



Belite Bio 2026 Commercial Day

September 2nd, 2026

8am-9:30am ET

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Belite Commercial Day Agenda



<i>Section</i>	<i>Length</i>	<i>Speaker(s)</i>
Opening	5 mins	• Tom Lin (Chief Executive Officer)
Living with Stargardt Disease	15 mins	• Tracey S. • Havah F.
Disease and Clinical Overview	15 mins	• Dr. Michel Michaelides
U.S. Key Opinion Leader	10 mins	• Dr. Paul Bernstein
Tackling an Important Cause of Blindness	5 mins	• Dr. Hendrik Scholl (Chief Medical Officer)
U.S. Commercial	15 mins	• Kelly Kilpatrick (Chief Commercial Officer)
Live Q&A	25 mins	

Opening



Tom Lin

Chairman, CEO





Mission:

To preserve vision and pioneer degenerative retinal disease treatments where few or none exist today

Vision:

To shine light on the shadows of vision loss and degenerative retinal disease by changing how it is recognized and treated

Key Highlights



1

FDA PRIORITY REVIEW

| PDUFA: Feb. 12, 2027



2

POTENTIAL FIRST & ONLY TREATMENT

| Stargardt disease type 1



3

U.S. LAUNCH READINESS

| Building capabilities to support patients if approved



4

COMMERCIAL-STAGE TRANSFORMATION

| Positioned for transition to a commercial-stage biotech

Joining Today



Tom Lin, MMED, PhD, MBA
Chairman, CEO



Hao-Yuan Chuang, CFA, MBA, FRM
CFO



Hendrik Scholl, MD, MA
CMO



Kelly Kilpatrick
CCO

Guest Speakers



Michel Michaelides,
BSc MB BS MD(Res) FRCOphth FACS

- Consultant Ophthalmologist at Moorfields Eye Hospital in the Departments of Medical Retina, Inherited Eye Disease and Pediatric Ophthalmology
- Professor of Ophthalmology at the UCL Institute of Ophthalmology



Paul S. Bernstein,
MD, PhD

- Val A. and Edith D. Green Presidential Endowed Chair in Ophthalmology and Visual Sciences
- Vice-Chair for Clinical Research
- Chief of the Retina Division, Moran Eye Center
- University of Utah School of Medicine

Living with Stargardt Disease



Tracey S.



Havah F.





Q1: What signs and symptoms led to your diagnosis of Stargardt disease?



Q2: What were you told to expect when you were diagnosed with Stargardt disease?



Q3: How does living with Stargardt disease impact your day-to-day life?



Q4: What is most challenging for you about living with Stargardt disease?



Q5: What are your hopes for the future for people living with Stargardt disease?

Disease and Clinical Overview



Michel Michaelides

BSc MB BS MD(Res) FRCOphth FACS



Stargardt Disease



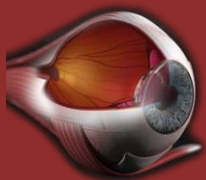
- **Most common** juvenile macular dystrophy
- Described by Karl Stargardt in 1909
- **Ocular exam signs:** areas of retinal atrophy centrally, and subretinal yellowish flecks more peripherally
- Manifestation **age range:** 1 → 84+ years

Stargardt K (1909) Über familiäre, progressive Degeneration in der Maculagegend des Auges (On familial, progressive degeneration in the macular region of the eye). *Zeitschrift für Augenheilkunde*. 22: 289–306.

Lambertus S et al. (2015) Early-onset Stargardt disease: phenotypic and genotypic characteristics. *Ophthalmology*. 122: 335–44.

Lambertus S et al. (2016) Progression of Late-Onset Stargardt Disease. *Invest Ophthalmol Vis Sci*. 57: 5186–5191.

Stargardt Disease Overview



Stargardt disease (STGD1) and/or *ABCA4*-associated retinal dystrophy is a rare and progressive eye disease leading to legal blindness in almost all cases.

There is no approved treatment for Stargardt disease.

Pathophysiological Changes

- **Autosomal recessive mutations** in the *ABCA4* gene, impair retinoid transport and lead to **toxic bisretinoid buildup** in the **retinal pigment epithelium (RPE)**
- **Bisretinoid accumulation** manifests as yellowish flecks underneath the retina and causes **oxidative stress, toxicity, and eventually RPE cell death**
- RPE damage leads to **secondary degeneration of macular photoreceptors**
- **Progressive macular atrophy** and **retinal degeneration**

Key Symptoms

- **Gradual central vision loss** in both eyes, often **starting in childhood or early adulthood**
- Blurry or **distorted** central vision
- **Central blind spots** (scotomas)
- **Photophobia** and **delayed dark adaptation**
- **Impaired color vision**
- **Difficulty** with **detailed tasks** like reading or recognizing faces
- **Peripheral vision preserved** in the majority of cases

Impact on Activities of Daily Living

- **Challenges** with **reading**, using **screens**, and **recognizing faces**, harming education and work
- Typically, **inability to drive**, reducing mobility and independence
- **Restrictions in sports, leisure, and simple tasks** like avoiding trips
- **Social struggles**, including interactions, relationships, and events
- Emotional effects like **frustration, worry, anger, and depression**
- Career changes or **job loss**, affecting finances and productivity

ProgStar Study: The Natural History of the Progression of Atrophy Secondary to Stargardt Disease



DDAF Represents Well-Demarcated Areas of Complete RPE Loss and Grows Predictably, Making It an Approvable Primary Endpoint

DDAF

Definitely Decreased Autofluorescence

Darkness level of at least **90%** relative to the ONH

QDAF

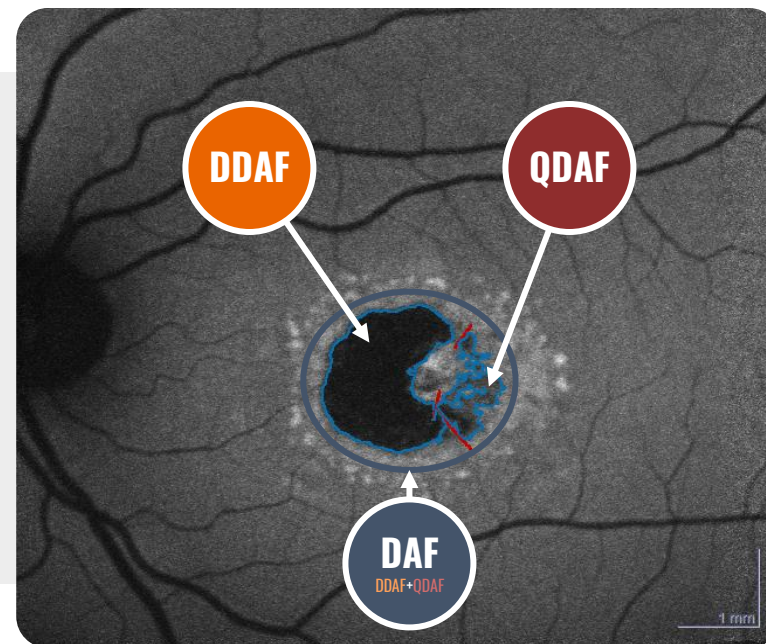
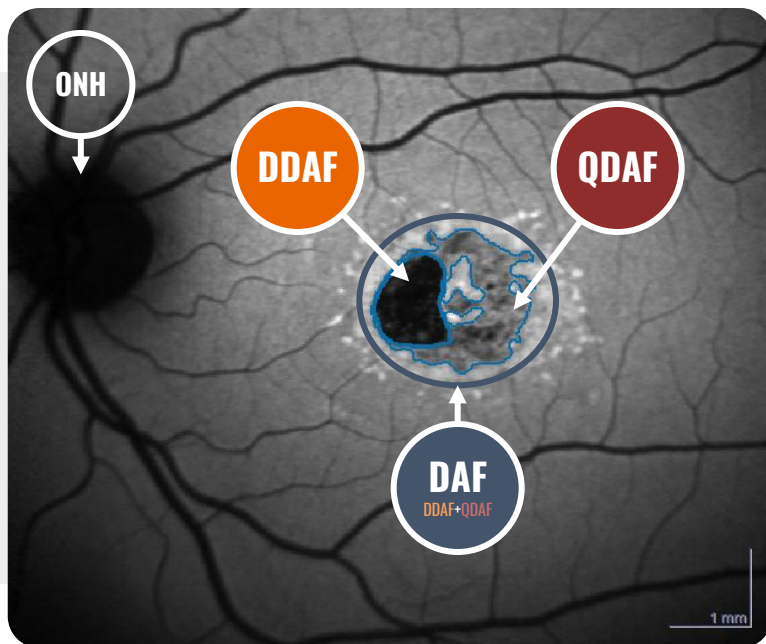
Questionably Decreased Autofluorescence

