



## Kodiak Sciences Announces Fourth Quarter and Full Year 2022 Financial Results and Recent Business Highlights

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PALO ALTO, Calif., March 28, 2023 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), a biopharmaceutical company committed to researching, developing and commercializing transformative therapeutics to treat high prevalence retinal diseases, today reported business highlights and financial results for the fourth quarter ended December 31, 2022.

"We are running a comprehensive development program for tarcocimab tedromer with topline data from four Phase 3 studies planned for 2023: two for the long-interval treatment of diabetic macular edema (GLEAM and GLIMMER studies), one for the long-interval treatment and prevention of worsening of non-proliferative diabetic retinopathy (GLOW study) and one for the short-interval treatment of wet age-related macular degeneration (DAYLIGHT study). We are on track to announce topline primary endpoint data from all four studies in the third quarter of this year. Durability clearly matters to the community of retina patients, physicians and payors, and our Phase 3 program is testing the longest treatment intervals of any intravitreal biologic while preserving dosing flexibility for high-need patients," said Victor Perlroth, MD, Chief Executive Officer of Kodiak Sciences. "We are also pleased to be screening patients in the Phase 1 clinical study of our second ABC platform product candidate to enter the clinic, KSI-501. KSI-501 is our bispecific antibody biopolymer conjugate which inhibits both VEGF and IL-6 and thus targets two important biological mechanisms in retinal diseases - angiogenesis and inflammation - and which represents an exciting new category of retinal medicine. As we enter 2023, we are strongly positioned to execute on our vision for tarcocimab, to become a true platform company as we bring KSI-501 with its bispecific mechanism of action into the clinic and to continue our unique franchise build in retinal science and medicines development."

### Recent Business Highlights

- **Tarcocimab pivotal program:** The tarcocimab pivotal program continues to make steady operational progress. In 2022, we completed enrollment in all four of our ongoing Phase 3 pivotal studies, namely our paired Phase 3 studies GLEAM/GLIMMER in DME, our Phase 3 GLOW study in NPDR and our Phase 3 study DAYLIGHT in wAMD. We were encouraged by the positive outcome of our Phase 3 BEACON study in RVO and by the promising safety profile tarcocimab demonstrated in BEACON. We are currently on track to release topline data from the four ongoing Phase 3 studies in the third quarter of 2023.
- **Commercial Manufacturing:** We continue to make substantial progress in our commercial manufacturing capabilities in collaboration with our partner Lonza. Our custom-built commercial scale manufacturing facility, Ursus, achieved mechanical completion in the first half of 2022, was commissioned as a cGMP facility in January 2023, and we began the manufacturing of commercial scale cGMP batches in the first quarter of 2023.
- **Pipeline Progression:** In 2022, we broadened our development pipeline of product candidates built on our ABC Platform with the filing of the Investigational New Drug (IND) application with the US FDA for KSI-501. KSI-501 is an investigational, first-in-class bispecific ABC that is designed to inhibit two mechanisms implicated in retinal diseases: vascular endothelial growth factor (VEGF) and interleukin-6 (IL-6). IL-6 is a pro-inflammatory cytokine and growth factor implicated in the pathophysiology of multiple retinal diseases and, in conditions for which anti-VEGF treatment is used, elevated levels of ocular IL-6 have been associated with poor anti-VEGF treatment response. KSI-501 is a trap-antibody fusion biopolymer conjugate designed to provide potent inhibition of (i) VEGF-mediated angiogenesis and vascular permeability through a soluble decoy receptor inhibiting the binding of VEGF-A and PLGF to their cognate receptors and (ii) IL-6 mediated inflammation through an antibody that binds soluble interleukin-6, inhibiting its binding to both soluble and membrane-bound IL-6 receptors. In preclinical studies KSI-501 was found to inhibit angiogenesis and also normalize inner and outer blood retinal barriers in primary-cell assays. Dual inhibition of VEGF and IL-6 by KSI-501 confers superior normalization of cell morphology and junctional biology compared to either anti-VEGF or anti-IL-6 monotherapy in cell-based assays. We believe KSI-501 has the potential to become a new category of retinal medicines with greater therapeutic efficacy than existing therapies while also benefiting from the promising long-interval durability of Kodiak's ABC Platform. The IND for KSI-501 has been cleared by the FDA, and the Phase 1 study in diabetic macular edema (DME) patients is now screening patients.
- **Technology Platform Development:** We continued progressing our technology development with our "triplet" platform. The triplet science is designed to bring our phosphorylcholine-based biopolymer, the central tenet of our ABC platform, together with many hundreds of copies of small molecules chemically embedded in that biopolymer, which is conjugated to an antibody therapeutic. We believe this new antibody conjugate drug format offers broad and important utility for multifactorial ophthalmic diseases and also has significant relevance for systemic diseases. We continue to advance our triplet platform towards its initial therapeutic concepts.
- **Digital Health Platform Development:** We are developing a visual engagement technology and imager ("VETi") designed

