Belite BIO

Early Intervention with an Oral Treatment for Macular Degeneration

Mission for Vision

Nasdaq: BLTE

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Experienced Leadership Team

Belite Management Team

Tom Lin, MMED, PhD, MBA
(Chairman, CEO)

- 10+ years of executive management roles in biotech
- Over 10 new drug developments in multiple therapeutic areas including ophthalmology
- University of Sydney, University of Melbourne, Harvard Medical School, Columbia University, London Business School, HK University

Nathan Mata, PhD
(CSO)

- 15+ years of ophthalmic drug development experience across numerous indications, including two NDAs (Durezol and Zirgan)
- Led clinical development efforts for the first RBP antagonist in advanced dry AMD and the first visual cycle modulator in dry AMD and STGD1
- Introduced the industry's first STGD1 ABCA4 knockout mice model
- University of Texas

Hao-Yuan Chuang, CFA, MBA, FRM
(CFO)

- 13+ years of capital market experience; closed more than US$32 billion of transactions
- Wanda, Suning, CITIC Securities
- Columbia University, London Business School, Hong Kong University

Belite Bio Pipeline Overview

	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA

Tinlarebant (LBS-008)

- **Stargardt Disease (STGD1)**
  - Ph2 24-month final data continues to **show slowing of lesion growth**
  - Ph3, 2-year treatment, global trial ("DRAGON" Study) is ongoing (completed enrollment, **104 subjects, age 12-20,** interim data expected in 4Q 2024)
  - Ph2/3, 2-year treatment, global trial ("DRAGON II" Study) is ongoing (**60 subjects, age 12-20**)
- **Geographic Atrophy (GA)**
  - A Ph3, 2-year treatment, global trial ("PHOENIX" Study) is ongoing

- **Tinlarebant** is a **novel, once daily oral tablet** designed to bind to serum **retinol binding protein 4 (RBP4)** as a means to specifically reduce retinol delivery to the eye. This approach is intended to **slow or halt the formation of the toxic retinol-derived by-products** that are generated in the visual cycle and are **implicated in progression of STGD1 and GA.**
- Belite Bio believes that **early intervention directed at emerging retinal pathology**, which is not mediated by inflammation, would be the best approach to potentially slow disease progression in STGD1 & GA.
- **Unmet Market Opportunity:**
  - No FDA approved treatments for STGD1
  - No FDA approved orally administered treatments for GA
- **Fast Track Designation & Rare Pediatric Disease** in US and **Orphan Drug Disease** designation in US / EU / JP for STGD1
- **14 active patent families**; composition of matter patent until at least **2040** without patent term extension

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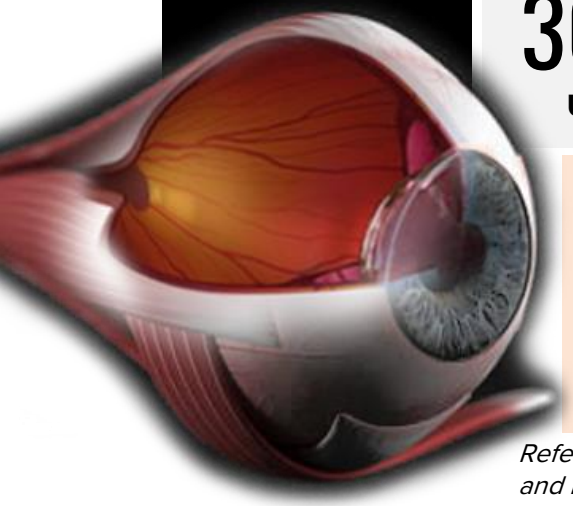
Tinlarebant Overview

Market Opportunity

Tinlarebant (LBS-008)

- DISCOVERY
- PRE-CLINICAL
- PHASE I
- PHASE II
- **PHASE III**
- MARKET



STARGARDT

1 in 10,000

The most common inherited retinal dystrophy

Patient population with Stargardt Disease:

