Kodiak Sciences Announces First Quarter 2023 Financial Results and Recent Business Highlights

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PALO ALTO, Calif., May 15, 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 quarter ended March 31, 2023.

"We are on the cusp of four Phase 3 study readouts in major indications, starting with results of our GLEAM, GLIMMER and DAYLIGHT studies expected in July and our GLOW study in September. Following our successful pivotal study readout in retinal vein occlusion last year, we look forward to unmasking the primary endpoint data in these next four studies shortly," said Victor Perlroth, MD, Chief Executive Officer of Kodiak Sciences. "Our regulatory strategy for tarcocimab tedromer is built on meeting the primary endpoint in two studies in diabetic eye disease (our GLEAM and GLIMMER studies in diabetic macular edema) and then meeting the primary endpoint in a single study in each of the other major retinal vascular diseases."

Dr. Perlroth continued, "Durability clearly matters to the community of retina patients, physicians and payers, and especially so in diabetic eye disease where many patients are working age and require good vision to maintain their livelihood. One third of anti-VEGF treated diabetic patients discontinue treatment each year, and so the promise of the anti-VEGF mechanism is not realized. Three out of our four ongoing Phase 3 studies of tarcocimab tedromer (tarcocimab, KSI-301) are in diabetic eye disease and are exploring 6-month dosing, the longest treatment interval that has been studied by any intravitreal biologic. If successful, we believe tarcocimab can be an important medicine for the 37 million people living with diabetes in the U.S. who are at risk of developing diabetic eye disease and losing vision."

Recent Business Highlights

- ***Tarcocimab pivotal program:*** We continued our ongoing Phase 3 studies of tarcocimab towards their primary endpoint readouts. The tarcocimab clinical program explores the potential for 6-month durability in patients with diabetic eye disease through the GLEAM and GLIMMER Phase 3 studies in diabetic macular edema ("DME") and the GLOW Phase 3 study in non-proliferative diabetic retinopathy ("NPDR") without DME. The tarcocimab clinical program is also exploring the product's durability, efficacy and safety in retinal vein occlusion ("RVO") via the BEACON Phase 3 study and in wet age-related macular degeneration ("wet AMD") via the ongoing DAYLIGHT Phase 3 study. The BEACON study met its primary endpoint in 2022, and we expect to announce topline data for the four ongoing Phase 3 clinical studies in the third quarter of 2023. If successful, we expect to file a single Biologics Licensing Applications ("BLA") for tarcocimab in the four major retinal vascular disease indications, with the potential for flexible dosing regimens from every month to every 6 months.
- ***Clinical pipeline expansion:*** We expanded our development pipeline with the dosing of patients in the Phase 1 study of KSI-501, a first-in-class bispecific ABC designed to inhibit both VEGF-mediated angiogenesis and vascular permeability and IL-6-mediated inflammation. The Phase 1 study is an open-label, multiple ascending dose study and is initially enrolling patients with DME. The primary objectives of the Phase 1 study are to evaluate ocular and systemic safety, to establish a maximum tolerated dose and to explore bioactivity of KSI-501.
- ***Recent scientific presentations:*** We shared scientific presentations on our clinical and research pipeline programs at the ARVO 2023 Annual Meeting in April, including presentations on tarcocimab's nonclinical pharmacokinetics, distribution and excretion, and on KSI-501's molecular and biological characterization.
- ***Commercial Manufacturing:*** Our custom-built commercial scale manufacturing facility, Ursus, 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.

Expected Upcoming Events/Milestones

- Announce topline data for ongoing Phase 3 pivotal studies of tarcocimab:
  - GLEAM and GLIMMER, paired Phase 3 studies of tarcocimab in diabetic eye disease (treatment of diabetic macular edema), expected July 2023
  - DAYLIGHT, Phase 3 study of tarcocimab in wAMD, expected July 2023
  - GLOW, Phase 3 study of tarcocimab in diabetic eye disease (treatment and prevention of worsening in non-proliferative diabetic retinopathy without DME), expected September 2023

First Quarter 2023 Financial Results

Cash Position

Kodiak ended the first quarter of 2023 with $421.2 million of cash, cash equivalents and marketable securities.

Net Loss

The net loss for the first quarter of 2023 was $70.8 million, or $1.35 per share on both a basic and diluted basis, as compared to a net loss of $95.7 million, or $1.83 per share on both a basic and diluted basis, for the first quarter of 2022. The net loss for the quarter ended March 31, 2023 included

non-cash stock-based compensation of $26.0 million, as compared to $28.1 million for the quarter ended March 31, 2022.

R&D Expenses

Research and development (R&D) expenses were $56.5 million for the first quarter of 2023, as compared to $76.2 million for the first quarter of 2022. The R&D expenses for the first quarter of 2023 included non-cash stock-based compensation of $14.7 million, as compared to $16.0 million for the first quarter of 2022. The decrease in R&D expenses for the first quarter of 2023 was primarily driven by the maturation of the tarcocimab clinical program and the timing of manufacturing activities.