by Kodiak engineers initially to be used by eye care professionals for vision and ophthalmic anatomical examination, diagnosis and monitoring. Our longer-term goal with VETi, built with semiconductor technologies, is to deliver a wearable device for long-term health engagement and monitoring. Importantly, we also believe the Kodiak VETi platform as a medical engagement and imaging platform has the potential to disrupt ophthalmology clinical trials by enabling new trial endpoints, thereby enabling faster and more cost-effective medicines development in ophthalmic disease, an area that historically requires lengthy and expensive trials. VETi may also aid in market build and shaping for undertreated or underdiagnosed diseases, such as diabetic eye diseases where Kodiak's product candidates tarcocimab and KSI-501 are being studied and where early treatment and prevention may allow patients to achieve better outcomes. The VETi platform is expected to begin pilot clinical testing mid-2023 to gather initial user input for continued innovation in the design and build of this new hardware and software platform.

#### **Expected Upcoming Events/Milestones**

- Treatment of first subjects in Phase 1 study of KSI-501 in DME, 2Q2023
- Announce topline data for ongoing Phase 3 pivotal studies of tarcocimab:
  - GLEAM and GLIMMER, paired Phase 3 studies of tarcocimab in DME, 3Q2023 (expected July)
  - DAYLIGHT, Phase 3 study of tarcocimab in wAMD, 3Q2023
  - GLOW, Phase 3 study of tarcocimab in NPDR without DME, 3Q2023

#### **Fourth Quarter and Full Year 2022 Financial Results**

##### **Cash Position**

Kodiak ended the fourth quarter of 2022 with \$478.9 million of cash, cash equivalents and marketable securities.

##### **Net Loss**

The net loss for the fourth quarter of 2022 was \$70.4 million, or \$1.35 per share on both a basic and diluted basis, as compared to a net loss of \$93.2 million, or \$1.79 per share on both a basic and diluted basis, for the fourth quarter of 2021. The net loss for the quarter ended December 31, 2022 included non-cash stock-based compensation of \$25.8 million, as compared to \$28 million for the quarter ended December 31, 2021.

##### **R&D Expenses**

Research and development (R&D) expenses were \$56.0 million for the quarter ended December 31, 2022, as compared to \$75.6 million for the quarter ended December 31, 2021. The R&D expenses for the fourth quarter of 2022 included non-cash stock-based compensation of \$14.3 million, as compared to \$15.6 million for the fourth quarter of 2021. The decrease in R&D expenses for the fourth quarter of 2022 was primarily driven by the maturation of the tarcocimab clinical program and the timing of manufacturing activities.

R&D expenses were \$267.6 million for the year ended December 31, 2022, as compared to \$217.3 million for the year ended December 31, 2021. The R&D expenses for the full year of 2022 included non-cash stock-based compensation of \$59.3 million, as compared to \$33.2 million for the full year of 2021. The increase in R&D expenses for the full year of 2022 was primarily driven by higher clinical trial costs to support ongoing trials, increased manufacturing activities, as well as higher non-cash stock-based compensation expense.

##### **G&A Expenses**

General and administrative (G&A) expenses were \$18.1 million for the quarter ended December 31, 2022, as compared to \$17.5 million for the quarter ended December 31, 2021. The G&A expenses for the fourth quarter of 2022 included non-cash stock-based compensation of \$11.5 million, as compared to \$12.4 million for the fourth quarter of 2021.

G&A expenses were \$73.8 million for the year ended December 31, 2022, as compared to \$49.7 million for the year ended December 31, 2021. The G&A expenses for the full year of 2022 included non-cash stock-based compensation of \$46.7 million, as compared to \$28.1 million for the full year of 2021, which was the primary driver for the G&A expense increase in 2022.