Darkness level between **50% and 90%** relative to the ONH

DAF

Decreased Autofluorescence

The combined sum of **DDAF + QDAF**



ONH = optic nerve head.

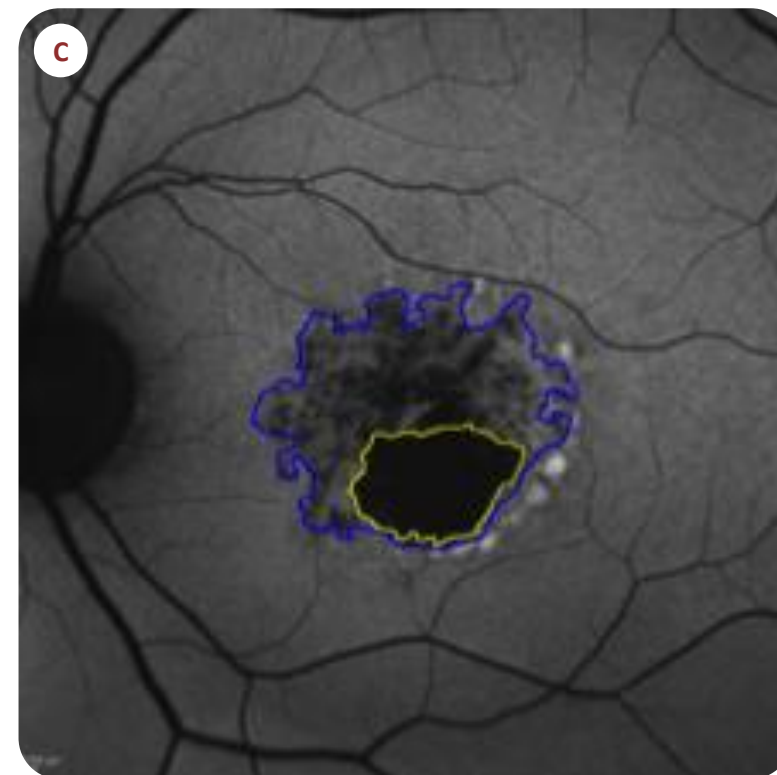
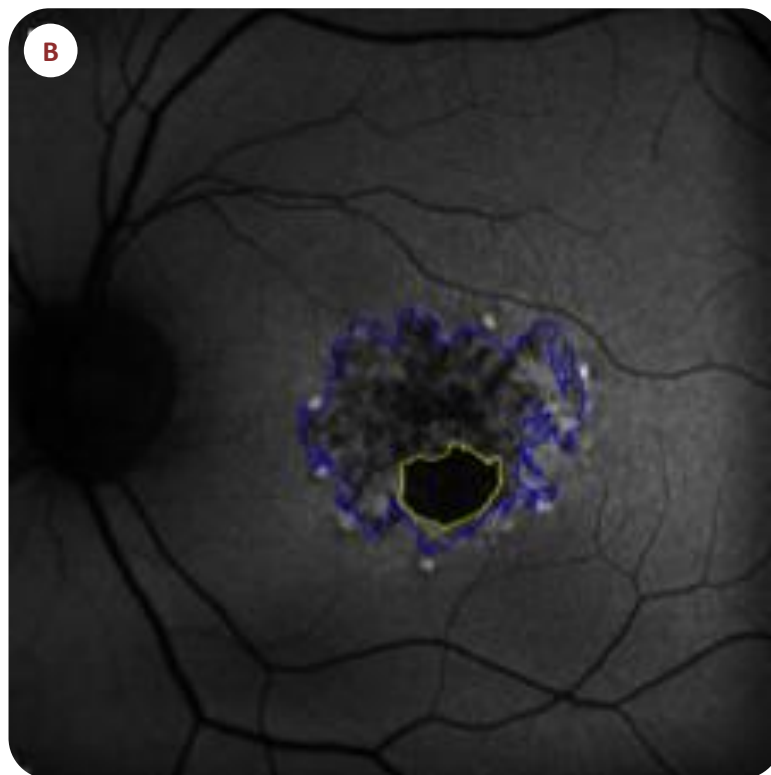
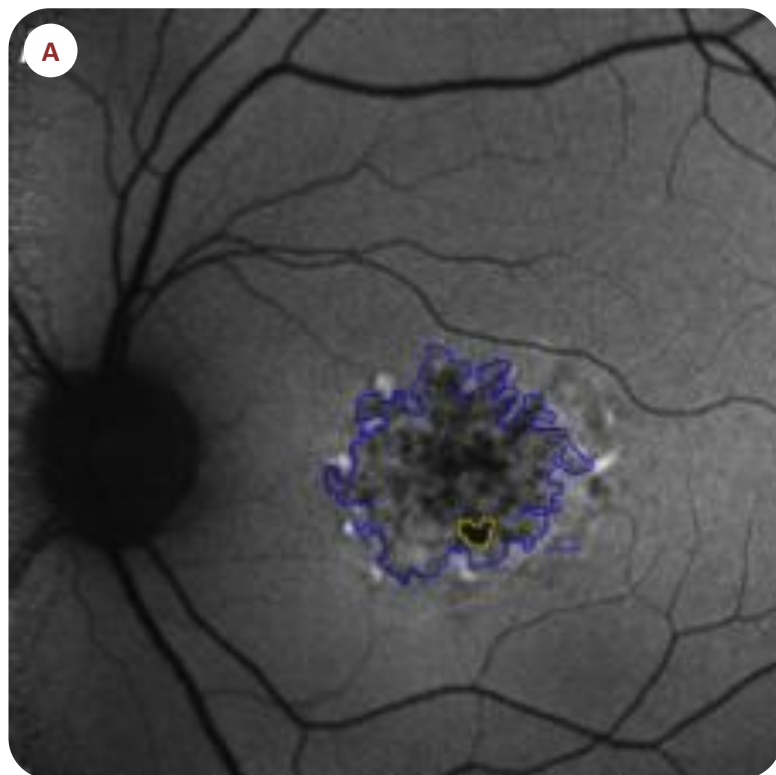
Strauss RW, Ho A, Jha A, Fujinami K, Michaelides M, Cideciyan AV, Audo I, Birch DG, Sadda S, Ip M, West S, Schönbach EM, Kong X, Scholl HPN; ProgStar Study Group (2023) The progression of Stargardt Disease as determined by fundus autofluorescence over a 24-month period (ProgStar Report No. 17). Am J Ophthalmol. 250: 157-170.

