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Follow-up data for Kodiak's KSI-101 from the APEX study showed continued strengthening of clinical effect (≥90% of patients achieving absence of intraretinal and subretinal fluid) through week 20 in macular edema secondary to inflammation (MESI)

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- Meaningful vision gains are rapidly achieved as early as week 4 and showed continued improvement in best corrected visual acuity (BCVA) through week 20, with more than half of patients achieving improvement of 3-lines or more on the eye chart (≥15 letter gain).
- ≥90% of patients in the top two dose levels achieved and sustained real dryness of the retina, as demonstrated by absence of intraretinal fluid (IRF) as well as subretinal fluid (SRF), key markers of disease activity.
- The Phase 3 PEAK and PINNACLE studies of KSI-101 are enrolling at a faster-than-expected pace, evaluating the top two dose levels (5 mg and 10 mg) in patients with MESI.

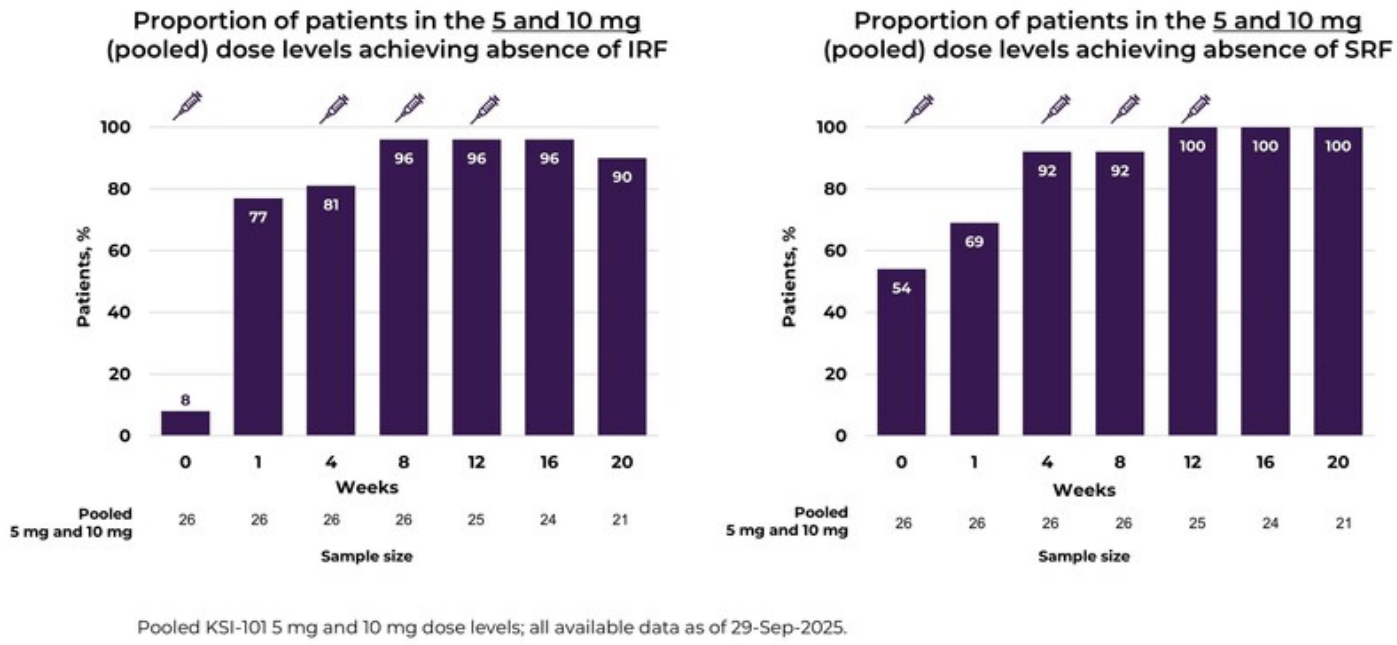
PALO ALTO, Calif., Nov. 5, 2025 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), a precommercial retina focused biotechnology company committed to researching, developing and commercializing transformative therapeutics, announced today follow-up data from the APEX study of KSI-101 in patients with MESI.

MESI is a heterogenous group of serious vision threatening retinal diseases that clinically present with macular edema (retinal fluid) and visual impairment, caused by a common pathophysiology of inflammation and blood retinal barrier disruption. Existing therapies remain limited by side effects and tolerability, underscoring the need for safer and more effective treatment options.

KSI-101 is novel, potent and high strength (100 mg/mL) antibody-based investigational therapy with a bispecific mechanism of action targeting both interleukin-6 (IL-6) and vascular endothelial growth factor (VEGF).

Week 20 Data Highlights from Phase 1b APEX Study in Patients with Macular Edema Secondary to Inflammation – Baseline to Week 20 (Patients dosed at Weeks 0, 4, 8 and 12)

	Dose Level		
	2.5 mg n=13 Patients	**5 mg n=13 Patients**	**10 mg n=13 Patients**
Proportion of Patients with ≥15 Letter Gain	38 %	62 %	54 %
Mean Change in Best Corrected Visual Acuity (BCVA) from Baseline to Week 20 (ETDRS Letters)	+11.8	+13.4	+15.4
Mean BCVA Score achieved at Week 20 (ETDRS Letters; Snellen equivalent)	74.5 ~20/32	79.1 ~20/25	79.0 ~20/25
Mean Change in Retinal Thickness (Ocular Coherence Tomography Central Subfield Thickness) from Baseline to Week 20 (microns)	-151.2	-218.1	-230.1
Mean OCT CST achieved at Week 20 (microns)	310.5	269.2	296.2



Pooled KSI-101 5 mg and 10 mg dose levels; all available data as of 29-Sep-2025.

