

NASDAQ: KOD

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THE OPHTHALMOLOGY MEDICINES COMPANY

3Q Business Highlights
November 12, 2019

SPECIAL NOTE REGARDING

FORWARD-LOOKING STATEMENTS

These slides and the accompanying oral presentation contain forward-looking statements and information. The use of words such as “may,” “might,” “will,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “project,” “intend,” “future,” “potential,” or “continue,” and other similar expressions are intended to identify forward-looking statements. For example, all statements we make regarding the initiation, timing, progress and results of our preclinical and clinical studies and our research and development programs, our regulatory strategy, our future development plans, including 2020 Vision, our ability to advance product candidates into, and successfully complete, clinical studies, and the timing or likelihood of regulatory filings and approvals are forward looking. All forward-looking statements are based on estimates and assumptions by our management that, although we believe to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that we expected. These statements are also subject to a number of material risks and uncertainties that are described in our most recent quarterly report on Form 10-Q, as well as our subsequent filings with the Securities and Exchange Commission. Any forward-looking statement speaks only as of the date on which it was made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

OUR MISSION



1 TRAILBLAZING SCIENCE

Our creative and thoughtful foundation



2 “GO-TO” MEDICINES

Our challenge to the status quo



3 SINGULAR FOCUS IN OPHTHALMOLOGY

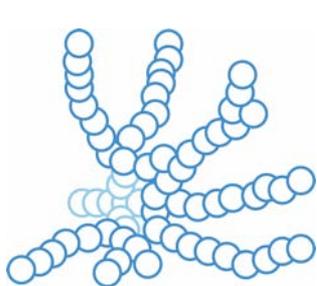
Our 24 / 7 / 365

ABC PLATFORM™

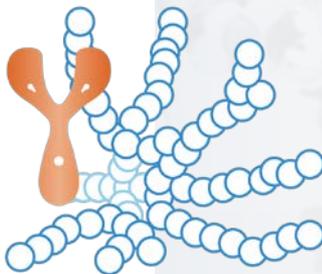
A new scientific approach and design platform for intravitreal medicines



+
stable
linkage



=



ANTIBODY

IgG1 with inert immune effector function

BIOPOLYMER

Optically clear, high molecular weight phosphorylcholine polymer

CONJUGATE

Antibody and biopolymer covalently bound via single site-specific linkage

Kodiak has designed ophthalmic antibody biopolymer conjugates for increased durability and efficacy.

SAME WHERE IT MATTERS

- Clinically proven targets
- Antibody-based biologic
- Intravitreal: safest method of administration
- Optically clear, no residues
- Fast and potent clinical responses

DIFFERENT WHERE IT COUNTS

- Designed-in ocular durability
- Designed-in rapid systemic clearance
- Improved bioavailability
- Improved biocompatibility
- Improved stability

KSI-301+

A PIPELINE OF ABCs FOR RETINA

—

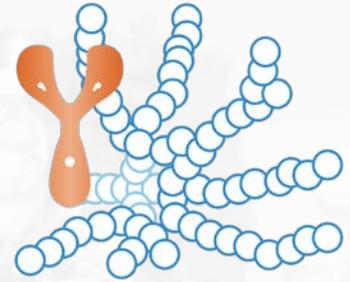
Kodiak's deepening pipeline of mono-, bi-specific and triplet inhibitors that merge biologics with small molecules to address major causes of vision loss beyond retinal vascular disease.

MONOSPECIFIC

1 Molecule, **1 Target**

Antibody conjugated to phosphorylcholine biopolymer

KSI-301 inhibits VEGF—
In clinical development



BISPECIFIC

1 Molecule, **2 Targets**

Bispecific antibody conjugated to phosphorylcholine biopolymer

KSI-501 inhibits VEGF and IL-6 for retinal diseases with inflammatory component—In GMP manufacturing

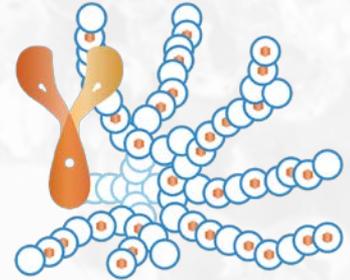


TRIPLET

1 Molecule, **3 Targets**

Bispecific antibody conjugated to phosphorylcholine biopolymer embedded with 100's of copies of small-molecule drug

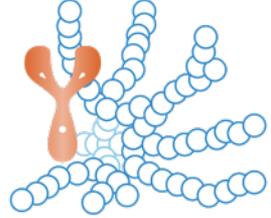
For high-prevalence multifactorial diseases, such as dry AMD and glaucoma—In research



Go Bigger to Last Longer

KSI-301: ABC designed to block all VEGF-A Isoforms

	Brolucizumab	Ranibizumab	Bevacizumab	Aflibercept
Molecule type	Single-chain antibody fragment	Antibody fragment	Antibody	Recombinant fusion protein
Molecular structure				
Molecular weight	26 kDa	48 kDa	149 kDa	115 kDa
Clinical dose	6 mg	0.3-0.5 mg	1.25 mg	2 mg
Equivalent molar dose	11	0.5	0.9	1
Equivalent ocular PK	< 0.7	0.7	1	1
Equivalent ocular concentration at 3 months	< 0.1	0.001	NA ¹	1

KSI-301
Antibody Biopolymer Conjugate (ABC)

950 kDa
5 mg (by weight of antibody)
3.5
3
1,000

Equivalent values are shown as (approximate) fold difference relative to aflibercept. kDa= kilodalton

1. Lower affinity of bevacizumab precludes a useful comparison

We are developing KSI-301 to have a **meaningfully differentiated** profile in the 4 major retinal vascular disease

Wet AMD

CURRENT BEST

Aflibercept
once every 2 months¹
after 3 monthly loading doses

Brolucizumab
once every 2 – 3 months²
after 3 monthly loading doses

—

KODIAK PIVOTAL STUDY DESIGN

KSI-301
once every 3, 4 or 5 months
after 3 monthly loading doses

Diabetic Macular Edema

CURRENT BEST

Aflibercept
once every 2 months¹
after 5 monthly doses

—

KODIAK PIVOTAL STUDY DESIGN

KSI-301
once every 3, 4, 5 or 6 months
after 3 monthly loading doses

Retinal Vein Occlusion

CURRENT BEST

Aflibercept
once every month¹

—

KODIAK PIVOTAL STUDY DESIGN

KSI-301
once every 2 months or longer
after 2 monthly loading doses

Non-Proliferative Diabetic Retinopathy

CURRENT BEST

Aflibercept
once every 2 months¹
after 5 monthly doses

—

KODIAK PIVOTAL STUDY DESIGN

KSI-301
once every 3, 4 or 6 months
no loading doses

Study Now Recruiting

1. Source: Aflibercept US Prescribing Information as of August 2019
2. Source: Brolucizumab US Prescribing Information as of October 2019

OUR 2022 VISION

WET AMD

2021 DAZZLE top-line data
2022 supplemental BLA



RETINAL VEIN OCCLUSION

2021 BRVO top-line data
2021 CRVO topline data
2022 BLA filing
2022 Potential U.S. approval

2022

THE OPHTHALMOLOGY
MEDICINES COMPANY



DIABETIC RETINOPATHY

2020 Phase 3 Start

DIABETIC MACULAR EDEMA

2022 Phase 3 top-line data
2022 supplemental BLA



KSI-501 anti-VEGF/IL-6

2021 IND submitted
2022 Phase 1a/1b data

1

Marketed product
(RVO)

1

Supplemental BLA
(wAMD, DME)

3

Clinical
molecules

1

IND per year
beginning 2021

PROGRAM ACCELERATION

Potential milestones

2019

KSI-301

- ✓ Safety, efficacy
- ✓ Durability proof-of-concept established
- ✓ Initiation of DAZZLE wAMD pivotal

2020

KSI-301

- Quarterly readouts of Phase 1b data
- Initiate RVO Phase 3 trials
- Initiate DME Phase 3 trial
- Initiate DR Phase 3 trial
- Optional DAZZLE interim: % patients on 3, 4, 5 month dosing

2021

KSI-301

- Three pivotal study readouts:
 - CRVO
 - BRVO
 - DAZZLE wAMD
- Optional DME Ph3 interim: % patients on 3,4,5,6 month dosing

