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, Hong Kong University

Hendrik Scholl, MD, MA (CMO)

- 25+ years of expertise in treating retinal diseases, including Stargardt disease and AMD
- Coordinating principal investigator of the largest natural history study of Stargardt disease (ProgStar Study)
- Participated in over 10 clinical studies both in Stargardt disease and AMD, over 280 publications in peer-reviewed journals
- University Eye Hospital Tübingen, University Eye Hospital Bonn, Wilmer Eye Institute at Johns Hopkins, University Eye Hospital Basel, Medical University of Vienna

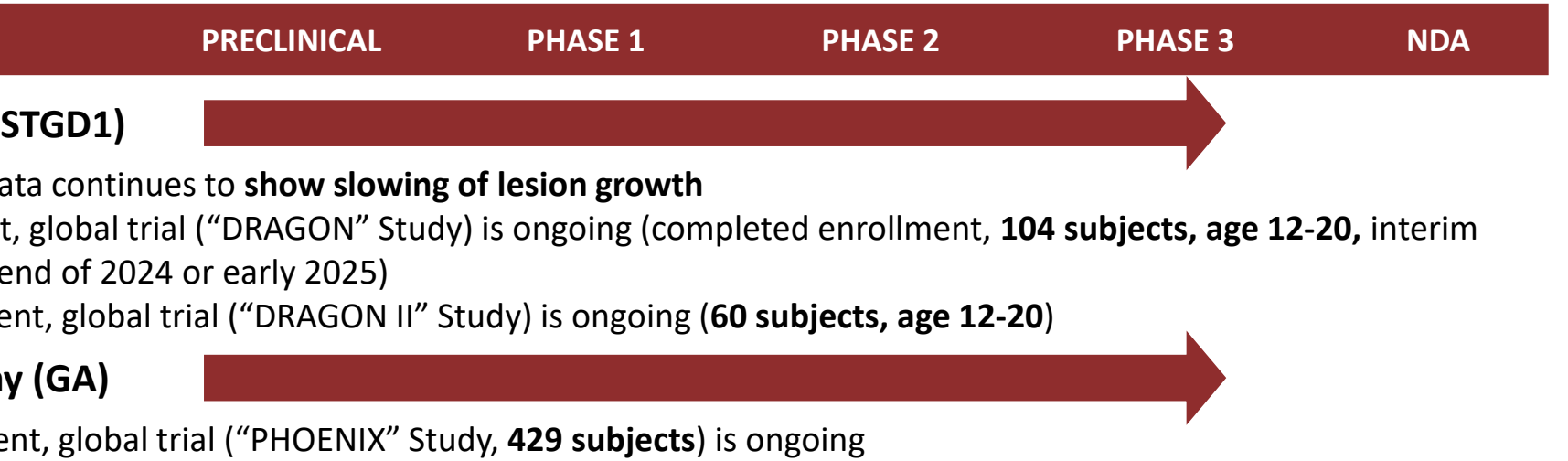
Nathan Mata, PhD (CSO)

- 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



- **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** designation in US / EU / JP, **Pioneer Drug** designation in JP, for STGD1
- **14 active patent families**; composition of matter patent until at least **2040** without patent term extension

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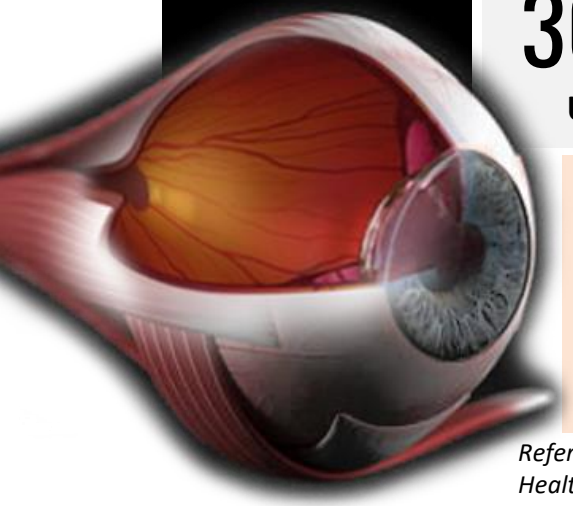
Tinlarebant Overview

Market Opportunity

Tinlarebant

- 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:

