

## **Kodiak Sciences Announces 1-Year Durability, Efficacy and Safety 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 2021 Annual Meeting**

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- **2 in every 3 patients are on a 6-month or longer treatment-free interval at Year 1 in each of the 3 major retinal vascular diseases, wAMD, DME and RVO, after only 3 loading doses**
- **78% of patients with wAMD, 84% with DME and 75% with RVO are on a 4-month or longer treatment interval at Year 1**
  - **Strong anti-VEGF efficacy and encouraging safety profile continue to be observed across all three diseases**
- **Mean of 2.0, 1.0, and 1.7 retreatments administered in the ten months following the loading phase in wet AMD, DME and RVO patients, respectively**

PALO ALTO, Calif., Feb. 13, 2021 /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 promising 1-year durability, efficacy and safety 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 (wet AMD), diabetic macular edema (DME) and retinal vein occlusion (RVO).

"The Year 1 data for KSI-301 presented today at Angiogenesis and the data presented on other late-stage molecules at the meeting continue to support a highly-differentiated durability profile for KSI-301 along with strong efficacy and an encouraging safety profile. We observed that two-thirds of patients in each disease cohort achieve a 6-month or longer treatment-free interval at the one-year mark – 66% of wet AMD patients, 69% of DME patients and 66% of RVO patients," said Jason Ehrlich, M.D., Ph.D., Chief Medical Officer at Kodiak Sciences. "Moreover, 78% of wet AMD patients and 84% of DME patients were on a 4-month or longer interval at Year 1, as were 75% of RVO patients. Said differently, an average of only 2.0, 1.0, and 1.7 retreatments were given in the ten months following the three loading doses in AMD, DME, and RVO patients respectively. Remarkably, 54% of wet AMD patients required only one retreatment and 50% of DME patients required no retreatment in Year 1."

"We are seeing strong anti-VEGF efficacy for KSI-301, when we look to historical data for anti-VEGFs and new late-stage trial data presented at today's meeting," continued Dr. Ehrlich. "In wet AMD, we observed a mean 5.7 letter improvement, to 69.7 ETDRS eye chart letters (~20/40 Snellen) at Year 1. In DME, we observed a mean 7.6 letter improvement to 73.9 eye chart letters (~20/32 Snellen) at Year 1, and in RVO we observed a mean 22.2 letter improvement to 76.6 letters (~20/32 Snellen). We also remain pleased with the safety profile of KSI-301, now with over 700 doses given in the Phase 1b study and over 2,000 administered across the ongoing KSI-301 clinical development program."

"KSI-301 has the potential to become the standard of care for patients with VEGF-mediated retinal diseases," said Victor Perloth, M.D., Chief Executive Officer of Kodiak Sciences. "Our Year 1 Phase 1b data, with two in three patients achieving a 6-month or longer treatment-free interval at Year 1, show the potential for KSI-301 to provide tangible benefits for patients and retina specialists alike. The DAZZLE wet AMD study is fully recruited with an expected data read-out in early 2022, and our GLEAM and GLIMMER studies in DME and BEACON study in RVO are actively recruiting. We are grateful for the enthusiastic support of these studies from the ophthalmology community."

The new KSI-301 data were presented online today at the Angiogenesis, Exudation, and Degeneration 2021 - Virtual Edition meeting by Diana V. Do, M.D., Professor of Ophthalmology and Vice Chair for Clinical Affairs at the Byers Eye Institute at Stanford University School of Medicine. The study findings presented by Dr. Do can be found on the Kodiak Investor Relations website at <http://ir.kodiak.com>.

### **About the DAZZLE Study**

The Phase 2b/3 DAZZLE study is a global, multi-center, randomized study designed to evaluate the durability, efficacy 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 has enrolled over 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](http://www.clinicaltrials.gov) under Trial Identifier NCT04049266 (<https://clinicaltrials.gov/show/NCT04049266>).

### **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 GLEAM (also called Study KS301P104) and GLIMMER (also called Study KS301P105) can be found on [www.clinicaltrials.gov](http://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](http://www.clinicaltrials.gov) under Trial Identifier NCT04592419 (<https://clinicaltrials.gov/show/NCT04592419>).

### **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 completed enrollment in November 2020, 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](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 statements regarding our beliefs about KSI-301's clinical efficacy, durability and safety, as well as KSI-301's potential to be a more pragmatic and achievable regimen compared to current medicines; our ability to achieve our 2022 Vision; 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 candidates 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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