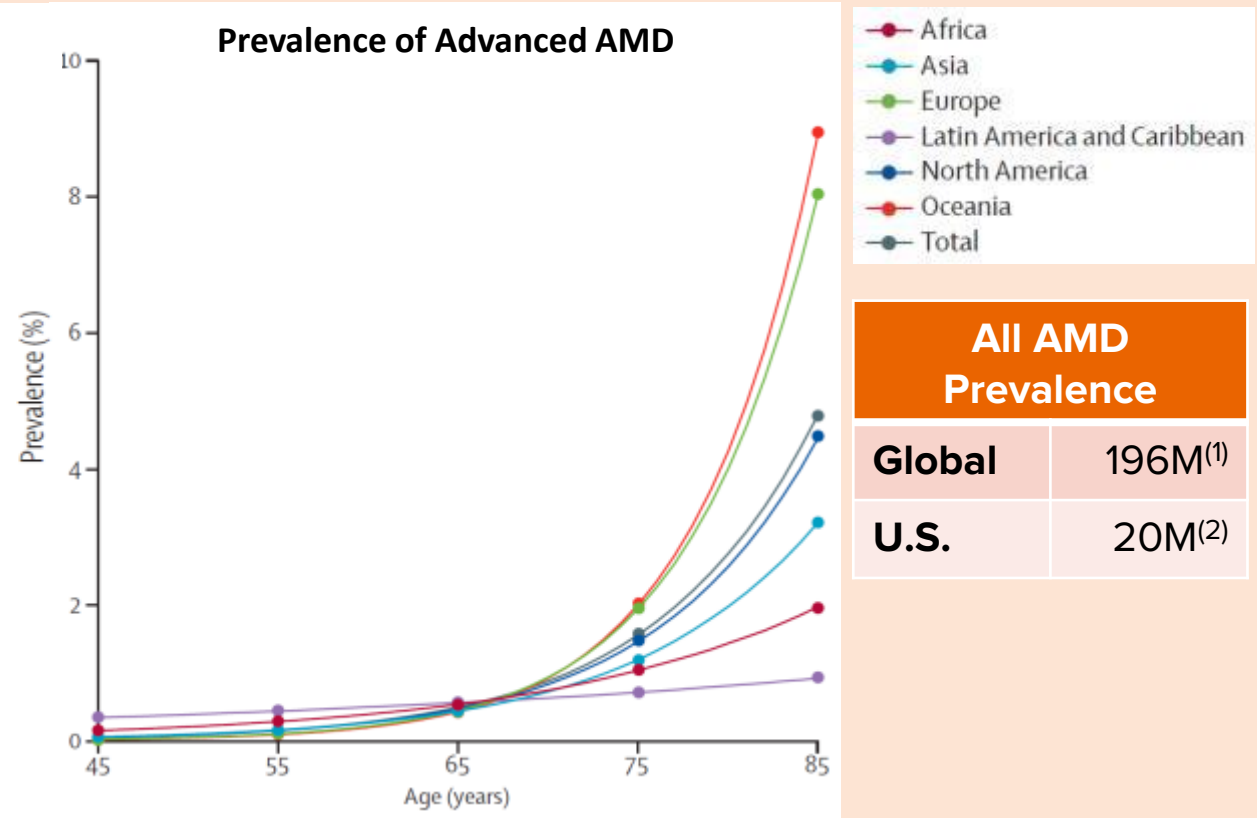
30k US

146k China

Columbia University + NIH Blueprint

"a promising first-in-class oral medication intended to slow or halt the progression of dry AMD"

ADVANCED AMD



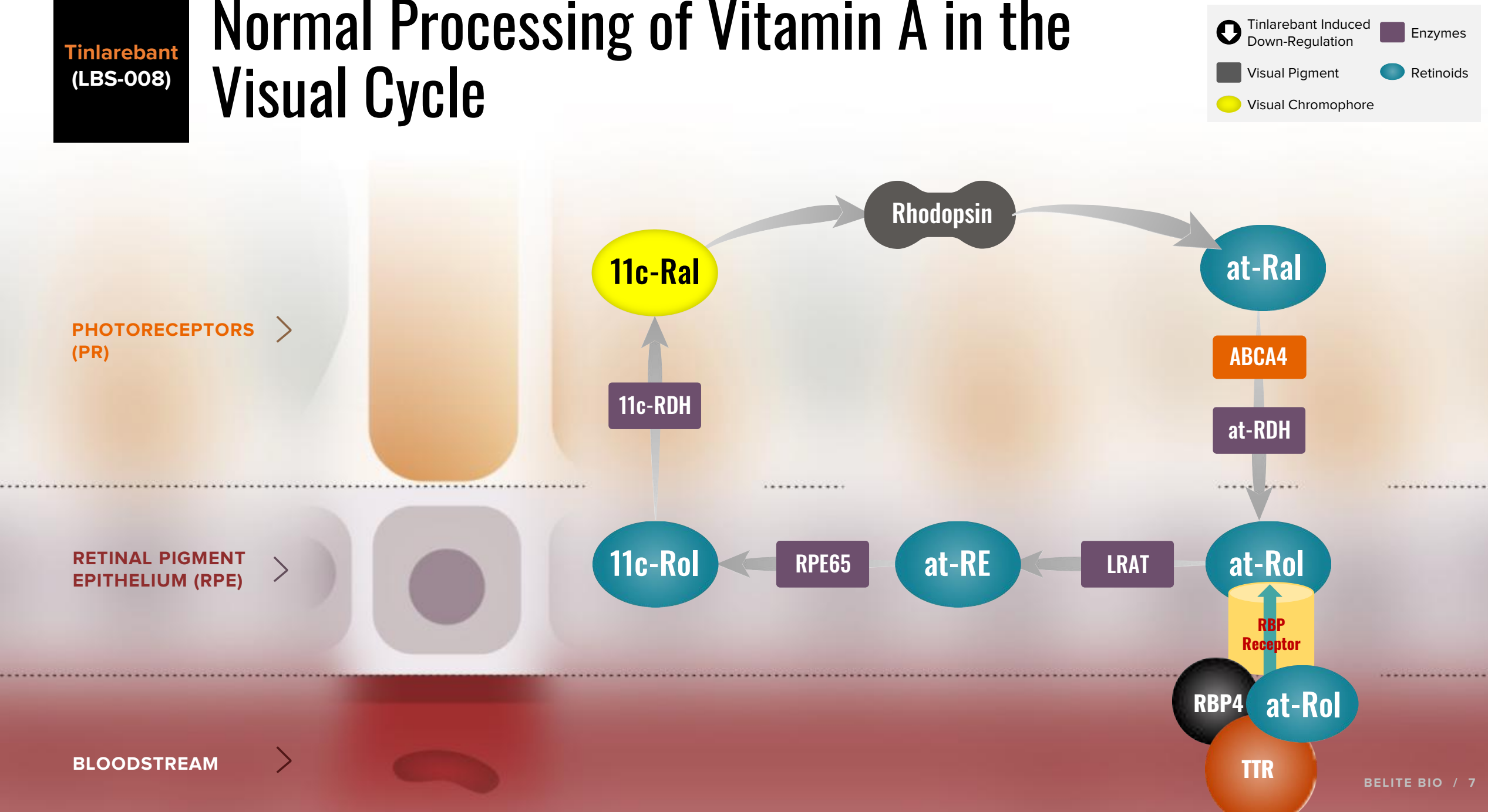
All AMD Prevalence	
Global	196M[1]
U.S.	20M[2]

- **AMD patient population is expected to grow from 196M in 2020 to 288M in 2040**[1]

Reference: (1) Wan LingWong et al. Global prevalence of AMD and disease burden projection for 2020 and 2040. 2014; (2) Prevalence Estimates Vision and Eye Health Surveillance System Vision Health Initiative (VHI) CDC, 2022