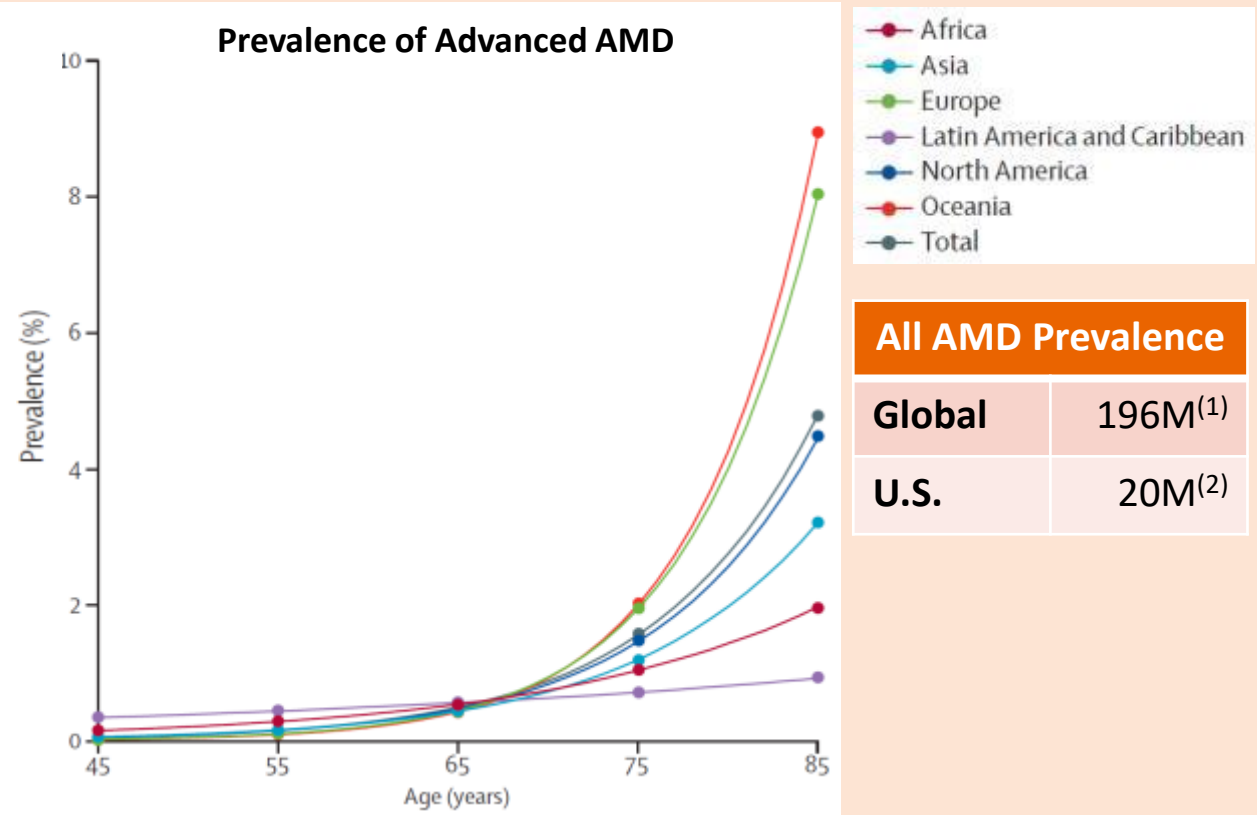
30k US

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

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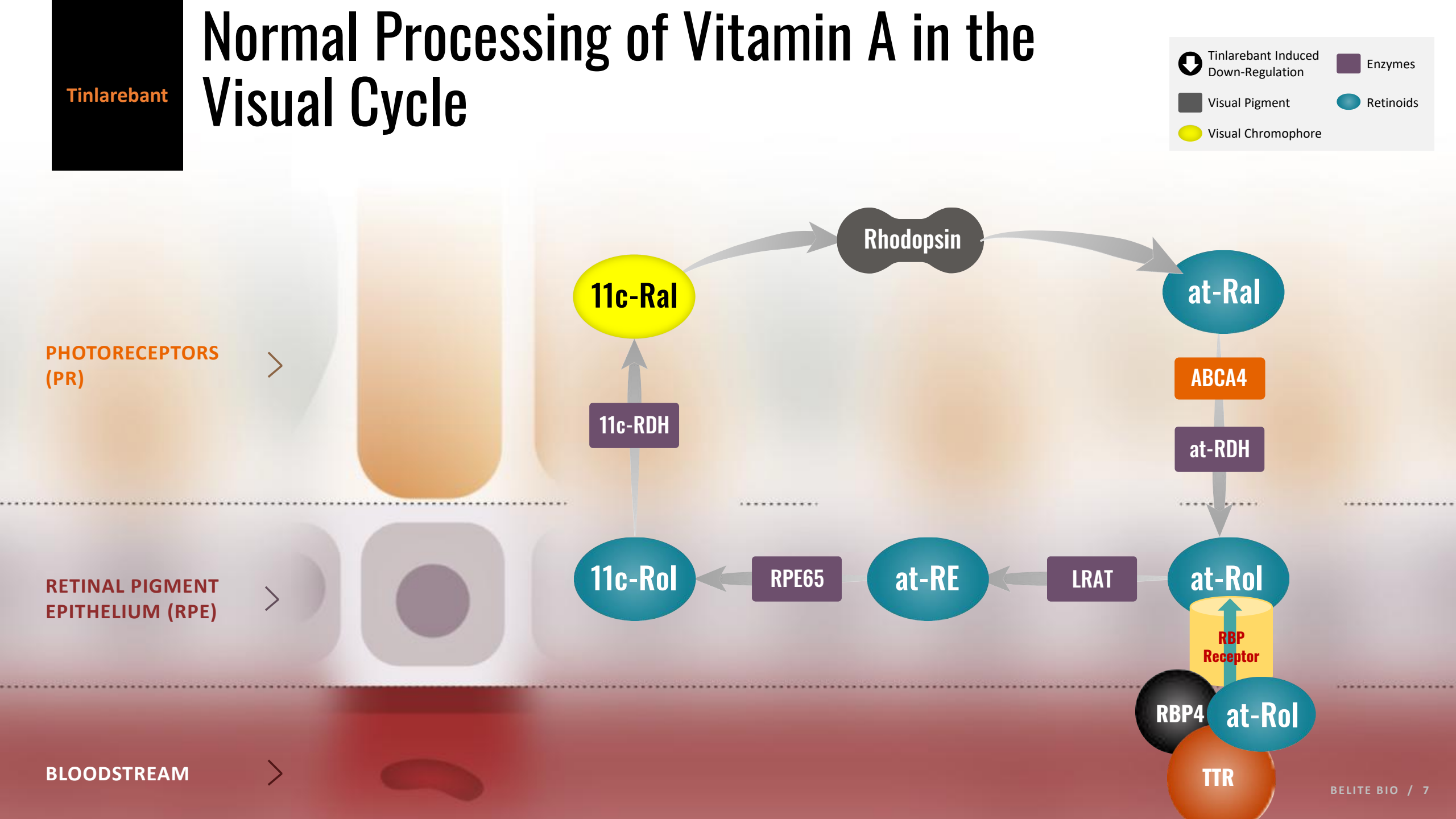
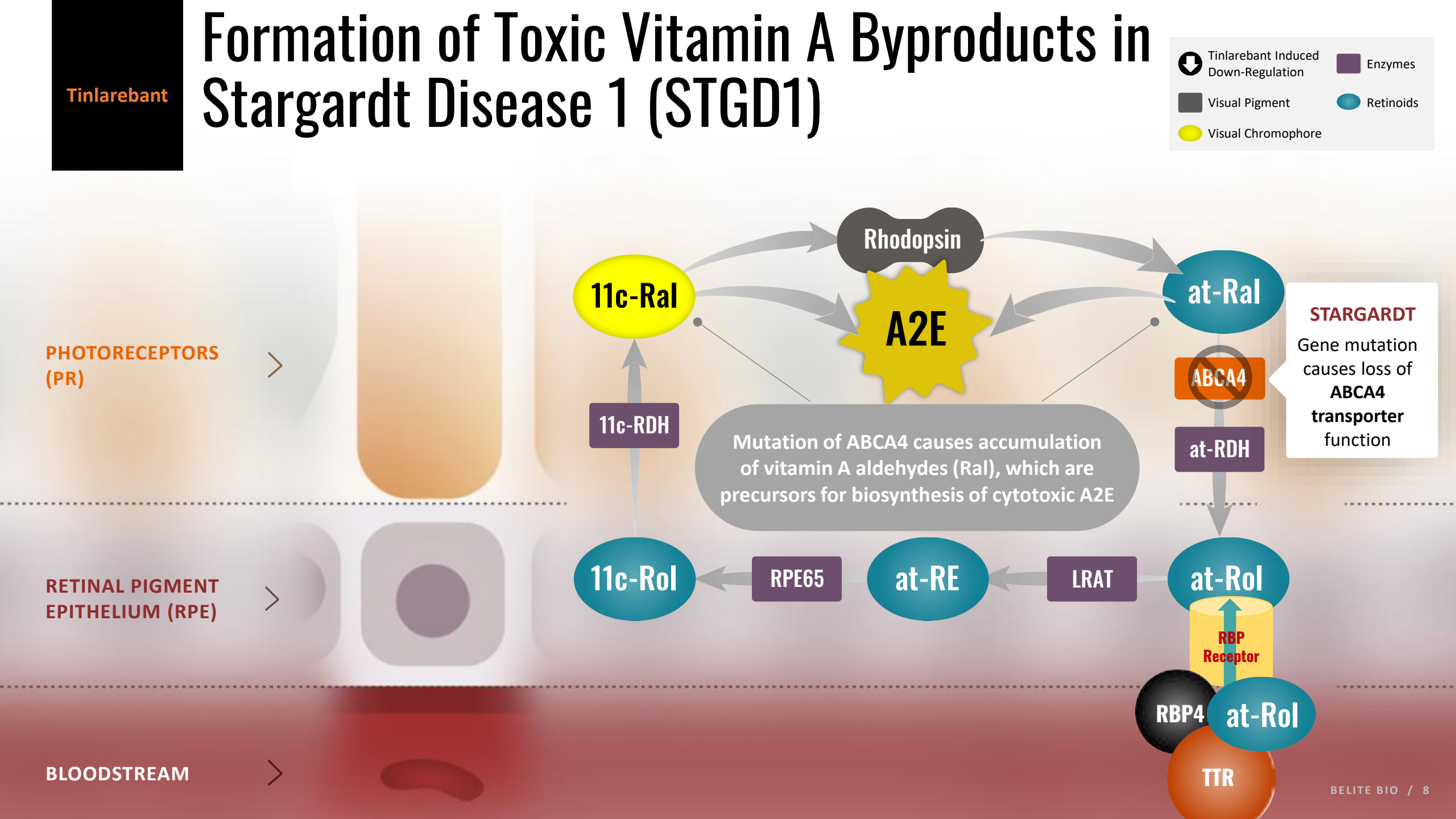
Normal Processing of Vitamin A in the Visual Cycle



