# KODIAK

THE OPHTHALMOLOGY MEDICINES COMPANY

Business Highlights and 4Q and Full Year 2023 Financial Results - Webcast

March 28, 2024

### FORWARD-LOOKING STATEMENTS

These slides contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements are not based on historical fact and include statements regarding: the potential benefits of KSI-501, including that it may represent a new category of retinal medicines with greater therapeutic efficacy than existing therapies; the prospects of the candidates in our pipeline, including tarcocimab, KSI-501, and KSI-101; our ability to apply our clinical experience with tarcocimab to allow us to design and run an additional pivotal study, and the potential success of such study; the expected enhancements and benefits of a new formulation; our and Lonza's (our manufacturing counterpart) ability to successfully execute on our manufacturing development plan and our guidance on our cash runway. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "plan," "believe," "intend," "pursue," and other similar expressions among others. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forwardlooking statements. The risks and uncertainties include, but are not limited to: the risk that cessation or delay of any of the on-going clinical studies and our development of tarcocimab or KSI-501 may occur; the risk that the BEACON and/or GLOW1 and/or GLOW2 and/or DAYLIGHT results may not provide the evidence, insights, or benefits as anticipated; the risk that safety, efficacy, and durability data observed in our product candidates in current or prior studies may not continue or persist; the risk that the results of the tarcocimab Phase 3 studies may not be sufficient to support a single Biologics License Application (BLA) submission for wet AMD, RVO and NPDR; the risk that a BLA may not be accepted by, or receive approval from, the FDA or foreign regulatory agencies when expected, or at all; future potential regulatory milestones of tarcocimab or KSI-501 or KSI-101, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; the risk that a new formulation of tarcocimab, KSI-501 or other ABC Platform derived molecules may not provide the benefits expected; our research and development efforts and our ability to advance our product candidates into later stages of development may fail; the risk that KSI-501 may not inhibit VEGF and IL-6 or have an impact on the treatment of patients as expected; any one or more of our product candidates may not be successfully developed, approved or commercialized; our manufacturing facilities may not operate as expected; adverse conditions in the general domestic and global economic markets, which may significantly impact our business and operations, including 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-K, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and Kodiak undertakes no obligation to update forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements. Kodiak®, Kodiak Sciences®, ABC™, ABC Platform™, and the Kodiak logo are registered trademarks or trademarks of Kodiak Sciences Inc. in various global jurisdictions.

#### 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

# A portfolio of 3 clinical programs: 2 are ABC Platform-derived and 1 is Platform-independent, with significant operational synergy and risk diversification







## Antibody Biopolymer Conjugate ("ABC") Platform-derived biologics for extended durability in high prevalence retinal diseases

- A protein therapeutic, engineered for high affinity and specificity, is combined with a bioinspired polymer designed for extended ocular half life and therapeutic benefit
- Precision engineered for increased durability in high prevalence retinal diseases
- Go-to-market formulation that improves the manufacturability in a prefilled syringe and may also enhance the utility of the product

# Unconjugated biologic for inflammatory retinal diseases

- First-in-class bispecific protein targets inflammation and vascular permeability
- Address the underlying disease mechanisms of vision-threatening retinal inflammatory conditions for which no approved intravitreal biologic therapies exist today

#### TARCOCIMAB TEDROMER (anti-VEGF ABC)

- 3 positive Phase 3 studies: Diabetic Retinopathy (DR), Retinal Vein Occlusion (RVO) and wet AMD
- Strong and consistent 6-month durability signal and favorable safety across the pivotal program
- · Regulatory alignment achieved on bridging strategy for go-to-market formulation
- Phase 3 study GLOW2 in DR now actively recruiting patients
- Added as an additional arm in DAYBREAK to validate the durability in wet AMD, strengthen its competitive position and bolster our ex-U.S. regulatory dossier

#### KSI-501 (anti-IL-6, VEGF trap bispecific ABC, formerly KSI-501ABC)

- Phase I study in DME met objectives: (1) repeated monthly dosing was safe and well tolerated; (2) KSI-50I achieved clinically meaningful and sustained visual acuity gains
- Being developed for high prevalence retinal vascular diseases to address the unmet needs of targeting multiple biologies and extended durability
- Enhanced formulation informed from tarcocimab's commercial manufacturing scale-up
- In process of gaining FDA alignment on the design of Phase 3 DAYBREAK study in wet AMD; targeting enrollment start mid-2024

