950 kDa**

**5 mg** (by weight of antibody)

**3.5**

**3**

**1,000**

Unique properties of tarcocimab tedromer enable best-in-class durability in Phase 1b study, Phase 2b/3 pivotal study in wet AMD and Phase 3 study in RVO

Phase 1b study<sup>1</sup> in treatment naïve patients with wet AMD, DME, RVO

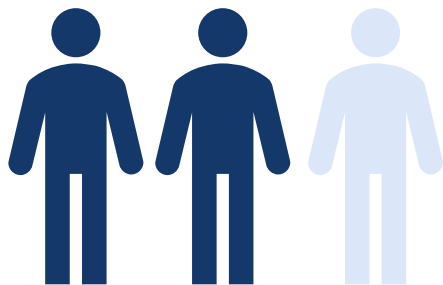
tarcocimab tedromer  
once every 1 to 6 months after 3 monthly loading doses *Extended durability shown*

Comprehensive pivotal program pursuing unmet need across all major indications for anti-VEGFs

<i>Extended durability shown</i> Wet AMD	<i>Extended durability shown</i> Retinal Vein Occlusion	Diabetic Macular Edema	Wet AMD	Non-Proliferative Diabetic Retinopathy
<b>DAZZLE Study<sup>2</sup></b> tarcocimab tedromer once every 3, 4 or 5 months after 3 monthly loading doses  versus  Aflibercept once every 2 months after 3 monthly loading doses	<b>BEACON Study<sup>3</sup></b> tarcocimab tedromer once every 2 months or longer after 2 monthly loading doses  versus  Aflibercept once every month	<b>GLEAM and GLIMMER Studies<sup>4</sup></b> tarcocimab tedromer once every 2 to 6 months after 3 monthly loading doses  versus  Aflibercept once every 2 months after 5 monthly doses	<b>DAYLIGHT Study<sup>5</sup></b> tarcocimab tedromer once every month  versus  Aflibercept once every 2 months after 3 monthly loading doses	<b>GLOW Study<sup>6</sup></b> tarcocimab tedromer once every 6 months after 3 initiating doses  versus  Sham
Primary results Feb 2022	Positive primary results Aug 2022	Primary results expected in 2023		

# PHASE 1B STUDY: TARCOCIMAB DEMONSTRATED UNPRECEDENTED DURABILITY ACROSS ALL MAJOR RETINAL VASCULAR DISEASES

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



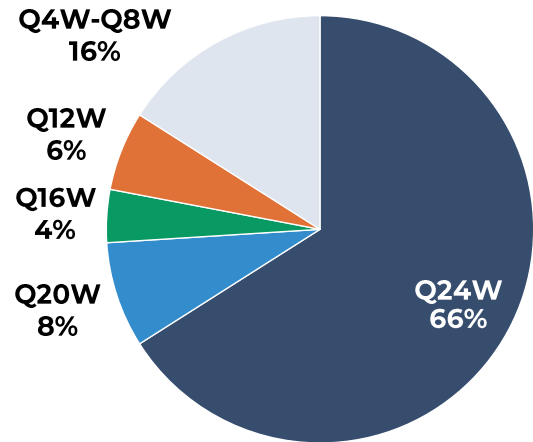
**2 in every 3 patients are on a 6-month or longer treatment-free interval at Year 1, after only 3 loading doses**

Dosing Interval and Outcome at Year 1	Wet AMD N = 50	DME N = 32	RVO N = 32
1 – 3 months	22%	16%	25%
4 months	4%	6%	6%
5 months	8%	9%	3%
<b>≥6 months</b>	<b>66%</b>	<b>69%</b>	<b>66%</b>
<b>Mean # Injections during Year 1</b>	<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)
<i>Mean ΔBCVA from Baseline (ETDRS Letters)</i>	+5.7	+7.6	+22.2
<i>Mean ΔOCT CST from Baseline (μm)</i>	-105	-136	-357
<b>Safety in line with today's first-line medicines</b>			