DDAF Progression Rate in Stargardt



Natural History of the Progression of Atrophy Secondary to Stargardt Disease (ProgStar) Study

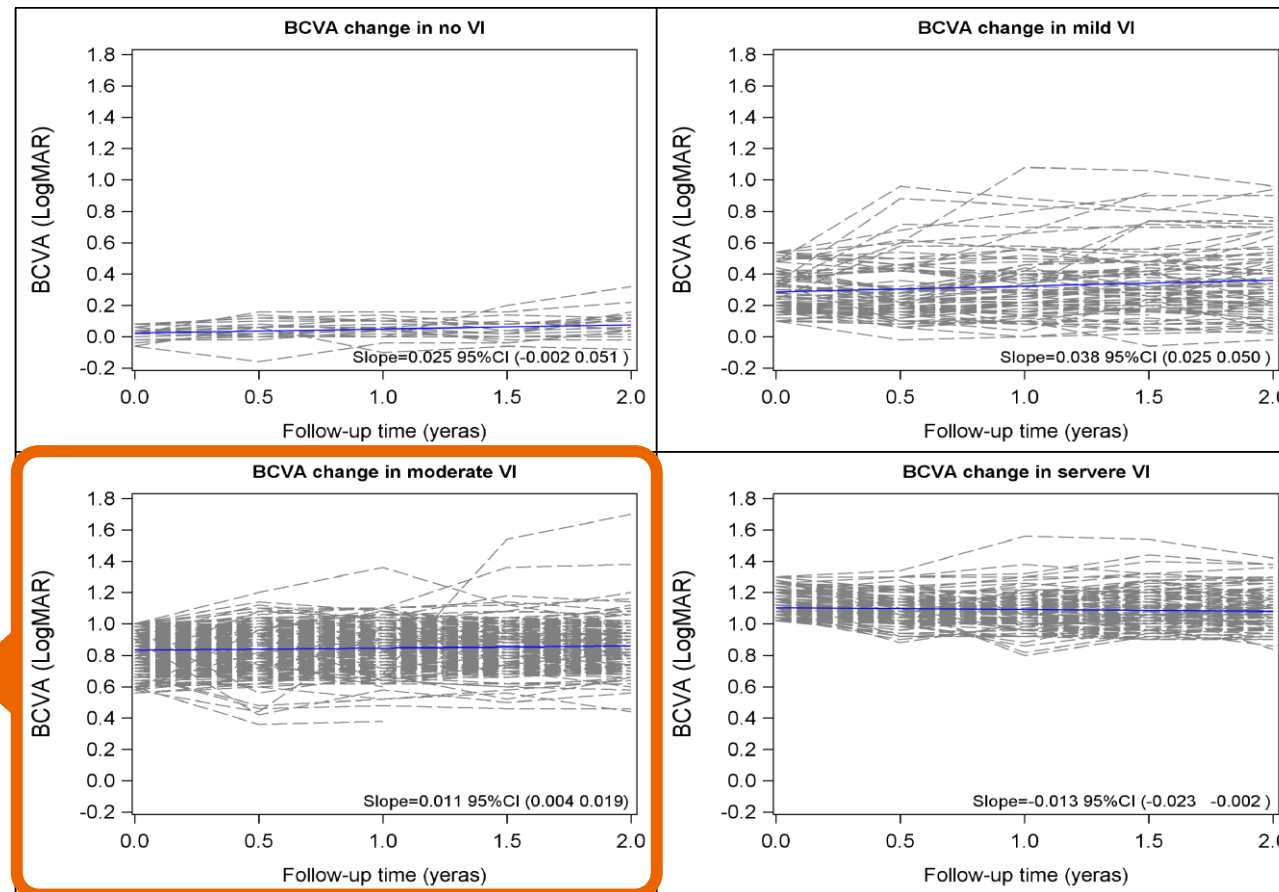
Overall DDAF growth rate in the ProgStar cohort over 24 months: 0.74 mm²/year
(confidence interval: 0.64 - 0.85 mm²/year)



ProgStar: Visual Acuity Change over 24 Months



Prospective Cohort (N=434)



**BCVA of eyes with baseline BCVA
between 20/70 and 20/200
declined at a rate of 0.6 letters/year**

Overall rate of BCVA loss was 0.55 letters/year over two years

BCVA = best-corrected visual acuity; LogMAR = logarithm of the minimum angle of resolution; VI = visual impairment.

Kong X, Fujinami K, Strauss RW, Munoz B, West SK, Cideciyan AV, Michaelides M, Sahel JA, Ahmed M, Ervin AM, Schönbach EM, Cheetham JK, Scholl HPN; ProgStar Study Group (2018) Visual Acuity Change over 24 Months and its Association With Foveal Phenotype and Genotype in Individuals With Stargardt Disease: ProgStar Report Number 10. JAMA Ophthalmol. 136: 920-928.

DRAGON Clinical Trial Design in Stargardt Disease



Reduction in atrophic lesion growth rate as measured by fundus autofluorescence imaging is the FDA's accepted primary endpoint in Stargardt disease and geographic atrophy secondary to age-related macular degeneration

DRAGON Design

Key Inclusion Criteria

- Clinical diagnosis of Stargardt disease
- 12-20 years old
- ≥ 1 mutation identified in the *ABCA4* gene
- Atrophic lesion size (DDAF) within 3 disc areas (7.62 mm^2)
- BCVA of 20/200 or better

