Kodiak Sciences Announces First Time Presentation of Primary Endpoint Data from Tarcocimab Tedromer Phase 3 GLOW Study in Patients with Diabetic Retinopathy at American Academy of Ophthalmology Annual Meeting

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PALO ALTO, Calif., Nov. 1, 2023 /PRNewswire/ -- Kodiak Sciences Inc (NASDAQ: KOD) today announced that data from tarcocimab tedromer will be presented during the annual meeting of the American Academy of Ophthalmology (AAO) to be held November 3-6 in San Francisco.

During the Retina Subspecialty Day on November 3, detailed results will be presented for the first time from the Phase 3 GLOW study of tarcocimab tedromer in patients with non-proliferative diabetic retinopathy.

In the pivotal GLOW study, all 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 was the proportion of tarcocimab-treated patients who experienced at least a 2-step improvement on the diabetic retinopathy severity scale (DRSS), a grading system measuring the degree of retinopathy, as compared to patients in the sham group. The Key Secondary Endpoint was the proportion of tarcocimab treated patients who suffered a sight threatening complication including progression to diabetic macular edema or proliferative diabetic retinopathy, as compared to patients in the sham group.

Diabetic retinopathy (DR) is a common complication of diabetes that affects the eye. If left untreated, diabetic retinopathy progresses and eventually can lead to serious vision-threatening complications, such as diabetic macular edema and proliferative diabetic retinopathy. It is estimated that of the 36 million American adults living with diabetes, 10 million have diabetic retinopathy.

"We are pleased to have topline results from the GLOW study ready to be presented at the AAO Retina Subspecialty Day," said Dr. Pablo Velazquez-Martin, Senior Vice President of Kodiak Sciences. "This dataset is the last of the six pivotal Phase 3 studies we have run with tarcocimab. Long interval dosing is particularly important in the diabetic retinopathy population, and the GLOW study explores the ability of tarcocimab, with all patients on an every 6-month dosing interval, to directly improve the disease (the primary endpoint) and to prevent vision threatening complications from the worsening of the disease (key secondary endpoint). In GLOW, there are no loading doses. Instead, tarcocimab is given in a progressive extended dosing regimen with all patients treated on a 6-month interval before the end of year 1. This translates to only 4 doses in the first year of treatment."

Presentation Details:

Friday, November 3rd (Retina Subspecialty Day)

Section IX: First-time Results in Clinical Trials

Outcomes From the Randomized, Controlled Phase 3 GLOW Trial: Management of Diabetic Retinopathy with KSI-301 (tarcocimab tedromer)

Presenting author: Charles C. Wykoff, MD, PhD

Oral presentation at 4:56 p.m. PDT.; Moscone Convention Center, room West 3004

The presentation material is expected to be posted under the Investor Relations section of the Kodiak corporate website concurrently with the start of the oral presentation and can be found at https://ir.kodiak.com/events-and-presentations/events.

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 treatment-naïve patients with moderately severe to severe non-proliferative diabetic retinopathy ("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 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.

SOURCE Kodiak Sciences Inc.

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