Tinlarebant

Formation of Toxic Vitamin A Byproducts in Stargardt Disease 1 (STGD1)



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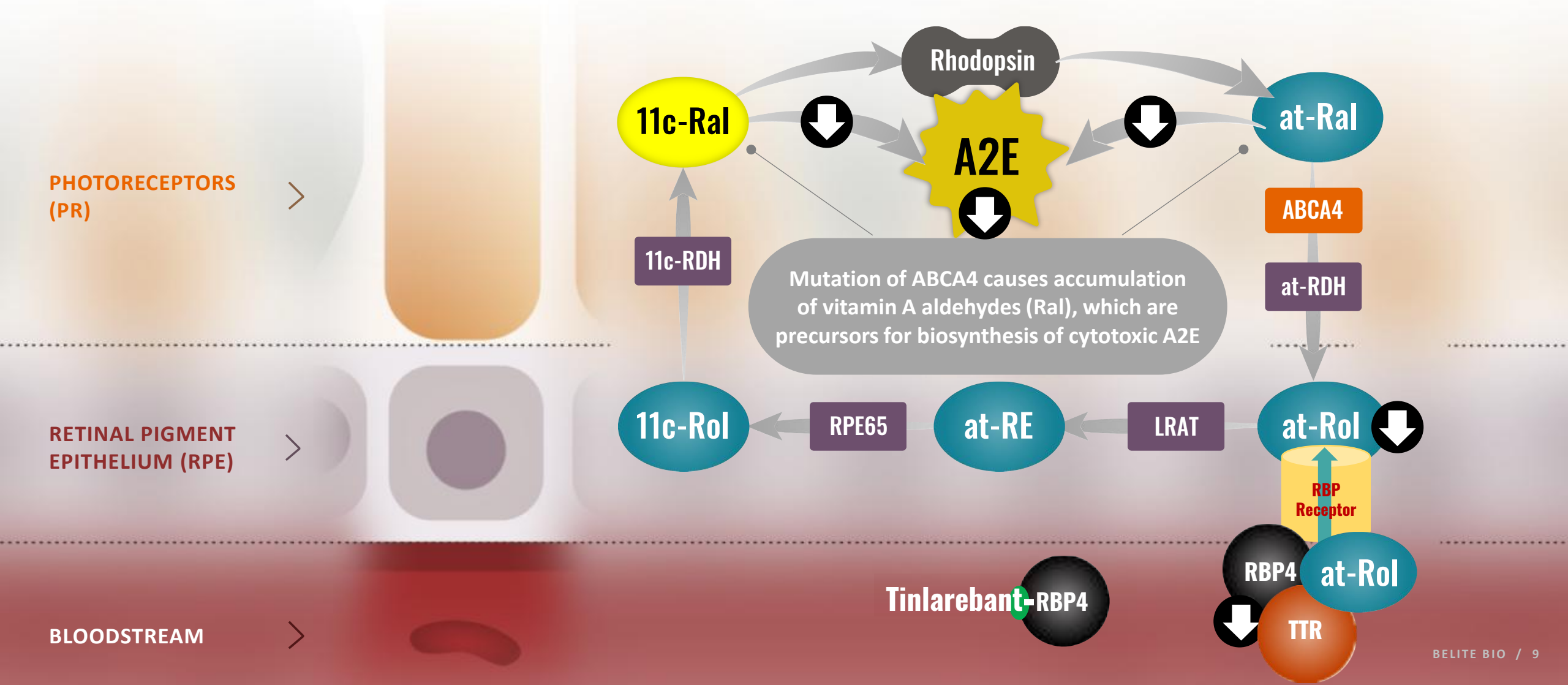
Mechanism of Tinlarebant Action