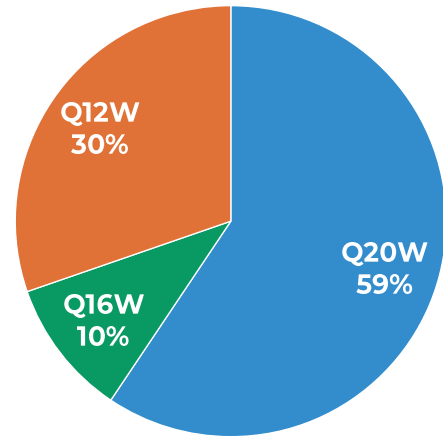
Phase 1b Year 1 data. 2.5 & 5 mg doses pooled. Includes only patients that received all (3) loading doses and either a) received a dose before Week 52 or b) did not receive a dose and were followed for at least six months after the last loading dose (Week 32 visit). Interval at Year 1 reflects the treatment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

**Phase 2b/3 study in wet AMD did not meet its primary endpoint due to undertreatment in some patients, though it demonstrated consistent durability for majority of tarcocimab patients**

**Phase 1b study durability in wet AMD (n=50)<sup>1</sup>**



**Phase 2b/3 study durability in wet AMD (n=238)<sup>2</sup>**



Proportion of patients in the tarcocimab arm on each treatment interval at Year 1













**Bioconjugate engineering leads to compelling durability of tarcocimab that has been demonstrated in both early and late-stage clinical studies in wet AMD**




1. Phase 1b is a randomized, open label study to evaluate multidose safety, efficacy and durability in wet AMD, DME and RVO. 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.

2. Phase 2b/3 is a randomized, double-masked non-inferiority study of tarcocimab tedromer Q12W to Q20W vs aflibercept Q8W in treatment-naïve wet AMD patients; data shown for patients completing Year 1

# BEACON Phase 3 study in RVO: Tarcocimab demonstrated non-inferiority in treatment-naïve RVO patients while doubling dosing interval compared to aflibercept – a first for anti-VEGFs

## BEACON Phase 3 Pivotal Study Design

Week	Fixed-Interval Treatment Period						PE
	0	4	8	12	16	20	24
Tarcocimab 5 mg (n=284)							
Aflibercept 2 mg (n=284)							

 Tarcocimab injection  
 Aflibercept Injection  
 Sham

Primary Endpoint

## Topline Results

- Tarcocimab dosed every 2 months met the primary endpoint of non-inferior visual acuity gains compared to standard of care aflibercept dosed monthly
- Statistically significant p-value of 0.0004 in BRVO patients
- Statistically significant p-value of 0.0243 in all RVO patients (BRVO + CRVO)
- Tarcocimab was safe and well tolerated with low intraocular inflammation (1.4% for tarcocimab vs. 0.4% for aflibercept) and no new or unexpected safety signals

**Tarcocimab is the first anti-VEGF to demonstrate robust vision and anatomic outcomes while doubling the treatment interval in patients with RVO**

“BEACON is the first study to successfully test a doubling of the treatment interval for anti-VEGF dosing in a pivotal trial in RVO patients. Testing only two loading doses and an extended, fixed dosing interval for *all* patients rather than assigning a subset of patients to extended dosing based on disease activity assessment is an especially high bar because eyes of patients with RVO can have the highest VEGF levels across retinal vascular diseases.”

-- BEACON study investigator

The ongoing Phase 3 studies will provide continuing data on the efficacy, safety and durability of tarcocimab tedromer, expected over the next 12 months

### Diabetic Macular Edema

#### Comparator

Aflibercept  
**once every 2 months**  
after 5 monthly doses

#### GLEAM and GLIMMER Studies<sup>1</sup>

Tarcocimab tedromer  
**once every 2 to 6 months**  
after 3 monthly loading doses

