# Kodiak Sciences Announces Presentation of KSI-301 Phase 1b Clinical Study Data Focused on Diabetic Macular Edema at American Academy of Ophthalmology (AAO) 2020 Virtual Meeting

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PALO ALTO, Calif., Nov. 11, 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 a pre-recorded presentation of clinical study data on its investigational therapy KSI-301 is available at the American Academy of Ophthalmology (AAO) 2020 Virtual Annual Meeting.

Details of the presentation are as follows:

**Event:** Late Breaking Developments, Part II
**Title:** One Year and Beyond: Long-term Multiple-dose Study of KSI-301, an Anti-VEGF Antibody Biopolymer Conjugate with Extended Durability, in wAMD, DME, and RVO
**Presenter:** Arshad M Khanani, M.D., M.A., managing partner and director of clinical research, Sierra Eye Associates, clinical associate professor of ophthalmology, University of Nevada
**Presentation date and time:** The pre-recorded presentation containing slides and audio will be available to AAO 2020 Virtual attendees starting on Wednesday, November 11. The presentation slides are also available on the "Events and Presentations" section of Kodiak's website at http://ir.kodiak.com/.

"As diabetic eye disease remains the leading cause of new blindness in working-aged Americans, and we recently started enrolling our GLEAM and GLIMMER pivotal studies in patients with Diabetic Macular Edema, Dr. Khanani's presentation at the AAO late-breaking session focuses on DME. The data suggest a transformative effect that allows for a combination of strong efficacy and remarkable durability. The results are out of the ordinary when benchmarked to current anti-VEGF agents," said Jason Ehrlich, M.D., Ph.D., Chief Medical & Development Officer of Kodiak Sciences. "We also remain very pleased with the safety profile of KSI-301, and the most recent Phase 1b safety data are reflected in Dr. Khanani's presentation. To date, KSI-301 has been administered more than 1,500 times to more than 400 patients across the entire development program, representing more than 250 patient-years of clinical experience. The presentation also refreshes the durability proportions of Phase 1b wet AMD and DME patients who achieved a 6 months or longer treatment-free interval during follow-up and RVO patients who achieved a 4 months or longer treatment-free interval during follow-up."

"Today's presentation provides perspectives on KSI-301's emerging efficacy and durability with an emphasis on helping the audience to understand and link the strong performance of KSI-301 to its precision engineering and underlying scientific rationale," said Victor Perlroth, M.D., Chief Executive Officer. "Today's presentation also includes new case examples showing long-term disease modification in diabetic macular edema and proliferative diabetic retinopathy patients with no or very few retreatments in treatment naïve patients following only three loading doses. Given the unsustainable treatment burden of current anti-VEGFs, the unmet need for longer-lasting treatment of diabetic eye disease is clear, and confirmation of KSI-301's durability, efficacy and safety profile in GLEAM and GLIMMER would be an important advance for patients and physicians."

**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 study (also called Study KS301P104) and the GLIMMER study (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 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) can be found on www.clinicaltrials.gov under Trial Identifier NCT04592419 (https://clinicaltrials.gov/show/NCT04592419).

**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 approximately 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 the KSI-301 Clinical Program**

The KSI-301 Clinical Program is designed to assess KSI-301's safety, efficacy and durability in wet AMD, DME, RVO and non-proliferative DR (without DME) through clinical studies run in parallel. We are conducting two Phase 3 studies in DME (the GLEAM and GLIMMER studies) to provide the mutually confirmatory studies required by FDA for initial demonstration of safety and efficacy. We also are conducting one study in wet AMD (our ongoing DAZZLE study) and one study in RVO (the BEACON study) to support approval in these indications. We intend to file this package together in a single BLA in 2022. We also plan to run an additional study in patients with non-proliferative DR without DME (the GLOW study). We expect that the global KSI-301 clinical program will be conducted at 150+ study sites in more than 10 countries.

**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 beliefs about KSI-301's clinical efficacy, durability and safety; our ability to achieve our 2022 Vision, including a single BLA submission in wet AMD, DME and RVO; 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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