#### KSI-101 (anti-IL-6, VEGF trap bispecific protein, formerly KSI-501P)

- · Being developed for macular edema associated with inflammation
- A greenfield market opportunity outside the established anti-VEGF class and uncoupled from the ABC platform
- Phase 1b planned for 2Q24 to identify 2 dose levels to progress into pivotal studies
- In process of gaining FDA alignment on the design of Phase 2b/3 pivotal studies, which are planned for 2024

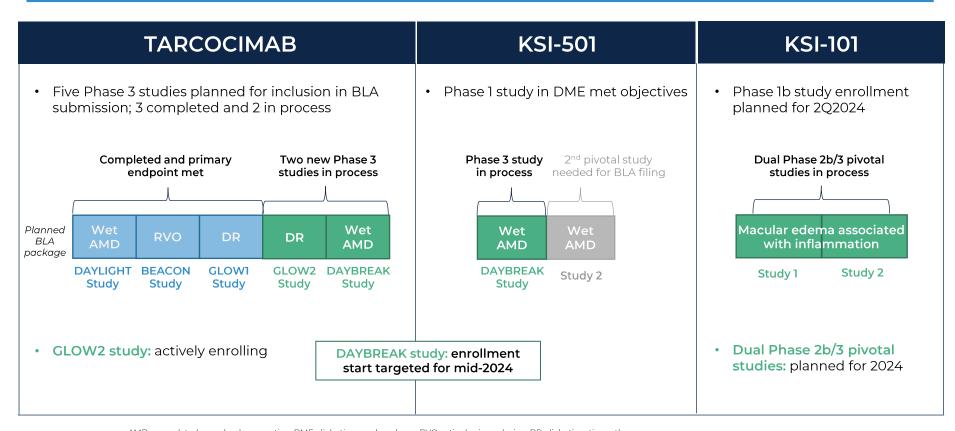
#### KODIAK SCIENCES

# WHERE WE ARE TODAY

- \$286 million in cash and cash equivalents as of end of 4Q23
- Advancing 3 clinical programs into Phase 3 studies in 2024
- Planning to achieve meaningful inflection points within our current cash runway

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# Advancing tarcocimab toward BLA with GLOW2; accelerating KSI-501 and KSI-101 development with rapid paths to Phase 3 value inflection points





# Tarcocimab Tedromer

**Anti-VEGF "ABC"** 





#### Three positive Phase 3 studies in large indications:

- Diabetic retinopathy (GLOW1)
- Retinal vein occlusion (BEACON)
- Wet AMD (DAYLIGHT)



**Signature durability derived from the ABC platform:** targeting 6-month durability in the majority of patients



Favorable safety with >2,500 patient years of exposure

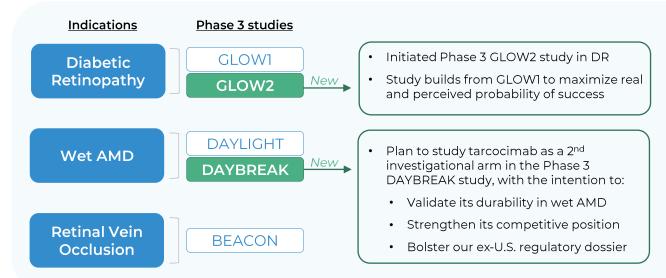


**Go-to-market formulation** that improves the manufacturability in a prefilled syringe and may also enhance the utility of the product

We believe tarcocimab can be a meaningfully differentiated product, and we intend to finish the clinical development of the program to enable marketing authorization application

# Plan to evaluate tarcocimab in two new Phase 3 studies, in DR and wet AMD, using the go-to-market formulation that improves manufacturability and may enhance utility