KSI-501

- Submit IND

2022

KSI-301

- Submit BLA for RVO with potential U.S. approval
- DME pivotal study readout
- Submit sBLA for wAMD and DME
- DR pivotal study readout

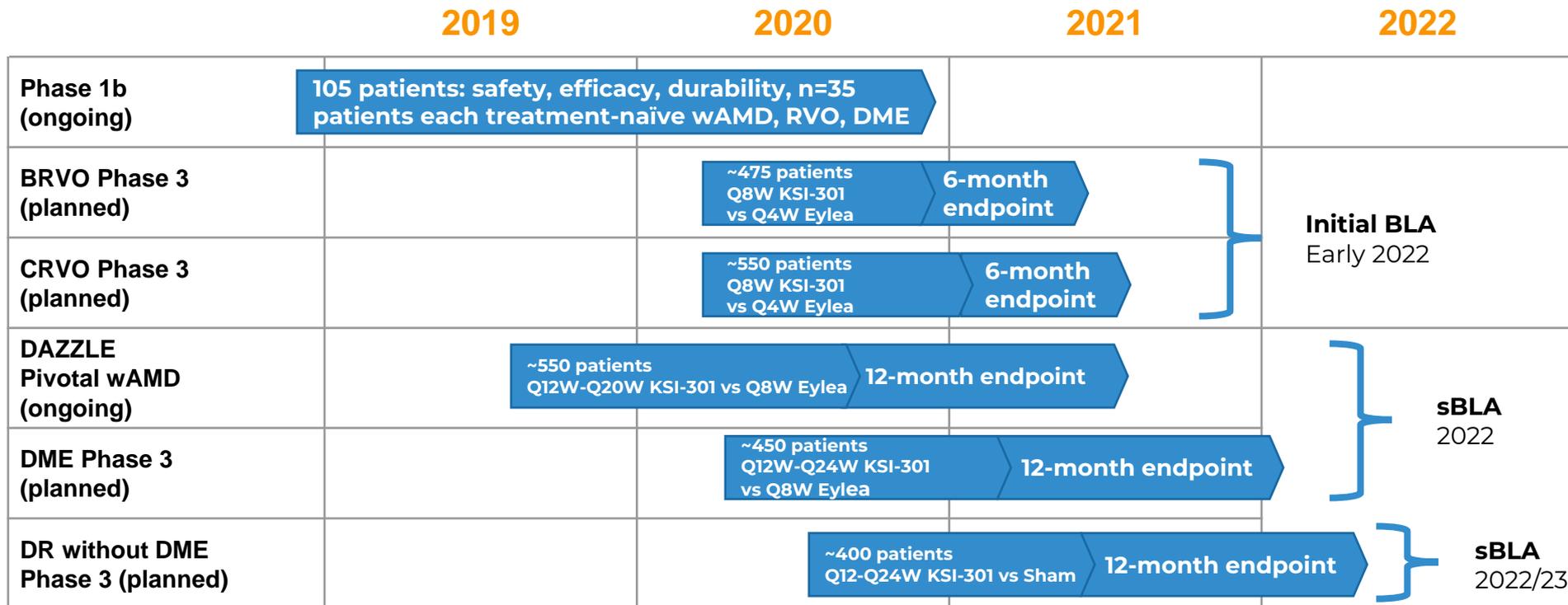
KSI-501

- Phase 1a/1b data in inflammatory retinal diseases

Additional ABC

- Submit IND

Clinical and Regulatory Timelines



BLA: biologics license application; sBLA: supplemental BLA; RVO: retinal vein occlusion; BRVO: branch RVO; CRVO: central RVO; wAMD: wet age-related macular degeneration; DME: diabetic macular edema; DR: diabetic retinopathy

PHASE 1B UPDATE

KSI-301 Phase 1b Study Design

insight into durability among treatment naïve subjects

Randomized, open label study to evaluate multidose safety, efficacy & durability (n=105)

wAMD (n=35)

DME (n=35)

RVO (n=35)

Randomized 1:3

KSI-301 2.5 mg (50 µL)

KSI-301 5 mg (100 µL)

Loading Phase

Durability Assessment Phase

Weeks:

0

4

8

12

16

20

24

28

32

36



Fixed Treatment

Re-Treatment As Needed

Treatment Schedule:



KSI-301 Phase 1b Retreatment Criteria

prespecified by disease state

■ wAMD

- Increase in CST ≥ 75 μm with a decrease in BCVA of ≥ 5 letters compared to Week 12, *OR*
- Decrease in BCVA of > 5 letters compared to Day 1, due to worsening wAMD activity, *OR*
- Decrease in BCVA of ≥ 10 letters compared to the best prior BCVA, due to worsening wAMD activity, *OR*
- 6 months has elapsed since the last retreatment

■ DME and RVO

- Increase in CST ≥ 75 μm with a decrease in BCVA of ≥ 5 letters compared to Week 12 or the prior visit, *OR*
- Decrease in BCVA of ≥ 10 letters compared to the best prior BCVA, due to worsening DME/RVO disease activity

For all subjects, investigators can retreat at their discretion if significant disease activity is present that does not meet the above criteria

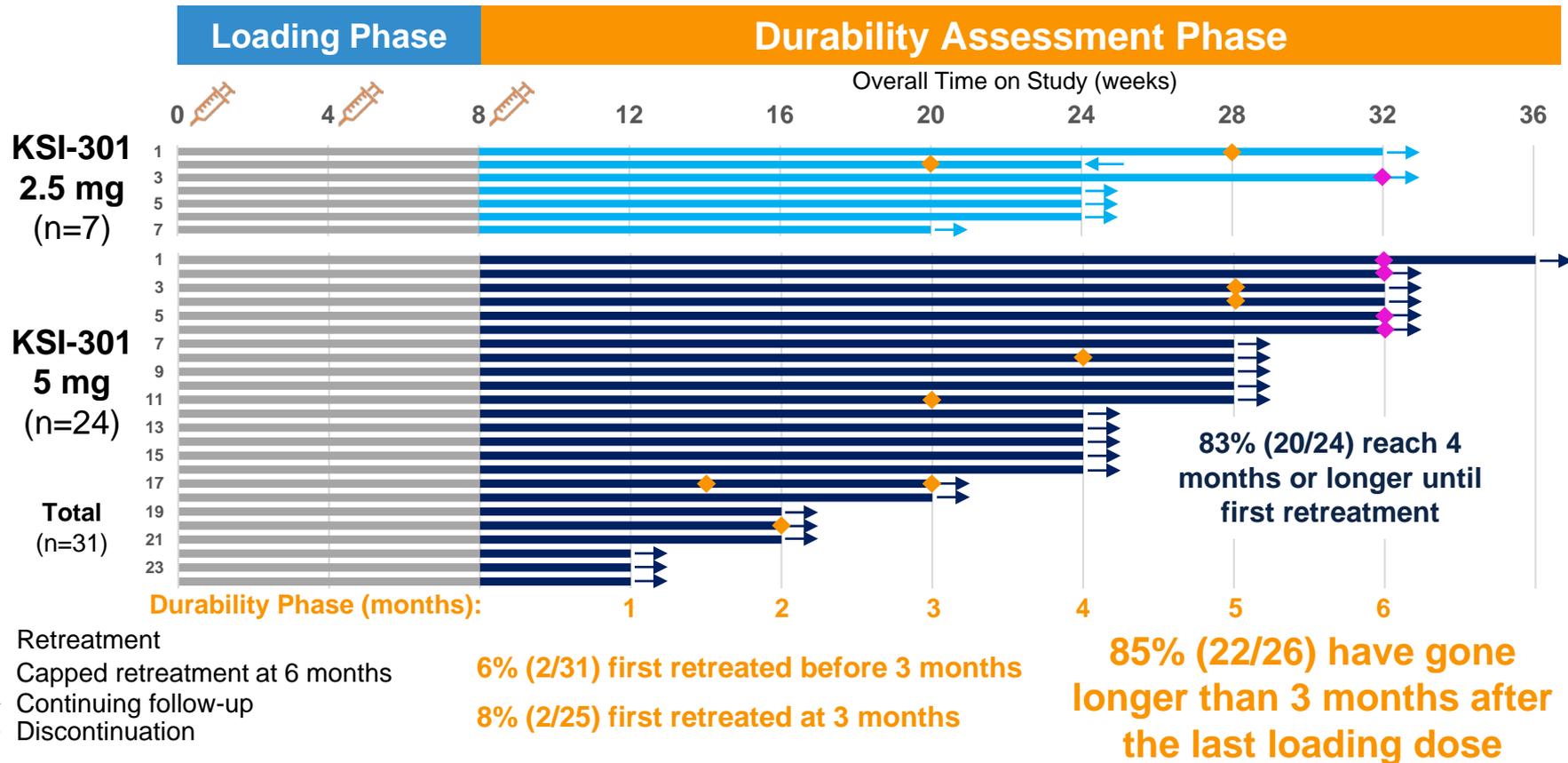
KSI-301 Phase 1b Baseline Characteristics

