New one-year results for Kodiak's tarcocimab tedromer in the pivotal BEACON trial reinforce durability signal and demonstrate matched efficacy and comparable safety and tolerability in retinal vein occlusion

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- Tarcocimab demonstrated strong durability, matched efficacy and comparable safety versus aflibercept in a head-to-head comparative pivotal trial over one-year
- After 4 initiating doses in the first 6 months, approximately half of tarcocimab-treated patients required no additional injections in the second 6 months
- Low and comparable rates of cataract adverse events were observed (tarcocimab 4.9% vs aflibercept 2.8%)
- These results provide additional supportive evidence for the development of Kodiak's ABC Platform and platform-derived medicines

PALO ALTO, Calif., Sept. 7, 2023 /PRNewswire/ -- Kodiak Sciences Inc. (NASDAQ: KOD) today announced top-line, one-year (48 weeks) results for its ABC Platform based investigational therapy tarcocimab tedromer 5 mg from the pivotal BEACON study in patients with macular edema due to retinal vein occlusion (RVO).

Macular edema due to retinal vein occlusion affects approximately 16.4 million adults worldwide and 1.1 million in the United States. Standard of care therapeutic agents are approved for monthly injections.

BEACON is a randomized, double-masked, multicenter, active comparator-controlled Phase 3 clinical trial in treatment naïve patients with vision loss and macular edema due to retinal vein occlusion, including both branch (BRVO) and central (CRVO) subtypes. BEACON randomized 568 participants 1:1 into two treatment arms: tarcocimab tedromer 5 mg versus aflibercept 2mg.

In the initial six months of the study, patients received Kodiak's tarcocimab tedromer 5 mg on a fixed every 8-week dosing regimen following only 2 monthly loading doses or aflibercept 2 mg on a fixed monthly (every 4-week) dosing regimen per its label.

In the second six months of the study, tarcocimab and aflibercept were tested head-to-head according to a *pro re nata* (PRN) protocol in which patients in both groups were treated only when disease reactivated according to matched predefined disease activity criteria.

The results were:

Differentiated Durability and Matched Efficacy Outcomes:

- Tarcocimab showed matched efficacy with differentiated durability versus aflibercept in the head-to-head comparison.
- After 4 initiating doses in the first 6 months, 47% of tarcocimab-treated patients required no additional injections in the second 6 months (while matching the vision and anatomic outcomes of aflibercept-treated patients). Despite receiving 6 initiating monthly doses, only 37% of aflibercept patients were injection free in the second half of the study.
- 77% of tarcocimab treated patients received 5 or fewer doses in year one, while 93% of aflibercept treated patients received 6 or more doses.
- BRVO patients received a median of 4.0 injections on tarcocimab versus 7.0 injections of aflibercept. Despite materially fewer injections in tarcocimab treated patients, vision outcomes favored tarcocimab-treated patients achieving an observed mean of 76.6 letters versus 75.6 letters for aflibercept treated patients.
- All RVO patients received a median of 5.0 injections on tarcocimab versus 7.0 injections of aflibercept. Despite materially fewer injections in tarcocimab treated patients, vision outcomes favored tarcocimab-treated patients achieving an observed mean of 74.6 letters versus 74.3 letters for aflibercept treated patients.

Comparable Safety and Tolerability

- Safety and tolerability were comparable between tarcocimab and aflibercept.
- Intraocular inflammation (IOI) rate was comparable between groups (tarcocimab 2.5% vs aflibercept 0.7%). No cases of inflammation associated with vascular occlusion or vasculitis were reported.
- The overall number of cataracts was low in the full year follow-up, comparable to prior aflibercept RVO studies (5% in BRVO pivotal trial VIBRANT at 6 months) and comparable between groups (tarcocimab 4.9 vs aflibercept 2.8%).

"These one-year results are remarkably strong," said Dr. Charles Wykoff, M.D., Ph.D., Director of Research, Retina Consultants of Texas and a trial investigator. "This is a first of its kind comparison in a pivotal study. After transitioning to as needed retreatment using identical criteria between the arms in the second 6 months, tarcocimab's efficacy is strong, notably matching that of aflibercept, while maintaining its signature durability advantage. Tarcocimab's durability has been consistent across each of the trials, and it is reassuring to see the signal when the medications are given head-to-head."

"BEACON is the only pivotal trial in RVO with less than monthly dosing in the first six months. And what we see is that, after 4 initiating doses, half of tarcocimab-treated patients required no additional injections through one-year while matching the vision outcomes in the aflibercept treated group.

This is not what we see or expect with current agents. This is an important and clinically relevant finding," said Andres Emanuelli, M.D., of Retina Care Puerto Rico and a trial investigator. "Having dosed nearly 100 patients in the tarcocimab pivotal clinical program, these one-year results reinforce my own experience that Kodiak's ABC Platform and tarcocimab are important innovations for our patients. The durability signal is real, the vision outcomes are matched, and the anatomy is strong and flat with no deficit despite materially fewer injections."