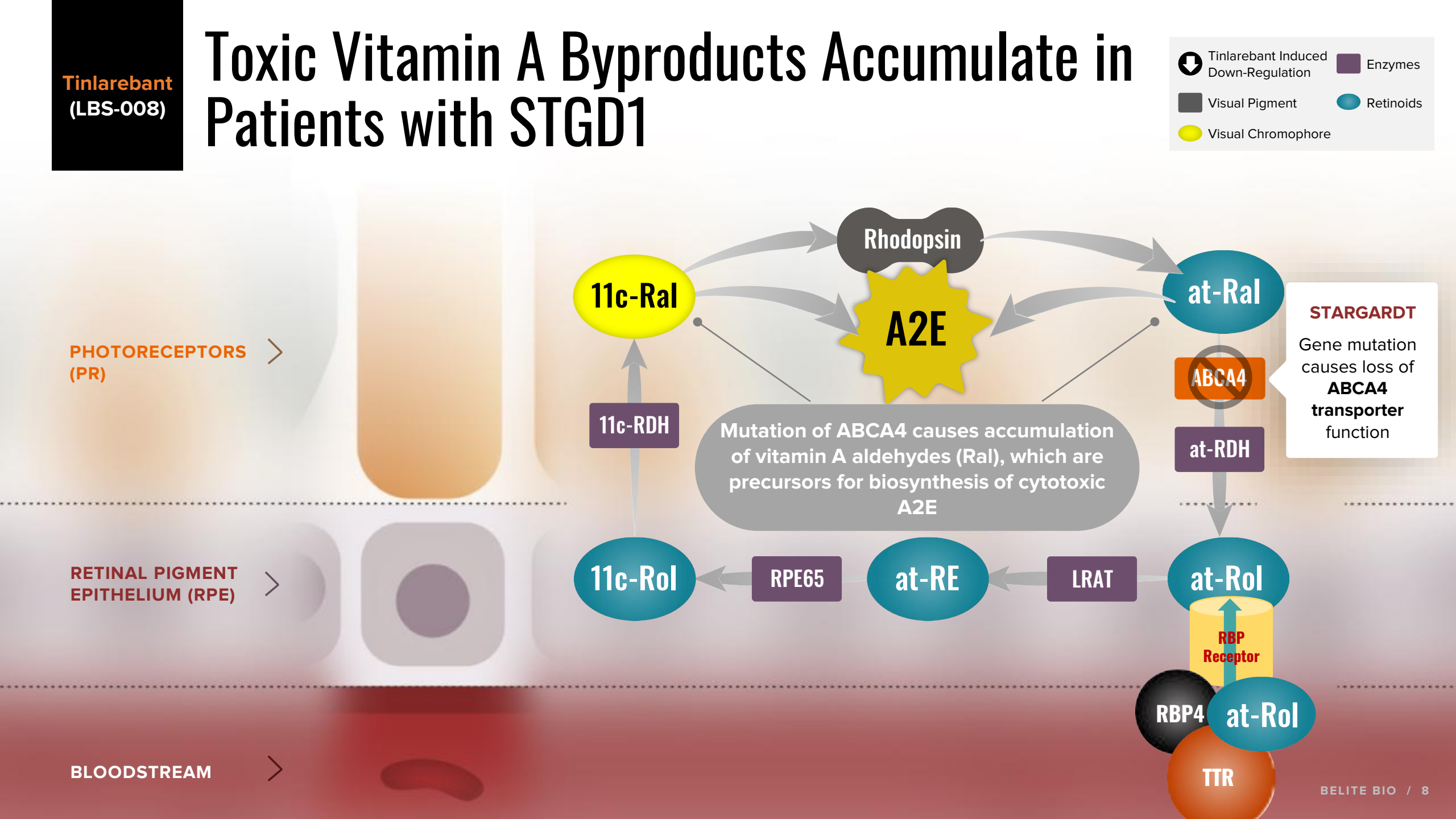
Tinlarebant (LBS-008)

Normal Processing of Vitamin A in the Visual Cycle



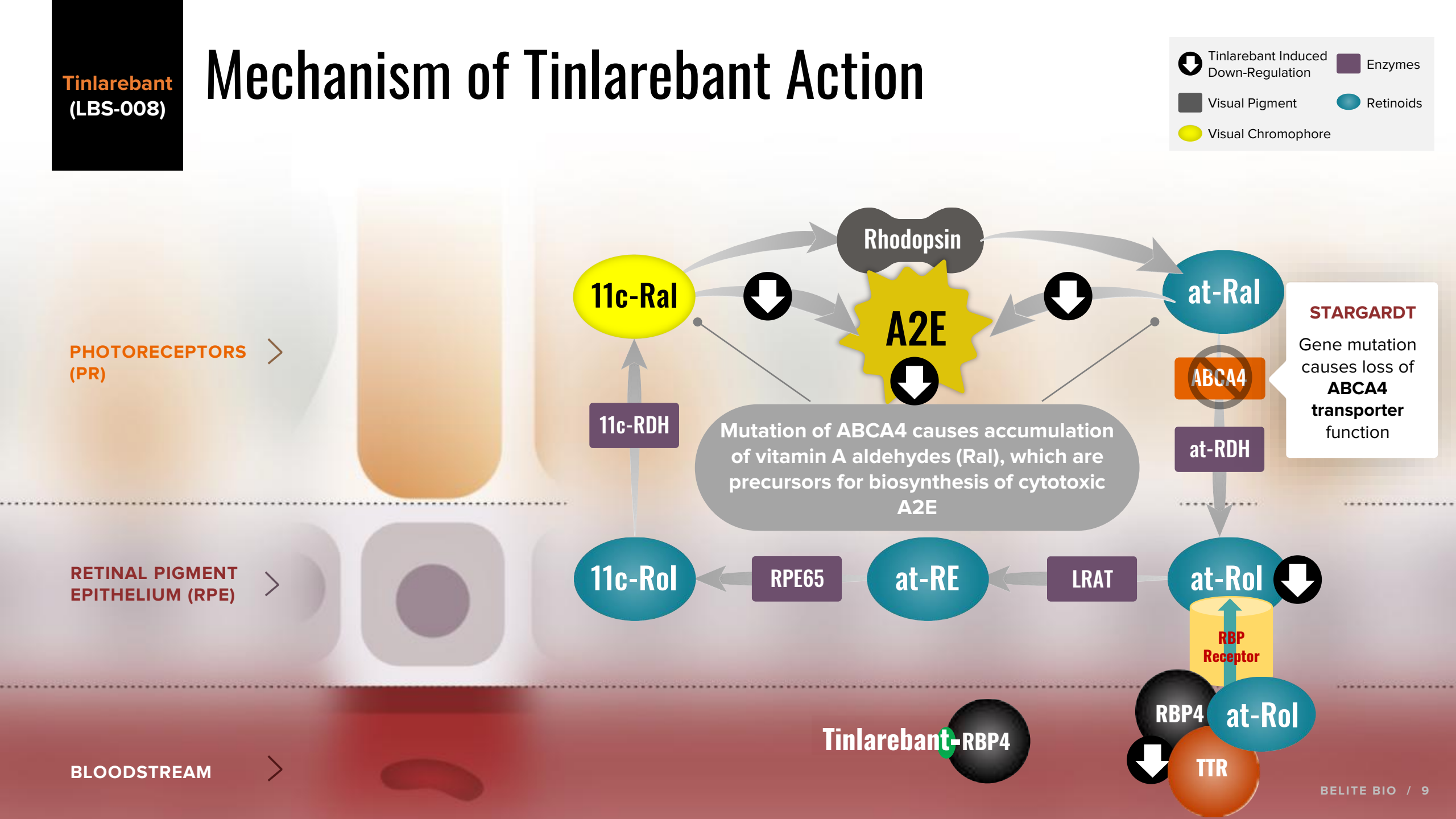
Tinlarebant (LBS-008)

