

Kodiak Sciences Announces Upcoming Presentations of Tarcocimab Tedromer (KSI-301) Phase 3 BEACON Study Results in Retinal Vein Occlusion (RVO)

August 18, 2022

Note: the presentation time at the 2022 American Academy of Ophthalmology Meeting, Retina Subspecialty Day was changed to 4:48pm CST after this press release was issued.

PALO ALTO, Calif., Aug. 18, 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 results from the Phase 3 BEACON study in Retinal Vein Occlusion (RVO) of its investigational therapy tarcocimab tedromer (KSI-301) will be presented at two upcoming ophthalmology conferences: the 22nd EURETINA Congress in Hamburg, Germany, and the 2022 American Academy of Ophthalmology Meeting in Chicago, Illinois.

Details of the presentations are as follows:

22nd EURETINA Congress, Euretina Session 8: Late Breakings (Hamburg, Germany)

Title: KSI-301 Anti-VEGF Antibody Biopolymer Conjugate for Retinal Vein Occlusion: Primary 24-Week Efficacy and Safety Outcomes of the BEACON Phase 3 Pivotal Study

Presenter: Arshad Khanani, M.D., M.A., FASRS, Director of Clinical Research, Sierra Eye Associates, Reno, NV

Presentation date and time: September 2, 2022; 16:45 CEST

2022 American Academy of Ophthalmology Meeting, Retina Subspecialty Day (Chicago, Illinois)

Title: KSI-301 Anti-VEGF Antibody Biopolymer Conjugate for Retinal Vein Occlusion: Primary and Secondary 24- Week Efficacy and Safety Outcomes of the BEACON Phase 3 Pivotal Study

Presenter: Michael A Singer, M.D., Clinical Professor of Ophthalmology, University of Texas Health Science Center, and Director of Clinical Research, Medical Center Ophthalmology Associates, San Antonio, TX

Presentation date and time: September 30, 2022; 4:39 PM CST

Kodiak plans to post the slides from these presentations on the "Events and Presentations" section of Kodiak's website at <http://ir.kodiak.com/> following each presentation.

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 studies in patients with diabetic macular edema, the BEACON study in patients with retinal vein occlusion, the DAYLIGHT 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 BEACON Study


The Phase 3 BEACON study is a global, multi-center, randomized study designed to evaluate the durability, efficacy and safety of tarcocimab tedromer in 568 patients with treatment-naïve macular edema due to retinal vein occlusion, including both branch and central subtypes. Patients are randomized 1:1 to receive tarcocimab 5 mg or aflibercept 2 mg. In the first six months, patients receiving tarcocimab are treated with a proactive, fixed regimen which includes two monthly loading doses followed by treatment every 8 weeks, and patients receiving aflibercept are treated monthly as per its label. In the second six months, patients in both groups will receive treatment on an individualized basis per protocol-specified criteria. Patients can then continue to receive tarcocimab tedromer for an additional six months on an individualized basis. In the BEACON study, tarcocimab tedromer dosed every two months met the primary endpoint of non-inferior visual acuity gains compared to aflibercept dosed every month. Tarcocimab is the first anti-VEGF therapy to achieve non-inferiority in visual acuity gains while doubling the treatment interval in patients with RVO. In the study, tarcocimab was well tolerated with a low rate of intraocular inflammation and no new or unexpected safety signals. Results from the BEACON study are intended to serve as the basis for the potential approval of tarcocimab in RVO. Additional information about the BEACON study (also called Study KS301P103) can be found on www.clinicaltrials.gov under Trial Identifier NCT04592419 (<https://clinicaltrials.gov/show/NCT04592419>).

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 our regulatory strategy, including the expected bases on which regulatory approval may be sought; and expansion of our research pipeline. 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 tarcocimab may occur; future regulatory milestones of tarcocimab, including related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; 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.

 View original content: <https://www.prnewswire.com/news-releases/kodiak-sciences-announces-upcoming-presentations-of-tarcocimab-tedromer-ksi-301-phase-3-beacon-study-results-in-retinal-vein-occlusion-rvo-301608924.html>

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