Zenkuda and tabirafusp-ted Meet Primary Endpoints in Pivotal DAYBREAK Trial in wAMD, with Zenkuda Demonstrating a Potential New Standard-of-Care Profile with Strong Immediacy and Sustained Clinical Effect with Majority of Patients on 24-week Dosing Interval Using Strict Treat-to-Dryness Real World Retreatment Criteria

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- Zenkuda (tarcocimab tedromer) met the primary endpoint (p-value of 0.0007) demonstrating meaningful vision gains as well as rapid and sustained retinal drying with the majority of patients (54%) on 6-month dosing, establishing a first-line benchmark in wet age-related macular degeneration (wAMD)
- Zenkuda multi-indication biologics license application (BLA) planned for the fourth quarter of 2026 to include five positive Phase 3 studies across wAMD, diabetic retinopathy and retinal vein occlusion
- Tabirafusp alfa tedromer (tabirafusp-ted) met the vision primary endpoint (p-value of 0.0036) and anatomical key secondary endpoint (p-value of <0.0001)
- Post-hoc analyses to identify which treatment naïve wAMD patient sub-groups can benefit from IL-6 inhibition are planned. Tabirafusp-ted development program is accelerating in diabetic macular edema and actively enrolling in the ALTO Phase 3 Study
- Zenkuda and tabirafusp-ted demonstrated safety consistent with the established safety profile of aflibercept

PALO ALTO, Calif., Sept. 28, 2026 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), a precommercial retina-focused biotechnology company committed to researching, developing and commercializing transformative therapeutics, today announced that the primary endpoints were met for both Zenkuda (tarcocimab tedromer) and tabirafusp-ted (KSI-501) in the Phase 3 DAYBREAK study in patients with wet age-related macular degeneration (wAMD). The DAYBREAK study in wAMD demonstrated that both Zenkuda and tabirafusp-ted achieved non-inferiority in vision gains compared to aflibercept at year one.

In DAYBREAK, Zenkuda demonstrated strong immediacy of clinical effect, matching and/or exceeding that of the aflibercept comparator through the loading phase. Zenkuda also demonstrated strong durability of clinical effect, with 54% of patients achieving 6-month durability at year one, while employing strict treat-to-dryness real world retreatment criteria. Zenkuda demonstrated favorable safety and was well tolerated in the study with a 0% intraocular inflammation rate and a 0.5% cataract adverse event rate (vs 0.9% with aflibercept comparator). Tabirafusp-ted also demonstrated favorable safety and was well tolerated in the study with a 0.4% intraocular inflammation rate and a 0% cataract adverse event rate (vs 0.9% with aflibercept).

Kodiak plans to submit Zenkuda data to regulatory authorities in 4Q2026 from five positive Phase 3 studies, DAYBREAK and DAYLIGHT in wAMD, GLOW and GLOW2 in diabetic retinopathy (DR) and BEACON in macular edema following retinal vein occlusion (RVO).

"The strength of these DAYBREAK data positions us for the next stage of Kodiak's evolution, as we prepare for the planned commercialization of Zenkuda as a potential best-in-class therapy for patients with wet AMD, diabetic retinopathy and retinal vein occlusion," said Victor Perlroth, M.D., Chief Executive Officer of Kodiak Sciences.

"The results generated in DAYBREAK with tabirafusp-ted are also highly encouraging, and we are enthusiastic to explore the potential for tabirafusp-ted to demonstrate superiority in patients with diabetic macular edema (DME) in the ongoing Phase 3 ALTO pivotal program. Our third late-stage asset, KSI-101, is being developed for macular edema secondary to inflammation, or MESI, with our first topline readout from its Phase 3 program expected in December 2026. Together, these three assets reflect the breadth of our late-stage opportunity and ambition to build a leading retinal medicines company with multiple therapies capable of providing meaningful and durable benefits to patients," continued Dr. Perlroth.

"These strong DAYBREAK data also have important ramifications for our ABC pipeline programs, as they reinforce the potential of our science and our ABC Platform to support a widening portfolio of proprietary and multi-functional medicines," concluded Dr. Perlroth.

"Today's results are deeply satisfying," said J. Pablo Velazquez-Martin, M.D., Chief Medical Officer. "Four years and seven months after our first Phase 3 readout, Zenkuda's profile has come fully into focus through rigorous science, disciplined learning and thoughtful execution. DAYBREAK demonstrated the attributes we designed Zenkuda to achieve: rapid disease control in wet AMD and the potential for six-month durability under stringent treat-to-dryness retreatment criteria. Together with our Phase 3 results in diabetic retinopathy and macular edema secondary to retinal vein occlusion, we now have five successful pivotal studies supporting Zenkuda's broad potential across major retinal vascular diseases."

