Kodiak Sciences Completes Enrollment in Second Registrational Trial of Tarcocimab in Patients with Diabetic Retinopathy

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- Topline clinical data of the confirmatory registrational study GLOW2 expected in 1Q 2026.
- GLOW2 study design mirrors GLOW1 study, which met primary endpoint and all key secondary endpoints with high statistical significance

PALO ALTO, Calif., March 10, 2025 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), today announced that it has completed enrollment in its GLOW2 Phase 3 clinical trial of tarcocimab tedromer in patients with diabetic retinopathy ("DR").

"We randomized more than 250 patients into our GLOW2 Phase 3 study, exceeding our enrollment target," said Victor Perlroth, M.D., Chief Executive Officer of Kodiak. "With its 48-week duration of treatment, all patients are expected to complete their primary endpoint visits by the end of January 2026, and we expect to announce topline clinical data in 1Q 2026."

"The GLOW2 design mirrors that of our successful GLOW1 study, with the advantage of an additional loading dose to provide dosing flexibility for providers. GLOW2 is our second registrational study in diabetic retinopathy and if there is a successful outcome, we anticipate having a regulatory package for tarcocimab that is ready to file. We remain focused on completing enrollment in our ongoing DAYBREAK Phase 3 study to broaden the efficacy profile for tarcocimab in wet age-related macular degeneration ("wet AMD"), and it is our plan to wait for DAYBREAK topline data expected in 2Q 2026 in order to file a single BLA for tarcocimab in wet AMD, DR and Retinal Vein Occlusion ("RVO")," concluded Dr. Perlroth.

Dr. Allen Hu, top enroller in the GLOW2 study and principal investigator at Cumberland Valley Retina Consultants commented on tarcocimab's potential in DR. "Fewer than 1% of subjects with diabetic retinopathy are treated today due to high treatment burden associated with frequent injections needed with today's approved therapies. If diabetic retinopathy is left untreated, the majority of patients —and this is millions of patients— will experience disease progression and develop vision-threatening complications. With only 4 doses in Year 1 and every 6-month dosing in every patient, the GLOW1 data showed us as a community that tarcocimab can potentially achieve strong efficacy both in treating existing disease *and* preventing disease progression in diabetic retinopathy."

"If GLOW2 mirrors these results, I believe tarcocimab as a biologic with twice yearly dosing in all patients can change the treatment landscape in diabetic retinopathy and help millions of patients," concluded Dr. Hu.

About the Phase 3 GLOW2 Study

The Phase 3 GLOW2 study is a prospective, randomized, double-masked, multi-center pivotal superiority study designed to evaluate the efficacy and safety of tarcocimab tedromer in treatment-naïve patients with diabetic retinopathy ("DR"). Patients are randomized 1:1 and receive either sham injections or tarcocimab via intravitreal injection at baseline, Week 4, Week 8, Week 20 and Week 44. The primary endpoint is the proportion of eyes improving ≥2 steps on Diabetic Retinopathy Severity Scale ("DRSS") from baseline at Week 48. Additional outcome measures include the proportion of eyes developing a sight threatening complication of diabetic retinopathy and the proportion of eyes improving ≥3 steps on DRSS from baseline at Week 48. Additional information about GLOW2 (also called Study KS301P108) can be found on www.clinicaltrials.gov under Trial Identifier NCT06270836 (https://clinicaltrials.gov/show/NCT06270836).

About tarcocimab tedromer (tarcocimab, KSI-301)

Tarcocimab is an investigational anti-VEGF therapy built on Kodiak's proprietary Antibody Biopolymer Conjugate ("ABC") Platform and is being developed as a "mainstay" intravitreal biologic monotherapy intended to provide high efficacy and high durability and a flexible 1-month through 6-month label.

To date, tarcocimab has completed three successful Phase 3 pivotal clinical studies: the Phase 3 GLOW1 study in diabetic retinopathy ("DR"), the Phase 3 BEACON study in retinal vein occlusion ("RVO") and the Phase 3 DAYLIGHT study in wet AMD. In the GLOW1 study, tarcocimab successfully treated DR patients and prevented disease progression with 100% of patients on extended 6-month dosing. In the BEACON study, in the first 6 months tarcocimab-treated patients were dosed on every 8-week interval and in the second 6 months nearly half of tarcocimab patients did not require any treatment while achieving similar vision and anatomical outcomes as the aflibercept group at one year.

