Kodiak Sciences Completes Enrollment in GLEAM and GLIMMER Phase 3 Clinical Trials of KSI-301 in Patients with Diabetic Macular Edema

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- Over 900 patients with diabetic macular edema enrolled worldwide

PALO ALTO, Calif., Feb. 3, 2022 /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 that it has completed enrollment in its GLEAM and GLIMMER Phase 3 clinical trials of KSI-301, Kodiak's anti-VEGF antibody biopolymer conjugate, in patients with diabetic macular edema ("DME").

"Diabetic macular edema is a leading cause of vision loss in working-age people, and the treatment burden imposed by current FDA approved anti-VEGF therapies is challenging for many DME patients," said Jason Ehrlich, MD, PhD, Kodiak's Chief Medical and Development Officer. "We are very pleased to have completed enrollment in our GLEAM and GLIMMER pivotal trials, where we are studying KSI-301's potential to be a longer-lasting DME treatment – as infrequent as once every six months. Enrollment is also proceeding well in our GLOW Phase 3 clinical trial, where we are studying every six-month dosing of KSI-301 in non-proliferative diabetic retinopathy patients who have not yet developed DME."

"With DAZZLE, BEACON, GLEAM and GLIMMER fully enrolled and with DAYLIGHT recruiting quickly," said Victor Perlroth, MD, Kodiak's Chief Executive Officer, "we have line of sight to topline results across the full portfolio of studies to support our single BLA submission for the three major anti-VEGF requiring diseases of wet age-related macular degeneration, diabetic macular edema and retinal vein occlusion. We remain on track to announce topline results this quarter for DAZZLE and mid-year for BEACON."

About KSI-301

KSI-301 is an investigational anti-VEGF therapy built on Kodiak's Antibody Biopolymer Conjugate (ABC) Platform and is designed to maintain potent and effective drug levels in ocular tissues for longer than existing available 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 KSI-301 clinical program is designed to assess KSI-301's durability, efficacy and safety in wet AMD, DME, RVO and non-proliferative DR (without DME) through clinical studies run in parallel. The Company's DAZZLE and DAYLIGHT pivotal studies in patients with treatment-naïve wet AMD, GLEAM and GLIMMER pivotal studies in patients with diabetic macular edema, and the BEACON pivotal study in patients with retinal vein occlusion are anticipated to form the basis of the Company's initial BLA to support potential approval and commercialization in multiple indications and with a full range of labeled and reimbursable dosing frequencies in each indication. An additional Phase 3 pivotal study, GLOW, in patients with non-proliferative diabetic retinopathy is also underway. The global KSI-301 clinical program is being conducted at 150+ study sites in more than 10 countries. Kodiak is developing KSI-301 and owns global rights to KSI-301.

About the DAZZLE Study

The Phase 2b/3 DAZZLE study is a global, multi-center, randomized pivotal 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 topline data are expected in early 2022. 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 under Trial Identifier NCT04049266 (https://clinicaltrials.gov/show/NCT04049266).

About the BEACON Study

The Phase 3 BEACON study is a global, multi-center, randomized study designed to evaluate the durability, efficacy 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. Following this, patients can continue to receive KSI-301 for an additional six months on an individualized basis. The study has enrolled over 550 patients worldwide. The primary endpoint is at six months, and patients will be treated and followed for 18 months. Additional information about the BEACON study (also called Study KS301P103) can be found on www.clinicaltrials.gov under Trial Identifier NCT04592419 (https://clinicaltrials.gov/show/NCT04592419).

About the DAYLIGHT Study

The Phase 3 DAYLIGHT study is a global, multi-center, randomized pivotal study designed to evaluate the efficacy and safety of high-frequency KSI-301 in patients with treatment-naïve wet AMD. Patients are randomized to receive either KSI-301 on a monthly dosing regimen or to receive standard-of-care aflibercept. The study is expected to enroll approximately 500 patients worldwide. The primary endpoint is at ten months, and the study is being planned and executed to allow for inclusion of its results in the initial BLA for KSI-301 along with the DAZZLE, BEACON, GLEAM and GLIMMER studies. The intent of this pivotal study is to broaden KSI-301's potential product labeling, explore the potential for improved treatment outcomes in certain patients with intensive anti-VEGF treatment, and eliminate possible barriers to market access and insurance reimbursement that have impeded or complicated the commercial uptake of other anti-VEGF medications in the past. We believe that pursuing a broad product label will provide physicians with the flexibility, agency, and reimbursement confidence required to consider KSI-301 treatment for all their patients. Additional information about DAYLIGHT (also called Study KS301P107) can be found on www.clinicaltrials.gov under Trial Identifier NCT04964089 (https://clinicaltrials.gov/show/NCT04964089).

About the GLEAM and GLIMMER Studies

The Phase 3 GLEAM and GLIMMER studies are global, multi-center, randomized pivotal studies designed to evaluate the durability, efficacy 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 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 under Trial Identifiers NCT04611152 and NCT04603937, respectively (https://clinicaltrials.gov/ct2/show/NCT04611152 and https://clinicaltrials.gov/ct2/show/NCT04603937).

About the GLOW Study

The Phase 3 GLOW study is a global, multi-center, randomized pivotal study designed to evaluate the efficacy and safety of KSI-301 in patients with treatment-naïve, moderately severe to severe non-proliferative diabetic retinopathy (NPDR). Patients are randomized to receive either KSI-301 on a once every six-month dosing regimen after three initiating doses or to receive sham injections. The study is expected to enroll approximately 240 patients worldwide. The primary endpoint is at one year and patients will be treated and followed for two years. Outcomes include changes in diabetic retinopathy severity, measured on a standardized photographic grading scale, and the rate of development of sight-threatening complications due to diabetic retinopathy. Additional information about GLOW (also called Study KS301P106) can be found on www.clinicaltrials.gov under Trial Identifier NCT05066230 (https://clinicaltrials.gov/show/NCT05066230).

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.

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 the potential for a single BLA submission in wet AMD, DME and RVO and a supplemental BLA in NPDR; the potential for KSI-301 to obtain a broad product label; our ability to complete patient enrollment and announce topline data in clinical studies; future development plans, including clinical and regulatory objectives and the timing thereof, anticipated design of planned clinical trials, and the anticipated presentation of data; and 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," "could," "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, including as a result of the ongoing COVID-19 pandemic; 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; 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, including the COVID-19 pandemic, which may significantly impact our business and operations, including out of our headquarters in the San Francisco Bay Area and our clinical trial sites, as well as the business or operations of our manufacturers, contract research organizations or other third parties with whom we conduct business; 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. Kodiak®, Kodiak Sciences®, ABC™, ABC Platform™ and the Kodiak logo are registered trademarks or trademarks of Kodiak Sciences Inc. in various global jurisdictions.

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