New data for Kodiak's KSI-101 from the APEX study reinforce its clinically meaningful vision gains and rapid retinal drying in macular edema secondary to inflammation (MESI)

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- Meaningful vision gains are rapidly achieved as early as week 4 and more than half of patients in the top two dose levels improved 3-lines or more on the eye chart (≥15 letter gain)
- A single dose of KSI-101 resulted in the majority of patients achieving resolution of intra-retinal and sub-retinal fluid and over 90% of patients achieved retinal dryness by Week 8
- The Phase 3 PEAK and PINNACLE studies of KSI-101 are actively enrolling, testing the top two dose levels (5 mg and 10 mg) in patients with MESI

PALO ALTO, Calif., Sept. 15, 2025 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), a precommercial retina focused biotechnology company committed to researching, developing and commercializing transformative therapeutics, announced today new data from the APEX study of KSI-101 presented at the Retina Society 58th Annual Scientific Meeting in Chicago, Illinois.

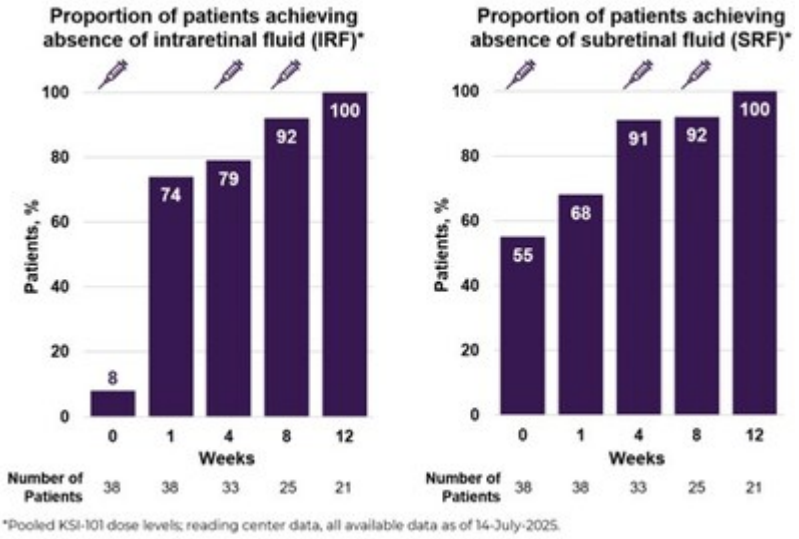
Dr. Charles Wykoff, MD, PhD, Deputy Chair of Ophthalmology, Blanton Eye Institute, presented continuing data from the three-arm, open-label Phase 1b APEX study of KSI-101 for the treatment of patients with macular edema secondary to inflammation (MESI), in which patients experienced a clinically meaningful gain in best-corrected visual acuity (BCVA) and rapid retinal drying from baseline to week 12.

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. No good treatment options exist today for patients with MESI.

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

Data Highlights from Phase 1b APEX Study in Patients with Macular Edema Secondary to Inflammation

	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	31 %	62 %	54 %
Mean Change in Best Corrected Visual Acuity (BCVA) from Baseline to Week 12 (ETDRS Letters)	+8.8	+10.7	+12.1
Mean Change in Retinal Thickness (Ocular Coherence Tomography Central Subfield Thickness) from Baseline to Week 12 (microns)	-165	-216	-240



*Pooled KSI-101 dose levels; reading center data, all available data as of 14-July-2025.

In a separate cohort of patients evaluated in the APEX study, patients with diabetic macular edema (DME, n=12) demonstrated meaningful visual and

anatomical gains with KSI-101, with patients gaining 12.0 letters and decreasing 157 microns in OCT CST from baseline to Week 24.

KSI-101 continued to be well tolerated with a favorable safety profile both in MESI patients and in DME patients.

Dr. Sumit Sharma, M.D., retina and uveitis specialist at the Cleveland Clinic's Cole Eye Institute, commented on the performance of KSI-101 in MESI patients. "The APEX data with KSI-101 bispecific antibody showed a drying effect that is on par with or even better than expected with the intraocular steroid implants such as Ozurdex but with none of the side effects. This is a fantastic effect and, if replicated in the ongoing Phase 3 studies, KSI-101 could significantly change how we treat the many patients with macular edema secondary to inflammation."

"It was a privilege to be able to present this new data from the APEX study at the Retina Society," said Dr. Wykoff, M.D., Ph.D., clinical investigator in the APEX study. "Although early in development, KSI-101 appears to be emerging as a powerful, dual-action, safe investigational therapy with potential applicability to a diverse set of pathologies that have relevance to retina specialists and uveitis specialists, many diseases of which currently have no approved treatment. As a retina community, we look forward to continuing our collaboration with Kodiak as they advance their portfolio of three late-stage medicines targeting a broad range of retinal diseases through their ongoing Phase 3 GLOW2, DAYBREAK, PEAK and PINNACLE studies."

Dr. Victor Perlroth, M.D., Chairman and CEO of Kodiak commented. "The continuing KSI-101 data presented by Dr. Wykoff represent the full cohort of MESI patients through Week 12. I would like to highlight the following key differentiators with KSI-101: (1) its bispecific mechanism of action, as an antibody-based inhibitor of IL-6 and a trap-based inhibitor of VEGF, (2) its rapid onset of action and powerful retinal drying effect, (3) its favorable early safety profile allowing the selection of our two highest dose levels (5mg and 10mg) for further testing in the Phase 3 program, and (4) its broad activity across the spectrum of MESI patients, irrespective of the location of the inflammation inside of the eye (anterior, intermediate, posterior or all intraocular compartments) or the specific etiology (uveitic macular edema, idiopathic macular edema, post-procedural macular edema, inflammatory choroidal neovascularization). Our focus is on the continued enrollment of patients into the PEAK and PINNACLE Phase 3 studies."

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 (uveitic macular edema, idiopathic macular edema, post-procedural macular edema, 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), a greenfield market opportunity, with topline data readouts expected in 4Q 2026 or 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: KSI-101's clinically meaningful vision gains and rapid retinal drying in MESI, KSI-101's bispecific mechanism of action as an antibody-based inhibitor of IL-6 and a trap-based inhibitor of VEGF, KSI-101's favorable safety profile both in MESI patients and in DME patients, KSI-101's potential applicability to a diverse set of pathologies that have relevance to retina specialists and uveitis specialists, the advancement of the ongoing Phase 3 GLOW2, DAYBREAK, PEAK and PINNACLE studies, the continued enrollment of patients into the PEAK and PINNACLE Phase 3 studies, the potential for KSI-101 to become a 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 safety, efficacy and durability data observed in our product candidates in current or prior studies may not continue or persist; 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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