LIGHTSITE IIIB Topline Results: Open-label, Prospective, Multi-center Extension of the LIGHTSITE III Dry AMD Trial Using the Valeda Light Delivery System

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LumiThera®

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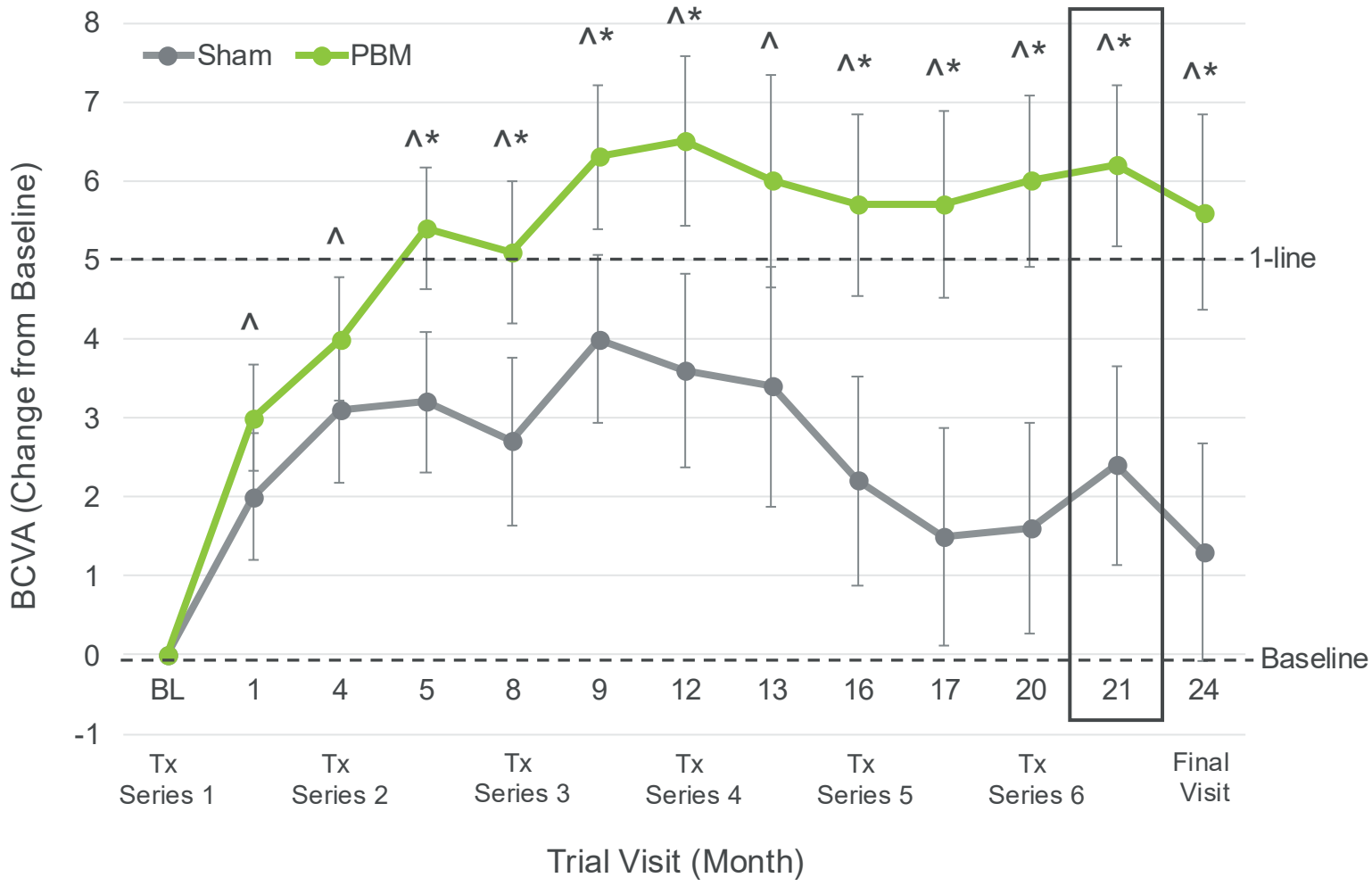
LIGHTSITE III: Primary BCVA Efficacy Endpoint Met

