Kodiak Sciences Completes Enrollment in GLOW Phase 3 Clinical Trial of Tarcocimab Tedromer (KSI-301) in Patients with Non-Proliferative Diabetic Retinopathy

August 5, 2022

PALO ALTO, Calif., Aug. 5, 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 GLOW Phase 3 clinical trial of tarcocimab tedromer (KSI-301), Kodiak's anti-VEGF antibody biopolymer conjugate, in patients with Non-Proliferative Diabetic Retinopathy ("NPDR") without diabetic macular edema ("DME").

"Diabetic retinopathy is the leading cause of vision loss in working-aged Americans and affects up to one third of patients with diabetes. Right now, patients typically wait to begin anti-VEGF treatment until they suffer a sight-threatening complication such as diabetic macular edema or proliferative diabetic retinopathy, partly because currently approved NPDR treatments require frequent eye injections. Not everyone recovers their sight after we treat these complications, so a medicine able to be given at meaningfully longer intervals could help patients and physicians better realize the long-recognized potential of anti-VEGF therapy as a preventive treatment for NPDR," said Charles C. Wykoff, MD, PhD, Director of Research, Retina Consultants of Texas, and a GLOW Study investigator.

"Currently approved medicines need to be injected in the eye every month or every 2 months after 5 monthly initiating doses which limits their utility as a preventive medicine," said Jason Ehrlich, MD, PhD, Kodiak's Chief Medical and Development Officer. "In our GLOW pivotal trial, we are studying tarcocimab tedromer's potential to be dosed just once every 6 months after a reduced density of initiating doses given at baseline, 8 weeks, and 20 weeks into the study. We believe tarcocimab can relieve the high treatment burden for NPDR patients, their family members and physicians and provide an opportunity for real prevention of vision loss among diabetic patients. We are very grateful to the patients and physicians participating in GLOW and the whole Kodiak team for working together to recruit the study well ahead of schedule, and we look forward to the primary results of the study in a year."

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 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 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 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 tedromer 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. 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, 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.

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 be able to be given at longer intervals to help patients and physicians realize the potential of anti-VEGF therapy as a preventive treatment for NDPR; tarcocimab to relieve the high treatment burden for NPDR patients; tarcocimab to provide for prevention of vision loss among diabetic patients; timing of primary results of the GLOW trial; tarcocimab tedromer to be a first-line agent to improve outcomes for patients with retinal vascular diseases and enable earlier treatment and prevention of vision loss for patients with diabetic eye disease; 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 to form the anticipated basis of the Company's BLA to support potential approval and commercialization in multiple indications; tarcocimab tedromer to be the longest-interval intravitreal therapeutic option for patients with diabetic retinopathy and; including the results of the GLOW study in a planned initial BLA submission for tarcocimab tedromer. 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 tarcocimab may not be able to be given at longer intervals; tacrocimab may not prevent vision loss among diabetic patients; primary results of the GLOW trial may not be available in a year; we may not develop a first-line agent to improve outcomes for patients with retinal vascular diseases; 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 may not form the basis of the Company's BLA to support multiple indications; tarcocimab tedromer may not be the longest-interval intravitreal therapeutic option for patients with diabetic retinopathy; the results of the GLOW study may not be in a planned initial BLA submission for tarcocimab tedromer; 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 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-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.

View original content:https://www.prnewswire.com/news-releases/kodiak-sciences-completes-enrollment-in-glow-phase-3-clinical-trial-of-tarcocimab-tedromer-ksi-301-in-patients-with-non-proliferative-diabetic-retinopathy-301601017.html

SOURCE Kodiak Sciences Inc.

John Borgeson, Chief Financial Officer, Tel (650) 281-0850, ir@kodiak.com