Toxic Vitamin A Byproducts Accumulate in Patients with STGD1



Tinlarebant (LBS-008)

Mechanism of Tinlarebant Action

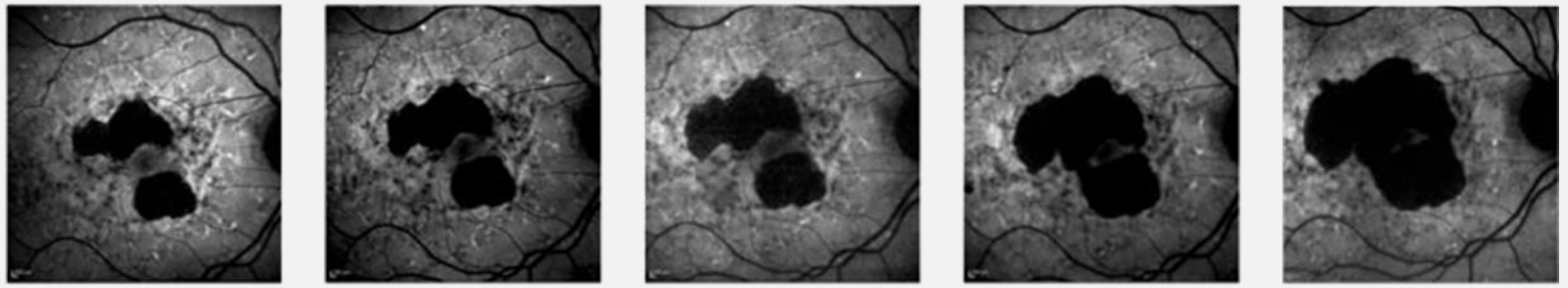


Tinlarebant (LBS-008)

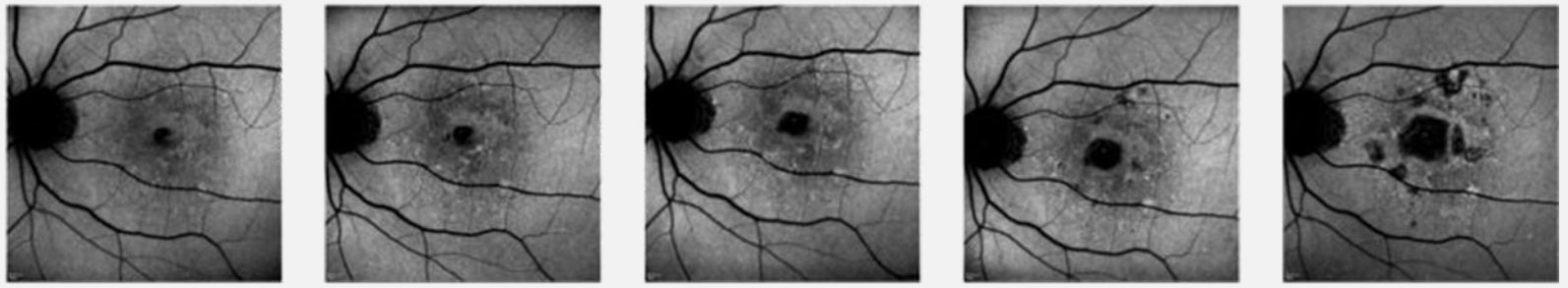
Similar Pathophysiology in STGD1 & Dry AMD

- **STGD1 and dry AMD share a similar pathophysiology** characterized by excessive accumulation of cytotoxic bisretinoids, retinal cell death, and loss of vision
- **Vision loss occurs slowly**, despite peripheral expansion of 'dead retina', until the disease reaches the center of the eye (the macula)
- **Slowing or halting the spread of 'dead retina'** is the intended **effect of Tinlarebant treatment**

STGD1: LATE-ONSET (61-YEAR OLD FEMALE)



Dry AMD: ADVANCED (73-YEAR OLD FEMALE)



Reference: Lindner et al. Differential Disease Progression in Atrophic Age-Related Macular Degeneration and Late-Onset Stargardt Disease. Invest Ophthalmol Vis Sci. 2017;58(2):1001-1007.