Tarcocimab is currently being studied in two Phase 3 clinical trials, the GLOW2 study in diabetic retinopathy and the DAYBREAK study in wet AMD.

The GLOW2 study has a similar design as GLOW1 in which all patients randomized to investigational therapy will receive tarcocimab on extended, 6-month dosing. GLOW2 features the benefit of an additional, third monthly loading dose (baseline, Week 4, Week 8) to explore even further benefits with tarcocimab in diabetic retinopathy patients.

The DAYBREAK study includes tarcocimab in a second investigational arm against active comparator aflibercept and incorporates learnings from prior pivotal trials of tarcocimab to maximize the probability of meeting the primary endpoint of non-inferiority in visual acuity gains. Patients randomized to tarcocimab will receive individualized dosing every 4 to 24 weeks on an as needed basis following four monthly loading doses. Patients randomized to aflibercept will be dosed per its label. The individualized dosing of tarcocimab is determined by a treat-to-dryness proactive approach, using presence of retinal fluid as a disease activity marker, which resembles retina specialists' practice and optimizes each patient's treatment, instead of a combination of central subfield thickness ("CST") and vision loss. The objectives for tarcocimab in DAYBREAK are to assess its 6-month durability potential, strengthen its competitive position in wet AMD and bolster the regulatory application package for the program.

Both GLOW2 and DAYBREAK use tarcocimab's enhanced 50 mg/mL formulation containing both conjugated and unconjugated antibody that is intended to balance immediacy and durability. DAYBREAK is actively enrolling patients. Additional information about GLOW2 can be found on

www.clinicaltrials.gov under Trial Identifier NCT06270836 (https://clinicaltrials.gov/study/NCT06270836). Additional information about DAYBREAK can be found on www.clinicaltrials.gov under Trial Identifier NCT06556368 (https://clinicaltrials.gov/study/NCT06556368).

About diabetic retinopathy and tarcocimab

Diabetic retinopathy is a common complication of diabetes that affects the eye. If left untreated, diabetic retinopathy progresses and eventually can lead to serious vision-threatening complications, such as diabetic macular edema and proliferative diabetic retinopathy. It is estimated that of the 36 million American adults living with diabetes, approximately 10 million have diabetic retinopathy and fewer than 1% will choose to be treated with today's available medicines due to the high treatment burden associated with frequent injections.

Long interval dosing is particularly important in the diabetic retinopathy population, and our GLOW1 and GLOW2 studies are designed to explore the ability of tarcocimab, with all patients on an every 6-month dosing interval, to directly improve the disease (the primary endpoint) and to prevent vision threatening complications from the worsening of the disease (key secondary endpoint).

At one year, GLOW1 met its primary endpoint of the proportion of patients with at least a 2-step improvement on the Diabetic Retinopathy Severity Scale (DRSS) score, a grading system measuring the degree of retinopathy. Tarcocimab achieved a 29-fold increased response rate ratio, with 41.1% of evaluable patients on tarcocimab demonstrating at least 2-step improvement versus 1.4% of evaluable patients in the sham group (p-value less than 0.0001). Visual acuity and retinal anatomy were improved and stable with tarcocimab on its extended-dosing intervals.

GLOW1 also met all key secondary endpoints, including greater reductions in the proportion of patients developing sight-threatening complications (such as diabetic macular edema and proliferative diabetic retinopathy), versus sham, demonstrating an 89% decreased risk, achieving 21.0% versus 2.3% (p-value less than 0.0001). Tarcocimab also showed a 95% risk reduction in the development of DME, versus sham, from 13.7% on sham versus 0.7% on tarcocimab.

After the occurrence of a sight-threatening complication, all subjects were rescued with open-label tarcocimab, where subjects received two loading doses once monthly followed by continued every 12-week dosing. In patients developing sight-threatening complications, the initial visual acuity decrease and retinal anatomy worsening were both rapidly controlled and then stabilized with every 12-week dosing of tarcocimab.

About Kodiak Sciences Inc.

Kodiak Sciences (Nasdaq: KOD) is a biopharmaceutical company committed to researching, developing, and commercializing transformative therapeutics to treat a broad spectrum of 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™ uses molecular engineering to merge the fields of protein-based and chemistry-based therapies and has been at the core of Kodiak's discovery engine. We are developing a portfolio of three clinical programs, two of which are late-stage today and derived from our ABC Platform and one which is platform-independent and which we believe can progress rapidly into pivotal studies.

