



## **Kodiak Sciences Announces 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 American Academy of Ophthalmology Annual Meeting Retina Subspecialty Day**

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**Promising clinical durability observed with 80% of wet AMD treated eyes and 78% of DME treated eyes extended to four months or longer without receiving retreatment**

**Strong anti-VEGF efficacy continues to be observed across the major retinal vascular diseases**

**Encouraging safety profile with zero cases of intraocular inflammation after 300+ doses in 100+ patients**

PALO ALTO, Calif., Oct. 11, 2019 /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 its ongoing Phase 1b study of its investigational therapy KSI-301 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 Charles C. Wykoff, M.D., Ph.D., a clinical investigator in the study, as an oral presentation at the "First-Time Results of Clinical Trials" session of the American Academy of Ophthalmology Annual Meeting's Retina Subspecialty Day. Dr. Wykoff is Director of Research at Retina Consultants of Houston. The study findings presented today by Dr. Wykoff can be found on the Kodiak Investor Relations website at <http://ir.kodiak.com>.

"We continue to observe encouraging safety and efficacy data in the Phase 1b study of KSI-301, and the emerging durability data are remarkable," said Jason Ehrlich, M.D., Ph.D., Chief Medical Officer of Kodiak Sciences. "In wet AMD, a next-generation intravitreal biologic would bring nearly all patients to a three month or longer dose interval. Our early data suggest this is achievable using KSI-301, with 87% of wet AMD patients extending beyond three months after the last loading dose without receiving retreatment. In DME, a pan-retinal disease that typically has a high initial treatment burden, we observed that 82% of patients were extended beyond three months without receiving retreatment following only three initial loading doses. Further, we are seeing promising early signs of improvement in diabetic retinopathy, with 40% of patients improving in diabetic retinopathy severity level within the first twelve weeks of treatment and no patients worsening. In RVO, a disease which typically requires monthly anti-VEGF therapy to achieve the best results, we observed that over half the patients were extended beyond three months after only three loading doses without receiving retreatment and over a quarter of patients received their first retreatment at two months. Interestingly, we also see potential signs of disease modification in RVO as evidenced by a sequentially increased time to retreatment in patients who have received more than one retreatment to date."

"These new results reinforce our belief in the potential for KSI-301 to reduce treatment burden and improve vision outcomes for patients. To that end, we are designing pivotal studies to demonstrate meaningful differentiation of KSI-301 in each of the retinal vascular diseases," said Victor Perloth, M.D., Chief Executive Officer of Kodiak Sciences. "We have begun dosing patients in our DAZZLE pivotal study of KSI-301 in wet AMD, where KSI-301 will be given on an every three-, four- or five-month dosing interval. We look forward to discussing our accelerating plans for the clinical development of KSI-301 at our R&D Day on Monday, October 14."

### **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 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 study is expected to enroll at least 368 patients worldwide. 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](http://www.clinicaltrials.gov) under Trial Identifier NCT04049266 (<https://clinicaltrials.gov/show/NCT04049266>).

### **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](http://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 reduce treatment burden 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 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 1b 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 forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements.

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