Variable	wAMD Cohort (n=35)	DME Cohort (n=34)	RVO Cohort (n=35)
Age, mean (SD), years	77.2 (11.0)	60.7 (10.4)	63.6 (12.6)
Gender, n (%), female	25 (71.4)	13 (38.2)	13 (37.1)
Race, n (%), White	32 (91.4)	28 (82.4)	31 (88.6)
BCVA, mean (SD), ETDRS letters	64.5 (11.1)	66.8 (10.3)	54.9 (15.4)
BCVA, Snellen 20/40 or better, n (%)	14 (40.0)	16 (47.1)	6 (17.1)
OCT CST, mean (SD), microns	426 (176)	449 (109)	675 (237)

WET AMD

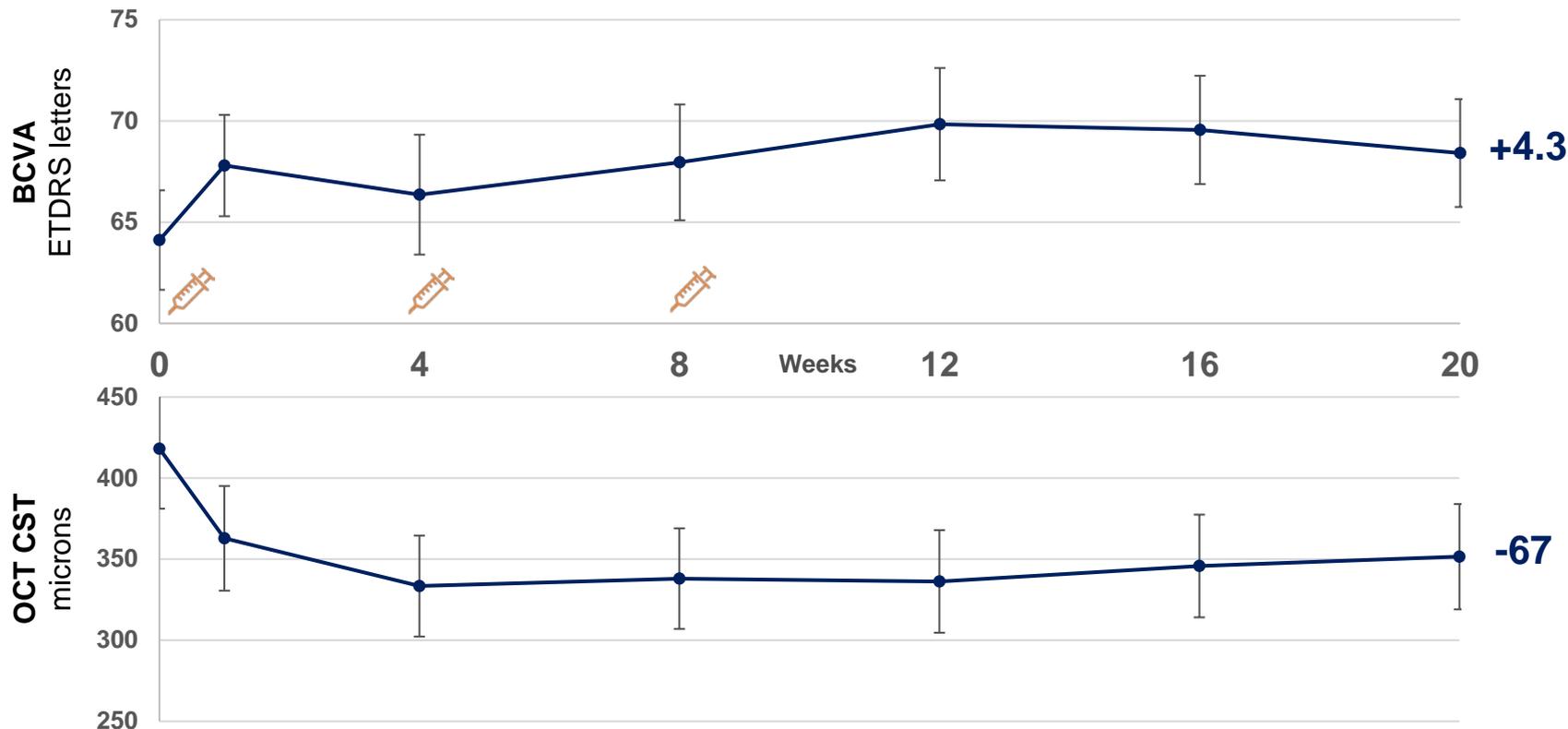
KSI-301 in wAMD: Durability Assessment

Emerging data support 3 to 5+ month durability



Efficacy of KSI-301 in Wet AMD

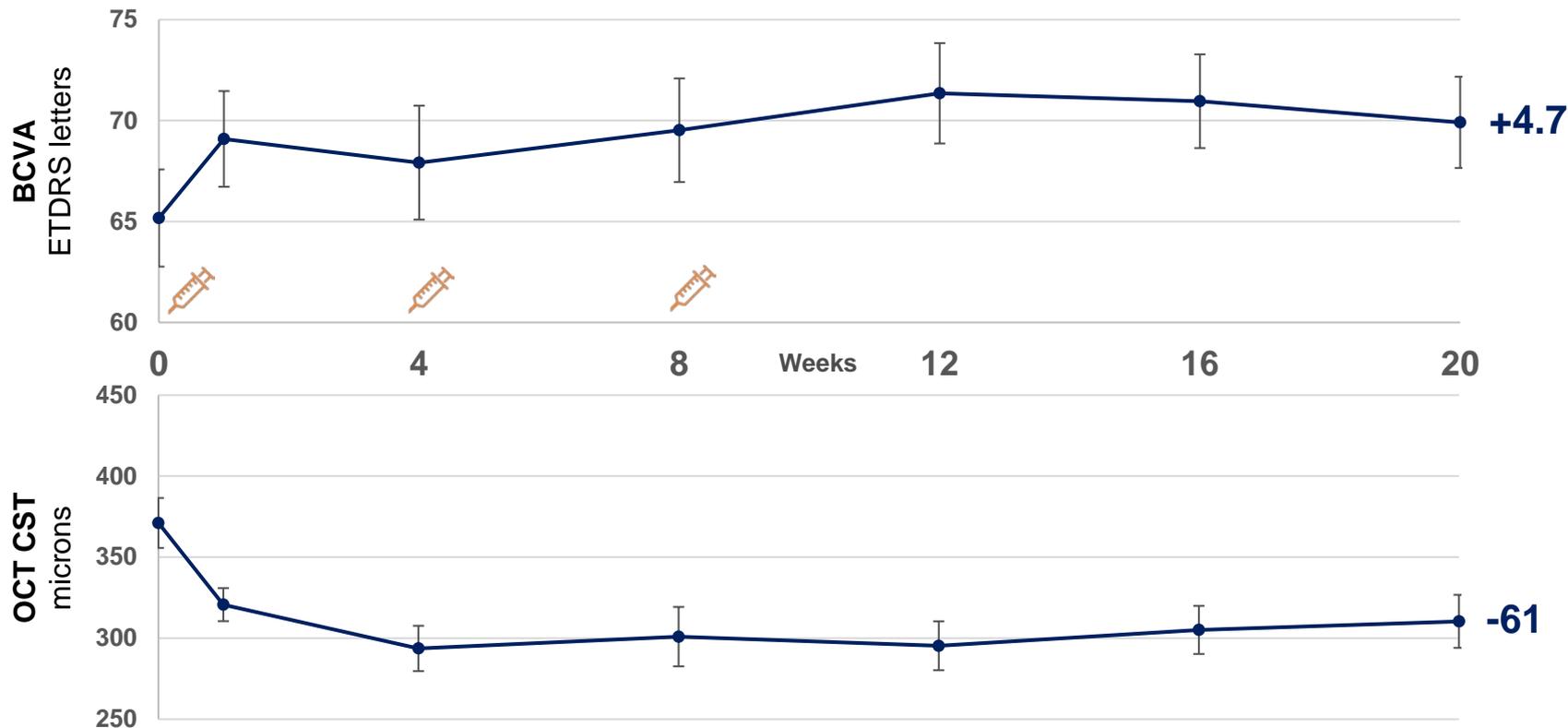
change from baseline to week 20 in mean BCVA & OCT