"We plan to submit the BLA for Zenkuda later this year. We also look forward to reporting Phase 3 results from the first MESI study of KSI-101, and we are advancing tabirafusp-ted in diabetic macular edema, a high-inflammation disease, through the ongoing Phase 3 ALTO pivotal program." continued Dr. Velazquez-Martin.

Charles Wykoff, M.D., Ph.D., Chairman of Research, Retina Consultants of Texas, Professor of Clinical Ophthalmology and Deputy Chair of Ophthalmology, Blanton Eye Institute, Houston Methodist Hospital, said: "The Zenkuda results exceeded my expectations, delivering the clinical profile retina specialists are seeking: rapid vision and anatomic improvements comparable to aflibercept during loading, followed by meaningfully longer intervals between treatment for a majority of patients, while maintaining optimal fluid control. More than half of patients reached a 24-week dosing interval using strict treat-to-dry retreatment criteria. This combination of immediacy, flexibility and true durability is unique and differentiated."

"The observed safety profile also appears consistent with expectations for aflibercept. Kodiak persevered through real challenges with the tarcocimab development program, incorporating multiple lessons learned, culminating in a successful DAYBREAK trial. These findings add to an extensive Phase

3 dataset across wet AMD, diabetic retinopathy and retinal vein occlusion. I look forward to the possibility of having Zenkuda available for patients."

"Twenty years after Lucentis (ranibizumab) was approved for wet AMD, the holy grail remains the same: robust anatomic disease control and maximal visual gains, sustained with less frequent dosing," said David M. Brown, MD, Chief Medical Officer, Retina Consultants of America. "The DAYBREAK results with Zenkuda are truly impressive. Under an AI-guided retreatment algorithm that closely mirrors the zero-fluid-tolerance approach we use in clinic, more than half of patients were maintained on 24-week dosing through year one."

"Zenkuda pairs free protein for immediate disease control with antibody conjugated to a high-molecular-weight biopolymer, giving a mean ocular half-life of about 20 days in humans, roughly three times that of approved therapies. We advocated for DAYBREAK's rigorous criteria which require retreatment for any detectable fluid on OCT. Those criteria also recognize that patients differ: some clear drug faster, while others sustain control much longer. The goal is not one-size-fits-all dosing, but extending each patient to the longest effective interval their biology allows."

"These Zenkuda data bring us closer to the best possible outcomes with fewer injections. I look forward to offering Zenkuda to my patients, if approved," concluded Dr. Brown.

Detailed DAYBREAK study results will be presented and discussed together with Dr. C. Wykoff and Dr. D. Brown at a company Webex at 8:30am ET on September 28, 2026.

The webcast can be accessed at the following link DAYBREAK Topline Results Webcast or from the Events and Presentations page on Kodiak's website at https://ir.kodiak.com/events-and-presentations/events.

About Zenkuda ™(tarcocimab tedromer)

Zenkuda (tarcocimab tedromer) is an investigational anti-vascular endothelial growth factor (VEGF) biopharmaceutical built on Kodiak's proprietary antibody biopolymer conjugate (ABC®) platform for intravitreal administration. Zenkuda has a mean ocular half-life in humans of 20 days, approximately three times longer than approved anti-VEGF therapies and is designed to maintain potent and effective drug levels in ocular tissues for longer. Zenkuda is being developed as a mainstay intravitreal biologic monotherapy that provides rapid initial effect and real-world durability, driven by the ABC® platform and Kodiak's science of durability, with the ultimate objective of providing, once approved, a flexible 1-month through 6-month label for all patients with retinal vascular disease (treatment-naïve, treatment-experienced, mild patients, and severe patients).

Zenkuda has completed five successful Phase 3 pivotal studies: the Phase 3 DAYBREAK and DAYLIGHT studies in wet AMD, the Phase 3 GLOW1 and GLOW2 studies in diabetic retinopathy (DR) and the Phase 3 BEACON study in retinal vein occlusion (RVO).

In the DAYBREAK study, Zenkuda successfully treated wAMD patients with strong immediacy of clinical effect, similar vision outcomes and a 6-month dosing interval in the majority of patients using strict treat-to-dryness, *i.e.* real-world, retreatment criteria.

In the GLOW1 and GLOW2 studies, Zenkuda successfully treated DR patients and prevented disease progression with 100% of patients on extended 6-month dosing at Year 1.

