Kodiak Reboots Tarcocimab Tedromer Development Program Following Strong Positive Results in Phase 3 Diabetic Retinopathy GLOW Study and Following Dialogue with US Regulatory Authorities on a Regulatory Pathway for BLA Submission

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- Primary endpoint and all key secondary endpoints met with high statistical significance in GLOW study.
- With 6-month dosing of all patients, tarcocimab and the ABC platform continue to demonstrate differentiated durability.
- Following dialogue with US regulatory authorities, Kodiak plans to conduct one additional pivotal study with a commercial formulation of tarcocimab.
- New regulatory strategy could support a single Biologics License Application (BLA) for macular edema following retinal vein occlusion (RVO), wet age-related macular degeneration (wAMD) and non-proliferative diabetic retinopathy (NPDR).
- Kodiak believes that it has sufficient capital to fund a comprehensive KSI-501 clinical program in parallel.

PALO ALTO, Calif., Nov. 6, 2023 /PRNewswire/ -- Kodiak Sciences Inc. (NASDAQ: KOD) today announced that its Phase 3 GLOW superiority study evaluating tarcocimab tedromer 5 mg in moderately severe to severe NPDR met its one-year primary endpoint.

"This is the first time that 6-month dosing in all patients succeeded in treating diabetic retinopathy which we believe is a meaningful and clinically relevant achievement", said Dr. J. Pablo Velazquez-Martin, Senior Vice President of Clinical Sciences at Kodiak Sciences. "We think that the consistency of the data across all endpoints, where tarcocimab significantly improved the diabetic eye disease status and, importantly, significantly prevented sight-threatening complications, is remarkable," continued, Dr. Velazquez-Martin. "The GLOW data reinforce the durability potential of tarcocimab and the antibody biopolymer conjugate platform (ABC Platform) in the management of retinal vascular diseases."

"We think that durability remains the most clinically relevant unmet patient need," said Dr. Victor Perlroth, CEO of Kodiak. "We now have three successful phase 3 pivotal studies with tarcocimab tedromer across three different retinal vascular and exudative diseases: wet AMD, RVO and NPDR. In recent discussions with the FDA, which included the GLOW data, we believe we have a clear regulatory pathway requiring one additional positive study to support a single BLA submission for all three indications," continued Dr. Perlroth.

"We have actionable learnings from the tarcocimab clinical program that we used to develop an enhanced commercial formulation of tarcocimab that balances free antibody and conjugated antibody to improve manufacturability and, importantly, to improve usability by reducing injection time from 7-10 seconds to 2-3 seconds. This formulation has already been manufactured at commercial scale and is ready for use in clinical trials. After evaluation of the Phase 3 data across the tarcocimab program and based on conversations with members of the retina community, we believe our commercial tarcocimab formulation could be an important future therapeutic option. As a result, we have decided to run another pivotal study with the intent to file a single BLA for RVO, wet AMD and NPDR. This enhancement to the ABC Platform is also being implemented in our first-in-class anti-IL-6 and anti-VEGF bispecific, KSI-501 ABC," Dr. Perlroth concluded.

Kodiak paused further development of tarcocimab last summer after its GLEAM and GLIMMER studies in diabetic macular edema did not meet their primary endpoint, in order to evaluate learnings from its pivotal BEACON study in patients with macular edema due to retinal vein occlusion and from its GLOW study.

The company believes that the one-year head-to-head BEACON results and primary endpoint and key secondary endpoint GLOW results support the development of three attractive clinical prospects: enhanced tarcocimab ABC, enhanced bispecific KSI-501 ABC, and our KSI-501 bispecific free protein (not conjugated) and that Kodiak has on hand sufficient capital to further develop in parallel all three of these prospects.

Dr. Perlroth added, "Kodiak thanks the GLOW investigators and patients whose participation and commitment helped us to generate strong data in GLOW and thus to recognize the continued importance for patients of our ABC Platform and our platform-derived medicines."

About the GLOW Study Results

First time results from GLOW were presented at the American Academy of Ophthalmology retina subspecialty day on November 3, 2023. View original content: https://ir.kodiak.com/static-files/ee94e5bd-da6e-4038-b00c-1956c72e5c72.

The Phase 3 GLOW study investigated an every 24-week tarcocimab dosing regimen for all subjects, versus sham, in patients with moderately-severe and severe NPDR without DME.