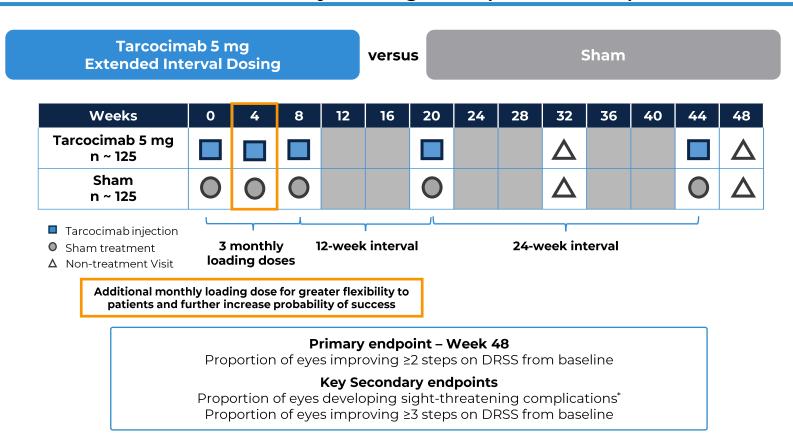
- · We believe tarcocimab can be an important medicine for patients and a meaningfully differentiated product in the marketplace
- Go-to-market formulation that improves manufacturability in a prefilled syringe and may also enhance the utility of the product is available at commercial scale (minimal incremental manufacturing cost to BLA filing and regulatory approval)
- Received FDA feedback that a single additional successful pivotal study using the go-to-market formulation should be sufficient to bridge clinical scale material to the go-to-market material



- Obtained FDA feedback on study design
- GLOW 2 is actively enrolling patients

- In the process of obtaining FDA feedback on study design
- Targeting mid-2024 to start recruitment

# GLOW2 features a similar study design as the successful GLOW1 study, with the benefit of an additional 3<sup>rd</sup> monthly loading dose (Week 0, 4, 8)



### **KSI-501**

Anti-IL-6 and VEGF trap bispecific "ABC"





#### First-in-class bispecific ABC designed to inhibit two mechanisms implicated in high-prevalence retinal vascular diseases

 IL-6 is implicated in anti-VEGF treatment resistance, stimulates defective angiogenesis and is associated with disease progression in AMD, DR and RVO



Targets two biologies (Innovation 1)



Potential for 6-month durability based on the ABC Platform (Innovation 2)

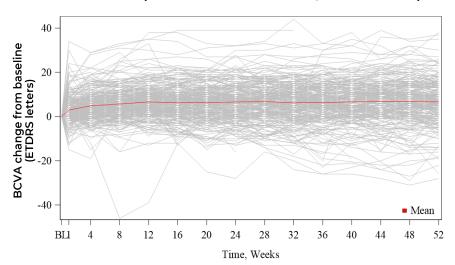


Enhanced formulation informed from tarcocimab's commercial manufacturing scale-up (Innovation 3)

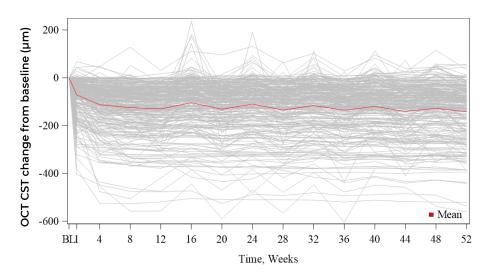
The KSI-501 program is the result of fine-tuning our ABC platform and Company, fast forwarding 10 years of design, manufacturing, clinical and operational expertise

# Substantial patient-to-patient variability is observed with anti-VEGF monotherapy, suggesting the need for additional mechanisms of action

### BCVA change from baseline during year 1 for individual patients treated with Q8W aflibercept



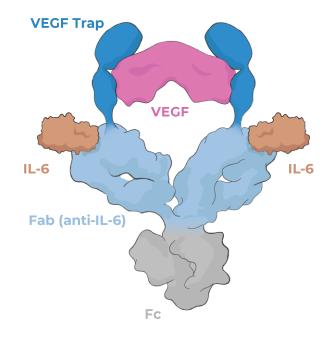
### OCT CST change from baseline during year 1 for individual patients treated with Q8W aflibercept



A substantial portion of patients underperform in vision and anatomical improvement compared to the mean BCVA and OCT responses



#### "Two hands on the ball"



### KSI-501 bispecific protein features unique design that enables highly efficient binding to both IL-6 and VEGF

#### BINDING CAPACITY OF UP TO 3 MOLECULES

This first-in-class bispecific has the capability of inhibiting one VEGF dimer in addition to two IL-6 molecules, simultaneously