4  
Minimum doses in  
Year 1<sup>a</sup>

Proactive, individualized dosing as  
often as every 8 weeks

Primary endpoint: average of weeks  
60 and 64

### Wet AMD

#### Comparator

Aflibercept  
**once every 2 months**  
after 3 monthly loading doses

#### DAYLIGHT Study<sup>2</sup>

Tarcocimab tedromer  
**once every month**

Monthly Dosing

Intensive treatment regimen

Primary endpoint: average of weeks  
40, 44 and 48

### Non-Proliferative Diabetic Retinopathy

#### Comparator

Sham

#### GLOW Study<sup>3</sup>

Tarcocimab tedromer  
**once every 6 months**  
after 3 initiating doses

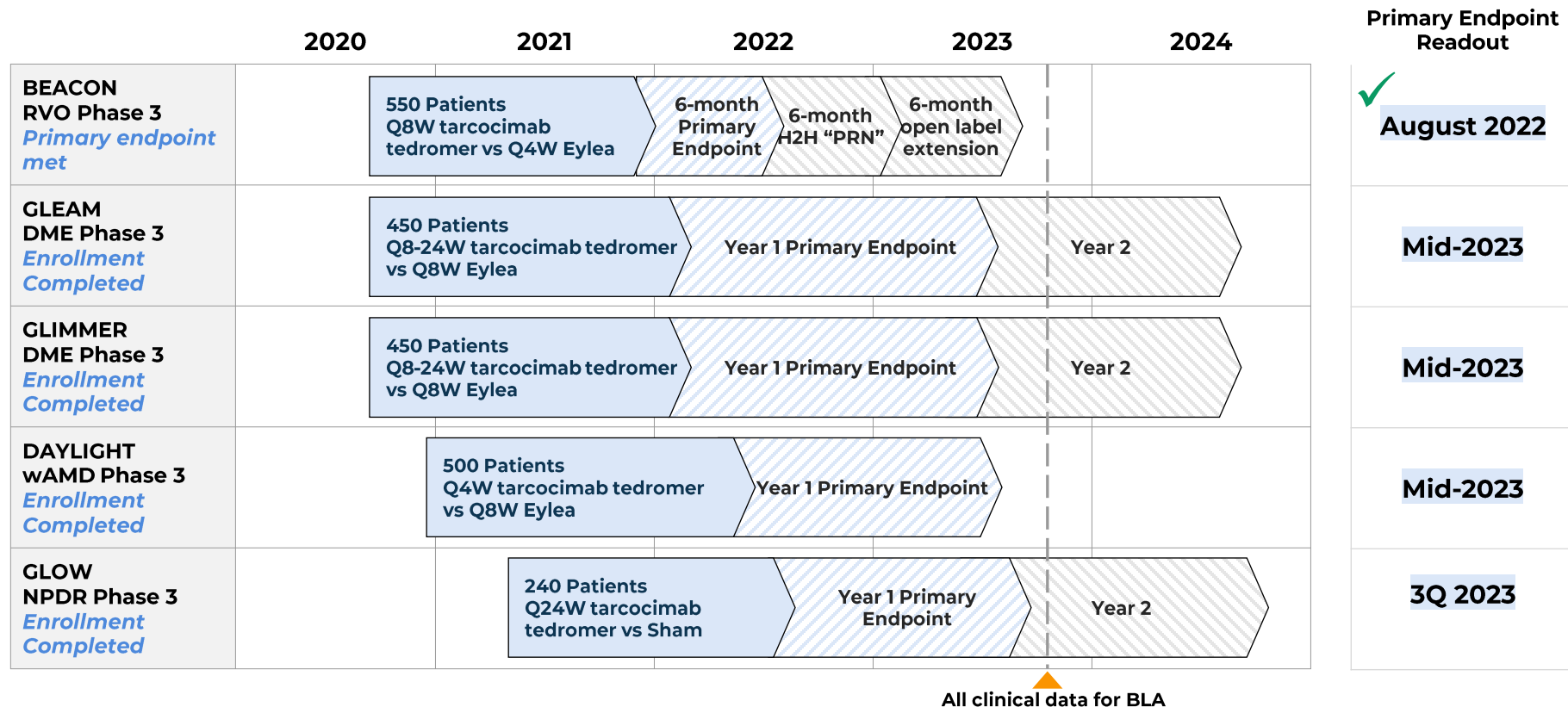
4  
Doses in  