Valeda Improves Vision

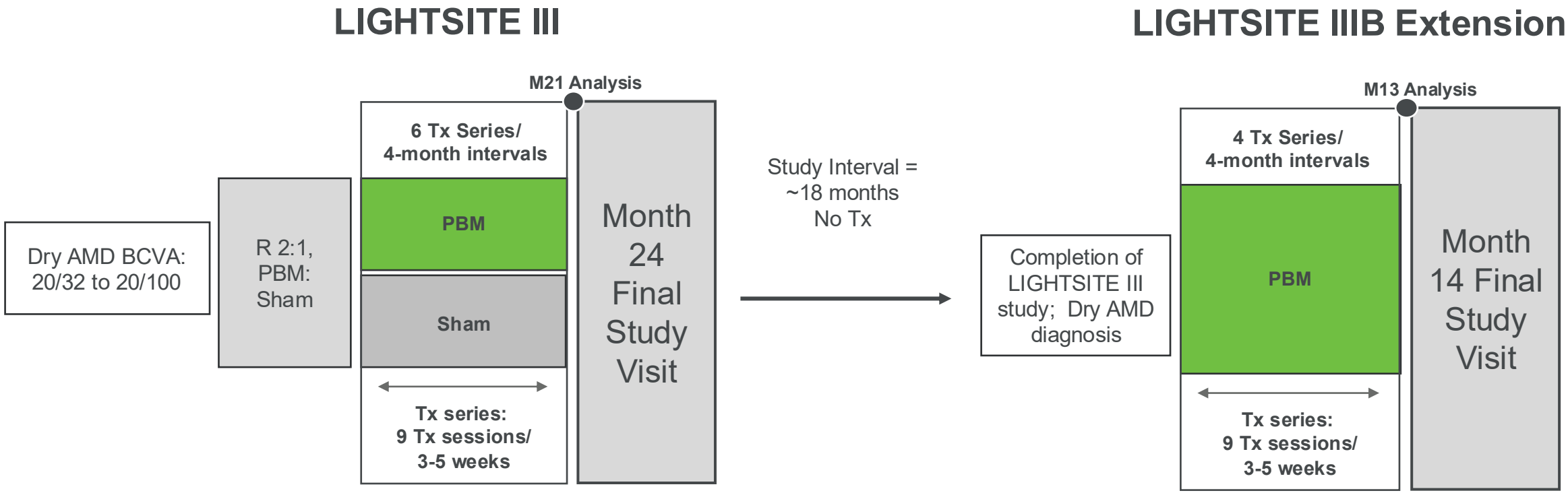
- The trial met the predetermined primary efficacy BCVA endpoint at Month 21 (p = 0.0036) with a gain of 6.2 letters in the PBM group (mean letter difference of 3.8 letters between Tx groups)
- A mean letter gain of 5.6 letters in the PBM group was maintained at Month 24 (mean letter difference of 4.3 letters between Tx groups, p = 0.0024)



LS mean presented with multiple imputation. *, p < 0.05 between groups; ^, p<0.0001 within group.

LIGHTSITE IIIB: Clinical Trial Design

An open-label, prospective, multi-center extension study on the continued use of PBM in subjects with dry AMD that participated in the CSP005 LIGHTSITE III study.



PBM Tx: 590, 660 and 850 nm

Sham: 10x and 100x reduction of 590 and 660 nm; Removal of 850 nm

Clinical and Safety Endpoints

- Best-corrected visual acuity (BCVA)
- New incident Geographic Atrophy (GA)
- Visual Function Questionnaire (VFQ-25) composite score and sub-categories
- Central drusen volume
- Ellipsoid zone atrophy
- GA lesion area growth
- Contrast sensitivity

Subject Demographics

	PBM (n=39) Mean (%)	Sham (n=15) Mean (%)	Total (n=63) Mean (%)
Diabetes	2 (5.1)	1 (6.7)	3 (4.7)
Hypertension	21 (53.8)	10 (66.7)	36 (57.1)
Smoker (History or Current User)	12 (30.7)	6 (40.0)	20 (31.8)
Family History of Dry AMD	25 (64.1)	6 (40.0)	35 (55.6)
Dry AMD Onset	9.5 years	9 years	9.3 years
Risk for Progression of Disease^	3.34 (SD 0.87)	3.47 (SD 0.92)	3.38 (SD 0.88)

^ *Modified Ferris scoring for disease progression risk*

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Study Population Characteristics

Total Eyes (subjects)	**63 eyes (36 subjects)**
LT3 Tx: PBM	39 eyes
LT3 Tx: Sham	15 eyes
LT3 Tx: Non-study	9 eyes
Days since last Tx, mean (SD)	604.2 (SD 137.2; Range, 350-834)
LT3 Tx: PBM	622.8 (SD 141.2; Range, 393-706)
LT3 Tx: Sham	555.7 (SD 116.8; Range, 350-834)
LT3B Mean BCVA Baseline	
LT3B PBM	74.8 (SD 10.1)
LT3B Sham	65.9 (SD 19.0)

