Kodiak Sciences Reports Positive Topline Results from BEACON Phase 3 Study of Tarcocimab Tedromer (KSI-301) in Patients with Retinal Vein Occlusion

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- Tarcocimab tedromer (KSI-301) dosed every two months met the primary endpoint of non-inferior visual acuity gains compared to aflibercept dosed every month
- First anti-VEGF therapy to achieve non-inferiority in visual acuity gains while doubling the treatment interval in patients with RVO
- Tarcocimab was well tolerated with a low rate of intraocular inflammation and no new or unexpected safety signals
- Study results will be presented at upcoming ophthalmology scientific meetings in September 2022

PALO ALTO, Calif., Aug. 8, 2022 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD) today announced that its BEACON Phase 3 study of tarcocimab tedromer (KSI-301; tarcocimab), its novel antibody biopolymer conjugate, met the primary endpoint of non-inferior change from baseline in visual acuity at week 24 compared to aflibercept in patients with macular edema due to retinal vein occlusion. Tarcocimab also demonstrated robust anatomic responses and a favorable safety profile. After two initial monthly loading doses, tarcocimab was dosed every two months compared to consistent monthly dosing for aflibercept.

"RVO is a disease with a heavy treatment burden, and all approved anti-VEGF treatments for RVO are labeled for monthly dosing," said Mark Barakat, MD, Director of the Retinal Research Institute at Retinal Consultants of Arizona and a BEACON study investigator. "BEACON is the first study to successfully test a doubling of the treatment interval for anti-VEGF dosing in a pivotal trial in RVO patients. Testing only two loading doses and an extended, fixed dosing interval for all patients rather than assigning a subset of patients to extended dosing based on disease activity assessment is an especially high bar because eyes of patients with RVO can have the highest VEGF levels across retinal vascular diseases. It's wonderful news for patients that the study was successful: it showed that treatment with tarcocimab results in non-inferior vision outcomes, while meaningfully reducing the treatment burden compared to monthly aflibercept."

The BEACON study is a randomized, double-masked, multicenter, active comparator-controlled Phase 3 clinical trial in treatment naïve patients with vision loss and macular edema due to retinal vein occlusion, including both branch (BRVO) and central (CRVO) subtypes. This condition occurs when a branch or central draining vein of the retina becomes blocked, for example due to chronic hypertension, and the retina becomes swollen as a result. The study randomized 568 participants (438 BRVO, 130 CRVO) from 11 countries 1:1 into two treatment arms: tarcocimab tedromer 5 mg on a fixed every-8-week dosing regimen following 2 monthly loading doses and aflibercept 2 mg on a fixed every 4-week dosing regimen per its label.

The primary efficacy endpoint of the study was change in best-corrected visual acuity (BCVA) score, a measure of the best vision a person can achieve when reading letters on an eye chart, from baseline at week 24. In the first 24 weeks of the study, patients randomized to tarcocimab received a total of 4 doses compared with 6 doses received by patients randomized to aflibercept.

The non-inferiority margin for the comparison to aflibercept at week 24 was established at 4.5 eye chart letters based on pretrial regulatory feedback and precedent. Under the study's prespecified statistical analysis plan and hierarchical testing strategy for control of type 1 error, non-inferiority of tarcocimab to aflibercept was first demonstrated in patients with branch RVO, with a statistically significant p-value of 0.0004, and then also demonstrated with a statistically significant p-value of 0.0243 in the overall RVO population (branch and central types combined). Tarcocimab tedromer was safe and well tolerated in the study, with no new safety signals identified. A low rate of intraocular inflammation was observed in both groups (1.4% vs 0.4% for tarcocimab and aflibercept, respectively) with no vasculitis or retinal arterial occlusion events reported in any patient.