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Fenretinide Proof-of-Concept Study

Reduction of RBP4 Slows Lesion Growth in GA Subjects

Sirion's Ph 2 Proof-of-Concept Fenretinide Study in GA Reinforces Tinlarebant Potential

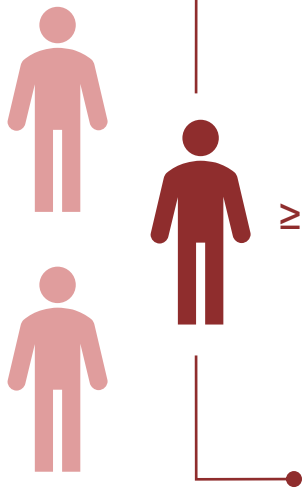
Fenretinide is a synthetic retinoid with **broad retinoid pathway capabilities**

- Developed as an anti-cancer drug
- Competing with retinol for RBP4 binding is a side effect

Tinlarebant is designed to overcome the lower potency and limited bioavailability of fenretinide

Agent	Ki RBP4
Tinlarebant	**2 nM**
Fenretinide	200 nM

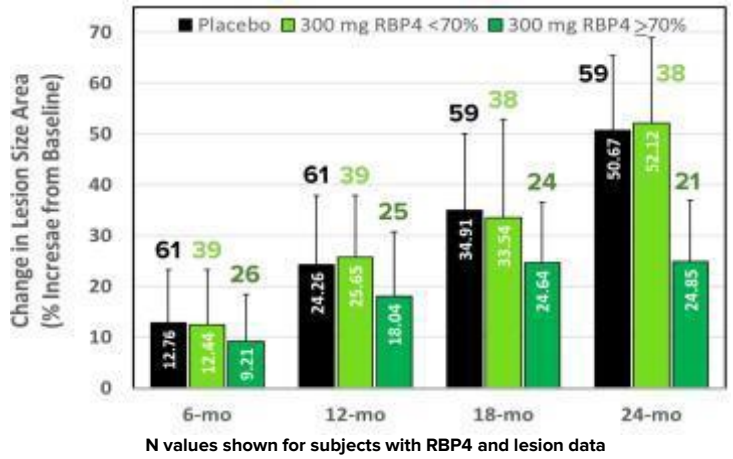
Only **1 out of 3** subjects treated with 300 mg of fenretinide **achieved RBP4 reduction ≥ 70%** relative to baseline



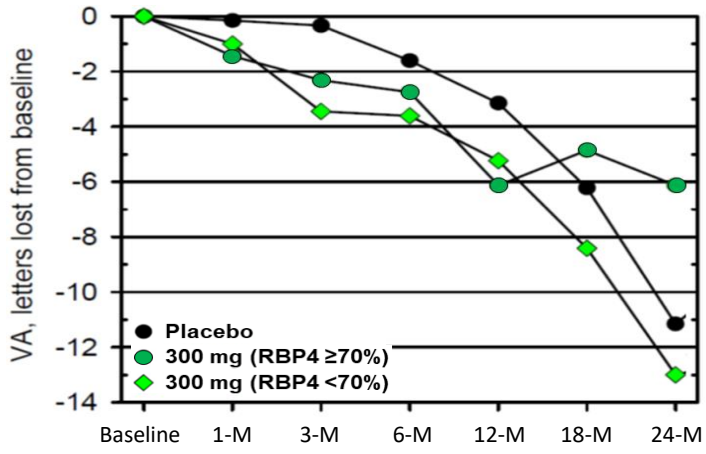
~25% statistically significant **slowing of lesion growth** vs placebo

≥ 70% RBP4 reduction

2-line gain in visual acuity at end of study



N values shown for subjects with RBP4 and lesion data



Reference: Mata et al. Investigation of oral fenretinide for treatment of geographic atrophy in age-related macular degeneration. Retina. 2013 Mar;33(3):498-507.

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STGD1 Clinical Trials

Tinlarebant (LBS-008)

Clinical Trial Design Overview in STGD1

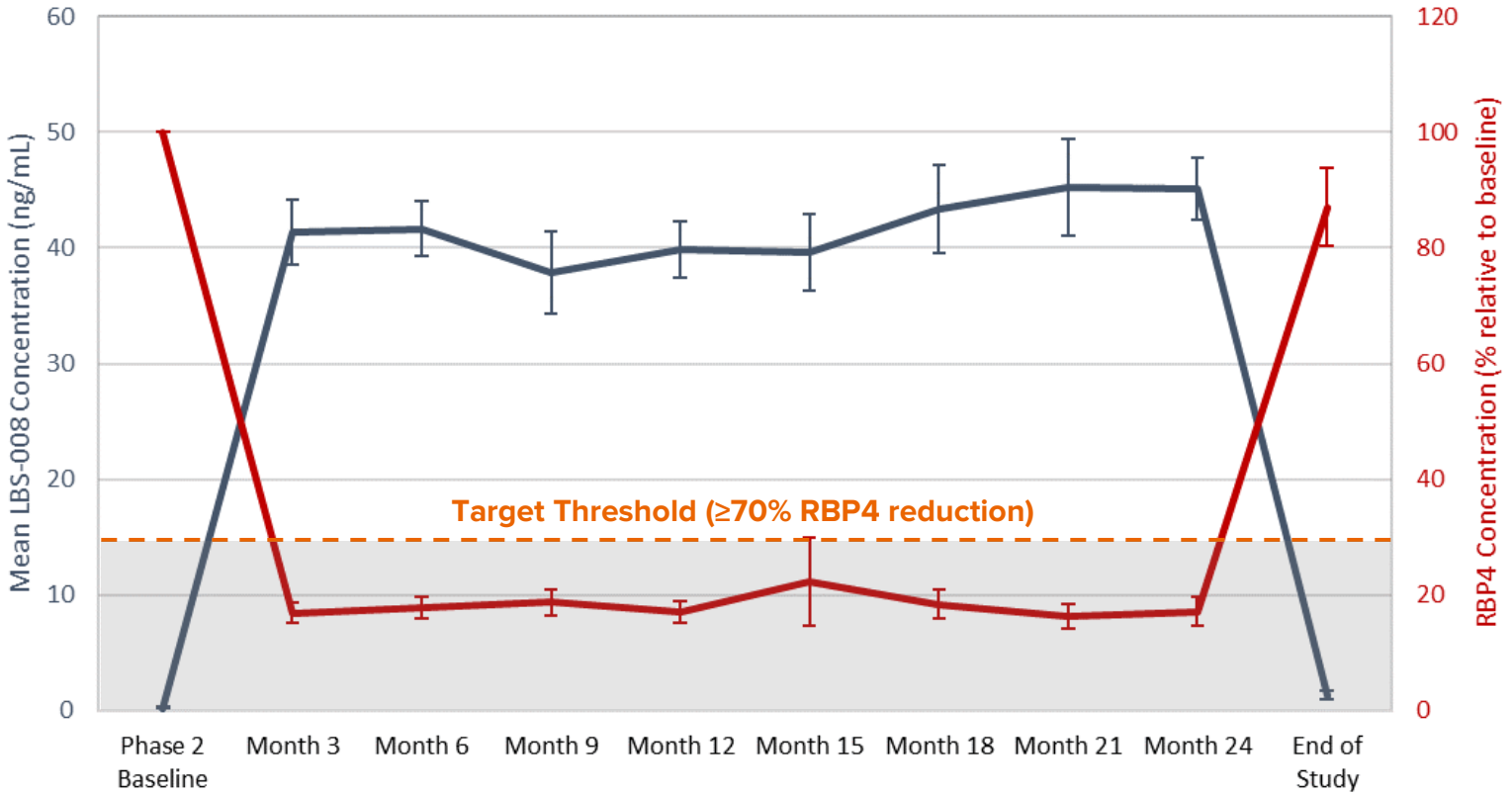
Reduction in Lesion Growth Rate (DDAF) as Measured by Retinal Imaging is the FDA Accepted Primary Endpoint in STGD1 and GA