Interim data. Includes only randomized patients that reached Week 20 visit by the data cutoff date of 8 Nov 2019; 2.5 & 5 mg doses pooled. Error bars represent standard error of the mean. OCT CST values are site reported. BCVA= best corrected visual acuity; OCT= optical coherence tomography; CST= central subfield thickness

n= 25 Patients reaching Week 20 visit by data cutoff

Efficacy of KSI-301 in Wet AMD in 23/25 subjects without high PEDs change from baseline to week 20 in mean BCVA & OCT

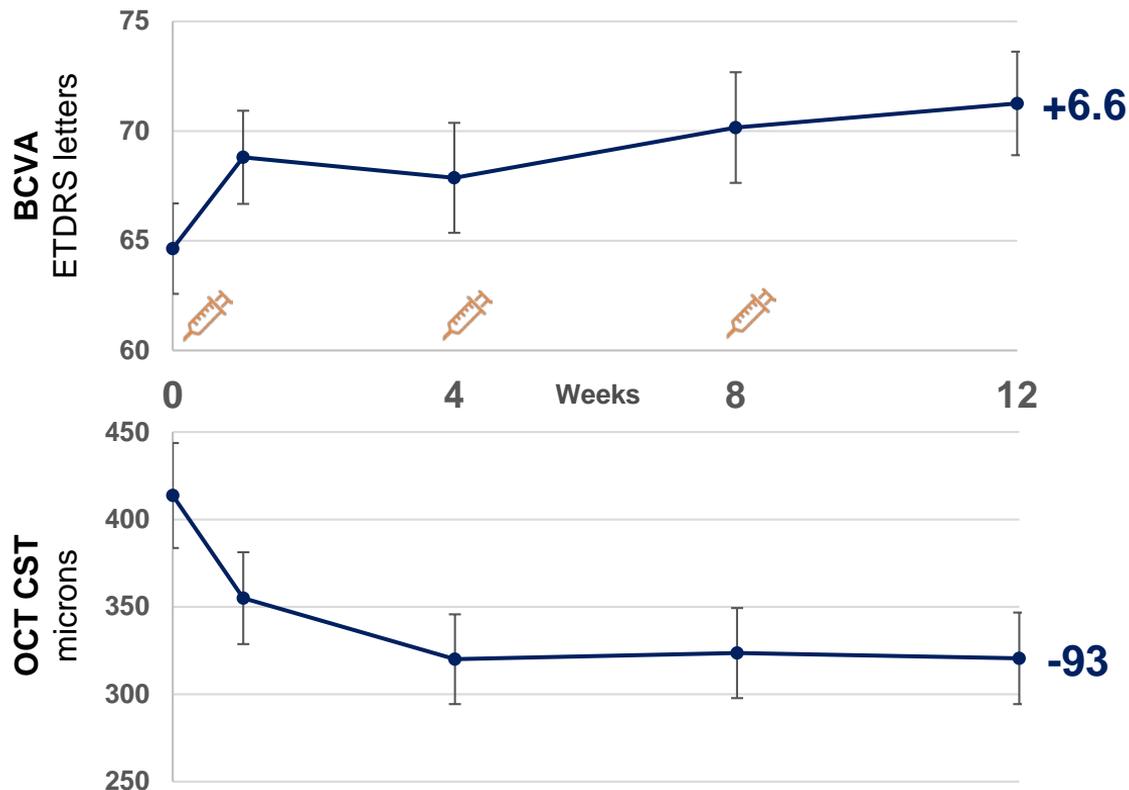


Interim data. Includes only randomized patients that reached Week 20 visit by the data cutoff date of 8 Nov 2019; 2.5 & 5 mg doses pooled. Error bars represent standard error of the mean. OCT CST values are site reported. BCVA= best corrected visual acuity; OCT= optical coherence tomography; CST= central subfield thickness. High PED defined as presence of a PED with baseline CST \geq 500 microns.

n= 23 Patients without high PEDs reaching Week 20 visit by data cutoff

Efficacy of KSI-301 in Wet AMD

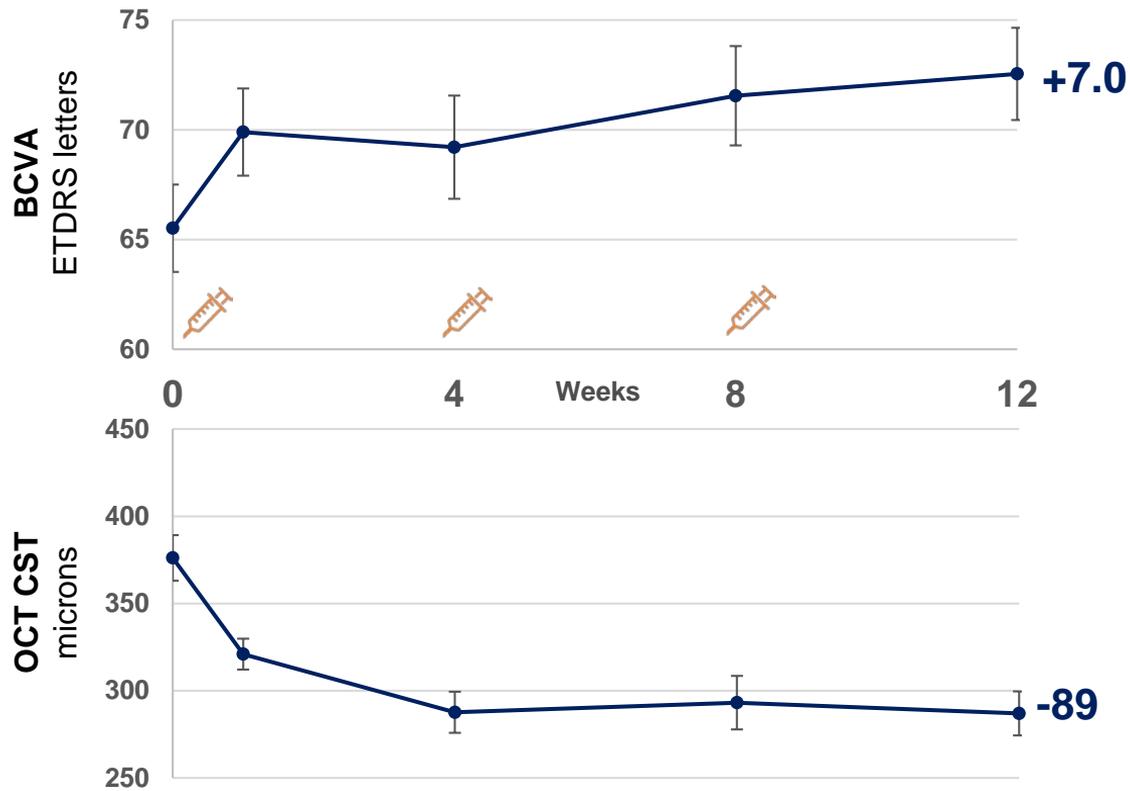
change from baseline to week 12 in mean BCVA & OCT



