Kodiak Sciences Data at ARVO 2025 Highlight Power and Versatility of ABC Platform in Addressing Complex Multifactorial Ocular Diseases

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PALO ALTO, Calif., May 1, 2025 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), a biopharmaceutical company committed to researching, developing and commercializing transformative therapeutics to treat high prevalence retinal diseases, announced today that seven scientific presentations on its research programs will be made at the Association for Research in Vision and Ophthalmology (ARVO) 2025 Annual Meeting, being held from May 4-8 in Salt Lake City, Utah.

"We are pleased to share new data from Kodiak's research and development efforts at this year's ARVO meeting. This body of work further highlights the power and versatility of Kodiak's ABC® (Antibody Biopolymer Conjugate) platform for the design and development of new medicines for complex multifactorial diseases with a high unmet need," said Dr. Victor Perlroth, MD and Chief Executive Officer.

"Our bispecific protein platform, the basis for KSI-101 currently in clinical development for macular edema secondary to inflammation (MESI), is fueling two new research programs in two new therapeutic categories: ocular inflammatory disease and geographic atrophy. We also present new data from our ABC® platform extension in which we embed diverse therapeutic payloads, such as oligonucleotides and peptides, into the biopolymer backbone at a high drug-antibody ratio (DAR) and deliver these payloads into targeted cells. We believe this is a promising strategy to power a next generation of targeted, high-DAR, multi-specific and multi-modality therapeutic candidates with relevance for retinal and systemic diseases."

The seven poster presentations are listed below, grouped by topic. The posters will also be made available under Kodiak's "Scientific Presentations" page on kodiak.com.

Ocular Inflammatory Disease
Ocular inflammatory disease, often called uveitis, is the fourth leading cause of vision loss for working aged adults in the developed world. One-third of patients with ocular inflammation develop macular edema, which is the leading cause of vision loss among patients with ocular inflammation. Steroids remain the mainstay treatment but can cause significant and permanent ocular adverse effects especially with long-term use or high doses. This body of work demonstrates Kodiak's strong protein engineering expertise to design innovative therapies, including KSI-101 (currently in Phase 1b) and KSI-102, by targeting the underlying and complex cytokine interactions underlying chronic inflammatory ocular diseases.

1. Title: Development of Anti-inflammatory Bispecific anti-TNF-α VHH anti-IL-6 Antibody Fusion for the Treatment of Inflammatory Retinal Diseases

Session Title: Anti-inflammatory agents, ocular toxicity, cytokines and growth factors
Presentation Date and Time: May 4, 2025; 8:00 – 9:45 AM (MT)
Presentation Type: Poster Session
Poster Number: 195-A0416

Elevated levels of pro-inflammatory cytokines such as tumor necrosis factor-alpha (TNF-α) and interleukin-6 (IL-6) play distinct yet complementary roles in driving inflammatory retinal diseases such as non-infectious uveitis. Treatments targeting these cytokines individually may fail to control inflammation in a comprehensive manner. Here we present preclinical data of KSI-102, a novel bispecific antibody that potently inhibits both TNF-α and IL-6 simultaneously, offering enhanced therapeutic potential for inflammatory ocular diseases.

2. Title: Preserving Endothelial Barrier Function with Novel Bispecific Anti-Inflammatory Agents for the Treatment of Retinal Inflammatory Diseases

Session Title: Anti-inflammatory agents, ocular toxicity, cytokines and growth factors
Presentation Date and Time: May 4, 2025; 8:00 – 9:45 AM (MT)
Presentation Type: Poster Session
Poster Number: 196-A0417

Inflammation contributes to ocular disease by triggering a cascade of pathological events, including disruption of the blood-retinal-barrier and recruitment of immune cells to retinal tissues. These processes can lead to edema and tissue damage, which are hallmark features of conditions such as macular edema and uveitis. Adalimumab is an anti-TNF-α biologic approved as a steroid-sparing agent for the treatment of non-infectious uveitis (NIU). However, more than 50% of patients with NIU experienced treatment failure over 85 weeks in the VISUAL I trial. This preclinical presentation demonstrates that Kodiak's anti-TNF-α, anti-IL-6 fusion protein normalizes human endothelial morphology and junctional proteins better than monotherapy agents.

