Kodiak Sciences Expands Development Pipeline with Treatment of First Patient in Phase 1 Clinical Study of KSI-501, an Investigational Bispecific Antibody Biopolymer Conjugate for Retinal Diseases

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PALO ALTO, Calif., April 3, 2023 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), a biopharmaceutical company committed to researching, developing and commercializing transformative therapeutics to treat high prevalence retinal diseases, announced today that the first patient has been treated in the Phase 1 study of KSI-501, an investigational bispecific antibody biopolymer conjugate targeting both VEGF and IL-6. KSI-501 is the second product candidate built on Kodiak's Antibody Biopolymer Conjugate (ABC) Platform to enter the clinic.

The Phase 1 study of KSI-501 is being conducted in the USA as an open-label, multiple ascending dose study and initially is enrolling patients with diabetic macular edema (DME). The primary objectives of the Phase 1 study are to evaluate ocular and systemic safety and to establish a maximum tolerated dose.

"We are proud to continue to be a key early participant in Kodiak's Phase 1 clinical studies," said Mark R. Barakat, M.D., an investigator in the study and Director of the Retinal Research Institute at Retinal Consultants of Arizona, Phoenix, AZ. "From our experience with tarcocimab tedromer, Kodiak's first ABC product candidate, we know that the ABC Platform has great potential for potent, durable responses in patients with retinal diseases. KSI-501 is unique in its dual mechanisms of action and inhibits both vascular endothelial growth factor (VEGF) and interleukin-6 (IL-6). I am enthusiastic about the potential for KSI-501 with its anti-IL-6 activity to achieve a greater therapeutic benefit for patients whose retinal disease has an inflammatory component. We look forward to learning more about KSI-501's safety and bioactivity from the ongoing Phase 1 study."

"We are very pleased to have initiated dosing in the Phase 1 study of KSI-501," said Jason Ehrlich, M.D., Ph.D., Chief Medical Officer and Chief Development Officer of Kodiak Sciences. "IL-6 is a pro-inflammatory cytokine and growth factor implicated in the pathophysiology of multiple retinal diseases and, in conditions for which anti-VEGF treatment is used, elevated levels of ocular IL-6 have been associated with poor anti-VEGF treatment response. We believe KSI-501 represents a new category of retinal medicine, uniquely designed to provide potent inhibition of both VEGF-mediated vascular permeability and IL-6 mediated inflammation in a single bispecific molecule and also with the benefits of extended durability enabled by our ABC Platform. Our Phase 1 study of KSI-501 will initially focus on establishing safety in patients with DME, a disease known for its high levels of microvascular inflammation, and we anticipate broadening the spectrum of diseases under study once dose escalation is complete. For example, KSI-501 may be an important new treatment option for diseases that currently lack targeted therapies such as uveitic macular edema."

About KSI-501

Also built on Kodiak's ABC Platform, KSI-501 is an investigational, first-in-class bispecific ABC that is designed to inhibit two mechanisms implicated in retinal diseases: vascular endothelial growth factor ("VEGF") and interleukin-6 (IL-6). IL-6 is a pro-inflammatory cytokine and growth factor implicated in the pathophysiology of multiple retinal diseases and, in conditions for which anti-VEGF treatment is used, elevated levels of ocular IL-6 have been associated with poor anti-VEGF treatment response. KSI-501 is a trap-antibody fusion biopolymer conjugate designed to provide potent inhibition of (i) VEGF-mediated angiogenesis and vascular permeability through a soluble decoy receptor inhibiting the binding of VEGF-A and PLGF to their cognate receptors and (ii) IL-6 mediated inflammation through an antibody that binds soluble interleukin-6, inhibiting its binding to both soluble and membrane-bound IL-6 receptors. In primary cell assays, KSI-501 inhibits angiogenesis and also normalizes inner and outer blood retinal barriers; dual inhibition of VEGF and IL-6 by KSI-501 confers superior normalization of cell morphology and junctional biology compared to either anti-VEGF or anti-IL-6 monotherapy. We believe KSI-501 has the potential to become a new category of retinal medicines with greater therapeutic efficacy than existing therapies while also benefiting from the promising long-interval durability of Kodiak's ABC Platform. A Phase 1 study of KSI-501 is currently enrolling patients in the United States to evaluate the safety, tolerability and bioactivity of KSI-501 in DME patients.

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. 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 antibody biopolymer conjugate platform, or 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, is a novel anti-VEGF antibody biopolymer conjugate being developed for the treatment of retinal vascular diseases including diabetic eye diseases, 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. The tarcocimab clinical program is designed to assess the product candidate's durability, efficacy and safety in major retinal vascular diseases in parallel, through the GLEAM and GLIMMER studies in diabetic macular edema, the BEACON study in retinal vein occlusion, the GLOW study in non-proliferative diabetic retinopathy and the DAYLIGHT study in wet age-related macular degeneration. Phase 3 data across the tarcocimab clinical program are expected in 3Q2023. 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) and is being investigated in a Phase 1 clinical study initially in patients with diabetic macular edema. We are expanding our early research pipeline to include ABC Platform based triplet inhibitors for multifactorial retinal diseases. 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 of the ABC Platform for potent, durable responses in patients with retinal diseases; the potential for KSI-501 to achieve a greater therapeutic benefit for patients whose retinal disease has an inflammatory component and to provide potent inhibition of

both VEGF-mediated vascular permeability and IL-6 mediated inflammation; 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 the 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 a 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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