	STGD1 Phase 2 "LBS-008-CT02" *(Preliminary 24-Month Interim Data Available)*	STGD1 "Dragon" Phase 3*
Enrollment	13 subjects** (QDAF, no DDAF)***	104 subjects (have DDAF)
Sites	Australia & Taiwan	Global
Masking	Open Label	Double Blind
Placebo	N/A	2:1 ratio (Tinlarebant : Placebo)
Treatment duration	2 years	2 years
Primary measures	Safety & tolerability, optimal dose	Efficacy as measured through DDAF lesion growth rate, safety & tolerability
Other measures	DDAF, QDAF, BCVA, SD-OCT, microperimetry	QDAF, BCVA, SD-OCT, microperimetry
Interim analysis	Yes	Yes
Key inclusion criteria	12-18 years old, diagnosed STGD1 with at least one mutation identified in the ABCA4 gene	12-20 years old, diagnosed STGD1 with at least 1 mutation identified in the ABCA4 gene, atrophic lesion size within 3 disc areas (7.62 mm^2), a BCVA of 20/200 or better

*FDA may require another clinical trial depending on the data from the ongoing Phase 3 study.
**LBS-008-CT02 initially enrolled 13 subjects in Australia and Taiwan. One subject in Australia was lost to follow up, therefore 12 subjects with complete 24-month data were evaluated.
***DDAF = definitely decreased autofluorescence; QDAF = questionably decreased autofluorescence.

Tinlarebant (LBS-008)

Ph2 24-month: Reduction of Plasma RBP4 Levels



- The 5 mg daily dose was effective to reduce RBP4 level by a mean of approximately 80% relative to baseline
- RPB4 levels returned to 87% of the baseline value at End of Study (28-days following drug cessation)
- Recovery of RBP4 concentration correlated well with the decreased tinlarebant exposure

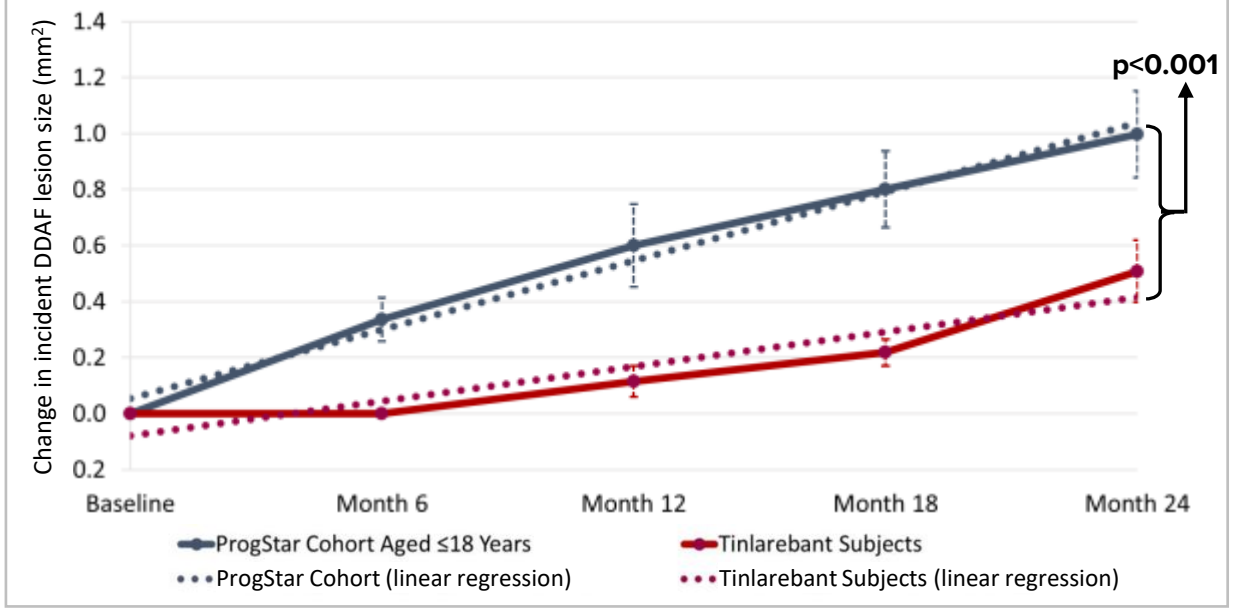
Note: Preliminary data and is subject to data verification and clean-up