Year 1<sup>a</sup>

Tarcocimab versus sham

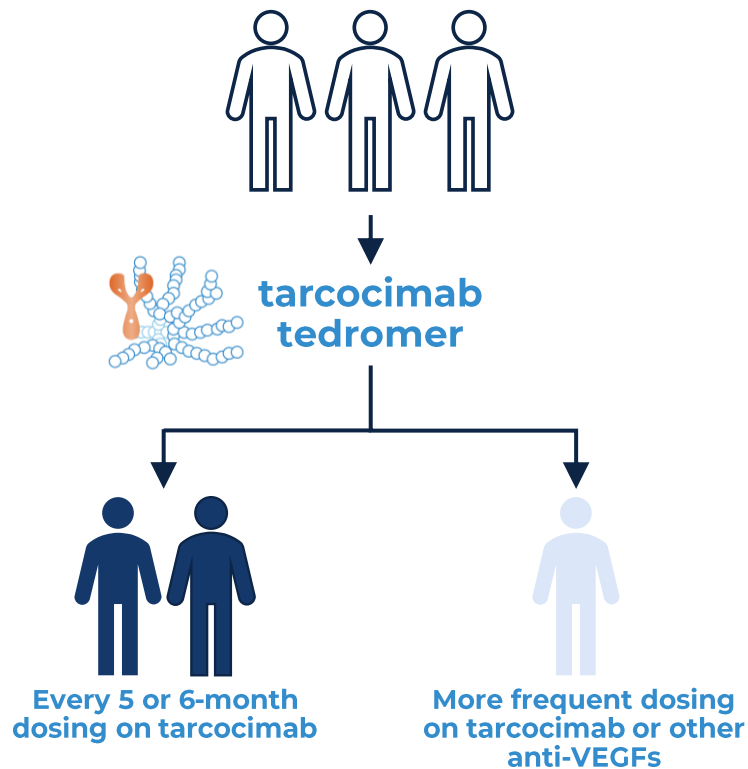
Treatment and prevention of  
diabetic retinopathy complications

Primary endpoint: week 48

# Tarcocimab clinical development: regulatory strategy anticipates a single potential BLA across the indications of RVO, DME, wet AMD and NPDR



# OBJECTIVE WITH TARCOCIMAB TEDROMER: A NEW FIRST-LINE ANTI-VEGF WITH THE PROMISE OF BEST-IN-CLASS DURABILITY



## DESIGNED WITH WATER IN MIND

- The ABC Platform is at the heart of our retinal medicines. Our bioconjugates are inspired by nature and precision engineered for increased durability and sustainable real-world efficacy