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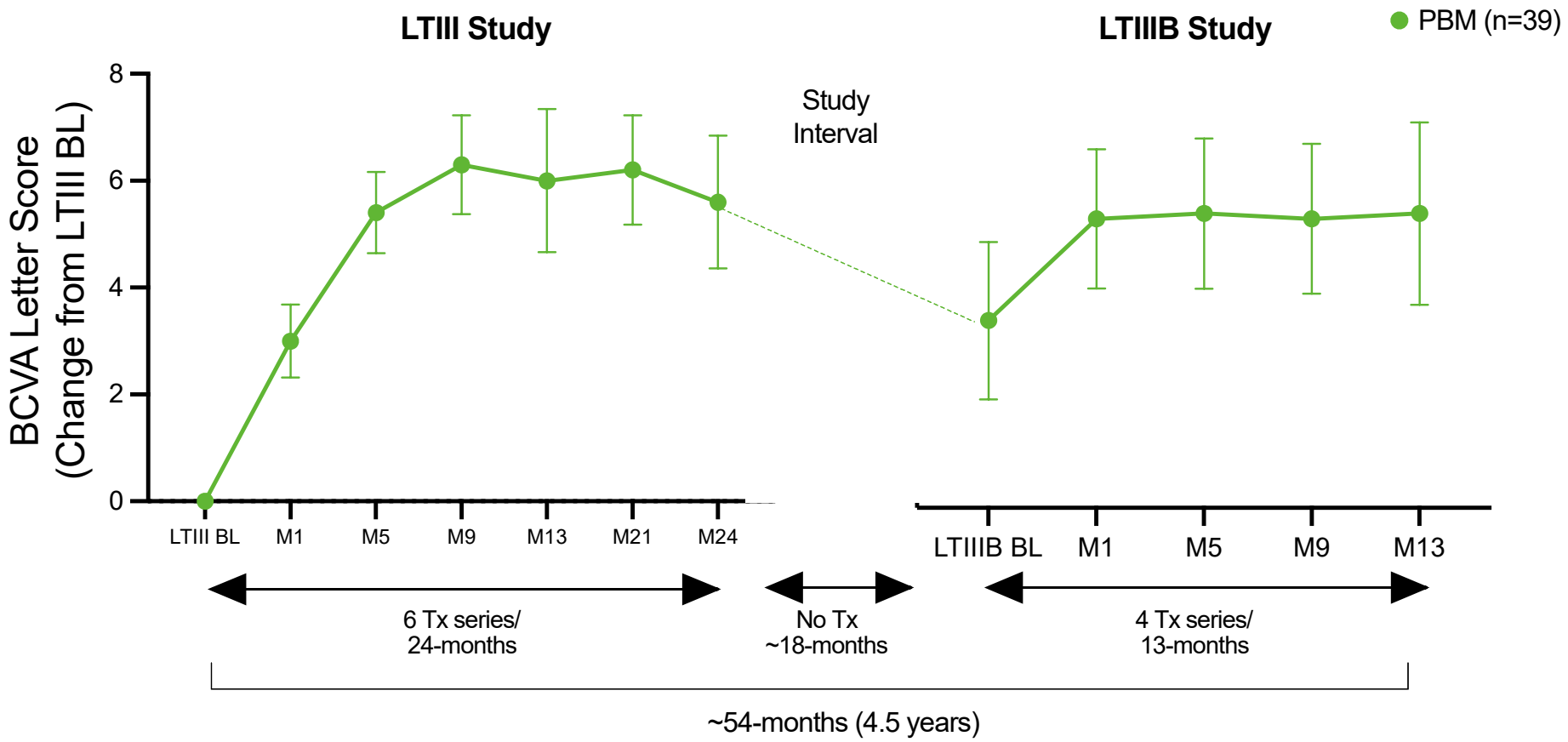
BCVA: Valeda Improves Vision for ~54 months (PBM Group Analysis)

LIGHTSITE III PBM Group

- Loss of 2.1 letters during ~18-month trial interval between LTIII and LTIIIB
- Restoration to >1-line gain following repeated PBM treatment delivered during LTIIIB