In the BEACON study, during the first 6 months, Zenkuda-treated patients were dosed at 8-week interval (as opposed to 4-week intervals for aflibercept). In the second 6 months, identical retreatment criteria were used for the Zenkuda and aflibercept arms, and nearly half of Zenkuda patients did not require any treatment while achieving similar vision and anatomical outcomes as the aflibercept group at one year.

The company is planning to submit a three-indication BLA for Zenkuda in 4Q2026.

About DAYBREAK (and Zenkuda)

The Phase 3 DAYBREAK study is a non-inferiority study evaluating parallel investigational arms of Zenkuda and KSI-501 against active comparator aflibercept. Patients randomized to Zenkuda received individualized dosing every 4 to 24 weeks on an as needed basis following four monthly loading doses. Patients randomized to aflibercept were dosed per label. The individualized dosing of Zenkuda was determined by a treat-to-dryness proactive approach using the presence of retinal fluid as a disease activity marker, which resembles retina specialists' practice and optimizes each patient's treatment, instead of using a combination of central subfield thickness and vision loss. Specific objectives for Zenkuda in DAYBREAK were (1) to assess safety, (2) to meet the primary endpoint of non-inferiority of best corrected visual acuity, (3) to explore the strength of fluid control vision gain through the loading phase, and (4) to demonstrate a differentiated, real-world durability profile. General objectives for Zenkuda in DAYBREAK are to strengthen its competitive position in wet AMD and bolster the possible regulatory application package for the program. DAYBREAK was designed to showcase the potential for Zenkuda to be a mainstay biologic for VEGF-driven retinal vascular diseases with both a strong efficacy/immediacy (driven by its enhanced formulation) and a strong durability (driven by its ABC design and science of durability). The Phase 3 DAYBREAK study met the one-year primary endpoint of non-inferiority of best corrected visual acuity in September 2026.

About tabirafusp alfa tedromer (KSI-501)

Tabirafusp-ted is an investigational anti-IL-6, VEGF-trap bispecific therapy built on the ABC platform and is being developed for high prevalence retinal vascular diseases to address the leading unmet needs of extended durability and targeting disease biology beyond VEGF for differentiated efficacy. Tabirafusp-ted is designed to provide high immediacy/efficacy, driven by the enhanced formulation, and high durability, driven by the ABC platform and our science of durability.

Kodiak advanced tabirafusp-ted into the registrational Phase 3 DAYBREAK study to evaluate its efficacy and safety in wet AMD. DAYBREAK uses tabirafusp-ted's enhanced 50 mg/mL formulation containing both conjugated and unconjugated antibody that is intended to balance immediacy and durability.

In the DAYBREAK study, tabirafusp-ted met the vision primary endpoint (p-value of 0.0036) and anatomical key secondary endpoint (p-value of <0.0001). Post-hoc analyses to identify which treatment naïve wAMD patient sub-groups can benefit from IL-6 inhibition are planned.

Kodiak has also advanced tabirafusp-ted into the registrational Phase 3 ALTO study designed to explore the superiority of bispecific tabirafusp-ted (anti-VEGF, anti-IL-6) versus monospecific aflibercept (anti-VEGF) in patients with diabetic macular edema. The ALTO study is now enrolling patients.

About DAYBREAK (and tabirafusp-ted)

The DAYBREAK study is a non-inferiority study evaluating parallel investigational arms of KSI-501 and Zenkuda against active comparator aflibercept. Patients randomized to KSI-501 received fixed every 8-week dosing with additional individualized dosing (up to monthly dosing) on an as needed basis after four monthly loading doses. Patients randomized to aflibercept were dosed per label. Using the same treat-to-dryness approach as Zenkuda, coupled with fixed intensive proactive dosing, the goal was to maximize both the probability of meeting the primary endpoint as well as the probability of demonstrating additional efficacy benefits. The primary endpoint was non-inferiority in change in visual acuity from baseline to the average of Week 40, 44 and 48. The objective for KSI-501 in DAYBREAK was to explore the efficacy potential of bispecific IL-6 and VEGF inhibition in a broad treatment-naïve wet AMD population. Additional information about DAYBREAK can be found on www.clinicaltrials.gov under Trial Identifier NCT06556368 (https://clinicaltrials.gov/study/NCT06556368).

About ALTO

The ALTO Study is a global, multicenter, randomized, double-masked, active comparator-controlled Phase 3 study evaluating the efficacy and safety of intravitreal tabirafusp-ted 5 mg compared with intravitreal aflibercept 2 mg in patients with visual impairment secondary to center-involved DME. Approximately 910 patients, treatment-naïve or previously treated, will be randomized 5:3:5 to one of three arms: (A) tabirafusp-ted 5 mg every 8 weeks, with monthly assessment for additional individualized dosing, following six monthly loading doses; (B) tabirafusp-ted 5 mg on an individualized regimen of every 4 to 24 weeks, following six monthly loading doses; and (C) aflibercept 2 mg every 8 weeks, following five monthly loading doses.

