Kodiak Sciences Announces Treatment of First Patients in Phase 3 GLOW2 Study of Tarcocimab Tedromer in Diabetic Retinopathy

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PALO ALTO, Calif., May 13, 2024 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), a biopharmaceutical company committed to researching, developing and commercializing transformative therapeutics to treat a broad spectrum of retinal diseases, announced today that the first patients with diabetic retinopathy (DR) have been treated in the randomized double masked Phase 3 GLOW2 study of tarcocimab tedromer.

GLOW2 is the second Phase 3 study of tarcocimab in diabetic retinopathy in which all patients on investigational therapy will receive tarcocimab on extended dosing intervals, including 6-month dosing for all patients. The GLOW2 study design mirrors the successful GLOW1 study in which tarcocimab-treated patients, over the 48-week study duration, saw 29-fold increased response rate in ≥ 2-step improvement in DRSS (treatment) and 89% decreased risk of developing sight-threatening complications (prevention).

Consistent with Kodiak's operational track record of running six pivotal studies in parallel for the tarcocimab program, GLOW2 is on an accelerating trajectory of site activations, new patient screenings and randomizations with the goal to complete enrollment before the end of this year.

"In recent months, competing long-acting retinal therapies in development have posted disappointing treatment and prevention results in diabetic retinopathy," said Dr. Victor Perlroth, Kodiak's Chief Executive Officer. "GLOW1 data showed unequivocally that treatment with tarcocimab in extended dosing intervals including 6-month dosing in all patients achieved two related but clinically distinct goals: *treating* existing disease (primary endpoint of 2-step improvement in DRSS) and *preventing* disease progression (key secondary endpoint of preventing sight-threatening complications). This is a key differentiator in the long-acting therapy space, where many therapies are only designed to maintain a patient's current disease status and not to improve it."

If successful, GLOW2 could serve as one of the two successful pivotal studies in one foundational indication, diabetic retinopathy, to support marketing authorization application for tarcocimab.

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 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 designed to maintain potent and effective drug levels in ocular tissues for longer than existing available agents. Kodiak's objective with tarcocimab is to enable earlier treatment and prevention of vision loss for patients with diabetic retinopathy and to develop a new durability agent to improve outcomes for patients with retinal vascular diseases.

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. Across the full tarcocimab pivotal program of six Phase 3 studies, tarcocimab has demonstrated what Kodiak believes to be consistent durability of approximately 6 months for the majority of patients and favorable safety.

Kodiak is initiating two additional BLA-facing Phase 3 studies: the GLOW2 study in diabetic retinopathy, and the DAYBREAK study in wet AMD. The GLOW2 study has a similar design as GLOW1 with the benefit of an additional, third monthly loading dose (weeks 0, 4 and 8). The DAYBREAK study will include investigational arms for tarcocimab and KSI-501, Kodiak's bispecific conjugate, to evaluate their efficacy, safety and durability versus aflibercept. DAYBREAK is designed to strengthen the competitive position of tarcocimab in wet AMD and bolster the ex-US regulatory dossier for the program. Both GLOW2 and DAYBREAK will use a go-to-market formulation of tarcocimab which we believe improves the manufacturability in a prefilled syringe and may also enhance the utility of the product. GLOW2 is actively enrolling patients, and we are operationalizing towards DAYBREAK study activation in mid-2024.

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 including diabetic retinopathy, the leading cause of blindness in working-age patients in the developed world, and wet age-related macular degeneration, the leading cause of blindness in elderly patients in the developed world.

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 multiple disease biologies for differentiated efficacy. Phase 1b data for KSI-501 was presented in February 2024, and the Phase 3 DAYBREAK study of KSI-501 in wet AMD is scheduled to be actively screening patients in mid-2024.

Additionally, Kodiak is developing a third product candidate, KSI-101, a novel anti-IL-6, VEGF-trap bispecific protein, the unconjugated protein portion of KSI-501. Kodiak intends to develop 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.

Kodiak has expanded its early research pipeline of duet and triplet inhibitors that embed small molecules and other active pharmaceutical ingredients ("API") in the biopolymer backbone to enable targeted, high drug-antibody ratio ("DAR") medicines. The diverse API's are designed to be released over time to achieve sustained modulation of targeted biological pathways. The unique combination of high DAR and tailored therapeutic benefit offers potential for broad application to multifactorial ophthalmic and systemic diseases.

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: GLOW2's trajectory of site activations, new patient screenings and randomizations with the goal to complete enrollment before the end of this year, the potential for GLOW2 to serve as one of the two successful pivotal studies in one foundational indication, diabetic retinopathy, to support marketing authorization application for tarcocimab, future development plans and the expected timing of clinical study readouts; the objectives and potential benefits of KSI-501, including its potential to be a first-in-class bispecific ABC inhibiting VEGF and IL-6 and its potential to provide extended durability; and the objectives of our tarcocimab clinical program. 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 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 KSI-501 may occur; the risk that KSI-501 may not inhibit VEGF and IL-6, provide extended durability or have an impact on the treatment of patients as expected; 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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