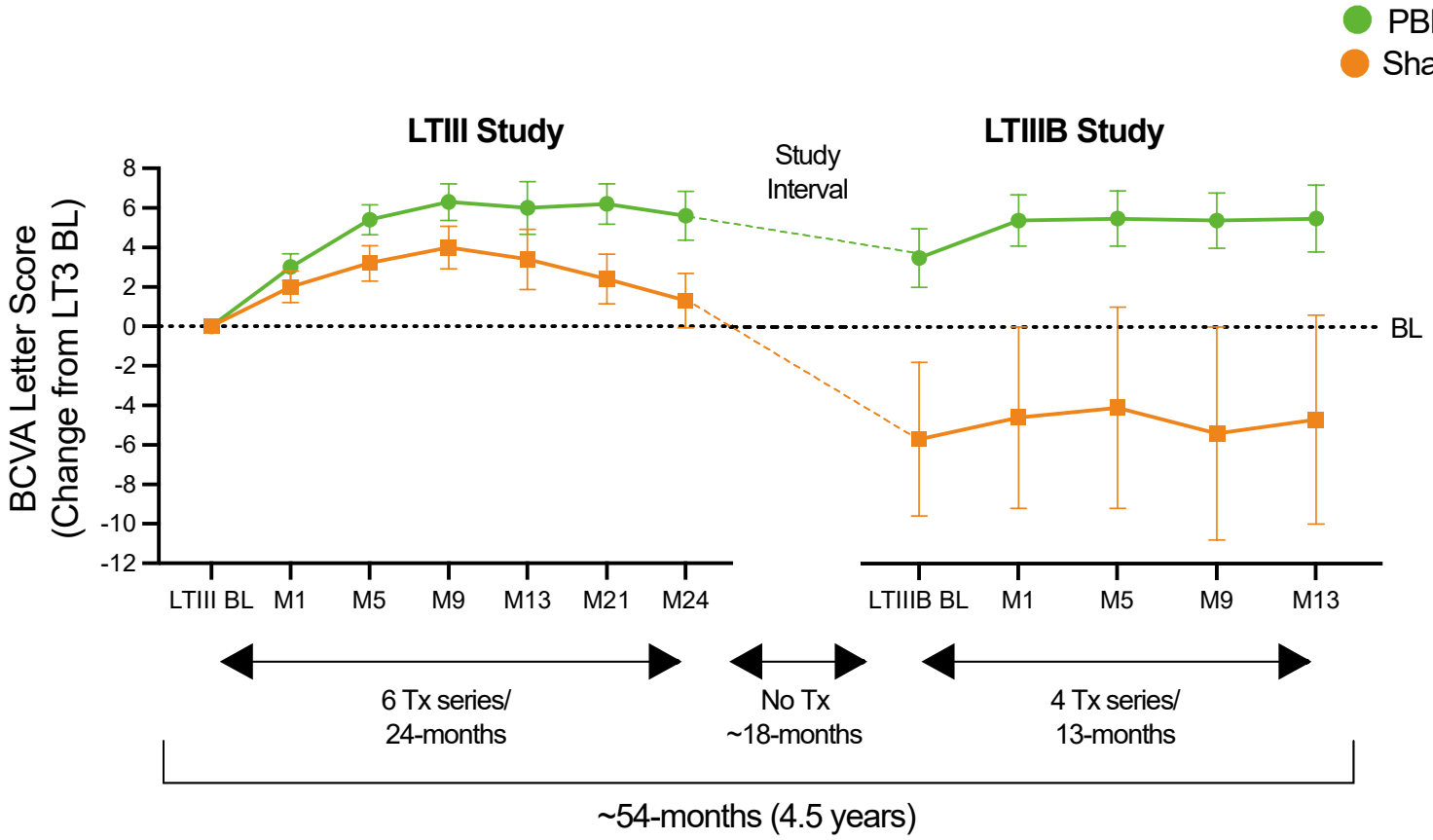


*LT3 data is the full dataset pulled from the final LS study results

BCVA: Valeda Improves Vision for ~54 months (PBM and Sham Group Analysis)

LIGHTSITE III Sham Group

- Loss of 5.7 letters during ~18-month study between LTIII and LTIIIB
- Minimal group effect on BCVA following PBM treatment delivered during LTIIIB