Kodiak's lead investigational medicine, tarcocimab, is a novel anti-VEGF antibody biopolymer conjugate under development for the treatment of high prevalence retinal vascular diseases. Tarcocimab is currently being studied in two Phase 3 clinical trials, GLOW2 in patients with diabetic retinopathy and DAYBREAK in patients with wet AMD. GLOW2 enrollment is complete, and DAYBREAK is actively enrolling patients.

KSI-501 is our second investigational medicine, a first-in-class anti-IL-6, VEGF-trap bispecific antibody biopolymer conjugate designed to inhibit both IL-6 mediated inflammation and VEGF-mediated angiogenesis and vascular permeability. KSI-501 is being developed for the treatment of high prevalence retinal vascular diseases to address the unmet needs of extended durability and targeting disease biology beyond VEGF for differentiated efficacy. The Phase 3 DAYBREAK study of KSI-501 in wet AMD is actively enrolling patients.

KSI-101, our third product candidate, is a novel anti-IL-6, VEGF-trap bispecific protein. Kodiak is developing KSI-101 for the treatment of retinal inflammatory diseases, as currently there are no available intravitreal biologic therapies addressing the spectrum of inflammatory conditions of the retina. The Phase 1b APEX study of KSI-101 is actively enrolling patients, as a precursor to activating the Phase 2b/3 PEAK and PINNACLE studies in patients with macular edema secondary to inflammation ("MESI").

Kodiak is advancing its platform technology to embed small molecules and other active pharmaceutical ingredients ("APIs") into Kodiak's proprietary biopolymer backbone to enable high drug-antibody-ratio ("DAR") medicines. The diverse APIs are designed to be released over time to achieve targeted, multi-specific and tailored modulation of biological pathways. The unique combination of high DAR and tailored therapeutic benefit offers potential for broad application to multifactorial diseases and builds directly from our Antibody Biopolymer Conjugate technology and its 15 years of design, development and manufacturing experience. We call this platform extension our Antibody Biopolymer Conjugate Drug ("ABCD") Platform because we are extending our platform capabilities to include the conjugation of small molecule drugs and other APIs whereas historically, we primarily conjugated biologics such as antibodies.

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 expected timing of patients in the GLOW2 Phase 3 study completing their primary endpoint visits and announcement of topline clinical data; the anticipation of having a regulatory package for tarcocimab that is ready to file; the ability of DAYBREAK to broaden the potential efficacy profile for tarcocimab in wet AMD and complete the BLA package; the ability to complete enrollment in DAYBREAK to enable topline clinical data announcement in 2Q 2026; the plan to file a single BLA for tarcocimab in wet AMD, DR and RVO; the potential for tarcocimab to change the treatment landscape in diabetic retinopathy and help millions of patients; the probability of the DAYBREAK study meeting the primary endpoint of non-inferiority in visual acuity gains; the potential of KSI-501 to be a first-in-class bispecific ABC inhibiting VEGF and IL-6 and its potential to provide extended durability; and the potential activation of Phase 2b/3 PEAK and PINNACLE studies in patients with macular edema secondary to inflammation ("MESI"). 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," "anticipate," "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 risks and uncertainties that could cause actual results to differ materially and adversely from those in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: cessation or delay of any clinical studies and/or development of tarcocimab, KSI-501 or KSI-101; the results of our ongoing studies may not provide the evidence, insights, or benefits as anticipated; the risk that safety, efficacy, and durability data observed in our product candidates in current or prior studies may not continue or persist; the risk that the results of the tarcocimab Phase 3 studies may not be sufficient to support a single BLA submission for wet AMD, DR and RVO; the risk that a BLA may not be accepted by, or receive approval from, the FDA or foreign regulatory agencies when expected, or at all; future potential regulatory milestones of tarcocimab, KSI-501 or KSI-101, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; the risk that a new formulation of tarcocimab, KSI-501 or other ABC Platform derived molecules may not provide the benefits expected; our research and development efforts and our ability to advance our product candidates into later stages of development may fail; adverse economic conditions may significantly impact our business and operations, including our clinical trial sites, and those of our manufacturers, contract research organizations or others with whom we conduct business; as well as the other risks identified in our filings with the Securities and Exchange Commission ("SEC"). 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 SEC. 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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