N=104

Phase 3 Trial

Randomized 2:1

Treatment
n=69

Placebo
n=35

Double-blinded, global trial of
oral tinlarebant 5mg/day

2-Year Duration

Primary Measures

- *Slowing of atrophic lesion growth (DDAF)*
- *Safety and tolerability*

Secondary Measures

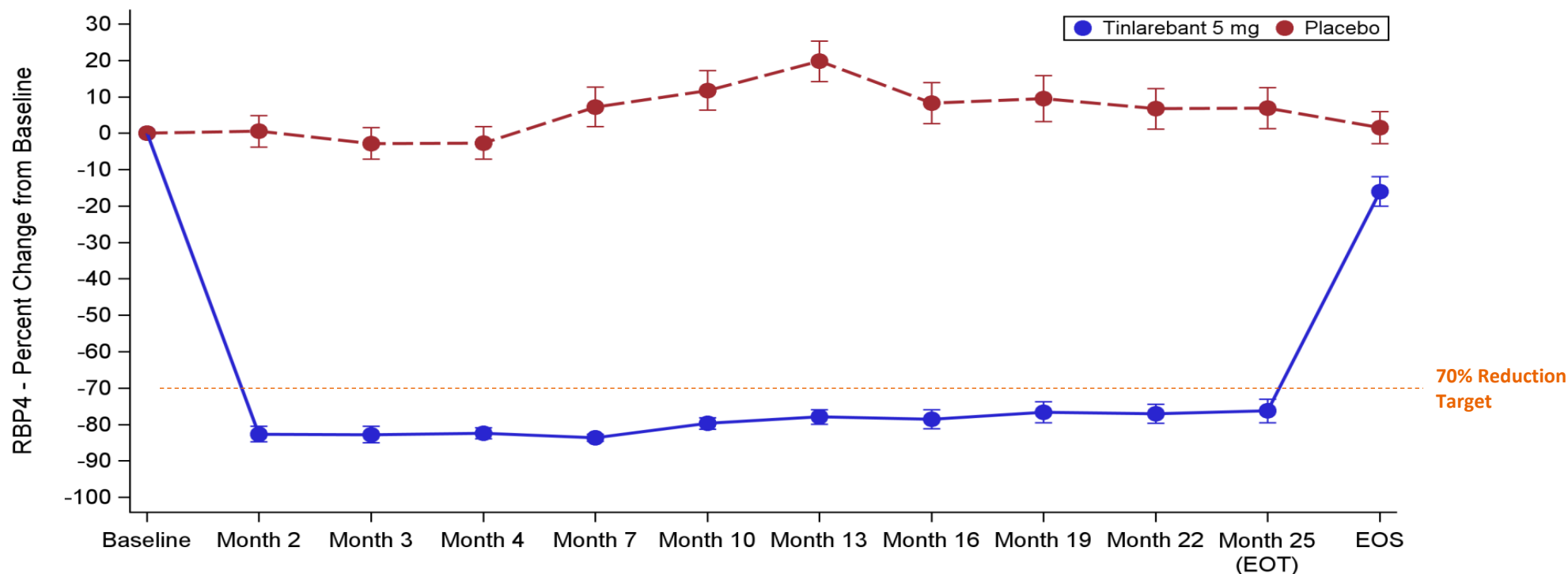
- *DAF*
- *BCVA*
- *SD-OCT*
- *Microperimetry*



Tinlarebant Treatment Led to 80% Reduction in RBP4, Well Above Goal of 70%*

Biomarker: RBP4 – Percent Reduction from Baseline

PD Set N=92



* In a prior study of a surrogate RBP4 antagonist (fenretinide) in patients with Geographic Atrophy, an RBP4 reduction of $\geq 70\%$ was associated with a statistically significant slowing of lesion growth [Mata et al., Retina. 2013; 33(3): 498-507.]

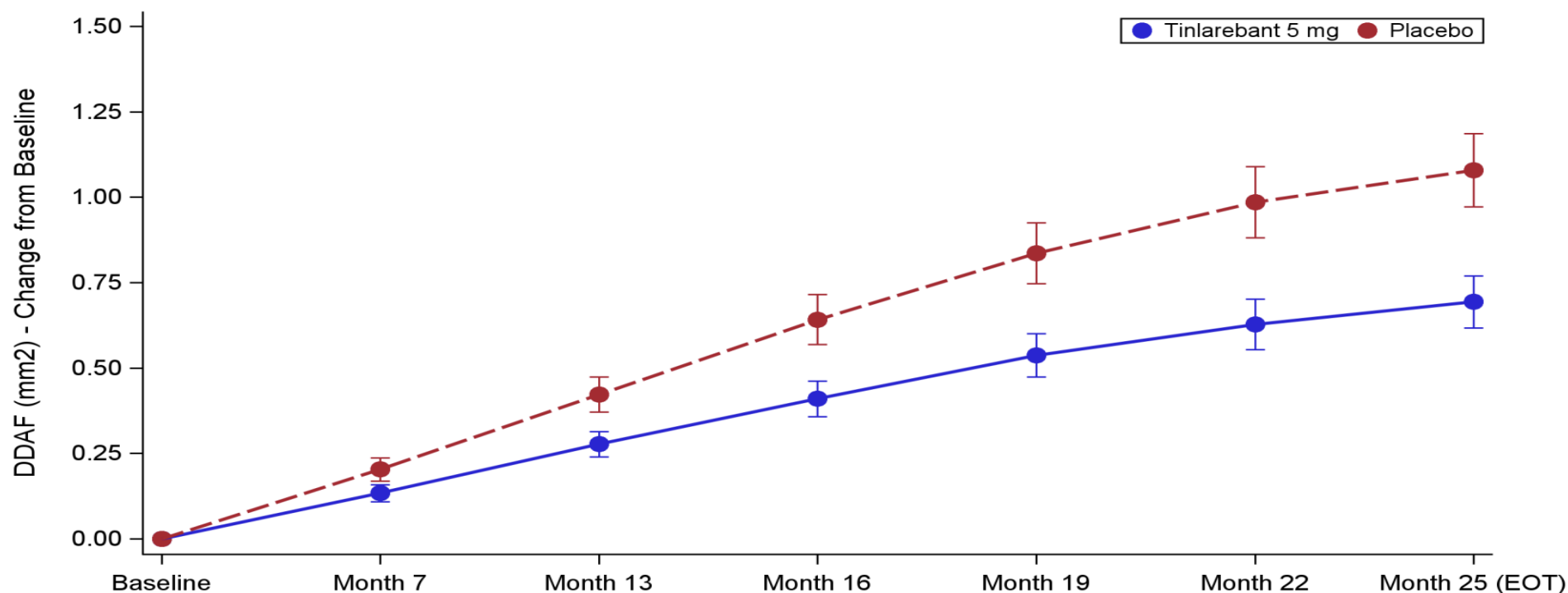
Daily dosing of 5mg/day tinlarebant led to a sustained 80% reduction of RBP4 and RBP4 levels returned to 84% of the baseline value at the End of Study (EOS)

Primary Endpoint Showed a Statistically Significant and Clinically Meaningful Outcome



Primary Endpoint: DDAF Change from Baseline (Study Eye)