Bisretinoids are derived from vitamin A (retinol). Therefore, reducing the delivery of retinol to the eye is expected to reduce bisretinoid levels in the eye leading to preservation of the retina



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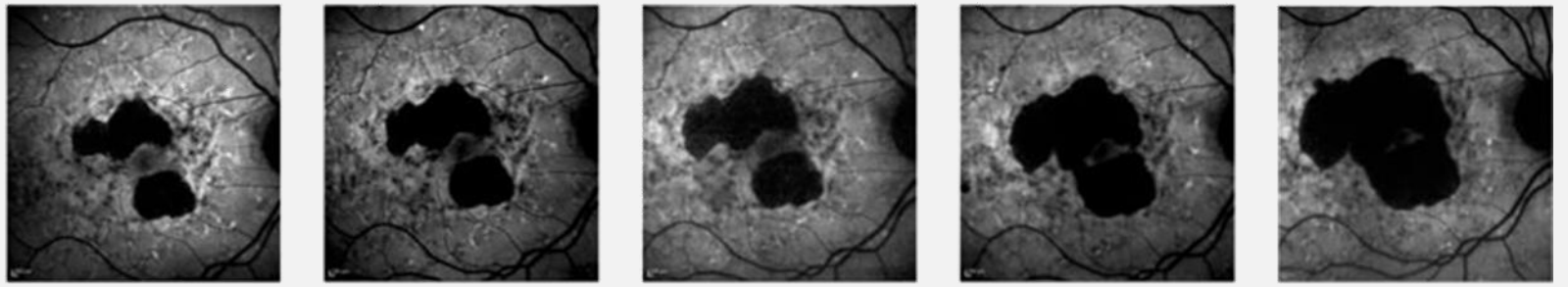
Similar Pathophysiology in STGD1 & GA

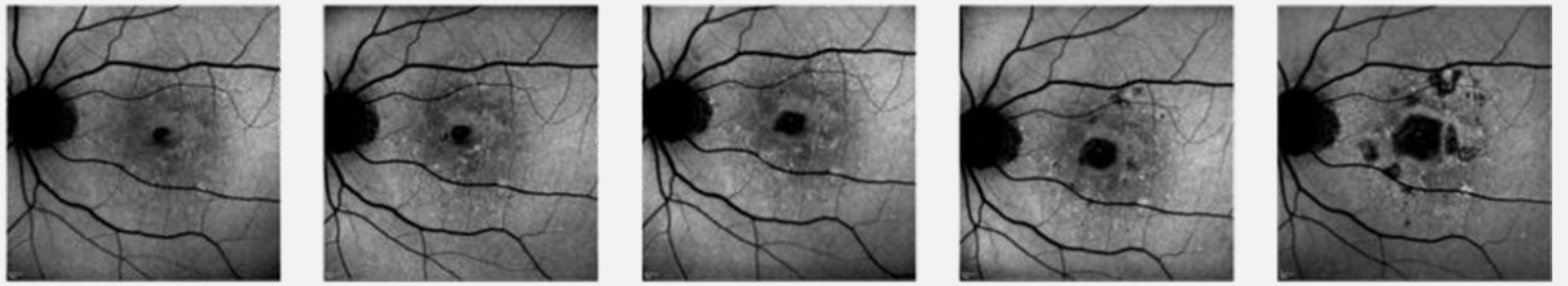
- **STGD1 and GA share a similar pathophysiology** characterized by excessive accumulation of cytotoxic bisretinoids, retinal cell death, and loss of vision
- **Vision loss occurs slowly**, despite peripheral expansion of 'dead retina', until the disease reaches the center of the eye (the macula)
- **Slowing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

STGD1: 61-YEAR-OLD FEMALE



Baseline: 0.1 LogMAR | +12 Months: 0.1 LogMAR | +24 Months: 0.0 LogMAR | +36 Months: 0.1 LogMAR | +57 Months: 0.5 LogMAR

GA: 73-YEAR-OLD FEMALE



BL: 0.2 LogMAR | +12 Mo: 0.2 LogMAR | + 24 Mo: 0.3 LogMAR | + 36 Mo: 0.4 LogMAR | +55 Mo: 0.6 LogMAR

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

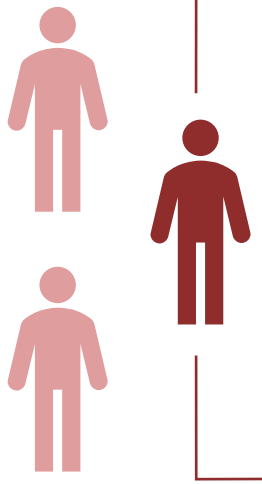
Fenretinide is an orally administered synthetic retinoid

- Developed as an anti-cancer drug
- Competes with retinol for binding to RBP4 as 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