"The positive results of the BEACON study show that tarcocimab can rapidly, robustly and safely improve vision and retinal anatomy in patients with macular edema due to RVO while substantially reducing the number of eye injections," said Jason Ehrlich, MD, PhD, Chief Medical Officer and Chief Development Officer of Kodiak. "We're hopeful that BEACON also bodes well for our ongoing Phase 3 GLEAM and GLIMMER studies of tarcocimab in diabetic macular edema, because both RVO and DME are diseases of the inner retina in which elevated VEGF levels in the vitreous and retina result in retinal vascular leakage and retinal swelling. We thank the patients who participated in BEACON and the many clinicians, site staff and Kodiak team members who worked together on this study and the broad tarcocimab clinical program."

"Our regulatory strategy is designed to have two successful studies in one indication and then individual studies in additional indications. Looking across our development program for tarcocimab, our paired Phase 3 GLEAM and GLIMMER studies in DME, if successful, are designed to serve as the primary basis for a licensing application and potential regulatory approval of tarcocimab," said Victor Perlroth, MD, Kodiak's Chief Executive Officer. "BEACON serves as the single pivotal study to support approval in macular edema following RVO. Our Phase 3 DAYLIGHT study and our Phase 3 GLOW study, if successful, would contribute data to support approvals in wet AMD and Non-Proliferative Diabetic Retinopathy (NPDR), respectively. All the studies are fully enrolled and expected to read out topline data within the next twelve months and, if successful, we would plan to file a single Biologics License Application (BLA) with the data across the program. As we learn more from the remaining Phase 3 studies, we look forward to continuing to work with the FDA and global health authorities to bring this medicine to patients."

Full primary results from the BEACON study are expected to be presented by BEACON Study Investigators at upcoming ophthalmology congresses in September 2022.

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 tarcocimab tedromer in patients with treatment-naïve macular edema due to retinal vein occlusion, including both branch and central subtypes. Patients are randomized 1:1 to receive tarcocimab 5 mg or aflibercept 2 mg. In the first six months, patients receiving tarcocimab are treated with a proactive, fixed regimen which includes two monthly loading doses followed by treatment every 8 weeks, and patients receiving aflibercept are treated monthly as per its label. 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 tarcocimab tedromer for an additional six months on an individualized basis. The study completed enrollment of 568 patients worldwide in the fourth quarter of 2021 and met its primary efficacy endpoint at six months. Results from the BEACON study are intended to serve as the basis for the potential approval of tarcocimab in RVO. 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 Retinal Vein Occlusion

Retinal Vein Occlusion (RVO) is a condition that results from blockage of the veins that carry blood away from the retina, the light sensitive tissue at the back of the eye. It is the second most common cause of vision loss due to retinal vascular disease. RVO is more likely to occur in patients who are older or have health conditions such as high blood pressure, diabetes, high cholesterol levels or a history of smoking or other health problems which affect vascular health or blood flow. Branch RVO (BRVO) occurs when a branch of the eye's retinal venous drainage system becomes blocked, and central RVO (CRVO) occurs when the eye's central retinal vein becomes blocked. RVO typically results in sudden, painless vision loss in the affected eye, because the venous blockage restricts normal blood flow in the affected retina, resulting in ischemia, bleeding, fluid leakage, and retinal swelling (called macular edema). Macular edema due to RVO is typically treated with repeated intravitreal injection of anti-vascular endothelial growth factor (VEGF) therapies. It is estimated that 16.4 million adults worldwide are affected by RVO – 13.9 million with BRVO and 2.5 million with CRVO. In the United States, approximately 850,000 adults have BRVO, and approximately 300,000 have CRVO.

About tarcocimab tedromer (KSI-301)

Tarcocimab tedromer 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 tarcocimab tedromer is 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. Kodiak is developing tarcocimab to be a new first-line agent which enables a majority of patients to be treated and maintained on an every 5 to 6-month treatment interval and a minority of high need patients to be treated as frequently as monthly. The tarcocimab tedromer clinical program is designed to assess the product'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 GLEAM and GLIMMER pivotal studies in patients with diabetic macular edema, the BEACON pivotal study in patients with retinal vein occlusion, the DAYLIGHT pivotal study in patients with wet AMD, and the GLOW study in patients with NPDR are anticipated to form the basis of the Company's BLA to support potential approval and commercialization in multiple indications. The global tarcocimab tedromer clinical program is being conducted at 150+ study sites in more than 10 countries. Kodiak is developing and owns global rights to tarcocimab tedromer.