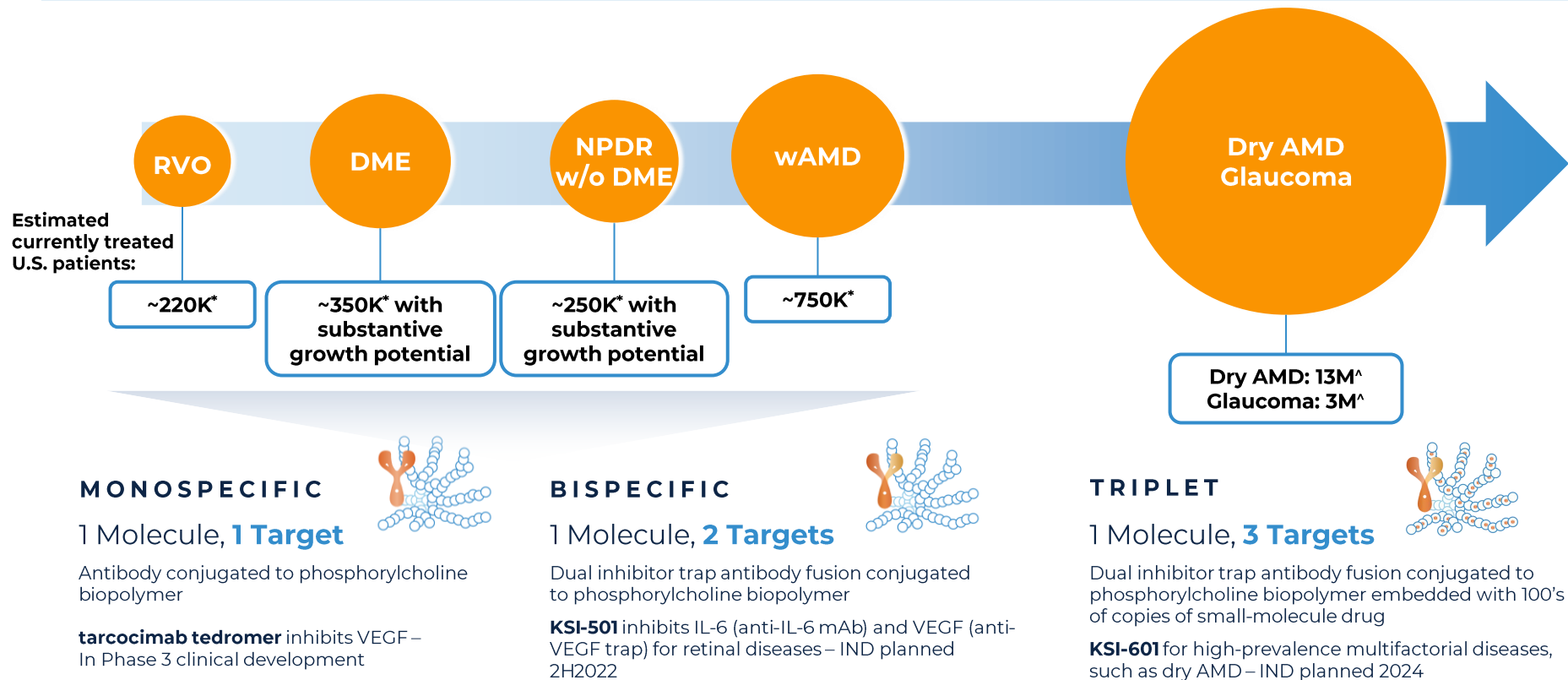
## TRUE LONG-INTERVAL DOSING

- Our lead product candidate tarcocimab tedromer has demonstrated in early and late-stage clinical studies the ability to bring nearly two thirds of patients to every 5 or 6-month dosing, unique among intravitreal anti-VEGF agents

## EVERY PATIENT'S GOAL

- Every patient needing anti-VEGF should be considered a first-line candidate to benefit from the promise of tarcocimab and our pipeline of next generation retinal medicines

# A pipeline of ABCs for retina: advancing Kodiak's pipeline to address major causes of vision loss beyond retinal vascular disease



Note: \*Estimated patients treated with intravitreal anti-VEGFs in the U.S.. ^Estimated prevalence in the U.S.

wAMD: wet age-related macular degeneration; DME: diabetic macular edema; RVO: retinal vein occlusion; NPDR: non-proliferative diabetic retinopathy

KODIAK SCIENCES

## WHERE WE ARE TODAY

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### TARCOCIMAB TEDROMER - COMPREHENSIVE DEVELOPMENT PROGRAM

- Objective: a new first-line anti-VEGF with the promise of best-in-class durability
- Recent milestone: Tarcocimab met primary endpoint of non-inferiority in vision while doubling treatment interval in BEACON Phase 3 study in RVO – a first for anti-VEGF agents
- All pivotal studies have completed enrollment; Topline results from DME studies, short-interval wAMD study and NPDR study expected in the next ~12 months



### PRAGMATIC OPERATING APPROACH

- Intent for single potential BLA in the key indications of DME, RVO, wAMD and NPDR
- Manufacturing investments, including pre-filled syringe, aligned to clinical and commercial opportunity



### MEANINGFUL COMMERCIAL OPPORTUNITY

- Pivotal clinical study package at BLA designed for broad dosing label across multiple indications
- 5 or 6-month durability in DME; Doubling of treatment interval in RVO; 6-month durability in NPDR; Approval (monthly) in wAMD would enable dose flexibility
- Compelling durability and comparable safety to standard of care would enable tarcocimab to play an important role in fulfilling unmet needs in retinal diseases



### PIPELINE AND TECHNOLOGY LEADERSHIP IN RETINA

- Bispecific ABC medicine with promise for increased efficacy and durability in DME and wAMD
- Triplet ABC medicines progressing towards multi-mechanism diseases, including dry AMD and glaucoma, as well as further improving outcomes in retinal vascular and exudative diseases



### HEALTHY CASH RUNWAY THROUGH 2024

- Well capitalized to build a successful and valuable ophthalmology medicines company