mFAS N=96



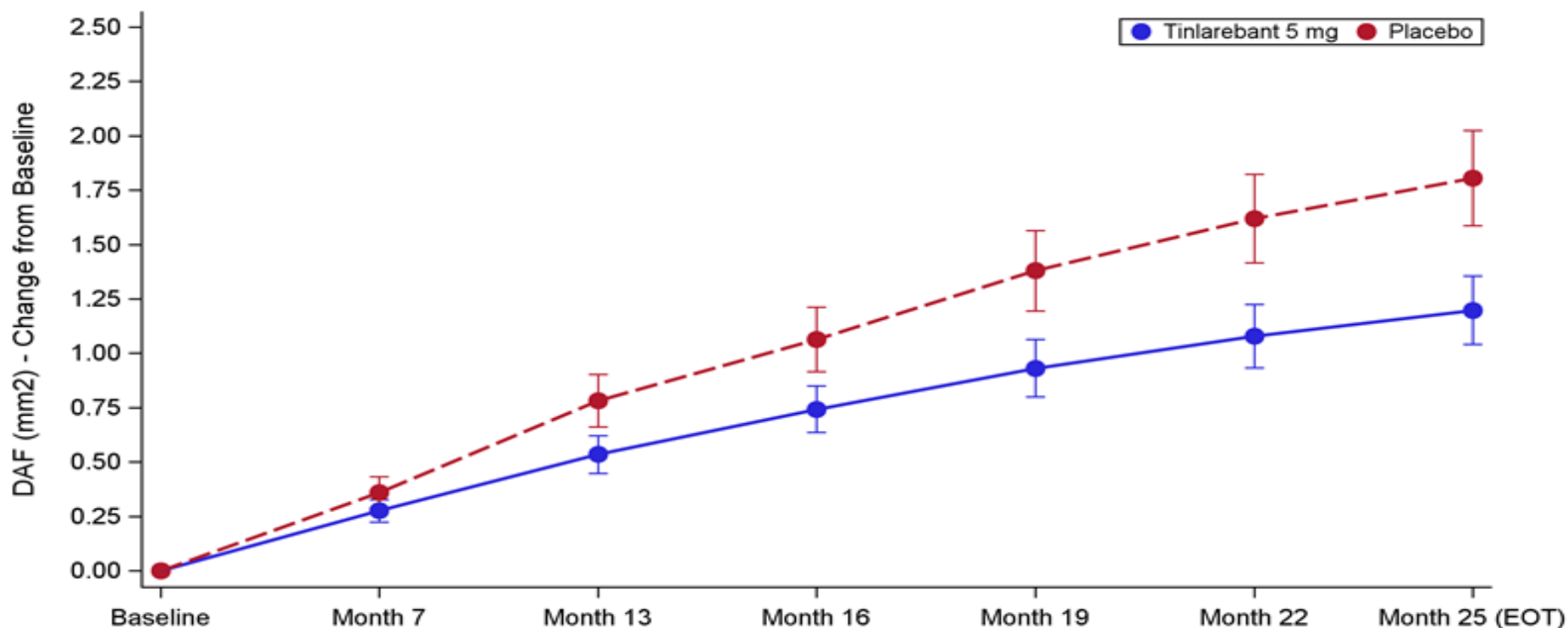
- Applying an unstructured covariance matrix, the **treatment effect size was 35.7%** compared to placebo and yielded a **p-value of 0.0033**
- With a first-order autoregressive covariance matrix, the **treatment effect size remained consistent (35.4%)** with **P<0.0001**
- DDAF lesion growth was **slowed to 0.38 mm²/year vs. 0.59 mm²/year for placebo and 0.74 mm²/year observed in ProgStar**



Tinlarebant Slowed DAF Lesion Growth, the Key Secondary Endpoint, in the Study Eye by 33.7%

Key Secondary Endpoint: DAF Change from Baseline (Study Eye)

mFAS N=96



Tinlarebant slowed DAF lesion growth by 33.7% compared to placebo (P=0.027)

As Expected, BCVA in Study Eye Did Not Show Any Significant Change



	Tinlarebant 5mg (N=69)	Placebo (N=35)
BCVA at Baseline	39.9	39.4
BCVA at EOS	39.7	40.0

- The overall change of visual acuity was minimal over the period of 24 months in both treatment groups
- Test–retest variability for ETDRS change scores in Stargardt disease are known to yield a repeatability coefficient ≈ 8 letters ⁽¹⁾
- Such minor changes in average visual acuity over two years are in line with the natural history of Stargardt disease and were observed in the ProgStar Study

ETDRS = Early Treatment Diabetic Retinopathy Study.

(1) Parker MA, Choi D, Erker LR, Pennesi ME, Yang P, Chegarnov EN, Steinkamp PN, Schlechter CL, Dhaenens CM, Mohand-Said S, Audo I, Sahel J, Weleber RG, Wilson DJ. Test-Retest Variability of Functional and Structural Parameters in Patients with Stargardt Disease Participating in the SAR422459 Gene Therapy Trial. Transl Vis Sci Technol. 2016 Oct 1;5(5):10.

Tinlarebant Demonstrated a Well Tolerated Safety Profile

Safety Set N=104



Subjects Who Experienced at Least One Non-Ocular Treatment-Emergent Adverse Event (TEAE), N / (%)

Category	Tinlarebant 5mg (N=69)	Placebo (N=35)
TEAE	59 (85.5%)	27 (77.1%)
Severe TEAE	2 (2.9%)	1 (2.9%)
Serious TEAE	2 (2.9%)	4 (11.4%)
Study Drug-Related TEAE	14 (20.3%)	4 (11.4%)
Study Drug-Related Serious TEAE	0 (0.0%)	0 (0.0%)
TEAE Leading to Study Drug Discontinuation	0 (0.0%)	0 (0.0%)
TEAE Leading to Study Discontinuation	0 (0.0%)	0 (0.0%)
TEAE Leading to Death	0 (0.0%)	0 (0.0%)

- Total of 6 serious adverse events (SAEs) reported in the study – all events were non-ocular, with 4 assessed as unrelated and 2 assessed as unlikely related to the study treatment
- Most reported Non-Ocular adverse events (AEs): Nasopharyngitis (all cases were assessed as unrelated/unlikely related to treatment), Headache, and Acne – most events were mild and resolved during the study period

The Majority of Ocular Adverse Events Was Mild

Safety Set N=104



Subjects Who Experienced at Least One Ocular TEAE, N / (%)

