Kodiak Sciences Announces Positive Interim Data from Ongoing Phase 1b Clinical Study of KSI-301, a Novel Anti-VEGF Antibody Biopolymer Conjugate for Treatment of Wet AMD, Diabetic Eye Disease, and Retinal Vein Occlusion, at the American Society of Retina Specialists 2019 Annual Meeting

July 27, 2019 at 12:47 PM EDT

- Antibody Biopolymer Conjugates are a new scientific approach and design platform for ophthalmic intravitreal drugs
- KSI-301 continues to achieve its development goals of demonstrating efficacy and safety in serious retinal vascular diseases
- Additional efficacy and durability data to be presented at the American Academy of Ophthalmology Retina Subspecialty Day in October 2019
- Pivotal Phase 2 clinical trial with KSI-301 in wet AMD anticipated to begin enrollment in the third quarter of 2019

PALO ALTO, Calif., July 27, 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 positive interim results from the ongoing Phase 1b study of KSI-301, its investigational intravitreal anti-VEGF antibody biopolymer conjugate in patients with anti-VEGF treatment-naïve neovascular (wet) age-related macular degeneration (AMD), diabetic macular edema (DME), and macular edema due to retinal vein occlusion (RVO).

The results were presented by Pravin U. Dugel, M.D., an investigator in the study, as an oral presentation at the American Society of Retina Specialists (ASRS) 2019 Annual Meeting. Dr. Dugel is Managing Partner, Retinal Consultants of Arizona and Retinal Research Institute, Phoenix, AZ, and Clinical Professor, Roski Eye Institute, USC Keck School of Medicine, Los Angeles, CA. The detailed study findings presented by Dr. Dugel can be found on the Kodiak Investor Relations website at http://ir.kodiak.com.

Summary of Efficacy Outcomes through Week 12

Across all three diseases under study, strong improvements in vision and retinal anatomy were observed over 12 weeks. Vision is measured as change in Best Corrected Visual Acuity (BCVA) on a standardized eye chart, and retinal anatomy is measured as change in retinal central subfield thickness (CST) using optical coherence tomography (OCT) imaging. The efficacy data presented at ASRS include outcomes from 35 patients in the study who had reached the week 12 visit. In the study, patients are being treated with three monthly doses of either 2.5 mg or 5 mg KSI-301 and followed for 7 months thereafter, with additional treatments according to protocol-specified retreatment criteria.

The following results were observed at Week 12*:

Disease (number of patients)	Median Baseline BCVA, letters	Median Baseline OCT CST, microns	Change in Median BCVA at Week 12, letters	Change in Median OCT CST at Week 12, microns
Wet AMD (n=17)	66	380	+8	-96
DME (n=8)	69.5	491	+9.5	-197
RVO (n=10)	52.5	513	+26.5	-209

*Includes patients who reached Week 12 visit by July 24, 2019 data cutoff date; 2.5 & 5 mg doses pooled.

"We are pleased with KSI-301's promising efficacy and safety data to date," said Jason Ehrlich, M.D., Ph.D., Kodiak's Chief Medical Officer and Chief Development Officer. "In addition to vision and anatomic improvements, we have observed encouraging signs of disease modification. In the individual case studies presented at ASRS, using OCT angiography we observed normalization of retinal vascular flow in an RVO patient seen as early as one week after the first dose and reduction in choroidal neovascularization size and vascular flow rate in a wet AMD patient. In a DME patient with proliferative retinopathy, we observed conversion to non-proliferative retinopathy and a two-step improvement in diabetic retinopathy severity score at the 12-week assessment. These findings increase our conviction in the promise of KSI-301 and the further potential of our ABC Platform. We look forward to presenting emerging durability data from the Phase 1b study at the American Academy of Ophthalmology Retina Subspecialty Day on October 11, 2019."

Summary of Safety Outcomes

A total of 200 injections with KSI-301 have been given to date across the Phase 1a and Phase 1b program with no intraocular inflammation or ocular serious adverse events reported.

As of the July 24, 2019 ASRS presentation's data cut-off date, a total of 77 patients were enrolled in the Phase 1b study. Multiple-dose exposure to KSI-301 has been well tolerated. A total of 77 patients have received one injection, 60 patients have received two injections and 44 patients have received three injections. No drug-related adverse events or serious adverse events have been reported. Most of the adverse events reported have been assessed as mild (70%) and are consistent with the profile of intravitreally-injected anti-VEGF agents. Eight non-ocular serious adverse events have been reported in four patients, none being assessed as drug-related.

Twelve leading retinal research centers in the United States are participating in the Phase 1b study. For additional details about the study, please see https://clinicaltrials.gov/ct2/show/NCT03790852.

Phase 1b Trial Expansion

The Phase 1b study of KSI-301 is nearing completion of enrollment of the planned cohorts. Based on the positive data observed to date, Kodiak is

planning for supplemental cohorts to explore additional scientific questions relevant to KSI-301 and its use for the treatment of retinal diseases.

Status of Phase 2 'DAZZLE' Study in Wet AMD

Recruitment in a Phase 2 head-to-head trial of KSI-301 versus aflibercept in treatment-naïve wet AMD patients is expected to begin in the third quarter of 2019. In this study, called DAZZLE, approximately 364 patients are planned to be enrolled worldwide. Patients will be randomized to receive either KSI-301 on a dosing regimen as infrequently as every 20 weeks or standard-care aflibercept on its every 8-week dosing regimen. All patients randomized to KSI-301 will be on an every 12-week or longer regimen after three monthly loading doses.

About KSI-301

KSI-301 is an investigational therapy 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 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 Sciences Inc.

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 as a potential first-line agent for 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 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, the anticipated presentation of additional data 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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