Kodiak Sciences Completes Enrollment in First Pivotal Cohort in the Phase 3 PEAK Trial of KSI-101 for Macular Edema Secondary to Inflammation and Reaffirms Topline Clinical Data Release Remains on Track for December 2026

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- *First pivotal cohort enrolled 300 subjects, with topline clinical data from 24-week primary endpoint on track for December 2026 release*
- *Completion of enrollment in the second pivotal cohort evaluating 600 subjects across the PEAK and PINNACLE studies is expected in 4Q 2026, with topline clinical data release anticipated in 2Q 2027*

PALO ALTO, Calif., Aug. 6, 2026 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD) today announced that it has completed enrollment of the first 300-patient cohort in its PEAK trial, supporting Pivotal Analysis 1 of the KSI-101 Phase 3 program in macular edema secondary to inflammation ("MESI"). Kodiak also reaffirmed its plan to release the topline data from Pivotal Analysis 1 in December 2026.

"We were pleased to complete this important enrollment milestone in early June , and we can now confidently plan for the topline data to be released in December 2026," said Victor Perlroth, M.D., Chief Executive Officer of Kodiak. "Our data from the Phase 1b APEX study meaningfully increased our conviction in KSI-101's potential to be a cornerstone therapy for MESI patients. The global registrational PEAK trial is the first pivotal test of that conviction, and we look forward to sharing topline data before the end of this year."

"Pivotal Analysis 1 gives us the opportunity to evaluate KSI-101 in patients with more severe MESI across our global site footprint," said J. Pablo Velazquez-Martin, M.D., Chief Medical Officer of Kodiak. "These are patients at high risk of losing meaningful vision, and the goal of treatment is not only to reduce inflammation but to dry the retina and improve vision without the toxicities and other limitations associated with today's complex patchwork of systemic and ocular therapies. KSI-101 was designed for this clinical challenge, and we are grateful to the patients, investigators and study teams who have helped bring the program to this important milestone."

"MESI encompasses a broad range of diseases resulting in a swollen macula and which are not attributable to other common causes of retinal edema such as wet AMD, diabetic macular edema and retinal vein occlusion. MESI represents a meaningful number of patients in my retina practice," said David Eichenbaum, M.D., Director of Research at Retina Vitreous Associates of Florida and a principal investigator in the PEAK and PINNACLE clinical trials. "Many of these patients have experience with corticosteroid use and understand its limitations, including the risks of elevated intraocular pressure and cataract. I am encouraged by the data generated to date with KSI-101 in which the therapy appears to work well and to date is demonstrating a favorable safety profile. KSI-101 could open up treatment for MESI to many more patients and may meaningfully change the treatment paradigm for this diagnosis in retina practice in the years ahead. I'm thrilled to be on the leading edge of this program."

About Macular Edema Secondary to Inflammation (MESI)

MESI is a heterogeneous group of diseases that clinically present with macular edema and visual impairment which are caused by a common pathophysiology of inflammation and blood retinal barrier disruption. The clinical presentation of retinal fluid and visual impairment is a mainstay in these patients, irrespective of the location of the inflammation inside of the eye (anterior, intermediate, posterior or all intraocular compartments) or the specific etiology (defined autoimmune associated, idiopathic, post-procedural, or inflammatory choroidal neovascularization).

Currently there are no available intravitreal biologic therapies addressing the spectrum of MESI diseases. Existing therapies remain limited by side effects and tolerability, underscoring the need for safer and more effective treatment options. MESI represents a new macular edema market segment separate from the established anti-VEGF market.