KSI-101 continued to be well tolerated with a favorable safety profile.

Dr. Victor Perlroth, M.D., Chairman and CEO of Kodiak commented. "These Week 20 follow-up results suggest even more strongly the potential for KSI-101 to become a cornerstone therapy for the treatment of MESI. The data show that achieving complete retinal drying, meaningful visual acuity gains and normalization of visual acuity is possible for most patients with MESI. Most importantly, we can achieve this with a safe profile. We believe that, if confirmed in our Phase 3 studies PEAK and PINNACLE,

KSI-101 may harmonize the MESI therapeutic landscape by becoming a safe, first-line unifying therapy for all causes of MESI."

"At the recent American Academy of Ophthalmology meetings, intraocular interleukin-6 inhibition was shown in Phase 3 clinical trials to deliver a meaningful improvement in vision and anatomy in patients with uveitic macular edema, a key component of MESI. Local IL-6 inhibition also appeared to be well tolerated in these trials. At the same time, there appears to be a significant opportunity for KSI-101, a potent inhibitor of interleukin-6 that layers on potent inhibition of VEGF, to drive a stronger clinical effect," continued Dr. Perlroth. "We believe KSI-101 has the potential to achieve best-in-class efficacy for patients with macular edema secondary to inflammation."

Dr. Velazquez-Martin, M.D., Chief Medical Officer of Kodiak commented. "It is reassuring to see the APEX Week 20 data further validate our own thinking of KSI-101 as a transformative therapy. Two key aspects of the extended data are very compelling and support our selection of the top two KSI-101 dose levels tested to move forward into our Phase 3 program: achieving and sustaining real dryness as defined by absence of intraretinal and subretinal fluid in more than ≥90% of the patients, as well as achieving an 'almost perfect' visual acuity at 20/25 Snellen equivalent. In addition, the fast onset of action across all three dose levels, with the vast majority of the drying effect already observed at Week 1, seems to be a clear differentiator."

Once completed, the results including Week 24 data will be presented by Dr. Sumit Sharma, M.D., retina and uveitis specialist at the Cleveland Clinic's Cole Eye Institute, on February 7th, 2026, at the Angiogenesis, Exudation, and Degeneration 2026 Annual Meeting.

The top two dose levels in APEX, KSI-101 5 mg and 10 mg have been advanced into the Phase 3 pivotal studies PEAK and PINNACLE. The PEAK and PINNACLE Studies are actively enrolling.

Week 20 follow-up results from the APEX study have been posted on the "Events and Presentations" page of Kodiak.com located here: https://ir.kodiak.com/events-and-presentations/events

About KSI-101

KSI-101 is a novel, potent and high strength (100 mg/mL) bispecific protein targeting IL-6 and VEGF. We are developing KSI-101 for patients with macular edema (retinal fluid) secondary to inflammation (MESI). MESI is a heterogenous group of diseases that clinically present with macular edema and visual impairment which are caused by a common pathophysiology–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. We believe that MESI represents a new market segment separate from the established anti-VEGF market.

We have completed enrollment in our dose-finding Phase 1b study APEX. The APEX study evaluates KSI-101 in two cohorts, Cohort 1 in patients with diabetic macular edema (DME) and Cohort 2 in patients with macular edema secondary to inflammation (MESI). APEX demonstrated that KSI-101 provides meaningful visual and anatomical gains in both DME and MESI and that KSI-101 is well tolerated. Meaningful treatment responses were seen in the MESI population, irrespective of the location of inflammation and specific MESI etiology, opening up the potential for KSI-101 to become a unifying treatment for this patient population.

Based on APEX, the top two dose levels tested were selected to advance into the Phase 3 program. The PEAK and PINNACLE Phase 3 studies are actively enrolling MESI subjects at the 5 mg and 10 mg dose levels versus sham.

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. Additional information about PEAK and PINNACLE can be found on www.clinicaltrials.gov under Trial Identifiers NCT06990399 and NCT06996080, respectively (https://clinicaltrials.gov/study/NCT06990399; https://clinicaltrials.gov/study/NCT06996080).

About Kodiak Sciences Inc.

Kodiak Sciences (Nasdaq: KOD) is a precommercial 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. Our ABC® Platform uses molecular engineering to merge the fields of protein-based and chemistry-based therapies and has been at the core of Kodiak's discovery engine. We are developing a portfolio of three late-stage clinical programs. Tarcocimab and KSI-501 are being explored in two BLA-facing Phase 3 studies in the retinal vascular diseases, targeting the $15 billion anti-VEGF marketplace, with topline data readouts expected in 1Q 2026 and 3Q 2026. KSI-101 is a bispecific protein being explored in two Phase 3 studies in Macular Edema Secondary to Inflammation (MESI), with topline data readouts expected in 4Q 2026 and 1Q 2027.

For more information, please visit www.kodiak.com.

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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: the potential for KSI-101 to fully dry the retina, achieve meaningful visual acuity gains and normalize visual acuity with a safe profile, the potential for KSI-101 to have a stronger clinical effect as a bispecific inhibitor of IL-6 and VEGF than individual inhibitors of Il-6 alone, and to possibly become a cornerstone or unifying treatment for the MESI patient population; the size of the anti-VEGF marketplace, expected topline data readouts in 1Q 2026 and 3Q 2026 for tarcocimab and KSI-501, the MESI market opportunity and the expected topline data readouts in 4Q 2026 or 1Q 2027 for KSI-101. 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 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: the risk that cessation, modification or delay of any of the ongoing clinical studies may occur; 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 any one or more of our product candidates may not be successfully developed, approved or commercialized; the risk that 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; 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 (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.

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