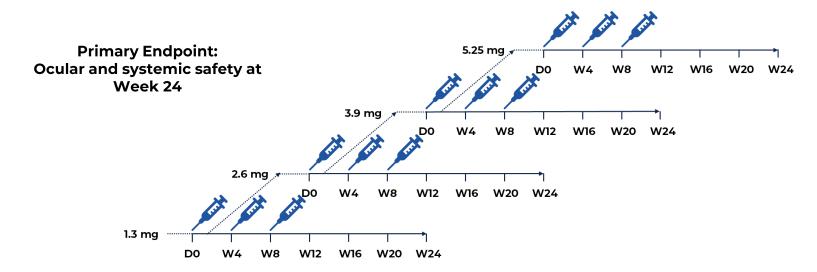
#### **BEST-IN-CLASS VEGF INHIBITION**

The VEGF trap mimics the native receptor and binds multiple targets including VEGF-A, VEGF-B and PIGF

#### ANTI-IMMUNE, ANTI-INFLAMMATION

The anti-IL-6 Fab blocks inflammation and normalizes the blood retinal barriers

# Phase 1 study of KSI-501 was a multiple ascending dose study in patients with diabetic macular edema



#### **Study Design**

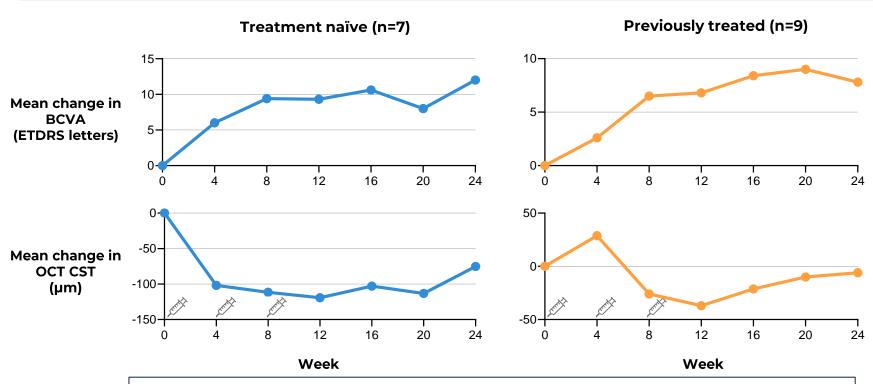
- Multiple ascending dose design
- Conducted at 5 sites in the US
- 3-5 subjects planned to be enrolled for each dosing group, with option for expansion of each group if indicated
- Each subject received 3 monthly doses and was followed for 24 weeks total

#### **Key Inclusion / Exclusion Criteria**

- Adults ≥21 years of age
- Diabetes mellitus type 1 and 2 (HbA1c ≤12%)
- Vision loss due to DME
- BCVA between 25 and 70 ETDRS letters (20/40 20/320 Snellen)
- DME (CST ≥320 microns)
- Treatment naïve and previously treated with an 8-week washout period



# KSI-501 demonstrated robust and meaningful visual acuity gains that were sustained over 16 weeks in both treatment naïve and pre-treated patients



- Corresponding anatomical improvement was observed in both treatment naïve and pre-treated patients, with meaningful and sustained improvement in treatment-naïve patients
- Treatment naïve patients are planned to be the target population of Phase 3 studies

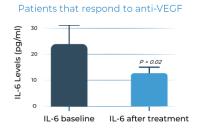


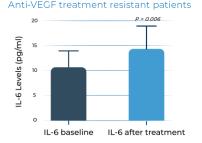
#### Plan to advance KSI-501 into the Phase 3 DAYBREAK study in wet AMD in 2024

- Abundant preclinical evidence shows that IL-6 promotes choroidal neovascularization in animal models of wet AMD
- Clinical evidence demonstrates that IL-6 is associated with:
  - Development and progression of AMD
  - Resistance to anti-VEGF treatment in wet AMD patients
  - Re-activation of disease by promoting growth of new neovascular membranes

 A meta-analysis across 19 studies found that systemic IL-6 level is positively associated with AMD (p=0.0005) and significantly elevated in wet AMD patients (p=0.003)<sup>1</sup>