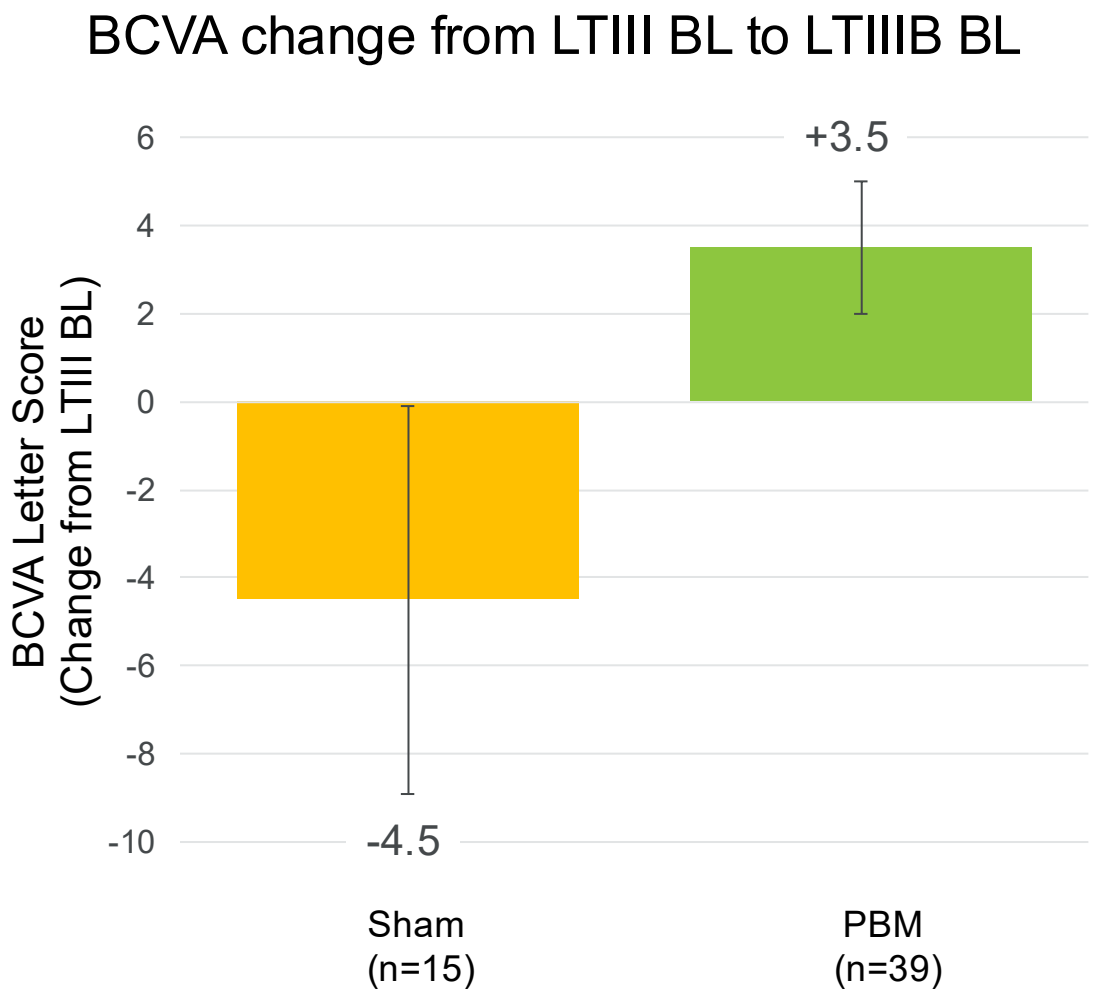


*LT3 data is the full dataset pulled from the final LS study results

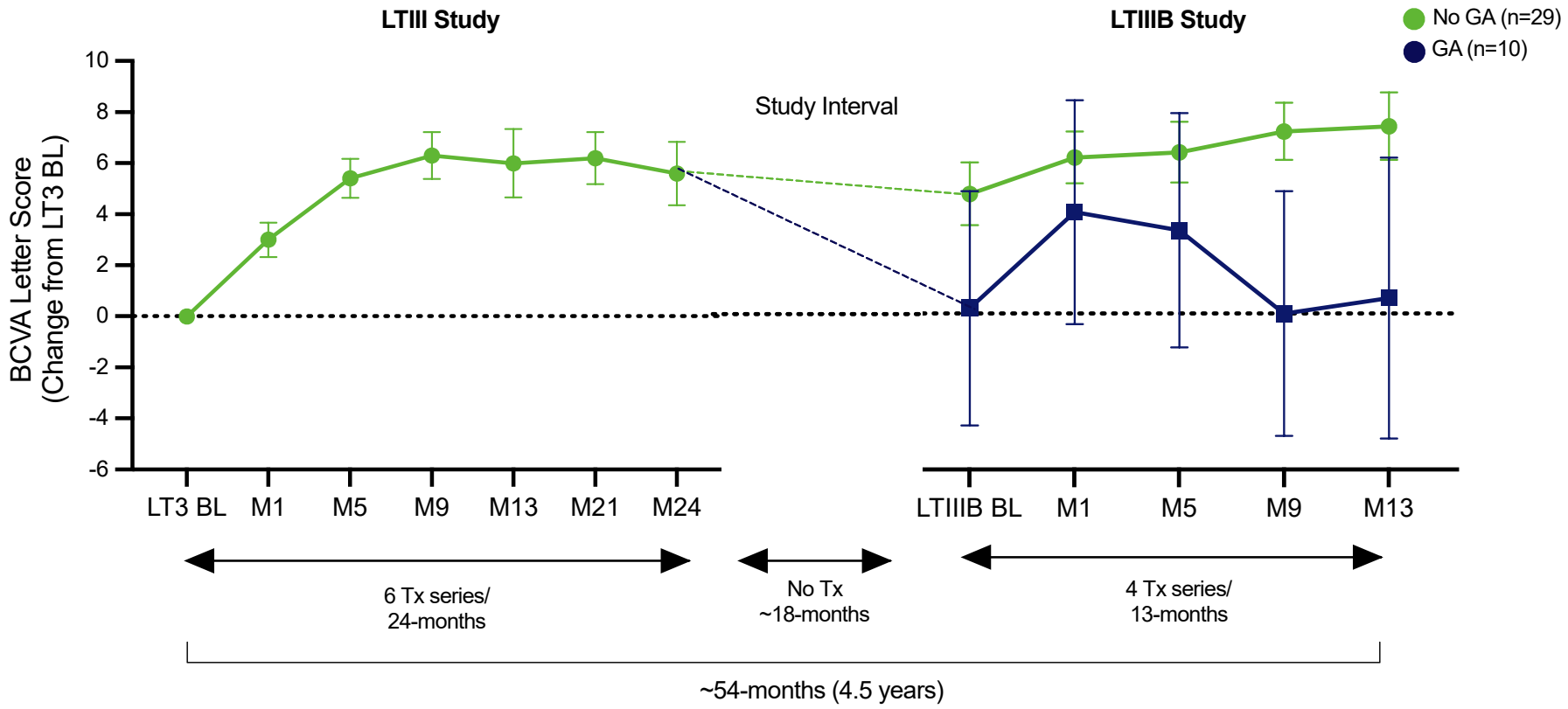
BCVA: Between Trial Interval

- On average, subjects had ~18 months between studies with no treatment
- Subjects previously treated with PBM showed sustained BCVA benefit while eyes in the Sham group showed further vision loss