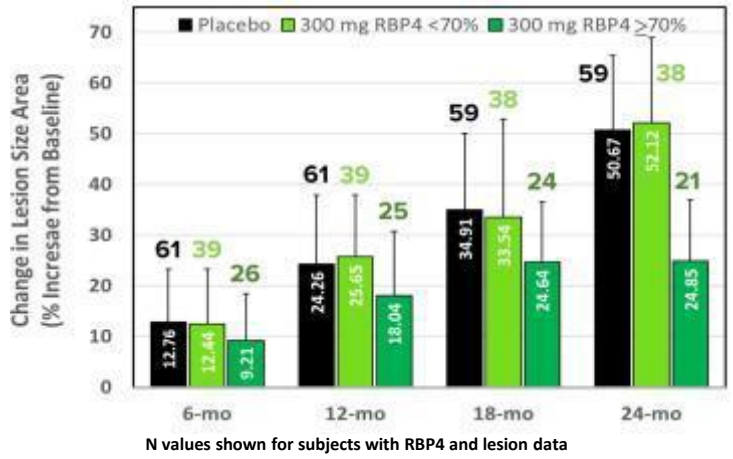
Only **1 out of 3** subjects treated with 300 mg of fenretinide **achieved RBP4 reduction ≥ 70%** relative to baseline



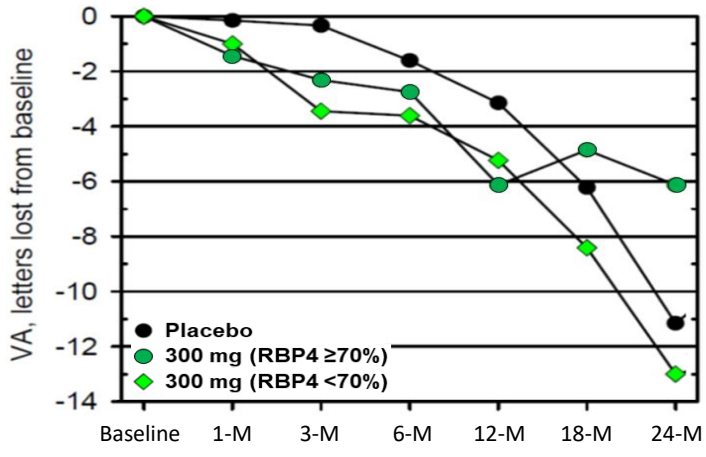
~25% statistically significant **slowing of lesion growth** vs placebo

≥ 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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Phase 2 STGD1 Trial

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Clinical Trial Design Overview in STGD1 Phase 2

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)*
Enrollment	13 subjects* (QDAF, no DDAF)**
Sites	Australia & Taiwan
Masking	Open Label
Placebo	N/A
Treatment duration	2 years
Primary measures	Safety & tolerability, optimal dose
Other measures	DDAF, QDAF, BCVA, SD-OCT, microperimetry
Interim analysis	Yes
Key inclusion criteria	12-18 years old, diagnosed STGD1 with at least one mutation identified in the ABCA4 gene

*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.

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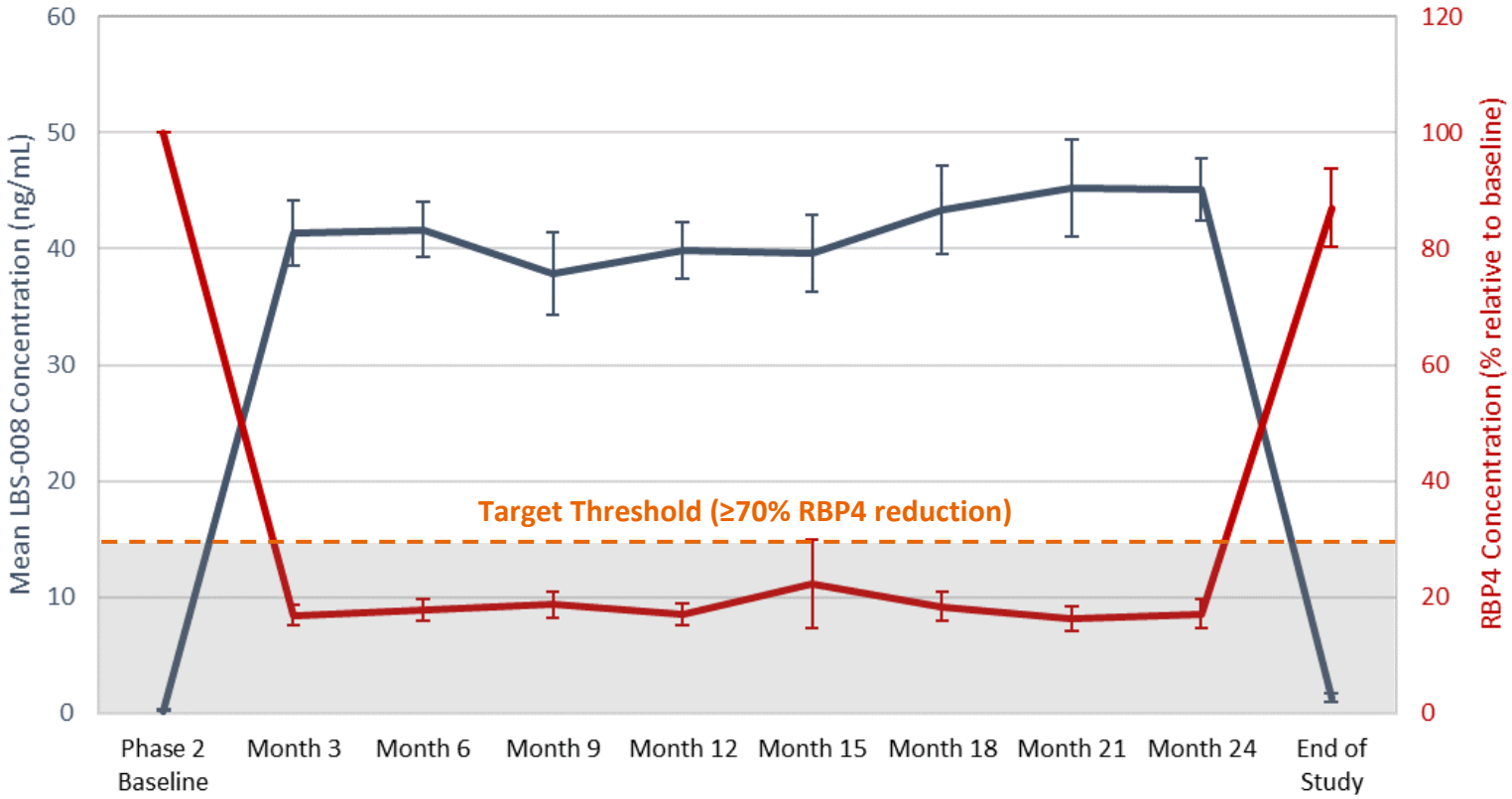
Ph2 24-month: Reduction of Plasma RBP4 Levels



