Kodiak Sciences Announces Completion of 12-Week Phase 1a Study of KSI-301 in Patients with Diabetic Macular Edema Demonstrating Safety and Durability of Responses Following Single Dose of Intravitreal Anti-VEGF Antibody Biopolymer Conjugate

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-- Rapid high-magnitude and durable treatment responses were seen at all dose levels tested in a heavily pre-treated Phase 1 patient population.

-- Twelve weeks after a single dose, median vision improvement from baseline of almost two lines of vision (9 eye chart letters) and median improvement in retinal edema of 121 microns were achieved across all three dose levels tested.

-- No dose-limiting toxicities, drug-related adverse events, or intraocular inflammation were observed through each patients' last visit at 12 weeks.

-- Multiple-dose Phase 1b study in patients with wet age-related macular degeneration, diabetic macular edema, and retinal vein occlusion now recruiting patients.

PALO ALTO, Calif., Dec. 21, 2018 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), a clinical stage biopharmaceutical company specializing in novel therapeutics to treat chronic, high-prevalence retinal diseases, today reported last visit (twelve-week) data from its Phase 1a single ascending dose clinical study of KSI-301, an investigational anti-VEGF antibody biopolymer conjugate, in nine patients with severe diabetic macular edema.

After a single dose, eight of nine patients responded to KSI-301, as assessed by improvement from baseline in vision, anatomy, or both. Rapid improvements were observed as early as one week after the injection. The treatment effect increased through four weeks resulting in a median Best Corrected Visual Acuity (BCVA) improvement of 12.5 eye chart letters and median Central Retinal Thickness on optical coherence tomography (OCT) improvement of 120 microns, pooled across all three dose levels.

Among the responders to KSI-301, all had sustained improvements from baseline (vision, retinal anatomy, or both) at the twelve-week last visit. At twelve weeks after the single dose, a median BCVA improvement of 9 eye chart letters (almost two lines of vision) and median OCT improvement of 121 microns were observed, pooled across all three dose levels. The single non-responder subject had previously failed to respond through a regimen of Lucentis and Eylea treatments.

Through the 12-week last visit, single doses of KSI-301 demonstrated no dose-limiting toxicities, no drug-related adverse events, and no signs of intraocular inflammation. As previously reported, the highest dose tested, 5 mg, has been selected for advancement into pivotal studies.

In a previously-published Phase 1 single-dose study with 4 mg aflibercept –twice the marketed dose of Eylea– in five patients with DME, six weeks after the single injection, four of the five patients showed improvement in BCVA (median improvement of 3 letters) and four of the five showed improvement in OCT (median improvement of 74 microns). At four weeks after the single injection, the median improvement in OCT was 49 microns and the median improvement in BCVA was 9 letters.[1]

"We are very encouraged by the depth and durability of treatment responses. This study of KSI-301 was designed as a first-in-human, single-dose safety study and has exceeded our expectations from the standpoints of bioactivity and durability. DME can be a challenging retinal disease to treat due to high intraocular VEGF levels and concurrent retinal vascular inflammation. For example, the approved dosing regimen for Eylea in DME commences with five monthly loading doses. In our Phase 1a study, we observed compelling responses after only a single dose," said Jason Ehrlich, M.D., Ph.D., Kodiak's Chief Medical Officer and Chief Development Officer. "We continue to believe KSI-301 has the potential to be a leading next-generation anti-VEGF therapy that addresses the heavy treatment burden and suboptimal real-world outcomes of current medicines. We are fully committed to the continued rapid clinical development of KSI-301 and will evaluate its potential broadly in the treatment of patients with retinal vascular diseases. Our Phase 1b multiple-dose study is now recruiting patients with neovascular (wet) age-related macular degeneration, DME, and macular edema due to retinal vein occlusion. Given the results of the Phase 1a study, we are excited about the potential for important durability signals to emerge in Phase 1b."

"These 12-week data also increase our confidence in the potential durability advantage of KSI-301 in wet AMD which is a more localized retinal disease with typically lower levels of VEGF compared to DME," said Victor Perlroth, M.D., Kodiak's Chief Executive Officer. "For this reason, we have enhanced our wet AMD pivotal Phase 2 study design to include evaluation of 20-week along with 16-week and 12-week dosing intervals in comparison to Eylea on its 8-week labeled regimen. We believe that, if successful, a regimen which provides nearly all patients with a 12-week or better treatment interval would be unique and industry-leading. We remain on track for this study to begin enrollment in the second quarter of 2019."

"Furthermore, the bioactivity and durability profile of the treatment responses seen so far, as well as the observed safety profile, support the evaluation of KSI-301 in earlier forms of diabetic eye disease such as non-proliferative diabetic retinopathy," said Dr. Perlroth. "Treating the right NPDR patients with an infrequent dose regimen and before vision loss occurs could have a tremendous public health impact. We look forward to sharing more about our strategy for earlier diabetic retinopathy over the course of the coming year."

"In addition to the early-onset responses observed in some patients (as reported earlier), we were also pleased to see that initial treatment responses in some patients continued to increase in magnitude through the 12-week last visit, suggesting that KSI-301 may be affecting the disease in a way that we have not seen with currently available anti-VEGF agents," said Diana Do, M.D., Professor of Ophthalmology at Stanford University School of Medicine and Chair of the Kodiak clinical advisory board. "The science underlying KSI-301's design and Kodiak's ABC Platform is intriguing, and I look forward to presenting the data at the upcoming ophthalmology Angiogenesis meeting in Miami on February 9, 2019."

About KSI-301

KSI-301 is an investigational compound that is not approved for any use in any country. KSI-301 is built on the Company's 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 improve real-world outcomes for patients with macular degeneration and diabetic macular edema and to enable earlier treatment and prevention of vision loss for patients with diabetic eye disease.

About Kodiak Sciences Inc.

Kodiak Sciences is a clinical stage biopharmaceutical company specializing in novel therapeutics to treat chronic, high-prevalence retinal diseases. Our Antibody Biopolymer Conjugate or ABC Platform merges the fields of antibody-based and chemistry-based therapies and is at the core of Kodiak's discovery engine. In addition to its lead product candidate, KSI-301, a novel anti-VEGF antibody biopolymer conjugate in clinical development for the treatment of age-related macular degeneration and diabetic retinopathy, 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 bioconjugate for the treatment of neovascular retinal diseases such as wet AMD and diabetic retinopathy. Kodiak is based in Palo Alto, CA. For more information, 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 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, 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 1 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

References:

1. Do DV, Nguyen QD, Shah SM, et al. An exploratory study of the safety, tolerability and bioactivity of a single intravitreal injection of vascular endothelial growth factor Trap-Eye in patients with diabetic macular oedema. British Journal of Ophthalmology. 2009; 93**:**144-149.

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