- A +3.5 letter gain in PBM-treated eyes compared to -4.5 letter loss in Sham-treated eyes was observed ~ 18 months after final LT3 treatment session
- Approximately 25.6% of PBM-treated eyes and 60.0% of Sham-treated eyes had GA upon enrollment into LT3B

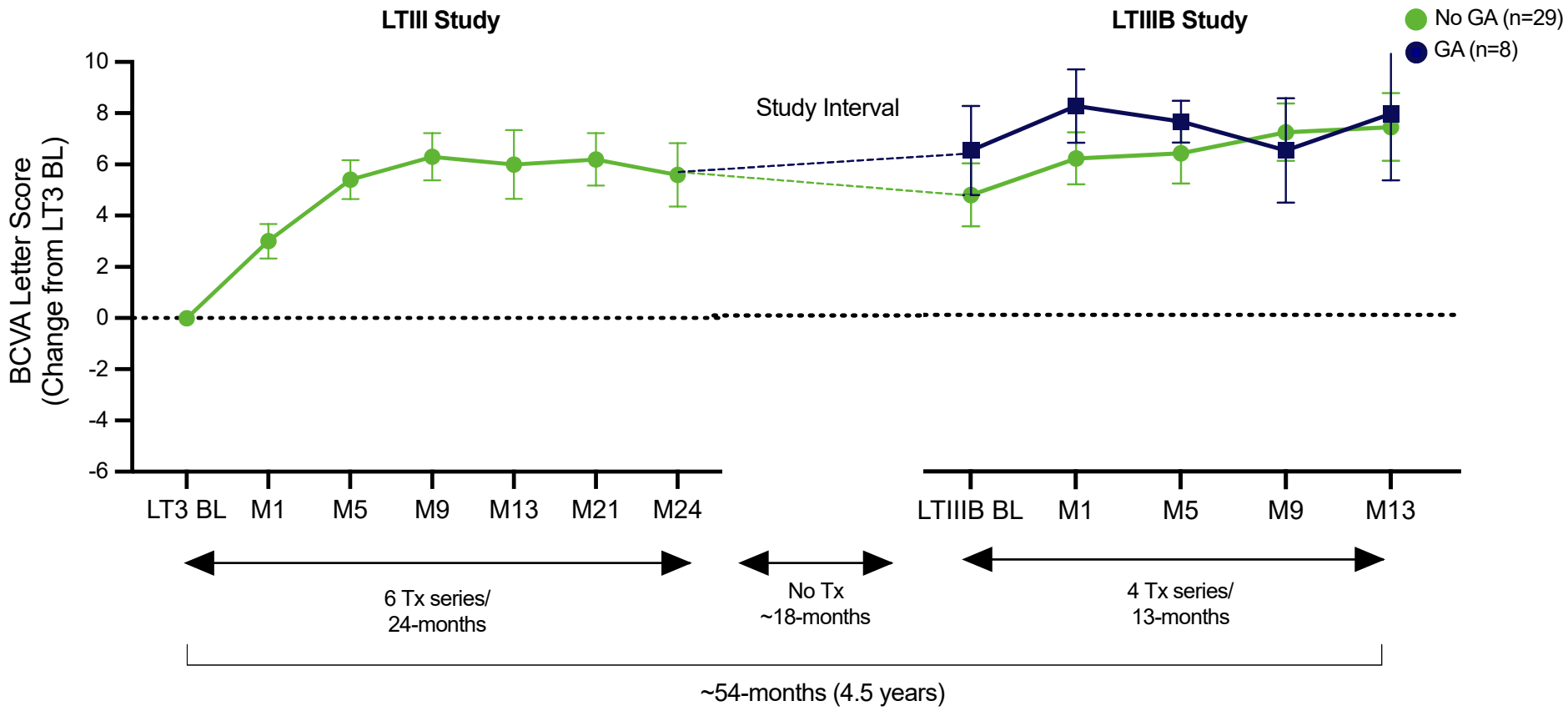
Geographic Atrophy at LT3B Baseline	# Eyes
LT3 PBM	10/39 (25.6)
LT3 Sham	9/15 (60.0)