- 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

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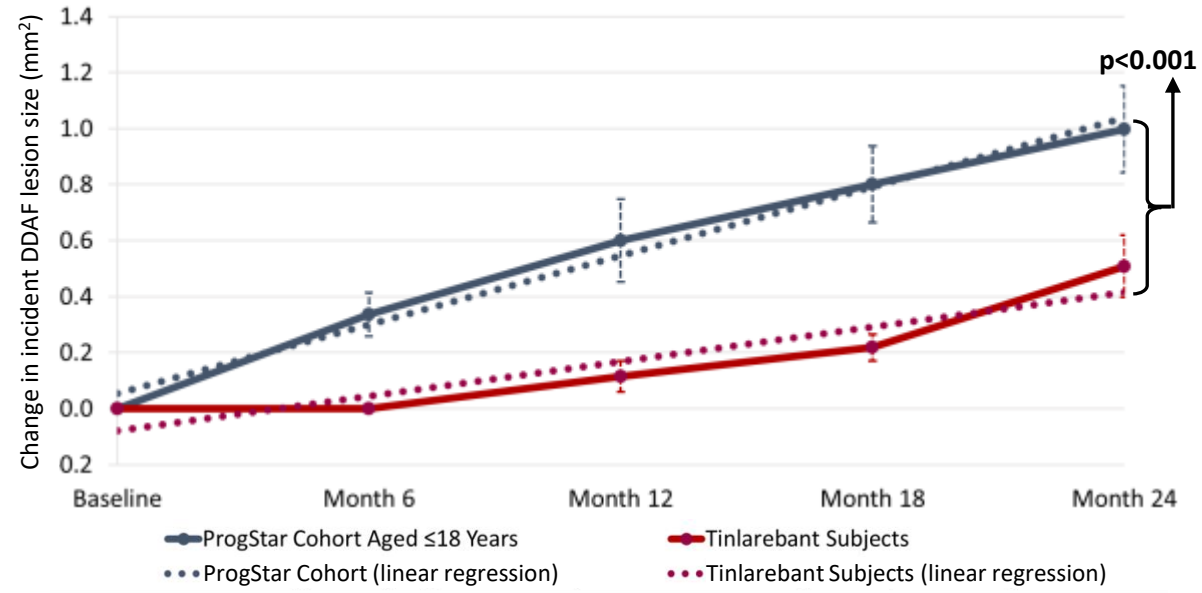
Ph2 24-month: Sustained Lower Lesion Growth Compared to ProgStar

- 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

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ABCA4 Mutations in the Phase 2 Study Cohort

- Severe biallelic ABCA4 mutations were found in 11 of 13 subjects (Subjects 3 and 5 harbored one moderate allele each)
- *In vitro* testing of the moderate alleles in Subjects 3 and 5 showed pathogenicity
- Variants with CADD score >20 predicted to be among the 1% most deleterious

Subject	cDNA change	Protein change	CADD v1.6[(1)]	Assessment	Function tested in vitro	ClinVar
1	c.1922G>C	p.Cys641Ser	25.7	likely severe		not provided
1	c.2905A>G	p.Lys969Glu	28.9	likely severe		Pathogenic
2	c.768G>T	p.(Leu257Valfs*17)	23.1	severe	yes	Pathogenic/Likely pathogenic
2	c.[1532G>A;6006-1G>C]	p.[Arg511His;?]	15.3; 34	severe		not provided
3	c.4539+2028C>T	p.[=,Arg1514Leufs*36]	1.79	moderate	yes	Pathogenic/Likely pathogenic
3	c.2894A>G	p.Asn965Ser	24.8	severe	yes	Pathogenic
4	c.2576del	p.Gln859Argfs*41	N/A	severe		Pathogenic
4	c.[2588G>C;5603A>T]	p.[Gly863Ala;Asn1868Ile]	31; 23.3	moderate/severe	yes; yes	Likely pathogenic
5	c.3260A>G	p.Glu1087Gly	29.5	likely severe		Pathogenic
5	c.5714+5G>A	p.[=,Glu1863Leufs*33]	19.1	moderate	yes	Pathogenic/Likely pathogenic
6	c.5461-10T>C	p.[Thr1821Aspfs*6,Thr1821Valfs*13]	16.8	severe	yes	Pathogenic
6	c.6079C>T	p.Leu2027Phe	27.6	severe	yes	Pathogenic/Likely pathogenic
7	c.634C>T	p.Arg212Cys	26.3	severe	yes	Pathogenic/Likely pathogenic
7	c.2894A>G	p.Asn965Ser	24.8	severe	yes	Pathogenic
8	c.161G>A	p.Cys54Tyr	33	severe	yes	Pathogenic/Likely pathogenic
8	c.4139C>T	p.Pro1380Leu	25.3	moderate/severe	yes	Pathogenic/Likely pathogenic
9	c.1804C>T	p.Arg602Trp	24.7	severe	yes	Pathogenic/Likely pathogenic
9	c.5645T>C	p.Met1882Thr	24.8	likely severe		Uncertain significance
10	c.1804C>T	p.Arg602Trp	24.7	severe	yes	Pathogenic/Likely pathogenic
10	c.5645T>C	p.Met1882Thr	24.8	likely severe		Uncertain significance
11	c.1804C>T	p.Arg602Trp	24.7	severe	yes	Pathogenic/Likely pathogenic
11	c.5761G>A	p.Val1921Met	25.5	likely severe		Pathogenic/Likely pathogenic
12	c.1804C>T	p.Arg602Trp	24.7	severe	yes	Pathogenic/Likely pathogenic
12	c.5645T>C	p.Met1882Thr	24.8	likely severe		Uncertain significance
13	c.1804C>T	p.Arg602Trp	24.7	severe	yes	Pathogenic/Likely pathogenic
13	c.5645T>C	p.Met1882Thr	24.8	likely severe		Uncertain significance