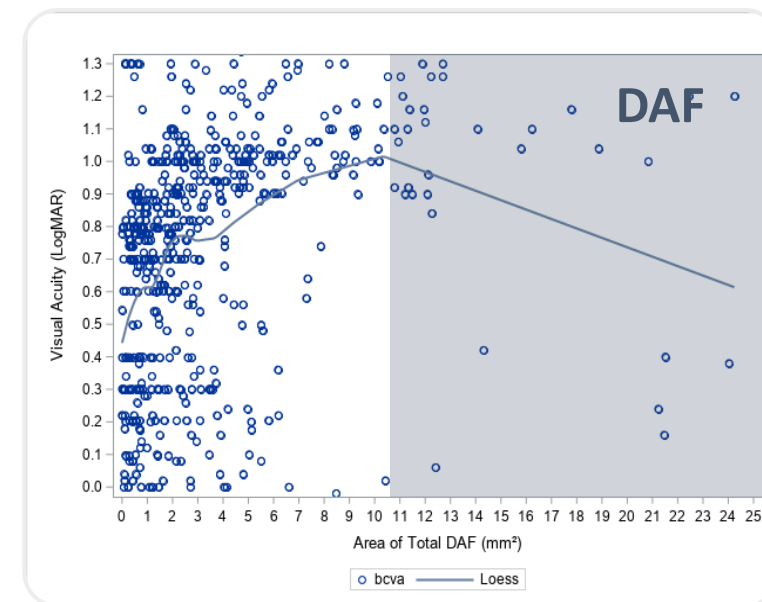
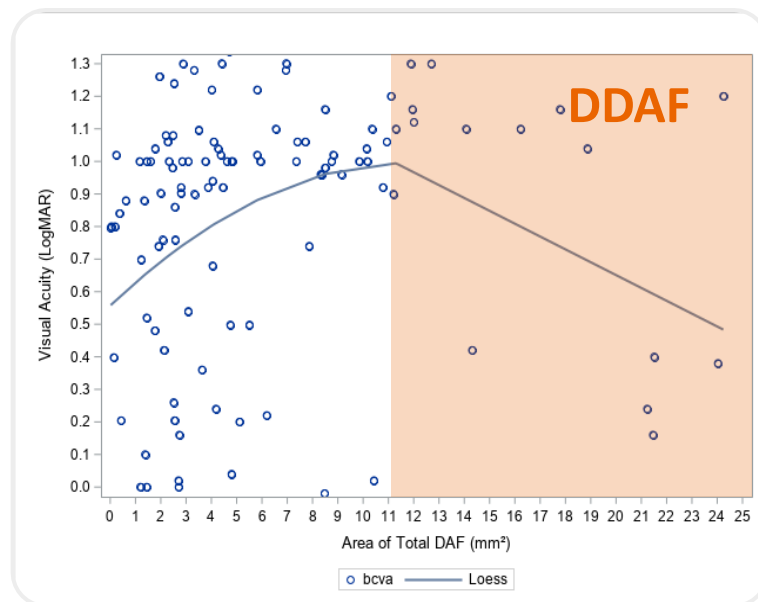
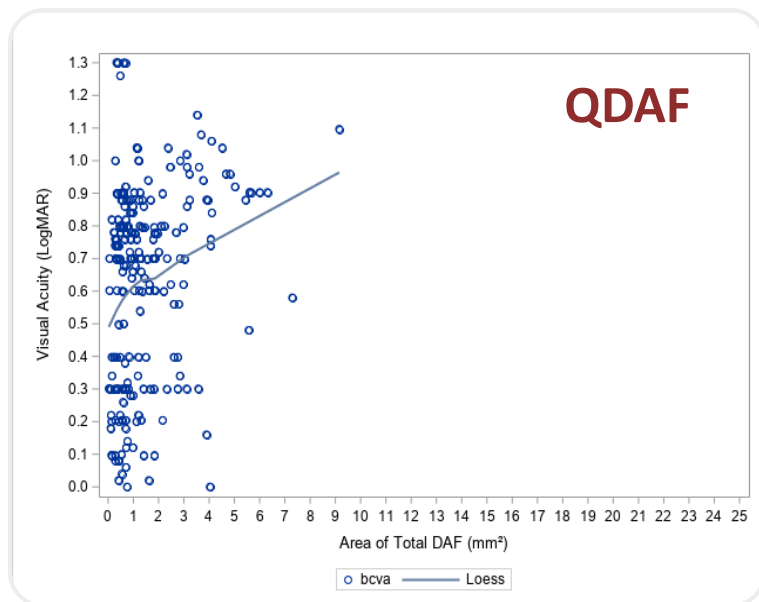
Category	Tinlarebant 5mg (N=69)	Placebo (N=35)
TEAE	53 (76.8%)	8 (22.9%)
Severe TEAE	2 (2.9%)	0 (0.0%)
Serious TEAE	0 (0.0%)	0 (0.0%)
Study Drug-Related TEAE	49 (71.0%)	8 (22.9%)
Study Drug-Related Serious TEAE	0 (0.0%)	0 (0.0%)
TEAE Leading to Study Drug Discontinuation	4 (5.8%)	0 (0.0%)
TEAE Leading to Study Discontinuation	2 (2.9%)	0 (0.0%)
TEAE Leading to Death	0 (0.0%)	0 (0.0%)

- **Most reported Ocular AEs: Xanthopsia, Delayed dark adaptation, and Night Vision Impairment**
- **The majority of the events were mild, and most resolved while on study**
- **There were no serious ocular TEAEs – 4 TEAEs led to study drug discontinuation and 2 TEAEs led to study discontinuation**

Association of QDAF, DDAF and DAF with Visual Acuity in Stargardt Disease



Secondary cross-sectional data analysis using data from 301 ProgStar Study participants (566 study eyes)



- For QDAF lesions, every 1mm² larger QDAF area was associated with **3.3 letters worse VA (p<0.001)**
- For DDAF lesions and lesion area <11mm², every 1mm² larger DDAF area was associated with **1.5 letters worse VA (p=0.02)**
- For DAF lesions (all eyes) and lesion area <11mm², every 1mm² larger DAF area was associated with **0.9 letters worse VA (p=0.003)**

Severe Loss of Light Sensitivity within DDAF



Microperimetry as an exploratory outcome measure in the DRAGON trial

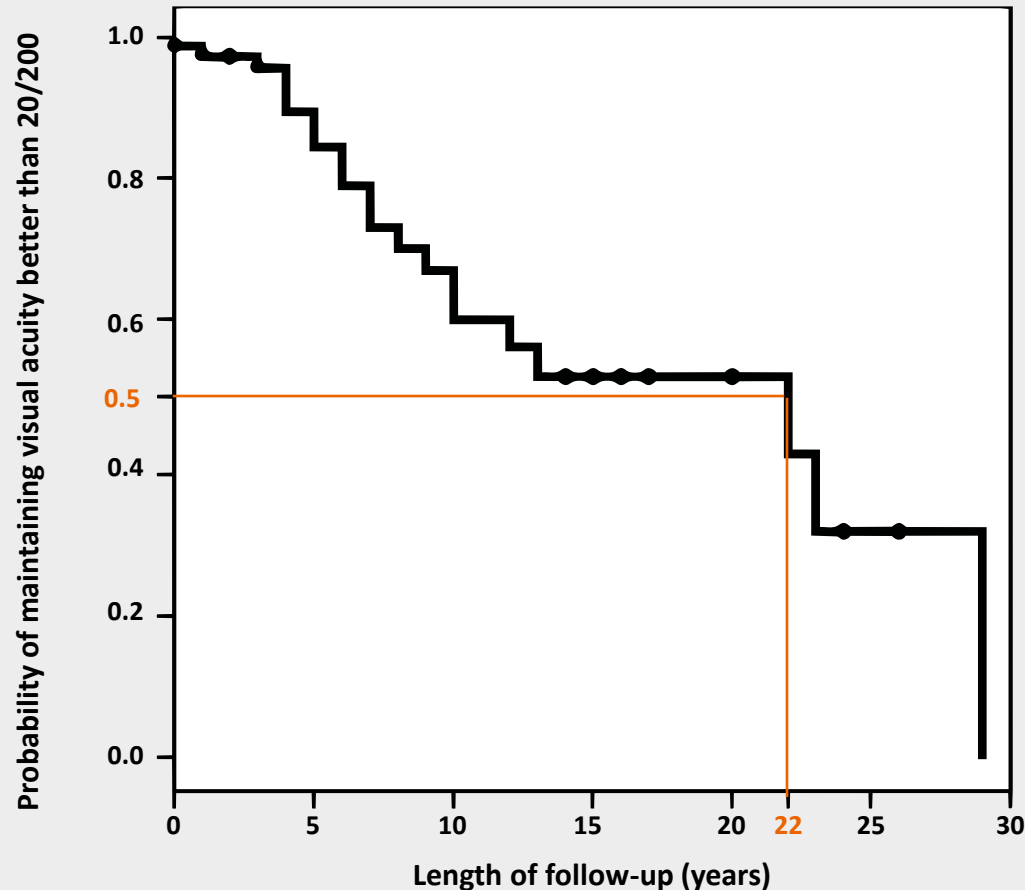


- Within DDAF lesions in the study eye, mean retinal sensitivity (at baseline) was **4.26 ± 5.59 dB** for the tinlarebant group and 4.28 ± 7.07 dB in the placebo group
- This corresponds to a marked reduction of approximately 2.2-2.6 log units (up to 400-fold) compared with an unaffected retina

Slow but Inevitable Loss of Visual Acuity in Stargardt Disease



Retrospective Mono-Center Study of N=361 STGD1 Patients at the
Department of Ophthalmology and Visual Sciences, University of Illinois at Chicago