BCVA: GA Impact (PBM Group Analysis)

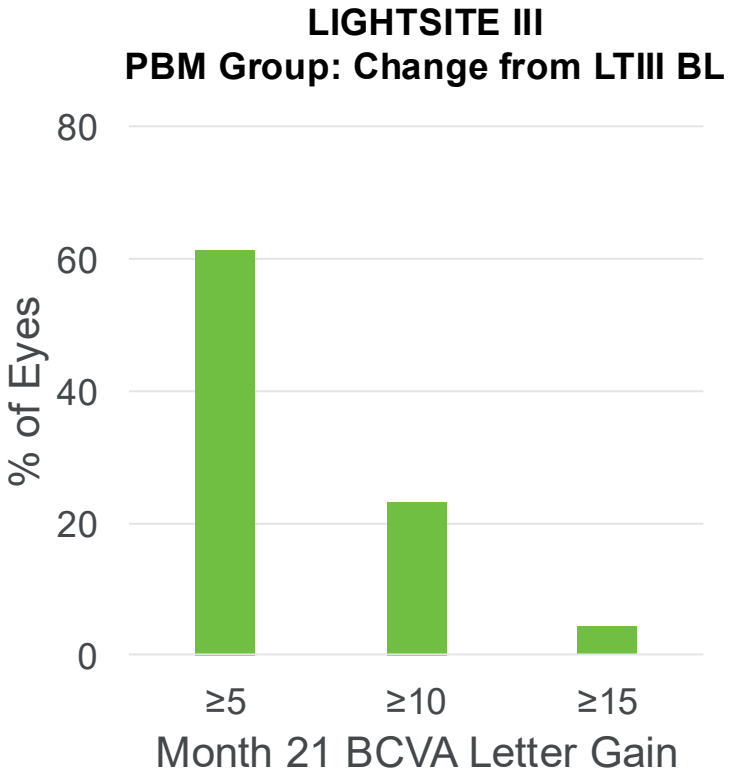


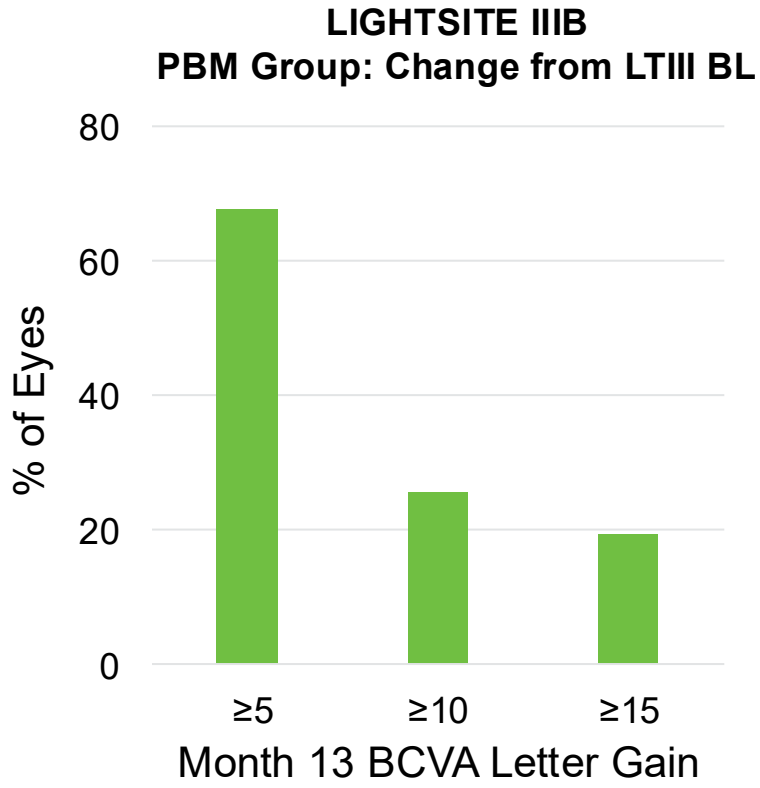
BCVA: GA Impact (PBM Group Analysis)



** Outliers removed*

BCVA: PBM Group Letter Gain (% of Eyes)