At one year, GLOW 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 less than 0.0001). Visual acuity and retinal anatomy were improved and stable with tarcocimab on its extended-dosing intervals.

GLOW 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 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.

The rates of serious ocular adverse events and intraocular inflammation in patients treated with tarcocimab and sham were similar in both groups.

About the GLOW Study Design

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 treatment-naïve patients with moderately severe to severe 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. Outcomes include changes in diabetic retinopathy severity, measured on a standardized photographic grading scale, and the proportion of tarcocimab treated patients who developed a sight threatening complication due to 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 the Primary Endpoint of ≥2-Step Improvement on the Diabetic Retinopathy Severity Scale (DRSS)

Derived from The Early Treatment Diabetic Retinopathy Study (ETDRS), the diabetic retinopathy severity scale (DRSS) is a systematic grading system developed to predict the risk of progression from NPDR to proliferative diabetic retinopathy (PDR). The DRSS characterizes retinopathy based on assessment of abnormalities in seven defined fields of fundus photographs. The scale divides diabetic retinopathy into levels ranging from absent to severe proliferative diabetic retinopathy. This scale is the most widely used standard for grading degrees of retinopathy in clinical studies.

About the Key Secondary Endpoint of Reducing Sight Threatening Complications

Approximately eight million people in the U.S. live with Diabetic Retinopathy (DR), a common complication of diabetes characterized by damage to the blood vessels in the retina. Diabetic retinopathy occurs when blood vessels in the retina are damaged by chronic high blood sugar levels caused by diabetes. DR is the leading cause of blindness among working-age American adults. The disease generally starts as NPDR and often has no warning signs or symptoms. Over time, patients with NPDR are at risk of suffering sight-threatening complications, including diabetic macular edema (DME), a swelling of the macula (the part of the retina responsible for central fine vision) and proliferative diabetic retinopathy (PDR) in which abnormal blood vessels grow on the surface of the retina and into the vitreous cavity. Sight-threatening complications can lead to severe vision loss in 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 ™ is at the core of Kodiak's discovery engine. Kodiak's first investigational medicine, tarcocimab tedromer, is a novel anti-VEGF antibody biopolymer conjugate explored for the treatment of retinal vascular diseases. Kodiak's second clinical program, KSI-501, built from a first-in-class bispecific protein targeting both IL-6 (anti-IL-6 antibody) and VEGF (VEGF-trap), is intended to treat both orphan and high prevalence 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: Kodiak's plans to resume development of tarcocimab tedromer, conduct an additional pivotal study and potentially submit a single BLA for wAMD, RVO and NPDR; the pathway for a single potential BLA submission for approval of tarcocimab for RVO, wAMD and NPDR on the basis of the BEACON, DAYLIGHT and GLOW plus one additional pivotal trial; the sufficiency of Kodiak's capital to fund tarcocimab and other clinical programs; tarcocimab and the ABC Platform's differentiated durability profile; the potential for Kodiak's ABC Platform and tarcocimab to be important innovations for patients; the expected enhancements and benefits of a new formulation of tarcocimab, KSI-501 or other ABC Platform derived molecules; and expectations and plans for the development of KSI-501. 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 the BEACON and/or GLOW results may not provide the evidence, insights or benefits as anticipated; the risk that the results of the tarcocimab Phase 3 studies plus one additional pivotal study may not be sufficient to support a single BLA submission for wAMD, RVO and NPDR; 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; the risk that a new formulation of tarcocimab, KSI-501 or other ABC Platform derived molecules may not provide the benefits expected; the risk that cessation, modification or delay of any of the ongoing clinical studies and our development of tarcocimab and/or KSI-501 may occur; 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 our ABC Platform or tarcocimab may not represent important innovations for patients; the risk that our research and development efforts and our ability to advance our product candidates into later stages of development may fail; the risk that KSI-501 may not inhibit VEGF and IL-6 or have an impact on the treatment of patients as expected; the risk that 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, 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; the risk that sufficient capital may not be available as expected, or at all, to complete the development of any products; 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.

View original content:https://www.prnewswire.com/news-releases/kodiak-reboots-tarcocimab-tedromer-development-program-following-strong-positive-results-in-phase-3-diabetic-retinopathy-glow-study-and-following-dialogue-with-us-regulatory-authorities-on-a-regulatory-pathway-for-bla-

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