Kodiak Sciences Announces First Quarter 2021 Financial Results and Recent Business Highlights

May 10, 2021

PALO ALTO, Calif., May 10, 2021 /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 first quarter ended March 31, 2021.

"Developing and launching a novel anti-VEGF medicine with extended durability is the central principle of our KSI-301 development program, and in the last quarter we have continued to make substantial progress in the recruitment of our pivotal studies evaluating long-interval dosing of KSI-301," said Jason Ehrlich, MD, PhD, Chief Medical Officer of Kodiak. "Our wet AMD pivotal study, DAZZLE, is fully enrolled, and our RVO and DME pivotal studies are all recruiting globally. Each is evaluating KSI-301's potential for best-in-class dosing regimens. Towards our goal of having KSI-301 be the anti-VEGF medicine of choice for all eligible patients, and through our continued engagement with the retina community, we have also learned that physicians and retina practices would like to see our labeling for KSI-301 include the option for more frequent dosing. This reduces barriers to reimbursement that have impeded the commercial uptake of other anti-VEGF medications in the past. A study of more intensive dosing also allows us to explore the potential for improved treatment outcomes in certain patients. Thus, we are launching the DAYLIGHT study which will evaluate monthly dosing of KSI-301 in patients with wet AMD. We believe that pursuing a very broad product label will provide physicians with the flexibility, agency, and reimbursement confidence required to individualize treatment for their patients. Based on our discussions with regulators, we also believe the DAYLIGHT study will provide the safety database needed to support monthly labeling not only in wet AMD but in the DME and RVO indications in the US as well. We expect recruitment in DAYLIGHT will begin in the summer of 2021, and we plan to include data from this fifth pivotal study of KSI-301 in our initial BLA submission."

"On all fronts, Kodiak's growing community of employees, partners and friends continues to put forth tremendous efforts to advance the care of patients with retinal vascular disease through our research, development and corporate activities", said Victor Perlroth, MD, Chief Executive Officer of Kodiak. "Operational activities continue to expand well within our KSI-301 development program with a focus on key activities needed to support our multi-indication BLA strategy. The new DAYLIGHT study, as Jason articulates above, is both label broadening and label enabling. The new GLOW study is our key next step towards long-interval dosing and prevention in diabetic retinopathy. The expanding portfolio of pivotal studies reflects our conviction in KSI-301 and our ABC Platform."

Recent Business Highlights

- ***KSI-301 Clinical Program Progress***

  In the third quarter of 2020, we initiated two Phase 3 studies of KSI-301 in DME (GLEAM and GLIMMER) and one Phase 3 study of KSI-301 in RVO (BEACON). We are pleased with the operational progress in the US and globally in site activation, patient screening and recruitment for these studies. All of our ex-US clinical trial application submissions are active and approved, and we are focused on further promoting patient enrollment in a competitive recruiting environment towards our goal of completing patient recruitment in 4Q2021 for all three studies. We also intend to begin recruitment of our GLOW study of KSI-301 in patients with non-proliferative Diabetic Retinopathy in the summer of 2021.

  Additionally, the DAZZLE study, our Phase 2b/3 study of KSI-301 in patients with wet AMD, remains on track with the last patient's last visit for the primary efficacy endpoint anticipated in late 4Q2021. To date, we continue to observe a low single digit overall rate of missed visits in our pivotal studies due to the continued COVID-19 pandemic.

- ***Further Expansion of KSI-301 Clinical Program: DAYLIGHT Study***

  We are adding another pivotal study of KSI-301 to the clinical development plan for our initial BLA. The intent of this fifth pivotal study is to broaden KSI-301's potential product labeling, explore the potential for improved treatment outcomes in certain patients with intensive anti-VEGF treatment and reduce possible barriers to market access and insurance reimbursement that have impeded or complicated the commercial uptake of other anti-VEGF medications in the past. We believe that pursuing a very broad product label will provide physicians with the flexibility, agency, and reimbursement confidence required to consider KSI-301 for all their patients.

  This study, called DAYLIGHT, will be an intensive treatment study of KSI-301 in treatment-naïve wet AMD patients. Patients will be randomized to receive either KSI-301 on a monthly dosing regimen or to receive standard-of-care aflibercept. The primary endpoint is evaluated at ten months. Wet AMD was chosen as the disease area for this intensive treatment study because of the broader availability of clinical trial sites and treatment-naïve wet AMD patients relative to the other diseases in which we also have KSI-301 studies ongoing. Based on our discussions with regulators, we also believe the DAYLIGHT study can provide the safety database needed to support monthly labeling across the wet AMD, DME and RVO indications in the US and thus maximize treatment flexibility and reimbursement confidence in all of the major anti-VEGF disease areas. We plan to initiate recruitment of DAYLIGHT in the summer of 2021 and to include data from this study in our initial BLA.