#### **About tarcocimab tedromer (tarcocimab, KSI-301)**

Tarcocimab is an investigational anti-VEGF therapy built on Kodiak's Antibody Biopolymer Conjugate ("ABC") Platform and is designed to maintain potent and effective drug levels in ocular tissues for longer than existing available agents. Kodiak's objective with tarcocimab is to develop a new first-line agent to improve outcomes for patients with retinal vascular diseases and to enable earlier treatment and prevention of vision loss for patients with diabetic eye diseases. The tarcocimab clinical program is designed to assess the product's durability, efficacy and safety in major retinal vascular diseases in parallel, through the GLEAM and GLIMMER studies in diabetic macular edema ("DME"), the BEACON study in retinal vein occlusion ("RVO"), the GLOW study in non-proliferative diabetic retinopathy ("NPDR") without DME and the DAYLIGHT study in wet age-related macular degeneration ("AMD"). The global tarcocimab clinical program is being conducted at 150+ study sites in more than 10 countries. Kodiak is developing and owns global rights to tarcocimab.

#### **About the GLEAM and GLIMMER Studies**

The Phase 3 GLEAM and GLIMMER studies are global, multi-center, randomized pivotal studies designed to evaluate the durability, efficacy and safety of tarcocimab in patients with treatment-naïve diabetic macular edema ("DME"). In each study, patients are randomized 1:1 to receive either

tarcocimab or aflibercept. The tarcocimab arm is treated with a proactive, individualized dosing regimen of every 8-, 12-, 16-, 20- or 24 weeks after three monthly loading doses. The aflibercept arm is treated with a fixed dosing regimen of every 8-weeks after five monthly loading doses, per its label. Both studies completed enrollment of approximately 450 patients each worldwide in the first quarter of 2022. The primary endpoint for both studies is at year one. We expect to announce topline data in the third quarter of 2023. If successful, we expect that data from our GLEAM and GLIMMER studies will serve as the primary basis for regulatory approval of tarcocimab. Additional information about GLEAM (also called Study KS301P104) and GLIMMER (also called Study KS301P105) can be found on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) under Trial Identifiers NCT04611152 and NCT04603937, respectively (<https://clinicaltrials.gov/ct2/show/NCT04611152> and <https://clinicaltrials.gov/ct2/show/NCT04603937>).

#### **About the GLOW Study**

The Phase 3 GLOW study is a global, multi-center, randomized pivotal superiority study designed to evaluate the efficacy and safety of tarcocimab in treatment-naïve, moderately severe to severe non-proliferative diabetic retinopathy ("NPDR"). Patients are randomized to receive either tarcocimab every six months after initiating doses given at baseline, 8 weeks and 20 weeks into the study, or to receive sham injections. The primary endpoint is at one year and patients will be treated and followed for two years. Outcomes include changes in diabetic retinopathy severity, measured on a standardized photographic grading scale, and the rate of development of sight-threatening complications due to diabetic retinopathy. We believe tarcocimab has the potential to be the longest-interval intravitreal therapeutic option for patients with diabetic retinopathy. GLOW has completed enrollment of approximately 240 patients in August 2022, and we expect to announce topline data in the third quarter of 2023. Additional information about GLOW (also called Study KS301P106) can be found on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) under Trial Identifier NCT05066230 (<https://clinicaltrials.gov/show/NCT05066230>).

#### **About the DAYLIGHT Study**

The Phase 3 DAYLIGHT study is a global, multi-center, randomized pivotal study designed to evaluate the efficacy and safety of high-frequency tarcocimab in patients with treatment-naïve wet age-related macular degeneration (wet "AMD"). Patients are randomized to receive either tarcocimab on a monthly dosing regimen or to receive standard-of-care aflibercept on a fixed dosing regimen of every 8-weeks after three monthly loading doses per its label. The primary endpoint is at year one. The DAYLIGHT study is intended to demonstrate the efficacy of tarcocimab to treat high need patients with wet AMD. DAYLIGHT has completed enrollment of approximately 550 patients worldwide and we expect to announce topline data in the third quarter of 2023. Additional information about DAYLIGHT (also called Study KS301P107) can be found on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) under Trial Identifier NCT04964089 (<https://clinicaltrials.gov/show/NCT04964089>).