n= 31 Patients reaching Week 12 visit by data cutoff

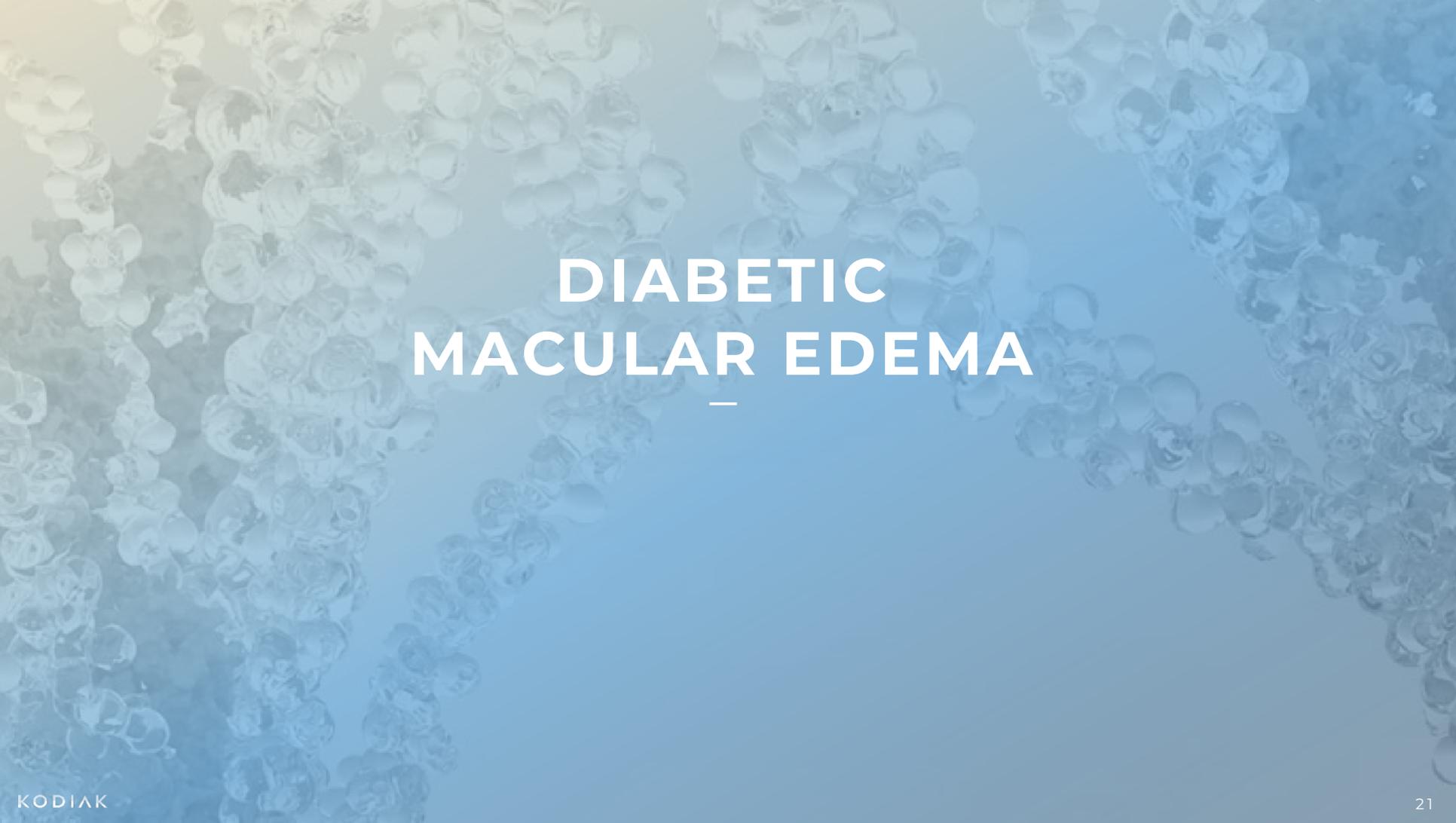
Interim data. Includes only randomized patients that reached Week 12 visit by the data cutoff date of 8 Nov 2019; 2.5 & 5 mg doses pooled. Error bars represent standard error of the mean. OCT CST values are site reported. BCVA= best corrected visual acuity; OCT= optical coherence tomography; CST= central subfield thickness

Efficacy of KSI-301 in Wet AMD in 29/31 subjects without high PEDs change from baseline to week 12 in mean BCVA & OCT



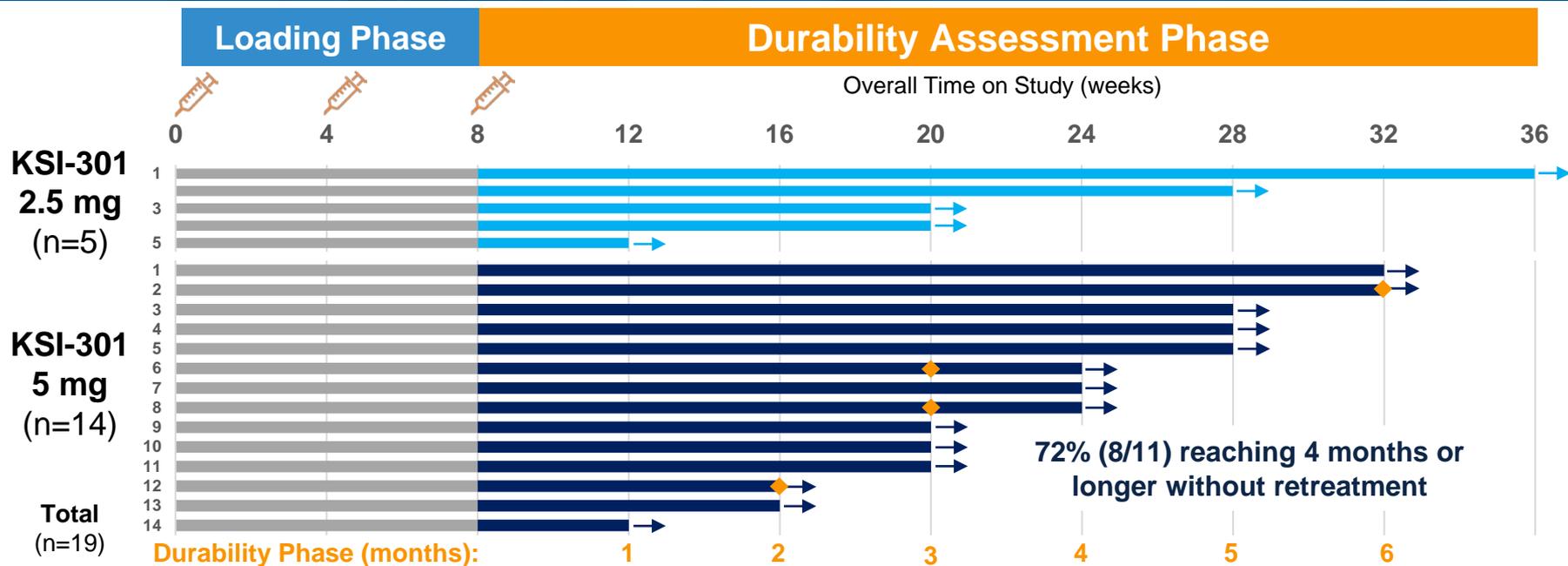
n= 29 Patients without high PEDs reaching Week 12 visit by data cutoff

Interim data. Includes only randomized patients that reached Week 12 visit by the data cutoff date of 8 Nov 2019; 2.5 & 5 mg doses pooled. Error bars represent standard error of the mean. OCT CST values are site reported. BCVA= best corrected visual acuity; OCT= optical coherence tomography; CST= central subfield thickness. High PED defined as presence of a PED with baseline CST ≥500 microns.