(1) Combined Annotation–Dependent Depletion (CADD) https://cadd.gs.washington.edu/

N/A: Not available

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ABCA4 Mutations in the Phase 2 Study Cohort (cont.)

- Subjects 1, 3, 4, 12, and 13
  - Did not develop atrophic lesions during the Phase 2 study
  - Despite harboring severe or likely severe alleles

Subject	cDNA change	Protein change	CADD v1.6[(1)]	Assessment	Function tested in vitro	ClinVar
1	c.1922G>C	p.Cys641Ser	25.7	likely severe		not provided
1	c.2905A>G	p.Lys969Glu	28.9	likely severe		Pathogenic
2	c.768G>T	p.(Leu257Valfs*17)	23.1	severe	yes	Pathogenic/Likely pathogenic
2	c.[1532G>A;6006-1G>C]	p.[Arg511His;?]	15.3; 34	severe		not provided
3	c.4539+2028C>T	p.[=,Arg1514Leufs*36]	1.79	moderate	yes	Pathogenic/Likely pathogenic
3	c.2894A>G	p.Asn965Ser	24.8	severe	yes	Pathogenic
4	c.2576del	p.Gln859Argfs*41	N/A	severe		Pathogenic
4	c.[2588G>C;5603A>T]	p.[Gly863Ala;Asn1868Ile]	31; 23.3	moderate/severe	yes; yes	Likely pathogenic
5	c.3260A>G	p.Glu1087Gly	29.5	likely severe		Pathogenic
5	c.5714+5G>A	p.[=,Glu1863Leufs*33]	19.1	moderate	yes	Pathogenic/Likely pathogenic
6	c.5461-10T>C	p.[Thr1821Aspfs*6,Thr1821Valfs*13]	16.8	severe	yes	Pathogenic
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7	c.634C>T	p.Arg212Cys	26.3	severe	yes	Pathogenic/Likely pathogenic
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11	c.5761G>A	p.Val1921Met	25.5	likely severe		Pathogenic/Likely pathogenic
12	c.1804C>T	p.Arg602Trp	24.7	severe	yes	Pathogenic/Likely pathogenic
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13	c.5645T>C	p.Met1882Thr	24.8	likely severe		Uncertain significance

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ABCA4 Mutations in the Phase 2 Study Cohort (cont.)

- Subjects 9 & 10 (brothers)
- Subjects 12 & 13 (brother/sister)
- These 4 Subjects harbor identical mutations
- BCVA and lesion data show a different course of disease

Subject	cDNA change	Protein change	CADD v1.6[(1)]	Assessment	Function tested in vitro	ClinVar
1	c.1922G>C	p.Cys641Ser	25.7	likely severe		not provided
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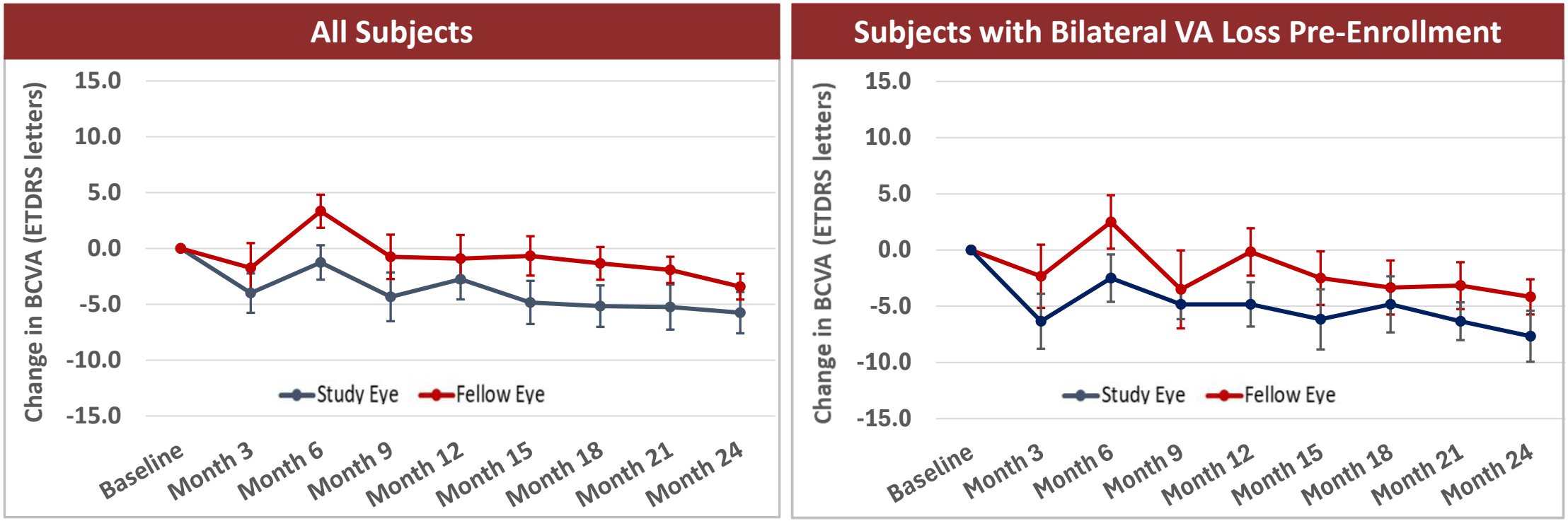
Visual Acuity Outcomes During the Phase 2 Study