Tinlarebant (LBS-008)

Ph2 24-month: Sustained Lower Lesion Growth Compared to ProgStar

- A comparison of incident DDAF lesion growth among ProgStar subjects with similar baseline characteristics as subjects in LBS-008-CT02 (i.e, ≤ 18 years old) was performed

Growth of Incident DDAF Retinal Lesions



	LBS-008-CT02	ProgStar Cohort [1, 2]
Patient Pool	**N=12**	**N=51* (aged ≤18 years)**
Mean change in incident DDAF lesion size at Month 24	**0.51± 0.4 mm²**	**1.00 ± 1.3 mm²**

Note:

** Only 50 patients from ProgStar Cohort (aged ≤18) were included in the analysis due to one subject having ungradable screening FAF data*

1. Strauss RW, Ho A, Muñoz B, et al. ProgStar Report No. 1. Ophthalmology. 2016;123(4):817-28.

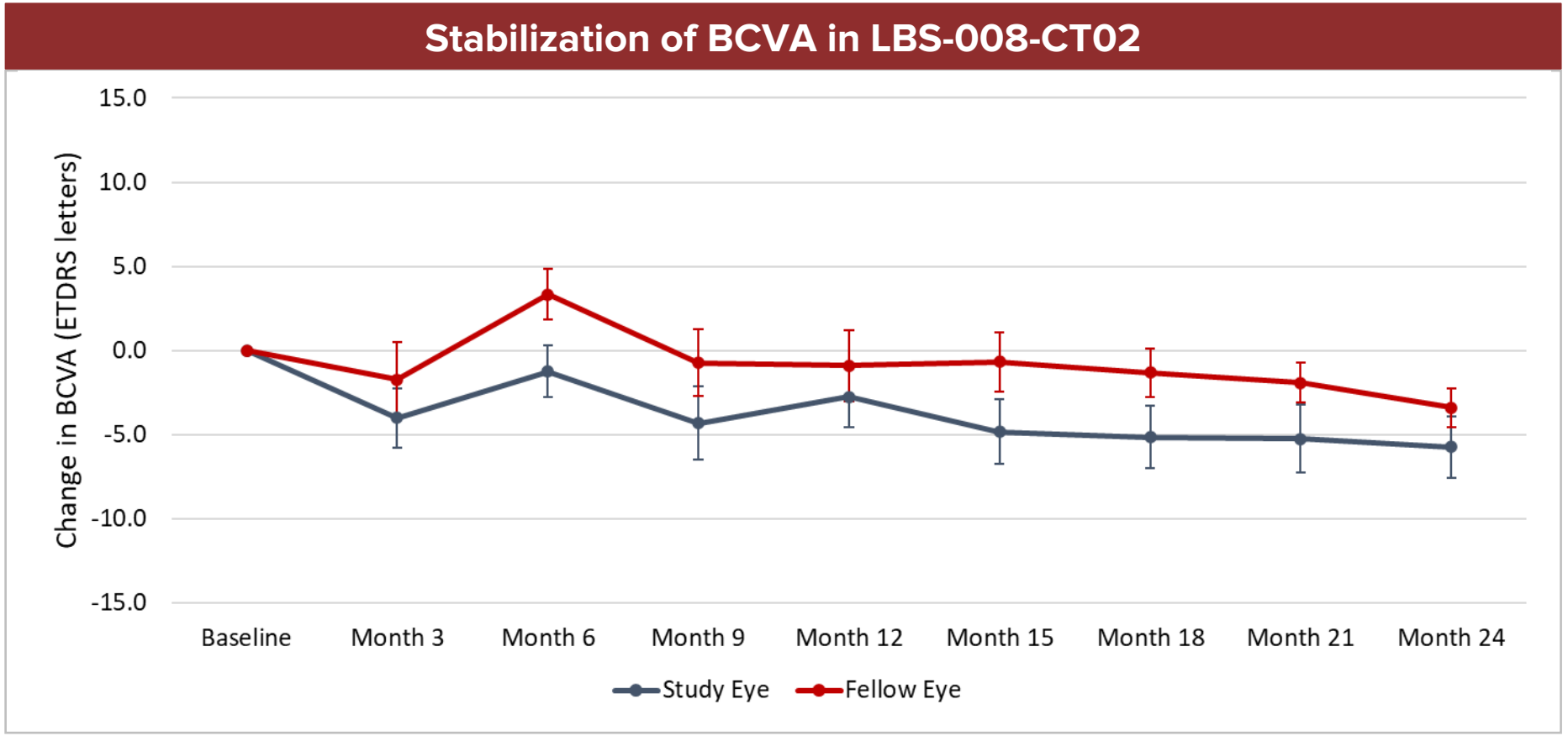
2. Strauss RW, Muñoz B, Ho A, et al. ProgStar Report No. 9. JAMA Ophthalmol. 2017; 135(11):1232-1241.

- **No development of DDAF** in 5 of 12 subjects at the 24-month timepoint
- A comparison of the 24-month DDAF lesion growth between Tinlarebant-treated subjects and ProgStar participants possessing similar baseline characteristics (aged ≤18 years) showed a sustained lower DDAF lesion growth in Tinlarebant-treated subjects over the 24-month treatment period (p<0.001)

Note: Preliminary data and is subject to data verification and clean-up

Tinlarebant (LBS-008)

Ph2 24-month: Visual Acuity Data



- **Visual acuity** was stabilized in majority of subjects during the study with a mean loss of **5 letters** following 24 months of treatment (a loss of <10 letters is not considered clinically significant)

Note: Preliminary data and is subject to data verification and clean-up

Tinlarebant
(LBS-008)

Ph2 24-month: Well-Tolerated Drug-Related Adverse Events

Adverse Events	Severity	Frequency (# and % of patients)
Xanthopsia/Chromatopsia	Mild	10/13 (76.9%)
Delayed Dark Adaptation	Mild	9/13 (69.2%)
Night Vision Impairment	Mild	1/13 (7.7%)
Increasing error score in FM100	Mild	1/13 (7.7%)
Intermittent headaches	Mild	2/13 (15.4%)

