



## **Kodiak Sciences Announces New Longer-Term 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 Society of Retina Specialists (ASRS) 2020 Virtual Annual Meeting**

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- Strong anti-VEGF safety, efficacy and durability continue to be observed across all three of the major retinal vascular diseases, with most patients achieving treatment-free intervals of 6-months in wet AMD, 6-months or longer in DME, and 4-months or longer in RVO**
- 82% of wet AMD eyes extended to 4-months or longer before first retreatment, with 68% achieving a six-month treatment-free interval**
- 76% of DME eyes extended to four-months or longer and 67% extended to 6-months or longer before first retreatment, with nearly half of DME eyes yet to require any retreatment following the loading phase**
- Mean of 1.3, 0.6, and 1.3 retreatments administered in the eight months following the loading phase in the wAMD, DME, and RVO patients, respectively**
- Encouraging safety profile maintained after 546 doses in 130 patients, with over 150 patient-years of clinical safety data across the KSI-301 development program**

PALO ALTO, Calif., July 10, 2020 /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 additional safety, efficacy and durability 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 data are presented online today at the American Society of Retina Specialists 2020 Virtual Annual Meeting by Mark Barakat, M.D., an investigator in the study and physician at Retina Consultants of Arizona, Phoenix, AZ. The study findings presented by Dr. Barakat can be found on the Kodiak Investor Relations website at <http://ir.kodiak.com>. A livestreamed Q&A panel discussion will be held on Sunday, July 26, 2020, for ASRS Virtual Annual Meeting attendees.

"Now supported by over 100 patient-years of clinical data in the Phase 1b study and over 150 patient-years across the KSI-301 development program, we continue to be very encouraged by the safety, efficacy, and durability of KSI-301," said Jason Ehrlich, M.D., Ph.D., Chief Medical Officer of Kodiak Sciences. "In the data presented today for Virtual ASRS, we observed that 82% of wet AMD eyes and 76% of DME eyes treated with KSI-301 were extended to four months or longer after the last loading dose before receiving their first retreatment. 68% of wet AMD eyes have achieved a six-month interval at least once during follow-up. In DME, with all patients having now been followed for six months or longer after only three initial loading doses (versus the five required with current standard-of-care), it is remarkable that nearly half of patients have yet to require any retreatment, and two-thirds of our DME patients have gone six months or longer before receiving their first retreatment."

"Importantly, KSI-301 is well-tolerated, and the safety profile of KSI-301 remains excellent," continued Dr. Ehrlich. "With 546 doses given in the Phase 1a/1b program, only two events of trace to 1+ intraocular inflammation have occurred, the same two cases as reported previously. These events resolved completely, and both patients have gained over five eye chart lines of vision from their baseline (+30 and +27 letters, respectively). The durability of KSI-301 is exceeding my expectations. It is notable that we see very few retreatment injections – in fact, only an average of 1.3 injections were given in the wet AMD patients in the eight months after the loading phase, and only 0.6 injections in DME patients and 1.3 in RVO patients. This compares very favorably to the best current standard-of-care anti-VEGF therapy (4.0, 5.0 and 8.0 injections, respectively). We believe these results strongly support both the disruptive KSI-301 dosing regimens in our pivotal study designs and the studies' likelihoods of success."

"The latest Phase 1b study data, where we see the durability of KSI-301 over longer periods of treatment and follow-up, strongly reinforce the potential for KSI-301 to be a foundational anti-VEGF therapy with a durability profile that patients, physicians and payors are asking for," said Victor Perloth, M.D., Chief Executive Officer of Kodiak Sciences. "We believe that a disruptive 'Generation 2.0' anti-VEGF therapeutic would allow nearly all wet AMD and DME patients to be treated on a three-month or longer dose interval and most RVO patients on a two-month or longer interval. Our maturing Phase 1b study data continue to surpass those goalposts. Indeed, for many wet AMD and DME patients, our data suggest KSI-301 may be a once every five- or six-month medicine."

"With all of our pivotal studies enrolling treatment-naïve patients similar to those in our Phase 1b, we retain a high confidence in our KSI-301 development program," Dr. Perloth continued. "Our DAZZLE study in wet AMD, where KSI-301 is given as infrequently as every five-months, continues to recruit well with over 340 patients randomized to date in the US and Europe. We are very appreciative of the support from the ophthalmology community. We look forward to initiating pivotal studies in DME, RVO, and potentially diabetic retinopathy later this year, as we continue advancing KSI-301 on track for our 2022 Vision of a BLA filing in these key indications. We will be discussing these clinical plans in more detail at our July 27, 2020, R&D webinar on the heels of the livestreamed Virtual ASRS panel."

### **About KSI-301**

KSI-301 is an investigational anti-VEGF therapy built on the Company's Antibody Biopolymer Conjugate, or 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 DAZZLE pivotal study in patients with treatment-naïve wet AMD was initiated in October 2019. Kodiak plans to initiate additional pivotal studies of KSI-301 in 2020 in diabetic macular edema, retinal vein occlusion and diabetic retinopathy. These studies are anticipated to form the basis of the Company's initial BLA to support potential approval and commercialization. KSI-301 is being developed and is fully owned globally by Kodiak Sciences Inc. In December 2019, Kodiak entered into an agreement to sell a 4.5% capped royalty right on global net sales of KSI-301 to Baker Bros. Advisors for \$225 million.

### **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 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 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 have agreed on the order and number of clinical studies required to support the licensure of KSI-301 in wet AMD, DME, RVO and non-proliferative DR at an end of phase 2 meeting with the U.S. Food and Drug Administration (FDA). We confirmed that two clinical studies conducted in a single indication are expected by FDA to demonstrate the initial safety and efficacy of KSI-301. One clinical study each in the additional disease indications, if successful, can be used to support approval in the additional indications. We intend to conduct 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 intend to conduct one study in wAMD (our ongoing DAZZLE study) and one study in RVO (the BEACON study) to support approval of these additional 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) which depending on data readiness may be combined either into the single initial BLA or may be filed as a supplemental BLA. We expect that the global KSI-301 clinical program will be conducted at 100+ study sites in more than 10 countries.

### **About Kodiak Sciences Inc.**

Kodiak (Nasdaq: KOD) is a clinical stage biopharmaceutical company developing novel therapeutics to treat chronic, 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, a leading cause of blindness in elderly patients, and diabetic retinopathy, a leading cause of blindness in working-age patients. 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 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 be a foundational anti-VEGF therapy with a durability profile that patients, physicians and payors will seek; our ability to initiate pivotal studies in DME, RVO and potentially diabetic retinopathy in 2020; our ability to achieve our 2022 Vision, including a single BLA submission in wet AMD, DME, RVO and diabetic retinopathy 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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Kodiak Contact: John Borgeson, Senior Vice President and Chief Financial Officer, Tel (650) 281-0850, ir@kodiak.com