3. Title: Ocular Toxicity Study of KSI-101 Demonstrates Tolerability after Intravitreal Administration in Cynomolgus Monkeys

Session Title: Retina/RPE: New drugs, mechanisms of action, and toxicity
Presentation Date and Time: May 8, 2025; 11:45 AM – 1:30 PM (MT)
Presentation Type: Poster Session
Poster Number: 5998-A0183

KSI-101 is a first-in-class, local, high-strength bispecific protein in clinical development for the treatment of macular edema secondary to inflammation (MESI). Early clinical data of KSI-101 in the Phase 1b APEX study, which is enrolling patients with MESI, demonstrates that at all dose levels, KSI-101 rapidly normalizes macular edema and improves vision. To inform and support further clinical development of KSI-101, which has demonstrated a positive safety profile in patients, here we demonstrate that repeated bilateral intravitreal administration of KSI-101 in non-human primates was safe and well tolerated.

The following poster was developed in collaboration with Chang Gung Memorial Hospital, Department of Ophthalmology:

4. Title: Systemic Review of Uveitic Macular Edema (UME) Outcomes in Children Versus Adults

Session Title: Uveitis Epidemiology and Clinical Characterization
Presentation Date and Time: May 6, 2025; 8:30-10:15 AM (MT)
Presentation Type: Poster Session
Poster Number: 2849-A0142

Macular edema secondary to inflammation affects adults and children, with differing underlying causes, inflammation patterns and clinical presentations. Treatment options vary by etiology, and steroids are generally avoided in children due to serious adverse effects. This study highlights the serious impact UME in particular has on vision, especially in children, and underscores the critical need for dedicated research and the development of safe and effective therapies tailored for pediatric UME.

Geographic Atrophy

Geographic atrophy (GA), the advanced form of dry age-related macular degeneration, affects approximately one million patients in the U.S. and is characterized by atrophic lesions in the retina that progressively expand to the central macular and fovea, leading to irreversible vision loss. Currently there are two approved therapies for GA, both are anti-complement therapies that offer modest therapeutic benefit and require monthly or every other month intravitreal injections.

5. Title: Development of Potent Bispecific Inhibitors Targeting Complement Activation and Cytokines for the Treatment of Geographic Atrophy (GA)

Session Title: New drugs, delivery systems, and mechanisms of action II
Presentation Date and Time: May 7, 2025; 10:15 AM – 12:00 PM (MT)
Presentation Type: Poster Session
Poster Number: 4337-A0493

Here we present new data on a promising therapeutic strategy to treat GA by combining complement regulators with an anti-VEGF antibody to prevent wet AMD conversion and anti-IL-6 antibody to further reduce GA progression, to achieve potent concurrent inhibition of complement pathway activation and VEGF pathway signaling.

Enhancing Therapeutic Efficacy with the ABCD Platform

Antibody Drug Conjugates (ADCs) and Antibody Oligonucleotide Conjugates (AOCs) are promising platforms for targeted drug delivery but have a limited drug-antibody ratio (DAR), which poses significant challenges in optimizing therapeutic efficacy. Kodiak's Antibody Biopolymer Conjugate Drug (ABCD) platform addresses this limitation by utilizing a customizable biopolymer to enable the design and development of multifunctional, high DAR therapeutics for ophthalmic and systemic applications.

6. Title: Delivery of Therapeutic Oligonucleotides by Antibody Biopolymer Conjugates (ABC®)

Session Title: New drugs, delivery systems, and mechanisms of action II
Presentation Date and Time: May 7, 2025; 10:15 AM – 12:00 PM (MT)
Presentation Type: Poster Session
Poster Number: 4334-A0490

Here we demonstrate the intracellular drug delivery capability and target knockdown potency of Antibody Biopolymer Conjugate Oligonucleotides (ABCO) in the target cells, providing a proof of concept for ABC® mediated intracellular delivery of oligonucleotide therapeutics. We demonstrate that (a) anti-TfR1 ABCO maintains high binding affinity to TfR1, (b) the antibody and its conjugates exhibit concentration dependent uptake in HepG2 cells, enabling delivery of RNA payloads, and (c) anti-TfR1 ABCOs with siRNA or ASO effectively modulate target gene expression.

