Kodiak Sciences Treats First Patients in Three Phase 3 Studies of KSI-301 - Two Studies in Diabetic Macular Edema and One Study in Macular Edema Due to Retinal Vein Occlusion

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- Concurrent development program compares Kodiak's long-acting anti-VEGF antibody biopolymer conjugate KSI-301 to standard of care in all major retinal disease indications: wet AMD, DME, and RVO.

- Kodiak also announces completion of U.S. patient enrollment in DAZZLE, its ongoing Phase 2b/3 study of KSI-301 in wet AMD.

- Phase 1b durability data continue to improve as they mature further: 72% of wet AMD patients and 79% of DME patients have now achieved a 6-month or longer treatment free interval at least once during follow-up; 81% of RVO patients have achieved a 4-month or longer interval.

PALO ALTO, Calif., Oct. 5, 2020 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), a biopharmaceutical company committed to researching, developing and commercializing transformative therapeutics to treat high prevalence retinal diseases, today announced that the first patients have been treated in the randomized, double-masked GLEAM, GLIMMER and BEACON studies, three pivotal Phase 3 studies of KSI-301, Kodiak's anti-VEGF antibody biopolymer conjugate, in treatment-naïve patients with diabetic macular edema (GLEAM and GLIMMER) and macular edema due to retinal vein occlusion (BEACON).

Recruitment of patients from the United States in Kodiak's ongoing global DAZZLE Phase 2b/3 study of KSI-301 in treatment-naïve wet (neovascular) age-related macular degeneration is now complete. Recruitment in Europe is ongoing, and Kodiak expects to complete DAZZLE enrollment this year.

Additional Phase 1b study data continue to show strong durability of KSI-301 compared to the current standard of care. In treatment-naïve patients, after only three loading doses, 72% of wAMD and 79% of DME patients have now achieved a six-month or longer treatment free interval at least once during follow-up. In RVO, 81% of patients have achieved a four-month or longer treatment free interval at least once during follow-up.

"Kodiak continues to make strong operational progress toward our 2022 Vision of submitting a single BLA for KSI-301 in wet AMD, DME and RVO, the main diseases treated today using intravitreal anti-VEGF therapy," said Victor Perlroth, M.D., Chief Executive Officer of Kodiak Sciences. "The randomization of treatment-naïve patients into these three pivotal studies in the third quarter is a critical step to build the clinical evidence for KSI-301 as a safe, effective and highly durable therapy for patients with retinal diseases. I am proud of our team's efforts to plan and initiate these pivotal studies while also continuing our efforts on the DAZZLE pivotal study, which completed enrolling patients in the U.S. in the third quarter as well. These are noteworthy accomplishments at any time, but in light of COVID-19 they are particularly impressive and reflect strong enthusiasm by the retina community for KSI-301 and its profile. With the mature data from our Phase 1b study and the enhancements we have designed into each of these four concurrent pivotal studies as detailed in our July webinar, we are investing with conviction in KSI-301 and our accelerating clinical, manufacturing and pre-commercial activities."

"While anti-VEGF therapies have been approved for the treatment of DME for nearly a decade, diabetes continues to be the leading cause of vision loss in working-age adults in the developed world," said Jason Ehrlich, M.D., Ph.D., Kodiak's Chief Medical and Development Officer. "Because of the high-frequency treatment required with current anti-VEGF medicines, real-world outcomes show that many patients are chronically undertreated and do not achieve optimal vision outcomes as a result. There is a tremendous unmet need for more durable, highly efficacious treatments for DME patients. Building on the strong safety, efficacy and durability data from our ongoing Phase 1b study, our GLEAM and GLIMMER Phase 3 studies are evaluating the efficacy of KSI-301 given as infrequently as every six-months (after three monthly loading doses) compared to aflibercept on its approved every two-month interval (after five monthly loading doses). If these studies are successful, we believe that KSI-301 can become the preferred, first-line treatment option for patients and retina specialists alike."

About the GLEAM and GLIMMER Studies

The Phase 3 GLEAM and GLIMMER studies are global, multi-center, randomized studies designed to evaluate the efficacy, durability 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 the change from baseline in best-corrected vision at one year, and patients will be treated and followed for two years. Additional information about the GLEAM and GLIMMER studies (also called Studies KS301P104 and KS301P105, respectively) will be available soon at www.clinicaltrials.gov.

About the BEACON Study

The Phase 3 BEACON study is a global, multi-center, randomized study designed to evaluate the efficacy, durability 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 the change from baseline in best-corrected vision at six months, and patients will be treated and followed for one year. Additional information about the BEACON study (also called Study KS301P103) will be available soon at www.clinicaltrials.gov.

About the DAZZLE Study

The Phase 2b/3 DAZZLE study is a global, multi-center, randomized study designed to evaluate the efficacy, durability 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 is expected to enroll 550 patients worldwide. The primary endpoint is at one year and 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 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 Company's Phase 2b/3 DAZZLE pivotal study in patients with treatment-naïve wet AMD was initiated in October 2019, 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. These studies are anticipated to form the basis of the Company's initial BLA to support potential approval and commercialization. An additional pivotal study in patients with non-proliferative diabetic retinopathy is planned. Kodiak Sciences Inc. is developing KSI-301 and owns global rights to KSI-301.

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 our belief that KSI-301 may achieve disruptive dosing regimens; the likelihood of success of our KSI-301 Clinical Program; the potential for KSI-301 to become a preferred, first-line treatment option with a durability profile that patients, physicians and payors will seek; our ability to complete enrollment in DAZZLE in 2020; our ability to achieve our 2022 Vision, including a single BLA submission in wet AMD, DME and RVO in 2022; 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; 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; 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 forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements.

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