DIABETIC MACULAR EDEMA

KSI-301 in DME: 3 loading doses can provide sustained disease control of 3 months or longer



One patient has been retreated before 3 months

13% (2/15) retreated at 3 months

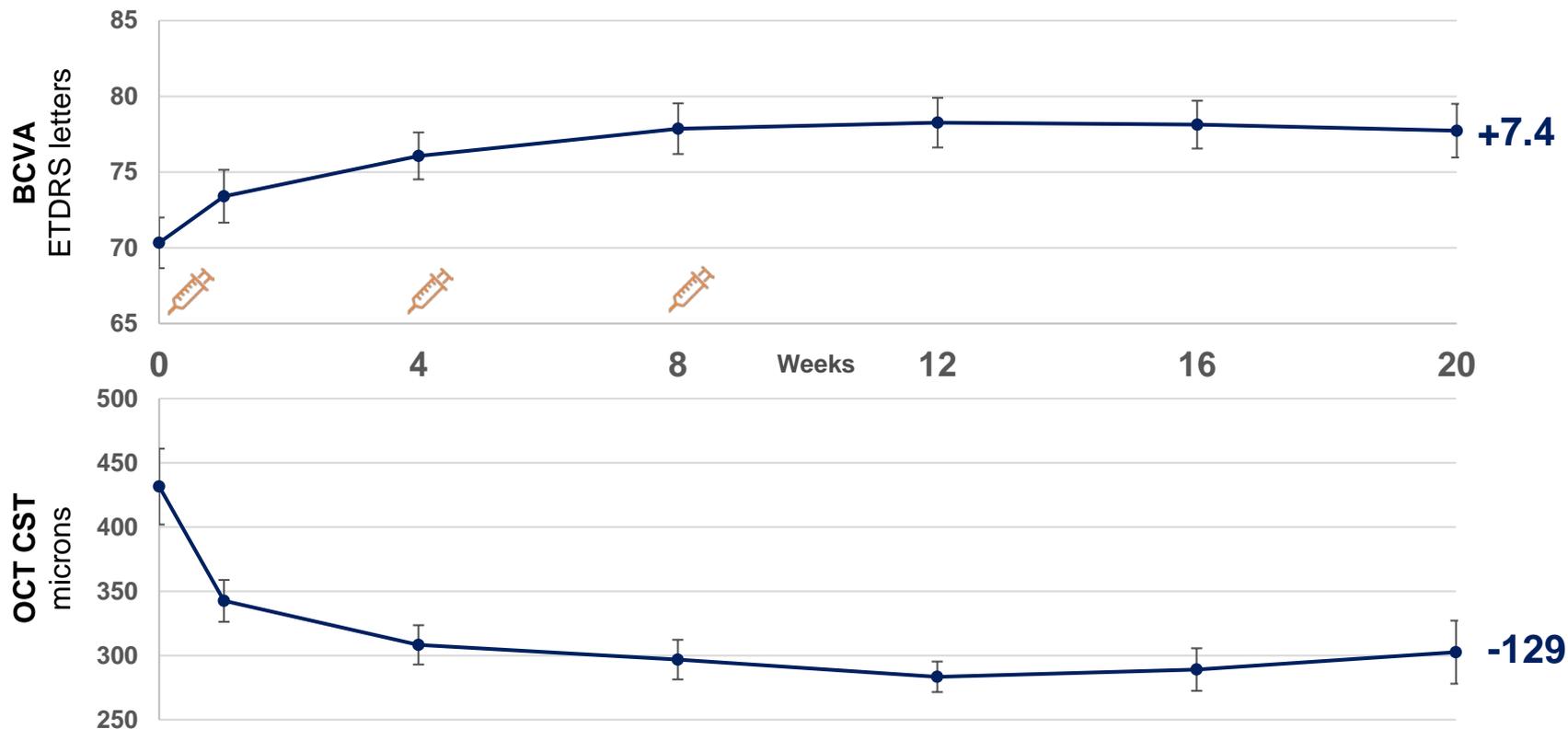
81% (13/16) have gone longer than 3 months after the last loading dose

- ◆ Retreatment with KSI-301
- Continuing follow-up

Interim data. Includes only randomized patients that reached the first retreatment opportunity (Week 12 visit) by the data cutoff date of 8 Nov 2019. Each bar represents an individual patient. All depicted patients continue to be followed (no discontinuations)

Efficacy of KSI-301 in DME

change from baseline to week 20 in mean BCVA & OCT

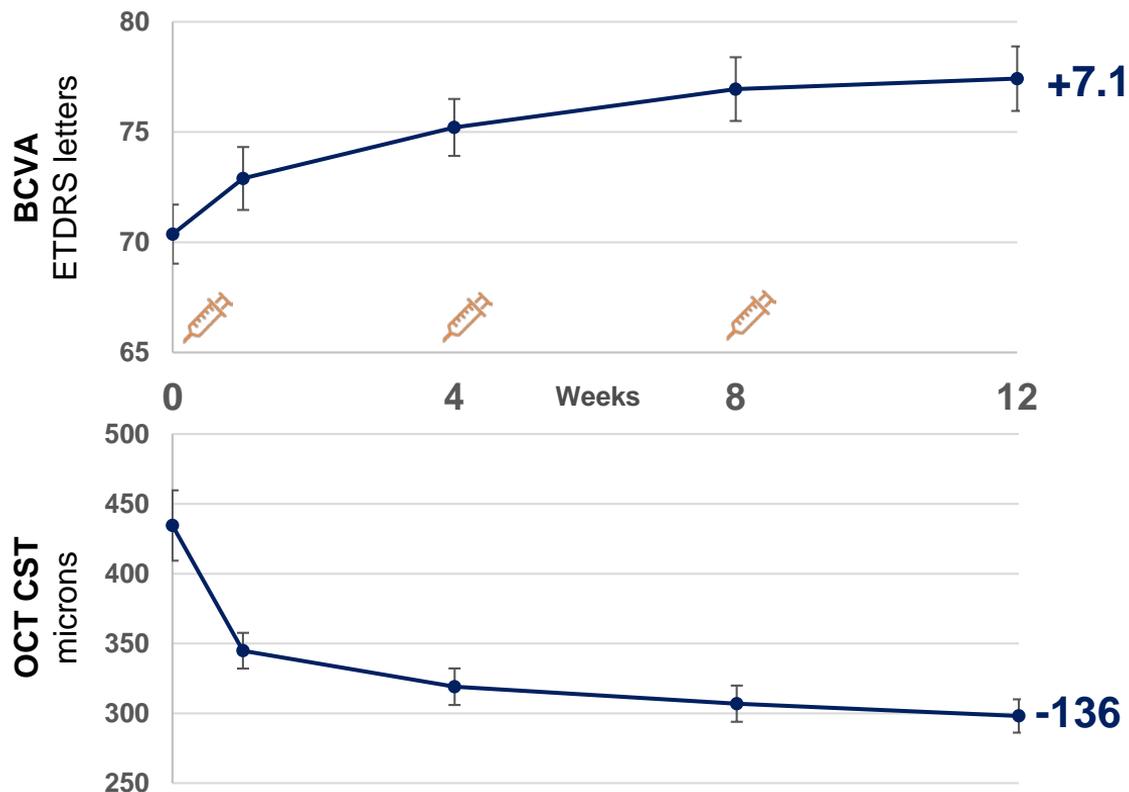


n= 15 Patients reaching Week 20 visit by data cutoff

Interim data. Includes only randomized patients that reached Week 20 visit by the data cutoff date of 8 Nov 2019; 2.5 & 5 mg doses pooled. Error bars represent standard error of the mean. OCT CST values are site reported. BCVA= best corrected visual acuity; OCT= optical coherence tomography; CST= central subfield thickness