7. Title: Effect of Polymer Architecture on Properties of Antibody Biopolymer Conjugates

Session Title: New drugs, delivery systems, and mechanisms of action II
Presentation Date and Time: May 7, 2025; 10:15 AM – 12:00 PM (MT)
Presentation Type: Poster Session
Poster Number: 4325-A0481

This study demonstrates how polymer architecture, specifically molar mass and number of arms in homopolymers, influences conjugate properties and explores the role of structural design. These findings guide optimization and further development of biopolymer conjugated therapeutic candidates with Kodiak's ABCD platform.

About Kodiak Sciences Inc.

Kodiak Sciences (Nasdaq: KOD) is a biopharmaceutical company committed to researching, developing, and commercializing transformative therapeutics to treat a broad spectrum of 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 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 clinical programs, two of which are late-stage today and derived from our ABC Platform and one which is platform-independent and which we believe can progress rapidly into pivotal studies.

Kodiak's lead investigational medicine, tarcocimab, is a novel anti-VEGF antibody biopolymer conjugate under development for the treatment of high prevalence retinal vascular diseases. Tarcocimab is currently being studied in two Phase 3 clinical trials, GLOW2 in patients with diabetic retinopathy and DAYBREAK in patients with wet AMD. GLOW2 enrollment is complete, and DAYBREAK is actively enrolling patients.

KSI-501 is our second investigational medicine, a first-in-class anti-IL-6, VEGF-trap bispecific antibody biopolymer conjugate designed to inhibit both IL-6 mediated inflammation and VEGF-mediated angiogenesis and vascular permeability. KSI-501 is being developed for the treatment of high prevalence retinal vascular diseases to address the unmet needs of extended durability and targeting disease biology beyond VEGF for differentiated efficacy. The Phase 3 DAYBREAK study of KSI-501 in wet AMD is actively enrolling patients.

KSI-101, our third product candidate, is a novel anti-IL-6, VEGF-trap bispecific protein. Kodiak is developing KSI-101 for the treatment of retinal inflammatory diseases, as currently there are no available intravitreal biologic therapies addressing the spectrum of inflammatory conditions of the retina. The Phase 1b APEX study of KSI-101 is actively enrolling patients, as a precursor to activating the Phase 2b/3 PEAK and PINNACLE studies in patients with macular edema secondary to inflammation ("MESI").

Kodiak is advancing its platform technology to embed small molecules and other active pharmaceutical ingredients ("APIs") into Kodiak's proprietary biopolymer backbone to enable high drug-antibody-ratio ("DAR") medicines. The diverse APIs are designed to be released over time to achieve targeted, multi-specific and tailored modulation of biological pathways. The unique combination of high DAR and tailored therapeutic benefit offers potential for broad application to multifactorial diseases and builds directly from our Antibody Biopolymer Conjugate technology and its 15 years of design, development and manufacturing experience. We call this platform extension our Antibody Biopolymer Conjugate Drug ("ABCD") Platform because we are extending our platform capabilities to include the conjugation of small molecule drugs and other APIs whereas historically, we primarily conjugated biologics such as antibodies.

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 power and versatility of Kodiak's ABC® platform; the enhanced therapeutic potential of KSI-102 for inflammatory ocular diseases; the potential of KSI-101 for the treatment of MESI; the potential for Kodiak's ABCD platform to enable the design and development of multifunctional, high DAR therapeutics for ophthalmic and systemic applications; and the optimization and further development of biopolymer conjugated therapeutic candidates with Kodiak's ABCD platform. 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.

View original content:https://www.prnewswire.com/news-releases/kodiak-sciences-data-at-arvo-2025-highlight-power-and-versatility-of-abc-platform-in-addressing-complex-multifactorial-ocular-diseases-302444839.html

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