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, tarcocimab tedromer, is a novel anti-VEGF antibody biopolymer conjugate being developed for the treatment of retinal vascular diseases including wet 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. KSI-501 is our dual inhibitor antibody biopolymer conjugate targeting both VEGF (VEGF-trap) and IL-6 (anti-IL-6 antibody) for the treatment of retinal diseases. 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.

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 tarcocimab in patients with treatment-naïve diabetic macular edema. In each study, patients are randomized 1:1 to receive either tarcocimab or aflibercept. The tarcocimab arm is treated with a proactive, individualized dosing regimen of every 8-, 12-, 16-, 20- or 24 weeks (utilizing tight dynamic retreatment criteria) after three loading doses. The aflibercept arm is treated with a fixed dosing regimen of every 8-weeks after five monthly loading doses, per its label. Both studies completed enrollment of approximately 450 patients each worldwide in the first quarter of 2022. The primary endpoint for both studies is the average of weeks 60 and 64, and patients will be treated and followed for a total of two years. We expect to announce topline data in mid-2023. If successful, we expect that data from our GLEAM and GLIMMER studies will serve as the primary basis for approval of tarcocimab in our anticipated BLA submission. 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 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 tarcocimab in patients with treatment-naïve wet AMD. Patients are randomized to receive either tarcocimab on a monthly dosing regimen or to receive standard-of-care aflibercept on a fixed dosing regimen of every 8-weeks after three monthly loading doses per its label. The primary endpoint is the average of weeks 40, 44 and 48. The DAYLIGHT study is intended to clarify the efficacy of tarcocimab to treat high need patients with wet AMD and, if successful, is intended to serve as the basis for approval in wet AMD with monthly dosing. DAYLIGHT has completed enrollment of approximately 550 patients worldwide and we expect to announce topline data in mid-2023. 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 GLOW Study

The Phase 3 GLOW study is a global, multi-center, randomized pivotal superiority study designed to evaluate the efficacy and safety of tarcocimab tedromer in approximately 240 patients with treatment-naïve, moderately severe to severe non-proliferative diabetic retinopathy (NPDR). Patients are randomized to receive either tarcocimab every six months after initiating doses given at baseline, 8 weeks and 20 weeks into the study, or to receive sham injections. 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. We believe tarcocimab tedromer has the potential to be the longest-interval intravitreal therapeutic option for patients with diabetic

retinopathy. GLOW has completed enrollment of approximately 240 patients in August 2022. Additional information about GLOW (also called Study KS301P106) can be found on www.clinicaltrials.gov under Trial Identifier NCT05066230 (https://clinicaltrials.gov/show/NCT05066230).

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 of tarcocimab to treat and prevent vision loss in certain patients, including the potential to improve vision and anatomic responses while substantially reducing the number of eye injections and the treatment burden for RVO patients; the potential implications of BEACON results for additional studies; our regulatory strategy, including the expected timing of results from various studies and the bases on which regulatory approval may be sought;. 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 risk that preliminary safety, efficacy and durability data for our tarcocimab tedromer product candidate may not continue or persist; the risk that tarcocimab tedromer may not have the anti-VEGF effect or impact on the treatment of RVO expected; cessation or delay of any of the ongoing clinical studies and/or our development of tarcocimab tedromer may occur, including as a result of the ongoing COVID-19 pandemic; the risk that our ABC Platform may not extend treatment intervals in retinal disorders as anticipated, or at all; future potential regulatory milestones of tarcocimab tedromer, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; adverse economic conditions may significantly impact our business and operations, including our clinical trial sites, and those of our manufacturers, contract research organizations or other 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-K, 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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John Borgeson, Chief Financial Officer, Tel (650) 281-0850, ir@kodiak.com