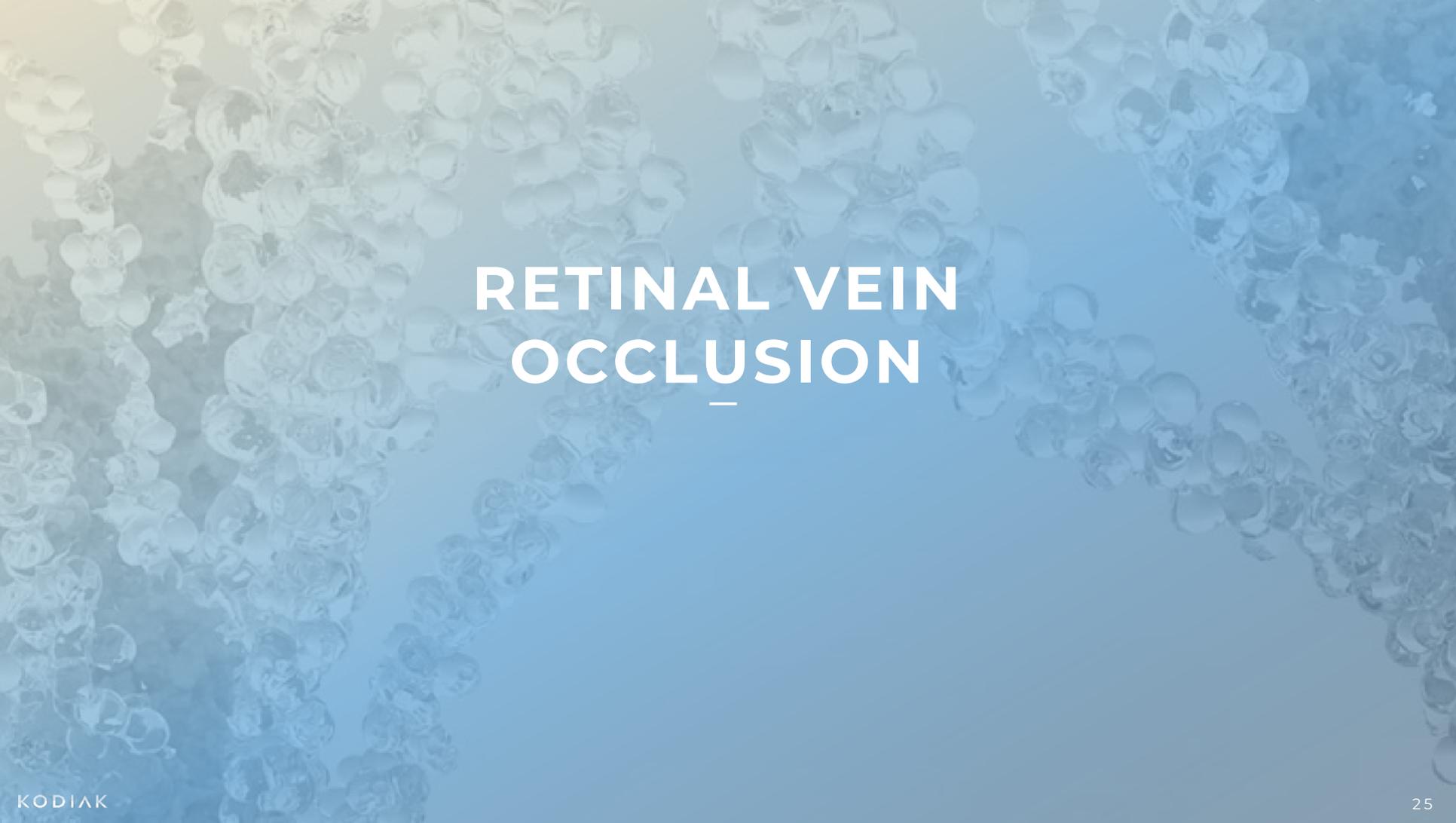
Efficacy of KSI-301 in DME

change from baseline to week 12 in mean BCVA & OCT



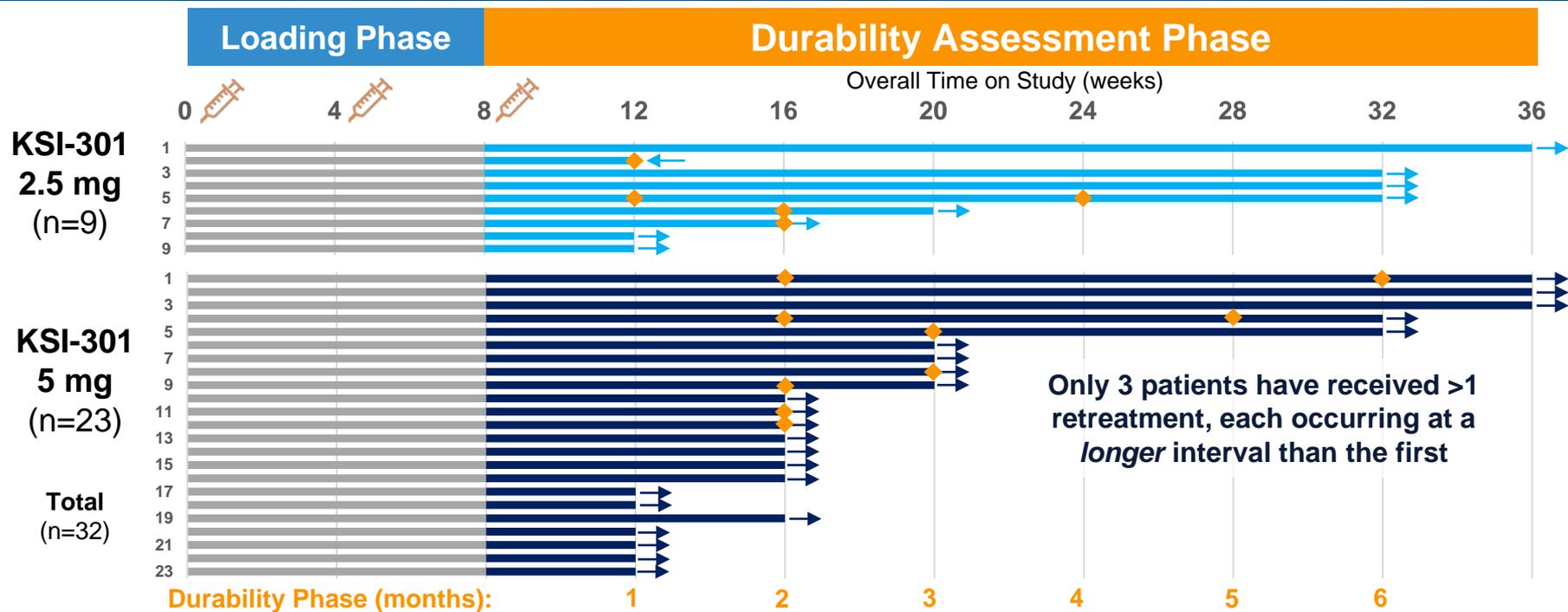
n= 19 Patients reaching Week 12 visit by data cutoff

Interim data. Includes only randomized patients that reached Week 12 visit by the data cutoff date of 8 Nov 2019; 2.5 & 5 mg doses pooled. Error bars represent standard error of the mean. OCT CST values are site reported. BCVA= best corrected visual acuity; OCT= optical coherence tomography; CST= central subfield thickness



RETINAL VEIN OCCLUSION

KSI-301 in RVO: *emerging durability data show potential for 2 to 3 month or longer dosing*



6% (2/32), 30% (7/23) & 14% (2/14) received first retreatment at 1, 2 & 3 months, respectively