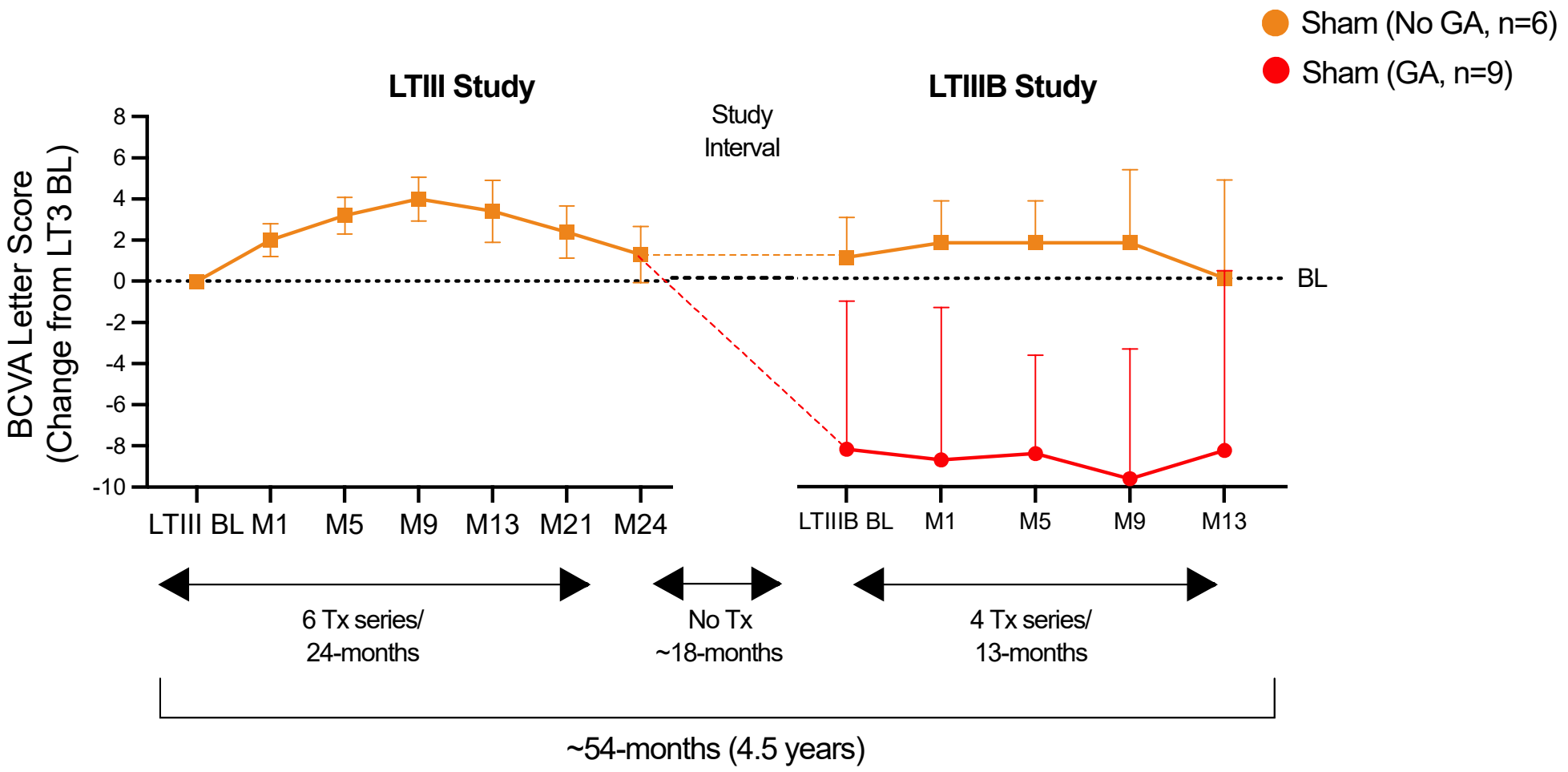




LIGHTSITE IIIB – Similar BCVA gains compared to LIGHTSITE III (~4.5 years after pre-treatment baseline)

- 67.7% of eyes showed over 1-line BCVA improvement (mean gain: 9.9 letters)
- 25.8% of eyes showed over 2-lines BCVA improvement (mean gain: 15.0 letters)
- 16.1% of eyes showed over 3-lines BCVA improvement (mean gain: 17.2 letters)

BCVA: GA Impact (Sham Group Analysis)



LTIIIB: Ocular Safety Outcomes

- No serious adverse events (AEs) considered related to the device
- 11 ocular AEs reported

Adverse Event Description	# Events	# Subjects
Blurred Vision [Possibly due to post injection of SYFOVRE]	1	1
Afterimage	1	1
Dry Eye	1	1
Floater	1	1
Irritation secondary to dry eye	2	1
nAMD	3	3
Stye	1	1
Watery eyes	3	2
Worsening Posterior Capsular Haze	1	1

LTIIIB Topline Data Highlights

- Following LIGHTSITE III, PBM-treated eyes maintained a BCVA benefit over ~18 months compared to a vision loss observed in Sham-treated eyes
- Re-treatment of PBM-treated eyes improved BCVA back to vision benefits observed in LIGHTSITE III (mean > 5 letter improvement) which was maintained over the 14-month LTIIIB study
- Larger BCVA gains were afforded by subjects with LTIIIB BCVA baseline scores of ≤ 70 letters
- Overall, repeated PBM-treatment improved vision over 1-line with maintained vision benefits throughout a 54-month (4.5 year) follow-up duration in moderate to high-risk Dry AMD eyes