- Tinlarebant (5 mg p.o., daily) continues to be **safe** and **well tolerated** in adolescent STGD1 patients
- Tinlarebant treatment produced a mean **80% reduction of RBP4** (from baseline) throughout the study
- Delayed Dark Adaptation and Xanthopsia/Chromatopsia are the most common drug related ophthalmic AEs
- All instances of Delayed Dark Adaptation, Night Vision Impairment, and Xanthopsia/Chromatopsia were **mild** and **transient**
- No severe and moderate drug related AEs reported and no AEs requiring discontinuation of treatment
- No clinically significant findings in relation to vital signs, physical exams, cardiac health, or organ functions

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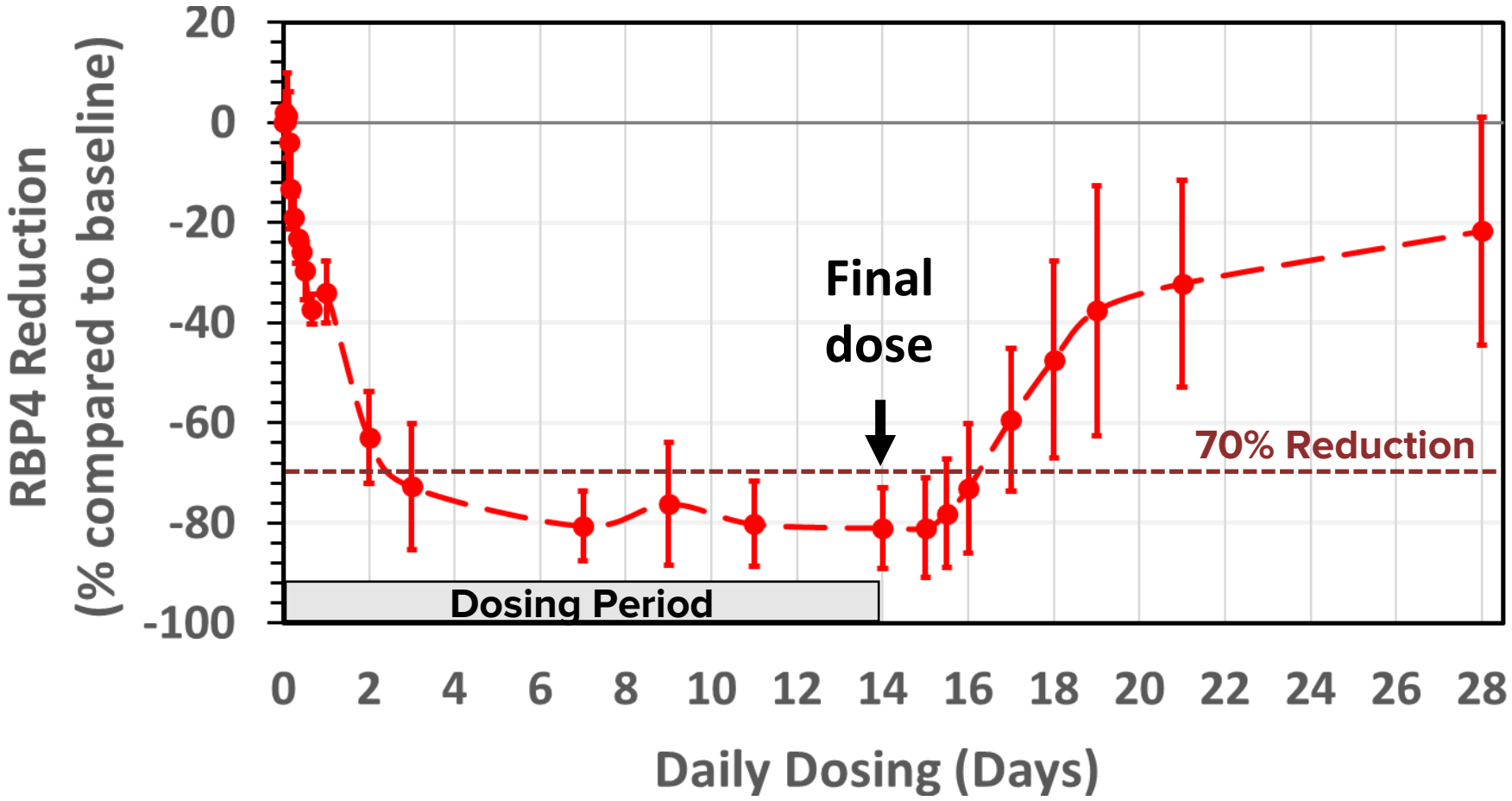
Phase 3 Geographic Atrophy

Tinlarebant
(LBS-008)

Tinlarebant: ≥ 70% Reduction of RBP4

Phase 1, 5mg Daily Dosing in Healthy Adults: Mean Percent Reduction of RBP4 (excludes placebo)



Tinlarebant
(LBS-008)

Clinical Trial Design Overview in GA

- **Established Efficacy Endpoint** – Reduction in lesion growth rate (DDAF) as measured by retinal imaging is the FDA accepted primary endpoint for STGD1 and GA
- **Early Intervention** – Targeting patients with small lesion size to potentially slow disease progress at an early stage
- **Oral Once a Day Treatment** – well suited for long-term treatment for chronic diseases
- **Broad Potential** – Primary focus on GA; potential to treat earlier stages (e.g., intermediate AMD)

	GA Phase 3 "Phoenix"*
Enrollment	Approximately 430 subjects targeted (Enrolling)
Sites	Global
Masking	Double Blind
Placebo	2:1 ratio (Tinlarebant : Placebo)
Treatment duration	2 years
Primary measures	Slowing of atrophic lesion growth, safety & tolerability
Other measures	BCVA, SD-OCT, microperimetry
Interim analysis	Yes

*Additional Phase 3 study expected to be required prior to NDA filing

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Thank you

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