Kaplan-Meier curve for the
**time to reach a visual acuity
of 20/200 or worse** in
Stargardt patients with visual
acuity of 20/40 or better at
initial visit

Tinlarebant Has the Potential to Be the First-Ever Approved Treatment for Stargardt Disease



Tinlarebant



First-ever oral therapy in a retinal degenerative disease to demonstrate a **clinically meaningful slowdown of neurodegeneration**

Efficacy



36% reduction in DDAF lesion growth rate, representing a statistically and clinically significant treatment effect in Stargardt disease

Safety



Well tolerated safety and tolerability profile across two years of treatment

Mechanism of Action



Addresses the root pathogenic mechanism (bisretinoid accumulation), offering a rational, disease-modifying approach where no approved therapies currently exist

Applicability



Broad applicability across disease stages, from early ABCA4-mediated changes to more advanced atrophy

U.S. Key Opinion Leader (KOL)

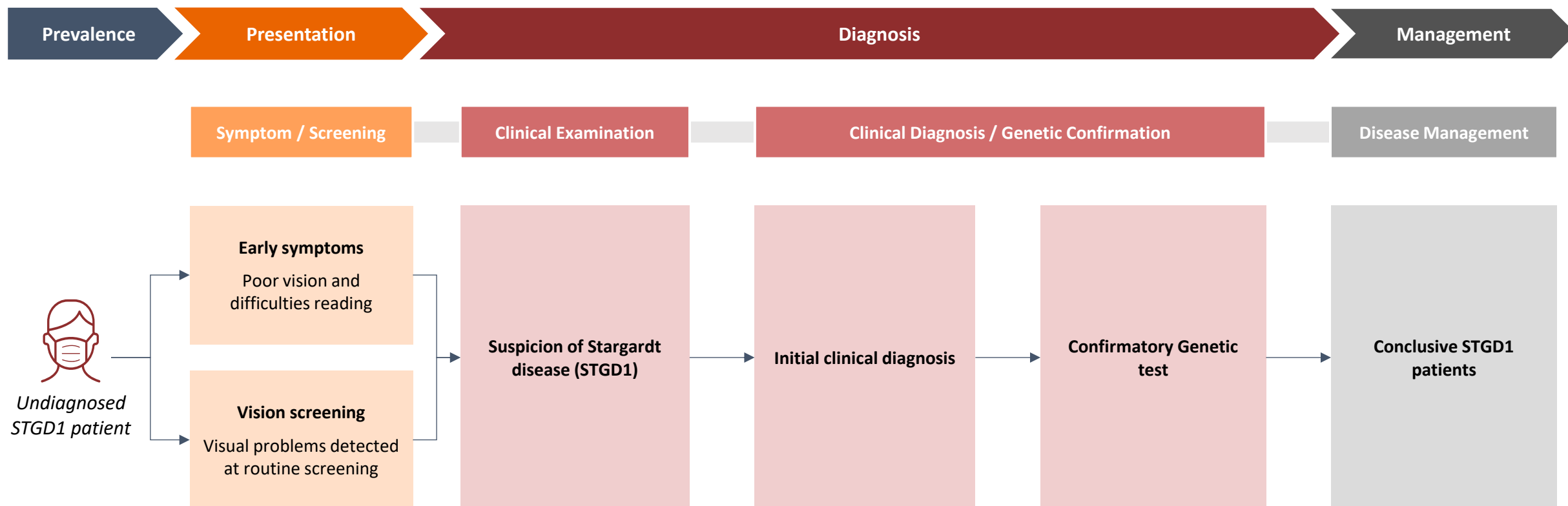


Paul S. Bernstein

MD, PhD



The Current Stargardt Disease Patient Journey Involves Multiple Specialists



HCPs
INVOLVED



Pediatrician



Optometrists



General
ophthalmologist



Retina specialist



Inherited retinal disease
specialist



Genetic
counselor

Retina Specialists' Diagnosis of STGD1 is Aided by Genetic Testing



Commonly Used Diagnostic Tests



Visual Function Tests

e.g., BCVA, Microperimetry, Color Vision Testing



Retinal Imaging Modalities

e.g., FAF, SD-OCT and Fundus Photography



Genetic Testing

e.g., gene panel or genomic sequencing

Genetic testing is critical:



Because of the presence of disease phenocopies, genetic testing is a critical component to confirm the STGD1 diagnosis

Follow-up is specialist-led:



IRD or retina specialists conduct regular follow-up, using functional tests and retinal imaging to monitor progression and document visual decline

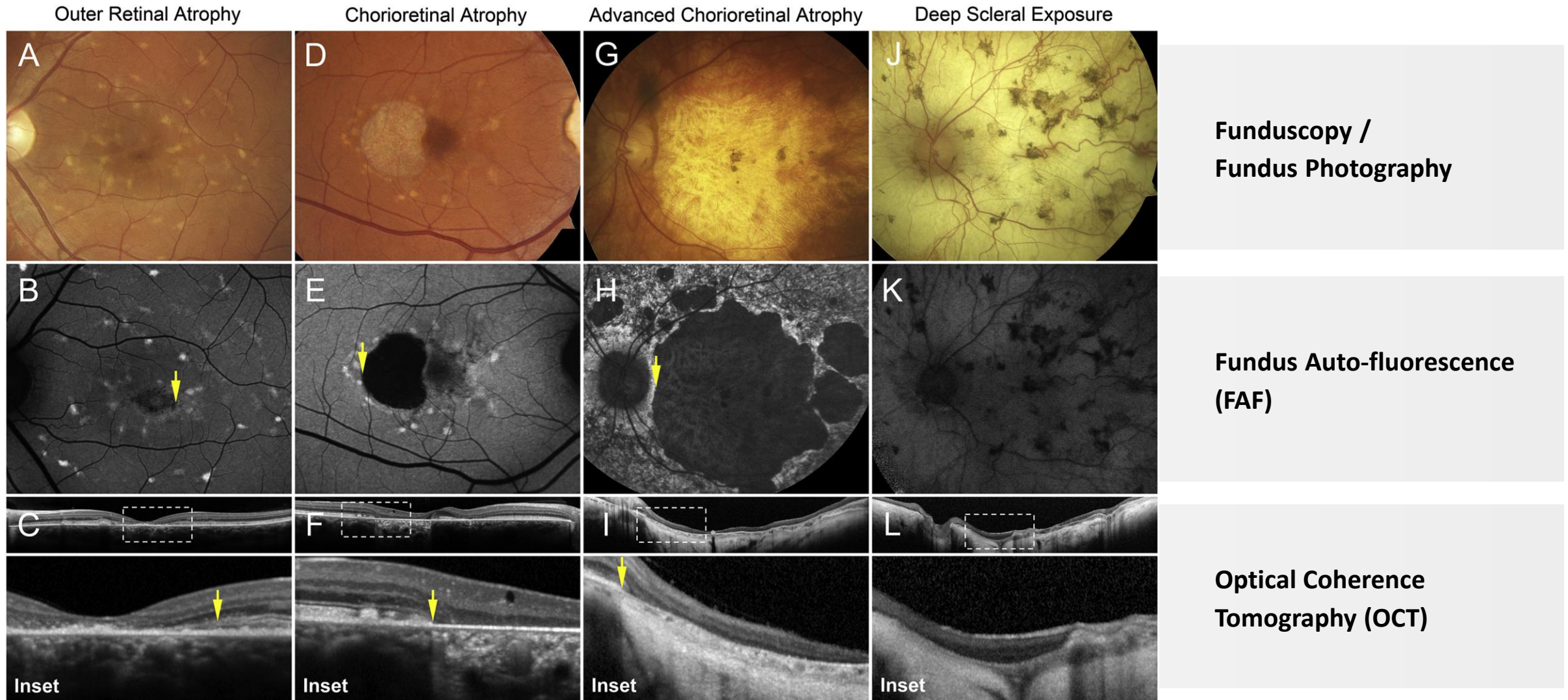
Visit frequency tapers over time:



Most patients see a specialist yearly post-diagnosis, though many gradually extend the interval between visits

Retina specialists are very familiar with Stargardt disease and comfortable with genetic testing, but general ophthalmologists – the referral entry point for most patients – have more limited knowledge of both Stargardt disease and genetic testing.

