Kodiak Sciences Announces Additional Safety, Efficacy and Durability Data from Ongoing Phase 1b Study of KSI-301 in Patients with Wet Age-Related Macular Degeneration, Diabetic Macular Edema and Retinal Vein Occlusion at the Angiogenesis, Exudation, and Degeneration 2020 Meeting

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Encouraging safety profile continues with zero cases of intraocular inflammation after 420 doses in 130 patients
Strong anti-VEGF efficacy with extended dosing intervals continues to be observed across all three of the major retinal vascular diseases
Promising clinical durability continues to be observed with 84% of wet AMD treated eyes and 76% of DME treated eyes extended to four months or longer before first retreatment
55% of wet AMD eyes extended to six months and 64% of DME eyes extended to six months or longer

PALO ALTO, Calif., Feb. 8, 2020 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), a clinical stage biopharmaceutical company specializing in novel therapeutics to treat chronic, high-prevalence retinal diseases, today announced promising safety, efficacy and durability data from the ongoing Phase 1b study of its investigational therapy KSI-301, an intravitreal anti-VEGF antibody biopolymer conjugate, in patients with treatment-naïve wet age-related macular degeneration (AMD), diabetic macular edema (DME) and retinal vein occlusion (RVO).

The results were presented by Diana V. Do, M.D., Professor of Ophthalmology at Byers Eye Institute, Stanford University School of Medicine as an oral presentation at the Angiogenesis, Exudation, and Degeneration 2020 meeting in Miami, FL. The study findings presented by Dr. Do can be found on the Kodiak Investor Relations website at http://ir.kodiak.com.

"With further maturation of the Phase 1b study, the safety and efficacy of KSI-301 continue to be very encouraging, and we continue to see the potential for KSI-301 to have class-leading durability across all of the common retinal vascular diseases," said Jason Ehrlich, M.D., Ph.D., Chief Medical Officer of Kodiak Sciences. "Our belief is that a next-generation biologic should bring nearly all wet AMD and DME patients to a three month or longer dose interval and the majority of RVO patients to a two month or longer interval. In the data presented today at Angiogenesis, we observed that 84% of wet AMD eyes and 76% of DME eyes were extended to four months or longer after the last loading doses before receiving their first retreatment. Remarkably, 55% of wet AMD eyes and 64% of DME eyes were extended to six months. In RVO, a disease which typically requires monthly anti-VEGF therapy to achieve the best results, we continued to observe that over half the patients were extended beyond three months after only three loading doses and without receiving retreatment."

"Compared to the data previously presented, more patients have been followed for longer intervals. The safety, efficacy, and durability data continue to be robust and are suggesting the potential for KSI-301 to demonstrate a novel Generation 2.0 durability profile," said Victor Perlroth, M.D., Chief Executive Officer of Kodiak Sciences. "We are very pleased with what we continue to learn about the clinical performance of KSI-301 in this exploratory study, and we are using the data to thoughtfully design high conviction pivotal studies of KSI-301 in each of the core indications. Our DAZZLE study in wet AMD, where KSI-301 is given on an every three-, four-, or five-month dosing interval, continues to recruit well. We appreciate the strong support from the ophthalmology community of patients and providers, and we look forward to initiating pivotal studies in DME, RVO, and NPDR later this year as part of our accelerating development program for KSI-301."

About KSI-301

KSI-301 is an investigational anti-VEGF therapy built on the Company's Antibody Biopolymer Conjugate, or 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 Company's DAZZLE pivotal study in patients with treatment-naïve wet AMD was initiated in October 2019. Kodiak plans to initiate additional pivotal studies of KSI-301 in 2020 in diabetic macular edema, retinal vein occlusion and diabetic retinopathy. These studies are anticipated to form the basis of the Company's initial and supplemental BLAs to support potential approval and commercialization. KSI-301 is being developed and is fully owned globally by Kodiak Sciences Inc.

About the DAZZLE Study

The DAZZLE study (also called Study KSI-CL-102) is a global, multi-center, randomized study designed to evaluate the safety and efficacy 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 standard-care aflibercept on its every eight-week dosing regimen, each after three monthly initiating doses. The primary endpoint is at one year and each patient will be treated and followed for two years. Additional information about DAZZLE can be found on www.clinicaltrials.gov under Trial Identifier NCT04049266 (https://clinicaltrials.gov/show/NCT04049266).

About Kodiak Sciences Inc.

Kodiak (Nasdaq: KOD) is a clinical stage biopharmaceutical company specializing in novel therapeutics to treat chronic, 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, a leading cause of blindness in elderly patients, and diabetic eye diseases, a leading cause of blindness in working-age patients. 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, but are not limited to, statements regarding our platform technology and potential therapies, future development plans, clinical and regulatory objectives and the timing thereof, expectations regarding the potential efficacy and commercial potential of our product candidates, including KSI-301 and its ability to reduce treatment burden, demonstrate a Generation 2.0 durability profile and improve vision outcomes, including its potential to bring patients to a three month or longer dose interval, 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, including those discussed in the section entitled "Risk Factors" in our most recent Form 10-Q, as well as 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.

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