The primary endpoint is the mean change in best-corrected visual acuity (BCVA) from baseline to the average of Week 48 and Week 52. The key secondary endpoint is the proportion of patients improving two or more steps on the DRSS from baseline at Week 48. Additional secondary and exploratory endpoints evaluate visual function, retinal anatomy, treatment burden and durability, and safety. Participants will be treated and followed for approximately 96 weeks.

About Kodiak Sciences Inc.

Kodiak (NASDAQ: KOD) is a precommercial biotechnology company and a leader in retinal medicines development. We plan to file a biologics license application (BLA) for Zenkuda in the fourth quarter of 2026. We believe Zenkuda is a potential new first-in-class investigational therapy for patients with wet age-related macular degeneration (wAMD), diabetic retinopathy (DR) and macular edema following retinal vein occlusion (RVO). In the recent DAYBREAK Phase 3 study comparing Zenkuda with standard of care aflibercept, patients treated with Zenkuda showed strong immediacy of clinical effect through the loading phase, comparable vision gains and fluid control through the one-year primary endpoint, with a majority of patients treated on an every 6 month dosing interval using a strict treat-to-dryness real world retreatment approach. We also remain on track to announce topline data in December 2026 for KSI-101 in the Phase 3 PEAK study in patients with macular edema secondary to inflammation (MESI), in which KSI-101 is being evaluated for superiority against sham-treated patients. We are planning to file a BLA for KSI-101 in the second quarter of 2027. Looking to Zenkuda and KSI-101, we have the potential to receive marketing authorization for two retinal medicines by the end of calendar year 2027 or early 2028. Additionally, we continue to accelerate our development plan for tabirafusp-ted in the currently enrolling ALTO Phase 3 study exploring the potential for tabirafusp-ted, our bispecific (anti-VEGF, anti-IL-6) antibody biopolymer conjugate (ABC), to demonstrate superiority versus standard of care aflibercept in patients with diabetic macular edema (DME). We wholly own global rights to all three of our late-phase assets Zenkuda, KSI-101 and tabirafusp-ted.

For more information, visit www.kodiak.com and follow Kodiak on LinkedIn.

Forward-Looking Statements

This press 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 planned multi-indication BLA submission for Zenkuda in the fourth quarter of 2026; the planned BLA submission for KS-101 in the second quarter of 2027; acceleration of the tabirafusp development program and the status of enrollment in, and expectations regarding the ALTO study; planned post-hoc analyses to identify patients that can benefit from IL-6 inhibition; and expectations regarding the announcement of topline data December 2026 for KSI-101 in the Phase 3 PEAK study in patients with macular edema secondary to inflammation (MESI). 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 "anticipate," "believe," "could," "expect," "intend," "may," "plan," "pursue," "should," "will," "would," 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 completed Phase 3 studies for Zenkuda may not be sufficient to support a BLA submission or approval in DR, RVO, or wet AMD; a BLA for tarcocimab tedromer or any other product candidate may not be accepted by, or receive approval from, the FDA or foreign regulatory agencies when expected, or at all; cessation, modification, or delay of any ongoing clinical studies and Kodiak's development of Zenkuda, KSI-501, KSI-101, or any other product candidate may occur; safety, efficacy, and durability data observed in Kodiak's product candidates in current or prior studies may not continue or persist; KSI-501 may not inhibit VEGF and IL-6 or have an impact on the treatment of patients as expected, and that preclinical data suggesting the possibility that KSI-501 may be a disease-modifying therapy may not translate to clinical outcomes; the PEAK Phase 3 study for KSI-101 may not achieve its primary endpoint or may not do so on the anticipated timeline; any one or more of Kodiak's product candidates may not be successfully developed, approved, or commercialized; sufficient capital may not be available as expected, or at all, to complete the development of any products; adverse conditions in the U.S. and global economic markets may significantly impact Kodiak's business and operations, including its clinical trial sites, as well as the business or operations of its manufacturers, contract research organizations, or other third parties with whom Kodiak conducts business; as well as the other risks identified in the section entitled "Risk Factors" in Kodiak's Annual Report on Form 10-K for the year ended December 31, 2025, as well as discussions of potential risks, uncertainties, and other important factors in Kodiak's subsequent filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and Kodiak undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise. Readers are cautioned not to place undue reliance on such forward-looking statements.

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