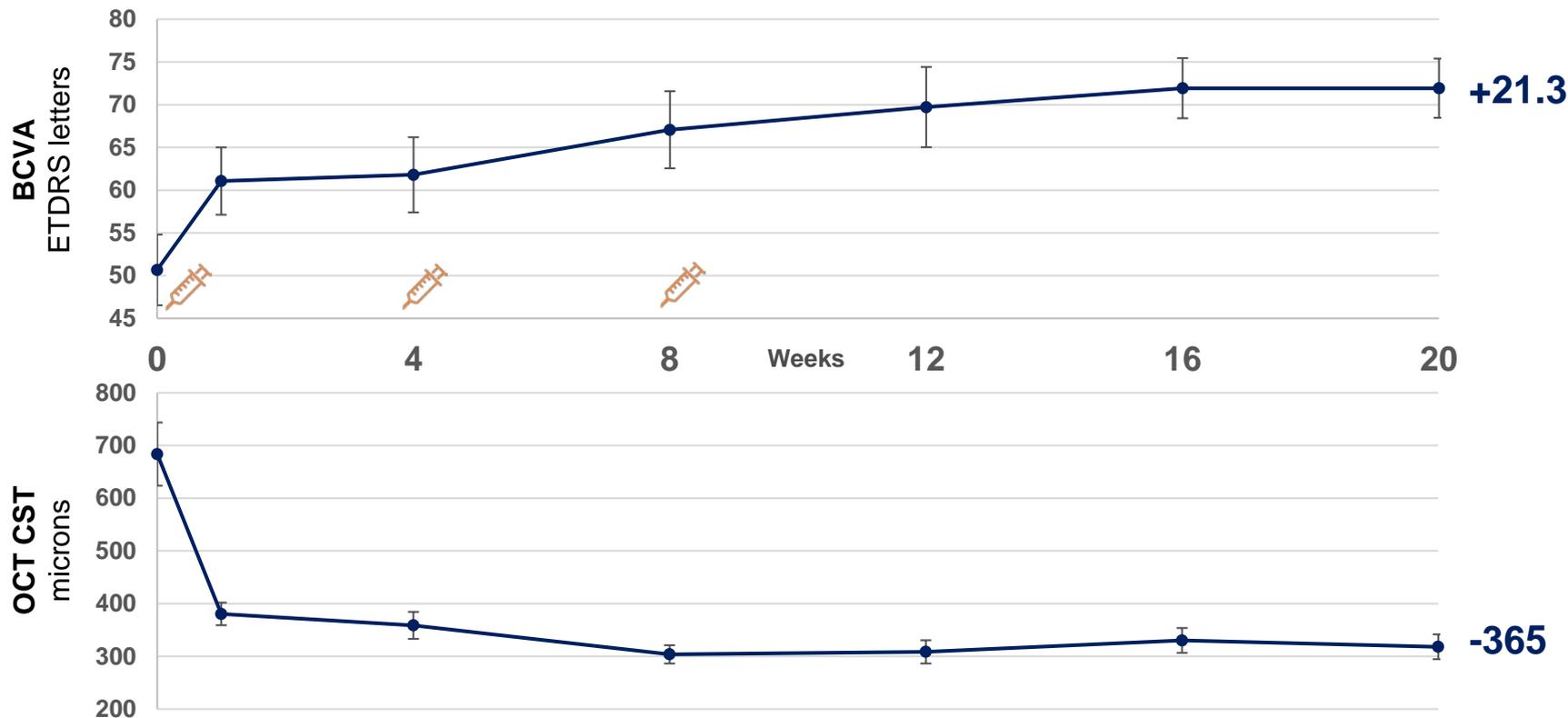
50% (9/18) have gone 3 months or longer after the last loading dose

- ◆ Retreatment
- Continuing follow-up
- ← Discontinuation

Interim data. Includes only randomized patients that reached the first retreatment opportunity (Week 12 visit) by the data cutoff date of 8 Nov 2019. Each bar represents an individual patient.

Efficacy of KSI-301 in RVO

change from baseline to week 20 in mean BCVA & OCT

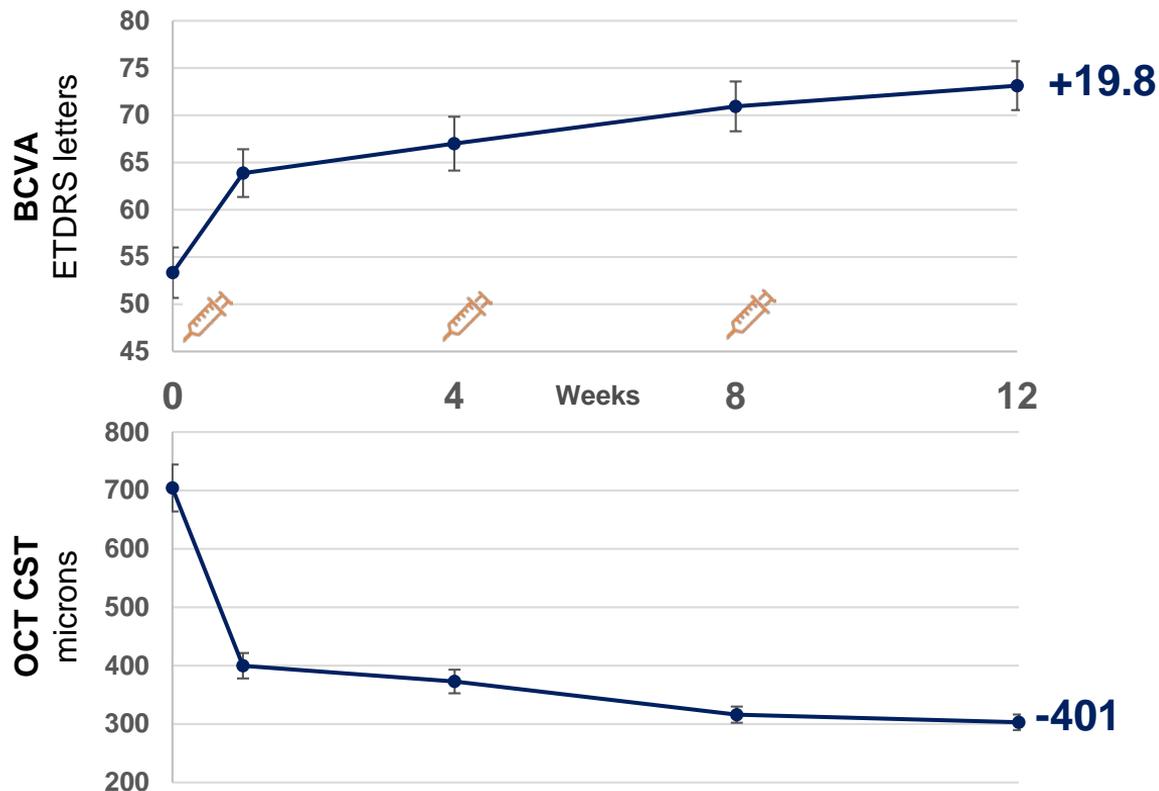


Interim data. Includes only randomized patients that reached Week 20 visit by the data cutoff date of 8 Nov 2019; 2.5 & 5 mg doses pooled. Datapoints include one subject that discontinued after Week 12. Error bars represent standard error of the mean. OCT CST values are site reported. BCVA= best corrected visual acuity; OCT= optical coherence tomography; CST= central subfield thickness

n= 15 Patients reaching Week 20 visit by data cutoff

Efficacy of KSI-301 in RVO

change from baseline to week 12 in mean BCVA & OCT



Interim data. Includes only randomized patients that reached Week 12 visit by the data cutoff date of 8 Nov 2019; 2.5 & 5 mg doses pooled. Error bars represent standard error of the mean. OCT CST values are site reported. BCVA= best corrected visual acuity; OCT= optical coherence tomography; CST= central subfield thickness

n= 32 Patients reaching Week 12 visit by data cutoff

SAFETY

Safety of KSI-301: *multiple-dose exposure is well-tolerated with no intraocular inflammation*

116

**Subjects dosed
in Phase 1a+1b**

338

**Total doses given
in Phase 1a+1b**



107

At Day 1



103

At Week 4



96

At Week 8

Phase 1b subjects with # of loading doses received

- No intraocular inflammation or ocular SAEs in the study eye reported to date
- No drug-related AEs or drug-related SAEs reported to date
- Most AEs were assessed as mild and are consistent with profile of intravitreal anti-VEGFs
- 12 non-ocular SAEs that were not drug-related have been reported in 7 subjects:
 - One 92 y/o RVO subject with hospitalization related to a pre-existing condition that resulted in death
 - Three (43, 56 and 62 y/o, respectively) DME subjects with hospitalization related to a pre-existing condition
 - One 66 y/o RVO subject with hospitalization related to dizziness
 - One 43 y/o RVO subject with a broken leg related to a motorcycle accident
 - One 85 y/o RVO subject with hospitalization related to a pre-existing condition



CONCLUSIONS Q&A

KODIAK SCIENCES

3Q19 BUSINESS HIGHLIGHTS



Initiated recruitment in our pivotal 'DAZZLE' clinical trial of KSI-301 in patients with treatment naïve wet AMD



Presented promising clinical safety, efficacy, and durability data from the ongoing Phase 1b study



Announced an accelerated development and registration strategy for KSI-301



Completed a End of Phase 2 meeting with FDA where we discussed and agreed on recommended clinical, non-clinical, and manufacturing activities to support licensure, including the number of clinical trials



Provided clarity on a capital efficient "2022 Vision" towards an initial FDA approval of KSI-301 in 2022 for RVO and supplemental BLA submissions in 2022 for wet AMD, DME and potentially DR without DME.

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