Kodiak Sciences Treats First Patients in DAZZLE Pivotal Study of KSI-301 in Wet Age-Related Macular Degeneration

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PALO ALTO, Calif., Oct. 10, 2019 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), a clinical stage biopharmaceutical company specializing in novel therapeutics to treat chronic, high-prevalence retinal diseases, announced that the first patients have been treated in the DAZZLE pivotal study of Kodiak's anti-VEGF antibody biopolymer conjugate, KSI-301, in patients with treatment-naïve wet (neovascular) age-related macular degeneration (AMD).

"Treating the first patients in this pivotal study is an important step for Kodiak as we grow the company and accelerate our efforts with KSI-301," said Victor Perlroth, M.D., Chief Executive Officer of Kodiak Sciences. "On World Sight Day, we recognize that patients with wet AMD often need frequent eye injections of an anti-VEGF medication to preserve their vision. Next generation anti-VEGF biologics are thought to support half the patients on an every two-month interval and half the patients on an every three-month interval. Using our proprietary ABC Platform™, we designed KSI-301 from the outset as a therapy with extended durability. In our DAZZLE study, we are comparing the efficacy of KSI-301 on every three-, four-, or five-month dosing versus aflibercept on its every two-month interval. We believe our dosing regimen, with all patients on every three-month dosing or better, if successful, could position KSI-301 to be a leading anti-VEGF therapy for patients with wet AMD. Early data presented last month from our ongoing Phase 1b data of KSI-301 showed the majority of wet AMD patients treated with KSI-301 reached a four- or five-month interval without receiving retreatment."

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 5 months and no more often than every 3 months or to receive standard-care aflibercept on its every 8-week dosing regimen, each after three monthly initiating doses. The study is expected to enroll at least 368 patients worldwide. The primary endpoint is at 1 year and each patient will be treated and followed for 2 years. Additional information about DAZZLE can be found on www.clinicaltrials.gov/show/NCT04049266).

About KSI-301

KSI-301 is an investigational therapy built on Kodiak's proprietary 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. KSI-301 is being developed and is fully owned globally by Kodiak.

About Kodiak Sciences Inc.

Kodiak[™] is a clinical stage biopharmaceutical company specializing in novel therapeutics to treat chronic, 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 ABC Platform[™] merges 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 and diabetic eye diseases. 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. Kodiak is based in Palo Alto, CA. For more information, 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, anticipated design of planned clinical trials, expectations regarding the potential efficacy and commercial potential of our product candidates, including KSI-301 and its ability to be a leading anti-VEGF therapy for patients with wet AMD, 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. Forwardlooking 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 forwardlooking 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 from the Phase 1 study will not continue or persist; cessation or delay of any of the ongoing clinical studies and/or our development of KSI-301 may occur; 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; 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 forwardlooking statements, and readers are cautioned not to place undue reliance on such forward-looking statements.

"Kodiak," "ABC Platform" and the Kodiak logo are registered trademarks or trademarks of Kodiak Sciences Inc. in various jurisdictions.

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John Borgeson, Senior Vice President and Chief Financial Officer, Tel (650) 281-0850, ir@kodiak.com