#### **About the BEACON Study**

In the Phase 3 BEACON study, tarcocimab dosed every two months met the primary endpoint of non-inferior visual acuity gains compared to aflibercept dosed every month in patients with macular edema due to retinal vein occlusion ("RVO"). Tarcocimab is the first anti-VEGF therapy to achieve non-inferiority in visual acuity gains while doubling the treatment interval in patients with RVO. The BEACON study is a global, multi-center, randomized study designed to evaluate the durability, efficacy and safety of tarcocimab in 568 patients with treatment-naïve macular edema due to RVO, including both branch and central subtypes. Patients were randomized 1:1 to receive tarcocimab 5 mg or aflibercept 2 mg. In the first six months, patients who received tarcocimab were treated with a proactive, fixed regimen which included two monthly loading doses followed by treatment every 8 weeks, and patients receiving aflibercept were treated monthly as per its label. In the study, tarcocimab was well tolerated with a low rate of intraocular inflammation and no new or unexpected safety signals. Results from the BEACON study are intended to serve as the basis for the potential approval of tarcocimab in RVO. Additional information about the BEACON study (also called Study KS301P103) can be found on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) under Trial Identifier NCT04592419 (<https://clinicaltrials.gov/show/NCT04592419>).

#### **About Ursus**

Ursus is a commercial scale manufacturing facility dedicated to the manufacture of Kodiak's Antibody Biopolymer Conjugate ("ABC") medicines. Ursus is designed, built and commissioned in collaboration with Kodiak's long-term CDMO partner Lonza and is located in the IBEX Biopark of Lonza AG in Visp, Switzerland. Ursus is custom designed to fulfill the requirement of premium manufacturing of complex antibody conjugate biotherapeutics and is expected to have the capacity to supply over 10 million dose equivalents annually. Ursus achieved mechanical completion in the first half of 2022 and was commissioned as a cGMP facility in January 2023. Kodiak began the manufacturing of commercial scale cGMP batches of tarcocimab tedromer, Kodiak's lead product candidate currently being investigated in multiple Phase 3 studies for retinal vascular diseases, in the first quarter of 2023.

#### **About KSI-501**

Also built on Kodiak's ABC Platform, KSI-501 an investigational, first-in-class bispecific ABC that is designed to inhibit two mechanisms implicated in retinal diseases: vascular endothelial growth factor ("VEGF") and interleukin-6 (IL-6). IL-6 is a pro-inflammatory cytokine and growth factor implicated in the pathophysiology of multiple retinal diseases and, in conditions for which anti-VEGF treatment is used, elevated levels of ocular IL-6 have been associated with poor anti-VEGF treatment response. KSI-501 is a trap-antibody fusion biopolymer conjugate designed to provide potent inhibition of (i) VEGF-mediated angiogenesis and vascular permeability through a soluble decoy receptor inhibiting the binding of VEGF-A and PLGF to their cognate receptors and (ii) IL-6 mediated inflammation through an antibody that binds soluble interleukin-6, inhibiting its binding to both soluble and membrane-bound IL-6 receptors. In preclinical studies KSI-501 was found to inhibit angiogenesis and also normalize inner and outer blood retinal barriers in primary-cell assays. Dual inhibition of VEGF and IL-6 by KSI-501 confers superior normalization of cell morphology and junctional biology compared to either anti-VEGF or anti-IL-6 monotherapy in cell-based assays. We believe KSI-501 has the potential to become a new category of retinal medicines with greater therapeutic efficacy than existing therapies while also benefiting from the promising long-interval durability of Kodiak's ABC Platform. The Investigational New Drug application ("IND") for KSI-501 has been cleared by the FDA, and a Phase 1 study in DME patients is on track to begin dosing patients in the second quarter of 2023.

#### **About Kodiak Sciences Inc.**

Kodiak (Nasdaq: KOD) is a biopharmaceutical company committed to researching, developing and commercializing transformative therapeutics to treat high prevalence retinal diseases. Founded in 2009, we are focused on bringing new science to the design and manufacture of next generation retinal medicines to prevent and treat the leading causes of blindness globally. Our ABC Platform™ uses molecular engineering to merge the fields of antibody-based and chemistry-based therapies and is at the core of Kodiak's discovery engine. Kodiak's lead product candidate, tarcocimab, is a novel anti-VEGF antibody biopolymer conjugate being developed for the treatment of retinal vascular diseases including diabetic eye diseases, the leading cause of blindness in working-age patients in the developed world, and wet age-related macular degeneration, the leading cause of blindness

in elderly patients in the developed world. Kodiak has leveraged its ABC Platform to build a pipeline of product candidates in various stages of development. KSI-501 is our dual inhibitor antibody biopolymer conjugate targeting both VEGF (VEGF-trap) and IL-6 (anti-IL-6 antibody) for the treatment of retinal diseases. We are expanding our early research pipeline to include ABC Platform based triplet inhibitors for multifactorial retinal diseases such as dry AMD and glaucoma. Kodiak is based in Palo Alto, CA. For more information, please visit [www.kodiak.com](http://www.kodiak.com).