We believe our expanded pivotal program for KSI-301 will thus be supportive of the broadest possible range of potential dosing intervals, from every 4-week dosing in all diseases to best-in-class every 20-week dosing for wAMD patients, every 24-week dosing for DME patients and every 8-week dosing for RVO patients.

- ***Commercial Manufacturing Update***

  We have expanded and finalized the design and scope of our bioconjugate manufacturing agreement with a revised estimated capital contribution of 74.5 million Swiss Francs. Construction of the manufacturing facilities is now targeted for completion in early 2022. The primary cause of the timeline shift from end 2021 is construction delays encountered at the Ibex Dedicate Facility in Switzerland due to COVID-19 vaccine related manufacturing activities, primarily limitation of construction and facility personnel resources. Manufacturing suite fees commence in 2022 at a cost of 14.5 million Swiss Francs per annum and continue for each year thereafter through 2029 at a cost of 20.0 million Swiss Francs per annum. The final design expands the size of our dedicated manufacturing facility and increases annual manufacturing capacity by upwards of 70%. The final design also separates the manufacturing core into separate suites with the benefit of allowing two manufacturing lines to operate separately and simultaneously.

- ***Year 1 KSI-301 Phase 1b Study Data Presentation***

  We presented Year 1 durability, efficacy and safety data from our ongoing Phase 1b study of KSI-301 in patients with treatment naïve wet AMD, DME or RVO at the Angiogenesis, Exudation, and Degeneration 2021 – Virtual Edition meeting in February 2021. We believe the Year 1 data continue to support the highly differentiated "anti-VEGF Generation 2.0" profile of KSI-301. The data show 2 in every 3 patients are on a 6-month or longer treatment-free interval at Year 1 in each of the three major retinal vascular diseases after only three loading doses. Vision gains and robust drying (particularly notable in the context of baseline characteristics) were seen across all three diseases being studied. An encouraging safety profile continues to be observed.

Expected Upcoming Events/Milestones

- Initiate pivotal Phase 3 randomized study of monthly KSI-301 in wet age-related macular degeneration (the DAYLIGHT study)
- Initiate pivotal Phase 3 randomized study of every 24-week KSI-301 in non-proliferative diabetic retinopathy patients (the GLOW study)
- Complete patient enrollment in Retinal Vein Occlusion (BEACON) and Diabetic Macular Edema (GLEAM and GLIMMER) pivotal clinical studies
- Complete wet AMD DAZZLE pivotal clinical study last patient last visit for primary endpoint
- Complete cGMP bioconjugate drug substance manufacturing of KSI-501, a novel bispecific antibody biopolymer conjugate

First Quarter 2021 Financial Results

Cash Position

Kodiak ended the first quarter of 2021 with $929.0 million of cash, cash equivalents and marketable securities.

Net Loss

The net loss for the first quarter of 2021 was $50.4 million, or $0.98 per share on both a basic and diluted basis, as compared to a net loss of $24.4 million, or $0.54 per share on both a basic and diluted basis, for the first quarter of 2020.

R&D Expenses

Research and development (R&D) expenses were $40.3 million for the first quarter of 2021, as compared to $20.2 million for the first quarter of 2020. The increase in R&D expenses was primarily driven by higher clinical trial costs for KSI-301, as well as higher payroll and stock-based compensation expense.

G&A Expenses

General and administrative (G&A) expenses were $10.2 million for the first quarter of 2021, as compared to $5.6 million for the first quarter of 2020. The increase in G&A expenses was primarily driven by higher payroll and stock-based compensation expenses.

About KSI-301

KSI-301 is an investigational anti-VEGF therapy built on the Kodiak's Antibody Biopolymer Conjugate (ABC) Platform and is designed to maintain potent and effective drug levels in ocular tissues for longer than existing agents. Kodiak's objective with KSI-301 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 disease. The KSI-301 Clinical Program is designed to assess KSI-301's durability, efficacy and safety in wet AMD, DME, RVO and non-proliferative DR (without DME) through clinical studies run in parallel. The Company's Phase 2b/3 DAZZLE pivotal study in patients with treatment-naïve wet AMD was initiated in October 2019 and completed enrollment in November 2020, and Kodiak initiated the Phase 3 GLEAM, GLIMMER and BEACON

pivotal studies of KSI-301 in diabetic macular edema and retinal vein occlusion in September 2020. The Company plans to initiate the Phase 3 DAYLIGHT pivotal study of monthly KSI-301 in wet AMD patients in summer 2021. These pivotal studies are anticipated to form the basis of the Company's initial BLA to support potential approval and commercialization in multiple indications and with a full range of labeled and reimbursable dosing frequencies in each indication. An additional Phase 3 pivotal study in patients with non-proliferative diabetic retinopathy (the GLOW study) is also expected to be initiated in summer 2021. The global KSI-301 clinical program is being conducted at 150+ study sites in more than 10 countries. Kodiak Sciences Inc. is developing KSI-301 and owns global rights to KSI-301.