"We continue to be informed by new data across the tarcocimab program as it becomes available," said Victor Perlroth, MD, Chairman and CEO of Kodiak Sciences Inc. "The one-year BEACON study design let the tarcocimab and aflibercept medicines show their relative strengths independent of clinical study design differences. We believe the results reinforce tarcocimab's differentiated durability profile with comparable potency and safety when dosed head-to-head in the retinal disease with the highest VEGF drive, RVO. As we look to the future, we are planning to unmask and share the one-year primary endpoint data for the pivotal GLOW study in non-proliferative diabetic retinopathy in the fourth quarter of 2023. The GLOW data combined with these one-year results from BEACON should provide us additional insights as we evaluate future options for our ABC Platform and platform derived medicines."

Dr. Perlroth continued, "These results increase our conviction in the KSI-501 program, a first-of-its-kind bispecific ABC medicine. We remain excited about the program, both in the form of a reformulated bioconjugate and also as a separate dosage form of the 'naked' bispecific protein. We are exploring a two-pronged development plan which includes orphan disease indications such as uveitic macular edema (UME) and also the high-prevalence retinal vascular diseases."

The BEACON study results demonstrated:

	Through 48 weeks (one year)			
	BRVO Patients		All RVO Patients	
	Tarcocimab	Aflibercept	Tarcocimab	Aflibercept
Median # of injections	4.0	7.0	5.0	7.0
Percentage of patients receiving 5 or fewer doses in year 1	79.5 %	6.9 %	76.7 %	6.8 %
Percentage of patients requiring no additional treatments in second 6 months	50.0 %	38.8 %	45.9 %	35.9 %
Mean observed BCVA value, letters	76.6	75.6	74.6	74.3
Mean observed BCVA improvement, letters	13.9	14.0	13.5	14.2
LS mean (SE) change from baseline, letters	13.0	13.0	11.7	12.8
Difference in LS mean (95% CI), letters:	0.0* (-1.91, 1.96)		-1.1^ (-3.11, 0.94)	
Mean observed OCT Central Subfield Retinal Thickness, microns	309	308	322	308
Proportion of patients losing ≥15 letters, per LOCF	2.3 %	1.8 %	3.5 %	3.5 %

BCVA: best corrected visual acuity; LS: least squares; SE: standard error ; LOCF: Last observation carried forward
*Nominal non-inferiority (margin of -4.5 letters) p-value: p<0.0001
^Nominal non-inferiority (margin of -4.5 letters) p-value: p=0.001

About Kodiak Sciences Inc.

Kodiak (Nasdaq: KOD) is a biopharmaceutical company committed to researching, developing and commercializing transformative therapeutics to treat high-prevalence 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 antibody biopolymer conjugate platform, or ABC Platform ™ is at the core of Kodiak's discovery engine. Kodiak's first investigational medicine, tarcocimab tedromer, is a novel anti-VEGF antibody biopolymer conjugate explored for the treatment of retinal vascular diseases. Kodiak's second clinical program, KSI-501, built from a first-in-class bispecific protein targeting both IL-6 (anti-IL-6 antibody) and VEGF (VEGF-trap), is intended to treat both orphan and high prevalence retinal diseases. Kodiak is based in Palo Alto, CA. For more information, please visit www.kodiak.com.

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 implications of the Beacon results, including their importance and clinical relevance, the possibility that they provide additional supportive evidence for the development of Kodiak's ABC Platform and platform-derived medicines, and additional insights that may be provided by the GLOW data combined with the BEACON results; tarcocimab's differentiated durability profile; the potential for Kodiak's ABC Platform and tarcocimab to be important innovations for patients; the expected timing for completion and release of topline data for the GLOW study; and expectations and plans for the development of KSI-501. 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 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 BEACON and/or GLOW results may not provide the evidence, insights or benefits as anticipated; the risk that cessation, modification or delay of any of the ongoing clinical studies and our development of tarcocimab and/or KSI-501 may occur; 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 our ABC Platform or tarcocimab may not represent important innovations for patients; our research and development efforts and our ability to advance our product candidates into later stages of development may fail; the risk that KSI-501 may not inhibit VEGF and IL-6 or have an impact on the treatment of patients as expected; the risk that any one or more of our product candidates may not be successfully developed, approved or commercialized; adverse conditions in the general domestic and global economic markets, which may significantly impact our business and operations, including our clinical trial sites, as well as the business or operations of our manufacturers, contract research organizations or other third parties with whom we conduct business; the availability of sufficient capital to develop products; as well as the other risks identified in our filings with the Securities and Exchange Commission. 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 Securities and Exchange Commission. 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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