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### Forward-Looking Statements

This release contains "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 of our ABC Platform to significantly extend treatment intervals in retinal disorders in a safe and convenient manner, the anti-VEGF effect of tarcocimab tedromer (tarcocimab, KSI-301), the expected advances for treatment of diabetic eye diseases and wAMD represented by tarcocimab, the anticipated safety profile of tarcocimab, planned activities in connection with the development of VETi; VETi's potential benefits, including but not limited to the potential to disrupt ophthalmology clinical trials and shape the market for undertreated or undiagnosed diseases; future development plans, including clinical objectives and the timing thereof, anticipated design and benefits of planned clinical trials, the expected timing of clinical study readouts; the objectives and anticipated benefits of our tarcocimab clinical program; and expansion of our research pipeline, and the anticipated presentation of data; the potential benefits of KSI-501, including its potential to be a first-in-class bispecific ABC inhibiting VEGF and IL-6; the anticipated commencement of a Phase 1 study of KSI-501; the potential for a single BLA submission in multiple retinal vascular disease indications; the potential for our products to obtain a product label in multiple indications and with a range of dosing intervals; expectations regarding commercial manufacturing capabilities; and the results of our research and development efforts and our ability to advance our product candidates into later stages of development. 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," "could," "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 forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that preliminary safety, efficacy and durability data for our tarcocimab product candidate may not continue or persist; the risk that tarcocimab may not have the anti-VEGF effect or impact on the treatment of diabetic eye diseases and wAMD as expected; cessation or delay of any of the ongoing clinical studies / our development of tarcocimab / KSI-501 may occur; the risk that our ABC Platform may not extend treatment intervals in retinal disorders as anticipated, or at all; future potential regulatory milestones of tarcocimab / KSI-501, 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; the risk that KSI-501 may not inhibit VEGF and IL-6 or have an impact on the treatment of patients as expected; the risk that VETi is not developed as anticipated, and/or may not have the expected benefits or capabilities; any one or more of our product candidates may not be successfully developed, approved or commercialized; manufacturing facilities may not be completed when expected, or at all; 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.

### Kodiak Sciences Inc.

#### Condensed Consolidated Statements of Operations

(Unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses				
Research and development	\$ 55,994	\$ 75,597	\$ 267,591	\$ 217,340
General and administrative	18,072	17,452	73,788	49,711
Total operating expenses	<u>74,066</u>	<u>93,049</u>	<u>341,379</u>	<u>267,051</u>
Loss from operations	(74,066)	(93,049)	(341,379)	(267,051)
Interest income	3,017	28	7,071	298
Interest expense	(4)	(5)	(18)	(47)
Other income (expense), net	605	(139)	503	(190)
Net loss	<u>\$ (70,448)</u>	<u>\$ (93,165)</u>	<u>\$ (333,823)</u>	<u>\$ (266,990)</u>
Net loss per common share, basic and diluted	<u>\$ (1.35)</u>	<u>\$ (1.79)</u>	<u>\$ (6.39)</u>	<u>\$ (5.16)</u>
Weighted-average shares of common stock outstanding used in computing net loss per common share, basic and diluted	<u>52,316,531</u>	<u>51,988,910</u>	<u>52,249,620</u>	<u>51,788,918</u>

Kodiak Sciences Inc.

**Condensed Consolidated Balance Sheet Data  
(Unaudited)  
(in thousands)**

	<b>December 31, 2022</b>	<b>December 31, 2021</b>
Cash, cash equivalents and marketable securities	\$ 478,933	\$ 731,510
Working capital	\$ 433,509	\$ 670,128
Total assets	\$ 666,628	\$ 904,220
Accumulated deficit	\$ (892,040)	\$ (558,217)
Total stockholders' equity	\$ 436,167	\$ 663,320

 View original content: <https://www.prnewswire.com/news-releases/kodiak-sciences-announces-fourth-quarter-and-full-year-2022-financial-results-and-recent-business-highlights-301783929.html>

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