- Visual acuity was stabilized during the study with a mean loss of 5 letters in the cohort over 24 months of treatment (2.5 letters lost/year, left panel)*
- For the 6 subjects with prior BCVA loss:
  - **Pre-enrollment, mean BCVA** loss pre-enrollment was **~10 letters/year**
  - **Following 24 months of treatment**, mean BCVA loss of was 6.1 letters **(3 letters/year**, right panel)*



*Mean BCVA values at each timepoint were used to calculate the mean BCVA change over 24 months

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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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DRAGON & DRAGON II
STGD1 Trials

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DRAGON & DRAGON II Clinical Trial Design in STGD1

Reduction in lesion growth rate (DDAF) as measured by retinal imaging is the FDA accepted primary endpoint in STGD1 and GA

	STGD1 "DRAGON" Phase 3[(1)]	STGD1 "DRAGON II" Phase 1b/2/3
Enrollment	104 subjects (have DDAF)	60 subjects (have DDAF)
Sites	Global	Japan, US, UK
Randomization	2:1 ratio (Tinlarebant : Placebo)	1:1 ratio (Tinlarebant : Placebo)
Masking	Double Blind	
Treatment duration	2 years	
Primary measures	Efficacy as measured through DDAF lesion growth rate, safety & tolerability	
Other measures	QDAF, BCVA, SD-OCT, microperimetry	
Interim analysis	Yes	
Key inclusion criteria	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	

[(1)] FDA may require another clinical trial depending on the data from the ongoing Phase 3 study.

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Phase 3 PHOENIX Trial in Geographic Atrophy

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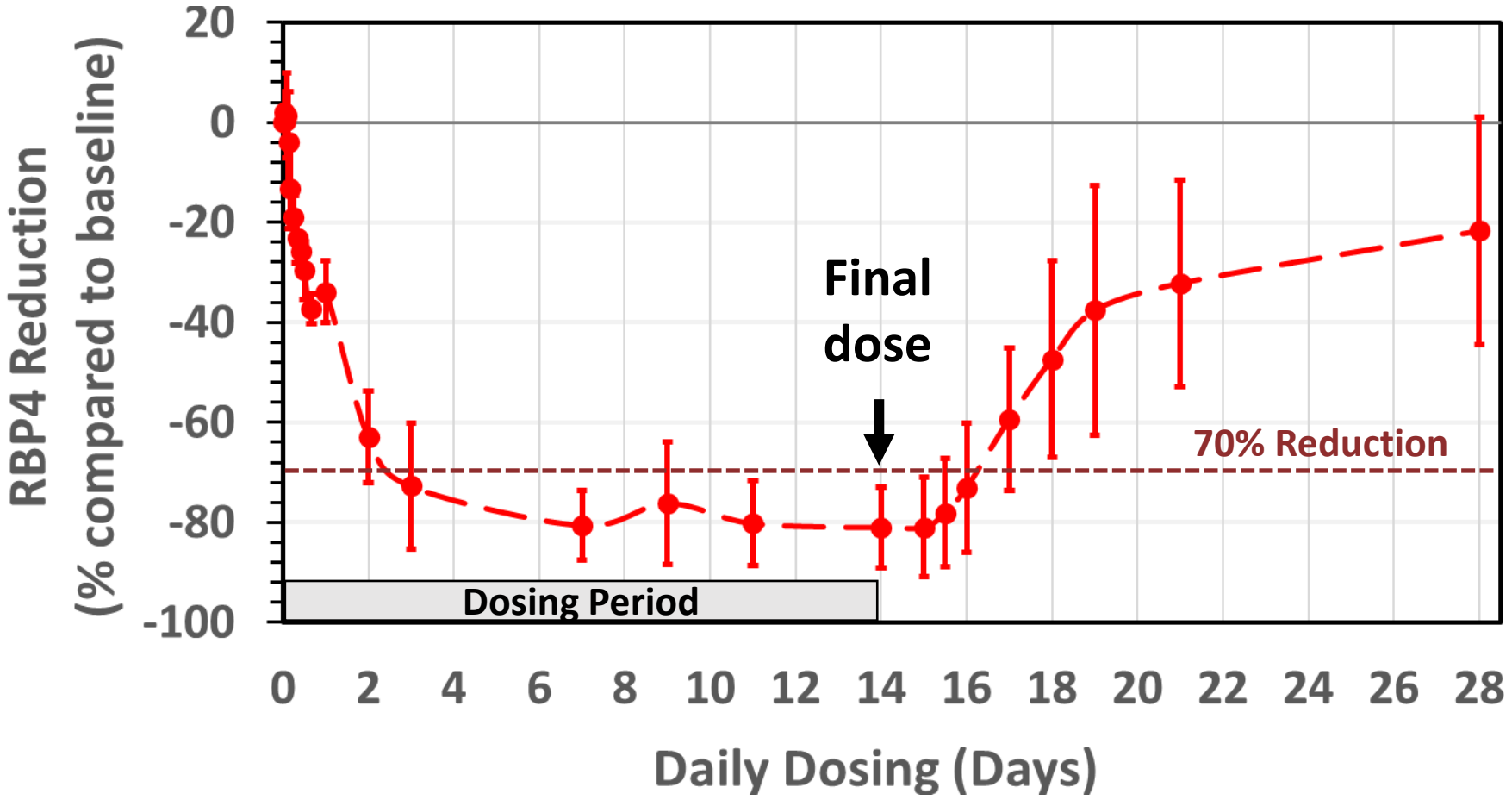
Tinlarebant: ≥ 70% Reduction of RBP4

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



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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" (1)
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

(1) Additional Phase 3 study expected to be required prior to NDA filing

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Thank You

For more info please visit: www.belitebio.com