About KSI-101

KSI-101 is a novel, potent and high strength (100 mg/mL) bispecific protein targeting IL-6 and VEGF for the treatment of MESI. Data from our dose-finding Phase 1b APEX study demonstrated robust anatomical and visual responses across MESI patients. More than half of patients achieved ≥15-letter gains in best corrected visual acuity, with additional benefit at higher dose levels. Rapid vision improvements and anatomical response were observed with 10-letter gains by Week 4 in top dose groups and OCT CST <325 microns achieved as early as Week 1 in top dose groups. Continued anatomical improvement was observed over time with >90% resolution of intraretinal ("IRF") and subretinal fluid ("SRF") by Week 8 and 20/25 Snellen visual acuity by Week 20. In top dose groups, ≥90% achieved complete absence of IRF and SRF, indicating retinal dryness and normalization of retinal architecture. KSI-101 also continued to be well tolerated with a favorable safety profile. The top two dose levels in APEX have been advanced into the Phase 3 pivotal studies, PEAK and PINNACLE. The PEAK and PINNACLE studies are actively enrolling.

About PEAK and PINNACLE

The PEAK and PINNACLE studies are superiority studies evaluating two dose levels of KSI-101 (5 mg and 10 mg) compared to sham treatment in patients with MESI. PEAK and PINNACLE are identical in study design with key differences in patient population. PEAK includes patients with more severe disease (moderate to severe macular edema and vision impairment) and PINNACLE includes patients with milder disease (mild macular edema and any vision impairment), as well as patients with moderate to severe macular edema with good vision. Together, PEAK and PINNACLE are designed to enroll complementary patient populations and to cover a wide spectrum of MESI patients.

Patients randomized to the KSI-101 treatment arms will receive fixed monthly dosing for 6 doses (from Day 1 to Week 20), with subsequent individualized dosing (up to monthly dosing) for 6 additional visits (Week 24 to Week 44). Patients in the sham arm will receive monthly sham dosing for 6 doses followed by sham PRN. The primary and key secondary endpoints will be evaluated at Week 24. PEAK and PINNACLE are now actively enrolling patients. Topline data readouts for Pivotal Analysis 1 (PEAK patients 1 – 300) and Pivotal Analysis 2 (PEAK patients 301 – 600 and PINNACLE patients 1 – 300) are expected in December 2026 and 2Q 2027, respectively.

About Kodiak Sciences Inc.

Kodiak Sciences (Nasdaq: KOD) is a pre-commercial retina-focused biotechnology company committed to researching, developing and commercializing transformative therapeutics. 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. We are developing a portfolio of three late-stage clinical programs. Zenkuda™ (tarcocimab tedromer) has a BLA-ready profile in diabetic retinopathy, retinal vein occlusion and wet AMD, and, together with KSI-501, is being explored in the BLA-facing Phase 3 DAYBREAK wet AMD study, with topline data expected in September 2026. Zenkuda and KSI-501 target the $15 billion anti-VEGF market across retinal vascular diseases. KSI-101 is a bispecific protein being explored in two BLA-facing Phase 3 studies in Macular Edema Secondary to Inflammation (MESI). Topline data for Pivotal Analysis 1 (PEAK) are expected in December 2026 and Pivotal Analysis 2 (PEAK+PINNACLE) in 2Q 2027.

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: Kodiak's plans to release topline data; Kodiak's expectation regarding the timing of completion of enrollment in the PEAK and PINNACLE studies; Kodiak's belief regarding KSI-101's efficacy and safety profile based on data from the Phase 1b APEX study and in the PEAK and PINNACLE studies. 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," "anticipate," 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 data observed to date in the Phase 1b APEX study or in the ongoing PEAK and PINNACLE studies may not continue or persist, or may not be replicated in later analyses or in a larger or more diverse patient population; the risk that KSI-101 may not achieve the primary or key secondary endpoints in the PEAK or PINNACLE studies or may not do so on the anticipated timeline; the risk that cessation, modification, or delay of the PEAK or PINNACLE studies, or of Kodiak's development of KSI-101 or any other product candidate, may occur; the risk that KSI-101 may not be successfully developed, approved, or commercialized; the risk that Kodiak's research and development efforts and ability to advance product candidates into later stages of development may fail; adverse conditions in the general domestic and global economic markets, which 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 most recent Annual Report on Form 10-K, 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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