G&A Expenses

General and administrative (G&A) expenses were $18.1 million for the first quarter of 2023, as compared to $19.6 million for the first quarter of 2022. The G&A expenses for the first quarter of 2023 included non-cash stock-based compensation of $11.3 million, as compared to $12.1 million for the first quarter of 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 enable earlier treatment and prevention of vision loss for patients with diabetic eye disease and to develop a new durability agent to improve outcomes for patients with retinal vascular diseases as a whole. The tarcocimab clinical program is designed to explore 6-month durability in patients with diabetic eye disease through the GLEAM and GLIMMER Phase 3 studies in diabetic macular edema ("DME") and the GLOW Phase 3 study in non-proliferative diabetic retinopathy ("NPDR") without DME. The tarcocimab clinical program is also exploring the product's durability, efficacy and safety in retinal vein occlusion ("RVO") via the BEACON Phase 3 study and in wet age-related macular degeneration ("wet AMD") via the DAYLIGHT Phase 3 study. The BEACON study met its primary endpoint in 2022, and four Phase 3 clinical studies are expected to announce topline data in 3Q2023. If successful, Kodiak plans to file a single Biologics Licensing Applications ("BLA") for tarcocimab in the four major retinal vascular disease indications. 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. The primary endpoint for both studies is at year one. We expect to announce topline data from GLEAM and GLIMMER in July 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 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 patients with 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. 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. We expect to announce topline data from GLOW in September 2023. If successful, results from the study are intended to serve as the basis for the potential approval of tarcocimab in NPDR. Additional information about GLOW (also called Study KS301P106) can be found on 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 evaluate the safety and efficacy of tarcocimab in treating high need patients with wet AMD. We expect to announce topline data from DAYLIGHT in July 2023. If successful, results from the study are intended to serve as the basis for the potential approval of tarcocimab in wet AMD. Additional information about DAYLIGHT (also called Study KS301P107) can be found on 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. 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 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 was 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 in Ursus in the first quarter of 2023.

About KSI-501

Also built on Kodiak's ABC Platform, KSI-501 is an investigational, first-in-class bispecific ABC 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 cell-based assays, KSI-501 inhibits angiogenesis and also normalizes inner and outer blood retinal barriers; 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. 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. A Phase 1 study of KSI-501 is currently dosing patients in the United States to evaluate the safety, tolerability and bioactivity of KSI-501 in DME patients.

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. 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 antibody biopolymer conjugate platform, or 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 investigational medicine, tarcocimab tedromer, is a novel anti-VEGF antibody biopolymer conjugate being developed for the treatment of retinal vascular diseases including diabetic eye disease, 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. The tarcocimab clinical program is designed to assess the product candidate's durability, efficacy and safety in major retinal vascular diseases in parallel, through the GLEAM and GLIMMER studies in diabetic macular edema, the BEACON study in retinal vein occlusion, the GLOW study in non-proliferative diabetic retinopathy and the DAYLIGHT study in wet age-related macular degeneration. Phase 3 data across the tarcocimab clinical program are expected in 3Q2023. 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) and is being investigated in a Phase 1 clinical study initially in patients with diabetic macular edema. We are expanding our early research pipeline to include ABC Platform based triplet inhibitors for multifactorial diseases. Kodiak is based in Palo Alto, CA. For more information, please visit www.kodiak.com.

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 expected timing of clinical study readouts; the objectives and anticipated benefits of our tarcocimab clinical program and the regulatory strategy for tarcocimab; the potential benefits of tarcocimab for people with diabetic eye diseases and to improve outcomes for patients with retinal vascular diseases as a whole; the potential for a single BLA submission in multiple retinal vascular disease indications, with the potential for flexible dosing regimens from every month to every 6 months; the potential benefits of KSI-501, including its potential to be a first-in-class bispecific ABC inhibiting both VEGF and IL-6; expectations regarding our commercial manufacturing capabilities; and planned expansion of our research pipeline. . 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 cessation or delay of any of the ongoing clinical studies and our development of tarcocimab or KSI-501 may occur; 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 impact on the treatment of diabetic eye diseases or improve outcomes for patients with retinal vascular diseases as expected; future potential regulatory milestones of tarcocimab or 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; 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.

Kodiak Sciences Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses		
Research and development	$ 56,520	$ 76,177
General and administrative	18,095	19,590
Total operating expenses	74,615	95,767
Loss from operations	(74,615)	(95,767)
Interest income	3,617	76
Interest expense	(4)	(5)
Other income (expense), net	222	(13)
Net loss	$ (70,780)	$ (95,709)
Net loss per common share, basic and diluted	$ (1.35)	$ (1.83)
Weighted-average shares of common stock outstanding used in computing net loss per common share, basic and diluted	52,337,603	52,172,918

Kodiak Sciences Inc.
Condensed Consolidated Balance Sheet Data
(Unaudited)
(in thousands)

	March 31, 2023	**December 31, 2022**
Cash, cash equivalents and marketable securities	$ 421,191	$ 478,933
Working capital	$ 362,180	$ 433,509
Total assets	$ 640,334	$ 666,628
Accumulated deficit	$ (962,820)	$ (892,040)
Total stockholders' equity	$ 392,587	$ 436,167

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