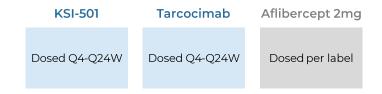
 Serum IL-6 level was found to be associated with the 20-year cumulative incidence of early AMD<sup>2</sup> Aqueous humor IL-6 levels significantly correlate with anti-VEGF treatment response in wAMD<sup>3</sup>





### DAYBREAK

- Designed to evaluate the efficacy, durability and safety of KSI-501 and tarcocimab in wet AMD
- Intended to be a non-inferiority study



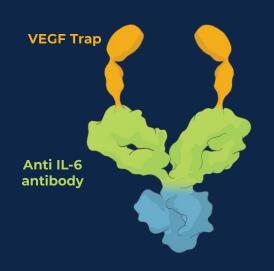
- Will use the go-to-market formulation of KSI-501 and tarcocimab
- In the process of obtaining FDA alignment on study design; targeting mid-2024 to start recruitment

1. Nahavandipour et al. (2020). ACTA OPHTHALMOLOGICA 98: 434-444. 2. Klein et al. 2014. JAMA Ophthalmol 132 (4): 446-455. 3. Adapted from Chalam et al. (2014). Journal of Ophthalmology, Article ID 502174. Mean with SEM plotted. pg/ml: picogram per milliliter



## **KSI-101**

Anti-IL-6 and VEGF trap bispecific protein





# First-in-class bispecific protein to address inflammation and vascular permeability concurrently

 Inflammation is present in a wide spectrum of retinal diseases that lack intravitreal biologic options today



A new market segment separate from the established anti-VEGF market



Opportunities and risks uncoupled from the ABC Platform



Highly potent inhibition of both targets and high formulation strength (100mg/ml)

KSI-101 is being developed for patients who have macular edema associated with inflammation

High unmet need for safer, disease modifying therapies. The opportunity is primed for safe and effective biologics to move up the treatment pathway towards first line therapy

#### Current treatment algorithm for macular edema associated with inflammation

1L 2L 2L or 3L 3L or 4L or adjunct

### Local or systemic corticosteroids

- Mainstay of therapies
- Associated with elevated intraocular pressure/glaucoma that often require therapy and even surgery as well as cataract progression
- 30–40% of patients do not respond

- Off-label use
- Used as steroidsparing agents
- Up to 50% of patients do not have macular edema resolved

**Immunomodulators** 

 ~35% of patients do not experience improvement in macular edema

#### Biologic

- Adalimumab (anti-TNFα) is currently the only FDA-approved nonsteroid therapy for NIU
- Used as a steroidsparing therapy
- ~55% of patients experienced treatment failure over 85 weeks
- Associated with serious side effects (e.g., infections, malignancies)

## Anti-VEGF agents

- Used for patients with persistent macular edema associated with inflammation that fail conventional therapies
- However, the underlying inflammatory component of the pathophysiological process is not addressed by inhibiting VEGF alone

# Plan to initiate a Phase 1b study in 2Q24; dual Phase 2b/3 pivotal studies planned for later in the year following regulatory alignment on study design

- Intend to start a dose-finding Phase 1b study in 2Q2024 to identify two dose levels to progress into pivotal studies
- Currently in conversation with the FDA on the design of Phase 2b/3 pivotal studies, which we hope to initiate later in 2024

### Tarcocimab tedromer



- Phase 3 GLOW2 in DR now recruiting
- Validating durability in Phase 3 DAYBREAK wet AMD study
- One successful clinical trial away from filing for registration

#### KSI-501



- First-in-class, anti-IL-6 and anti-VEGF bispecific ABC
- Phase 3 DAYBREAK in wet AMD targeted for enrollment mid-2024

#### **KSI-101**



- First-in-class, anti-IL-6 and anti-VEGF bispecific protein
- Phase 1b in macular edema associated with inflammation planned for 2Q2024
- Dual Phase 2b/3 pivotal studies planned for 2024

#### KODIAK SCIENCES

# NEXT STEPS

- \$286 million in cash and cash equivalents as of end of 4Q23
- Advancing 3 clinical programs into Phase 3 studies in 2024
- Planning to achieve meaningful inflection points within our current cash runway