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 KSI-301 in patients with treatment-naïve wet AMD. Patients are randomized to receive either KSI-301 on a monthly dosing regimen or to receive standard-of-care aflibercept. The study is expected to enroll at least 500 patients worldwide. The primary endpoint is at ten months, and the study is being planned and executed for inclusion of its results in the initial BLA for KSI-301 along with the DAZZLE, BEACON, GLEAM and GLIMMER studies. The intent of this pivotal study is to broaden KSI-301's potential product labeling, explore the potential for improved treatment outcomes in certain patients with intensive anti-VEGF treatment, and eliminate possible barriers to market access and insurance reimbursement that have impeded or complicated the commercial uptake of other anti-VEGF medications in the past. We believe that pursuing a broad product label will provide physicians with the flexibility, agency, and reimbursement confidence required to consider KSI-301 treatment for all their patients.

About the DAZZLE Study

The Phase 2b/3 DAZZLE study is a global, multi-center, randomized pivotal study designed to evaluate the durability efficacy and safety of KSI-301 in patients with treatment-naïve wet AMD. Patients are randomized to receive either KSI-301 on an individualized dosing regimen as infrequently as every five months and no more often than every three months or to receive aflibercept on its labeled every eight-week dosing regimen, each after three monthly initiating doses. The study has enrolled over 550 patients worldwide. The primary endpoint is at one year, and the Last Patient Last Visit (LPLV) for the primary endpoint is expected to occur in 4Q 2021. Each patient will be treated and followed for two years. Additional information about DAZZLE (also called Study KSI-CL-102) can be found on www.clinicaltrials.gov under Trial Identifier NCT04049266 (https://clinicaltrials.gov/show/NCT04049266).

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 KSI-301 in patients with treatment-naïve diabetic macular edema (DME). In each study, patients are randomized to receive either intravitreal KSI-301 on an individualized dosing regimen every eight to 24 weeks after only three loading doses or intravitreal aflibercept every eight weeks after five loading doses per its label. Each study is expected to enroll approximately 450 patients worldwide. The primary endpoint for both studies is at one year, and patients will be treated and followed for two years. 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 BEACON Study

The Phase 3 BEACON study is a global, multi-center, randomized study designed to evaluate the durability, efficacy and safety of KSI-301 in patients with treatment-naïve macular edema due to retinal vein occlusion (RVO), including both branch and central subtypes. Patients are randomized to receive either intravitreal KSI-301 every eight weeks after only two loading doses or monthly intravitreal aflibercept per its label, for the first six months. In the second six months, patients in both groups will receive treatment on an individualized basis per protocol-specified criteria. The study is expected to enroll approximately 550 patients worldwide. The primary endpoint is at six months, and patients will be treated and followed for one year. 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 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, KSI-301, is a novel anti-VEGF antibody biopolymer conjugate being developed for the treatment of retinal vascular diseases including age-related macular degeneration, the leading cause of blindness in elderly patients in the developed world, and diabetic eye diseases, the leading cause of blindness in working-age patients in the developed world. Kodiak has leveraged its ABC Platform to build a pipeline of product candidates in various stages of development including KSI-501, our bispecific anti-IL-6/VEGF biopolymer conjugate for the treatment of neovascular retinal diseases with an inflammatory component, and 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.

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 licensure of KSI-301 and a single BLA submission in wet AMD, DME, RVO and diabetic retinopathy in Q1 2023; the sufficiency of our cash, cash equivalents and marketable securities to fund our operations; our platform technology and potential therapies; future development plans, including our ability to initiate the GLOW study in the summer of 2021; the potential for KSI-301 to obtain a broad product label and reduce barriers to reimbursement; the potential for KSI-301 to offer best-in-class dosing regimens; Kodiak's ability to initiate recruitment in DAYLIGHT in the summer of 2021; clinical and regulatory objectives and the timing thereof, anticipated design of planned clinical trials, expectations regarding the potential efficacy and commercial potential of our product candidates; and the anticipated presentation of data; 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," "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 preliminary safety, efficacy and durability data for our KSI-301 product candidate will 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 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. 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 Sciences Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses		
Research and development	$ 40,337	$ 20,170
General and administrative	10,221	5,553
Total operating expenses	50,558	25,723
Loss from operations	(50,558)	(25,723)
Interest income	149	1,208
Interest expense	(6)	(7)
Other income (expense), net	(32)	130
Net loss	$ (50,447)	$ (24,392)
Net loss per common share, basic and diluted	$ (0.98)	$ (0.54)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	51,573,909	44,824,587

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

	March 31, 2021	**December 31, 2020**
Cash, cash equivalents and marketable securities	$ 928,985	$ 968,974
Working capital	$ 896,839	$ 940,583
Total assets	$ 1,032,734	$ 1,067,347
Accumulated deficit	$ (341,674)	$ (291,227)
Total stockholders' equity	$ 821,677	$ 860,751

View original content:http://www.prnewswire.com/news-releases/kodiak-sciences-announces-first-quarter-2021-financial-results-and-recent-business-highlights-301287302.html

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