Progressive Retinal Degeneration Leads to Visual Decline in Stargardt Disease



Critical Gap in Care: No Current Standard of Treatment for Stargardt Disease



Stargardt Management Today – No Approved Disease-Modifying Therapy



Recommend UV-blocking glasses/sunglasses



Recommend avoidance of Vitamin A supplementation



Counseling on lifestyle and career choices



Prescribe low-vision aids (e.g., magnifiers)

Current Patients and Caregivers Unmet Need



Difficulty reading



Loss of independence – most profound impact



Ongoing social challenges

Care today can help patients adapt to vision loss – but it does not impact the disease itself, leaving patients and caregivers to navigate a profound burden largely alone.

Tackling an Important Cause of Blindness

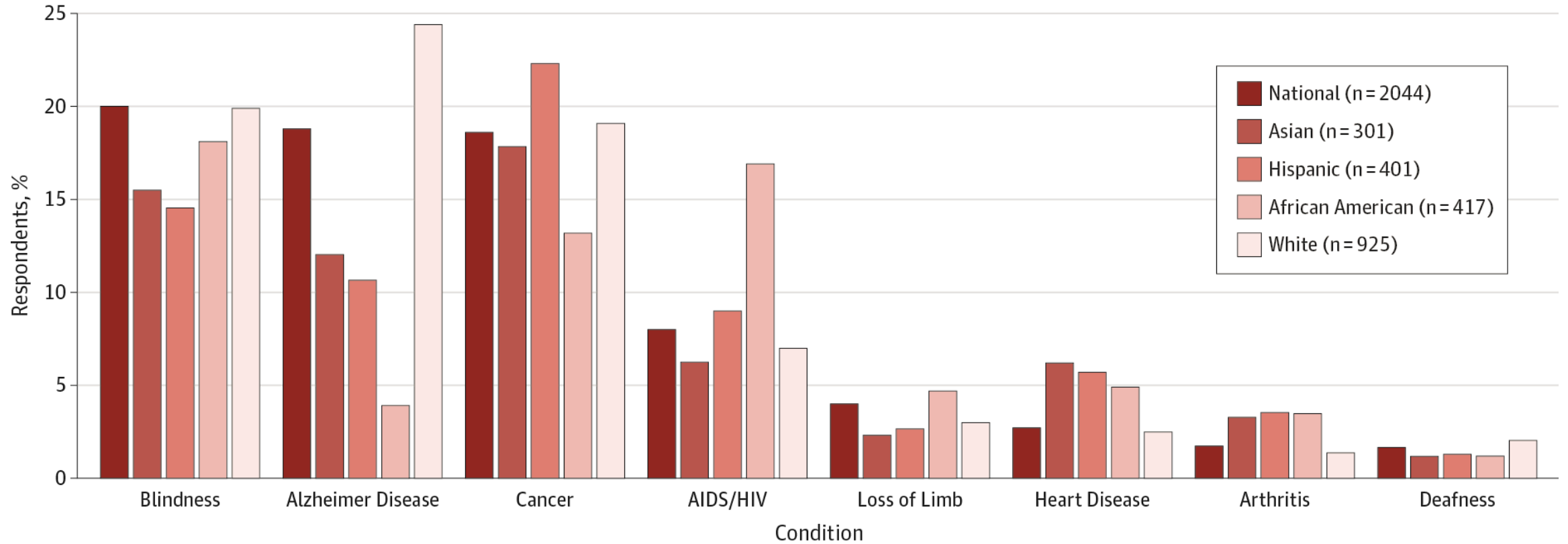


Hendrik Scholl

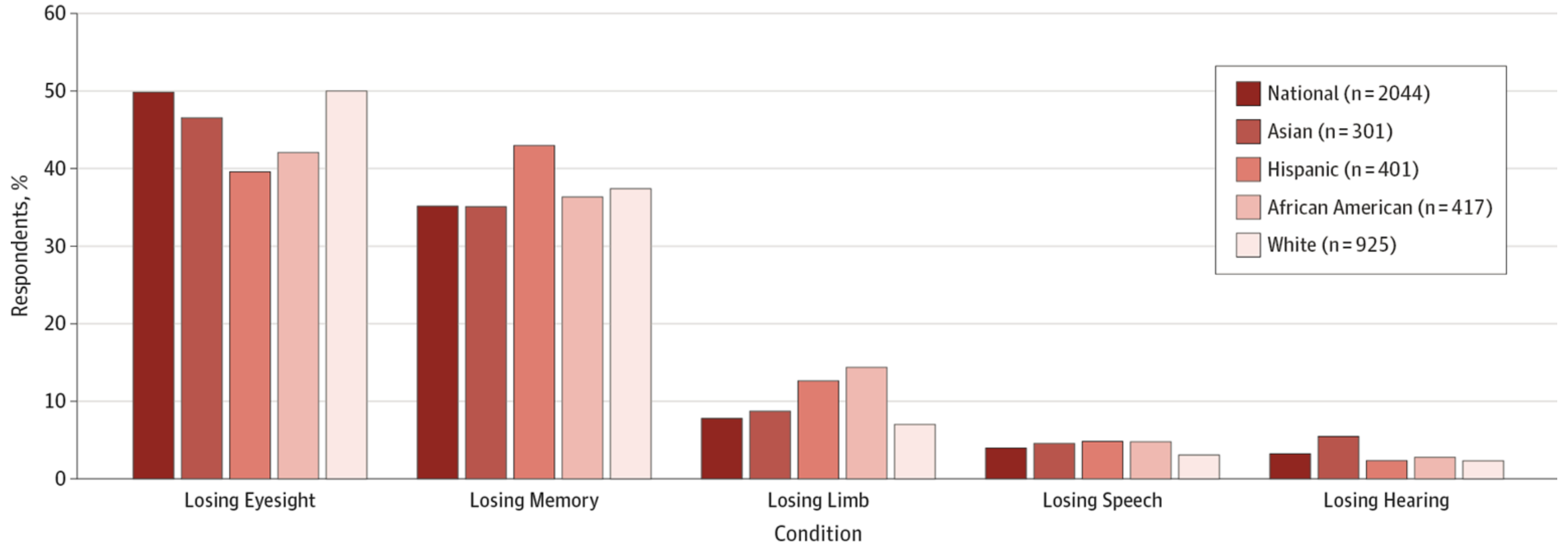
Chief Medical Officer



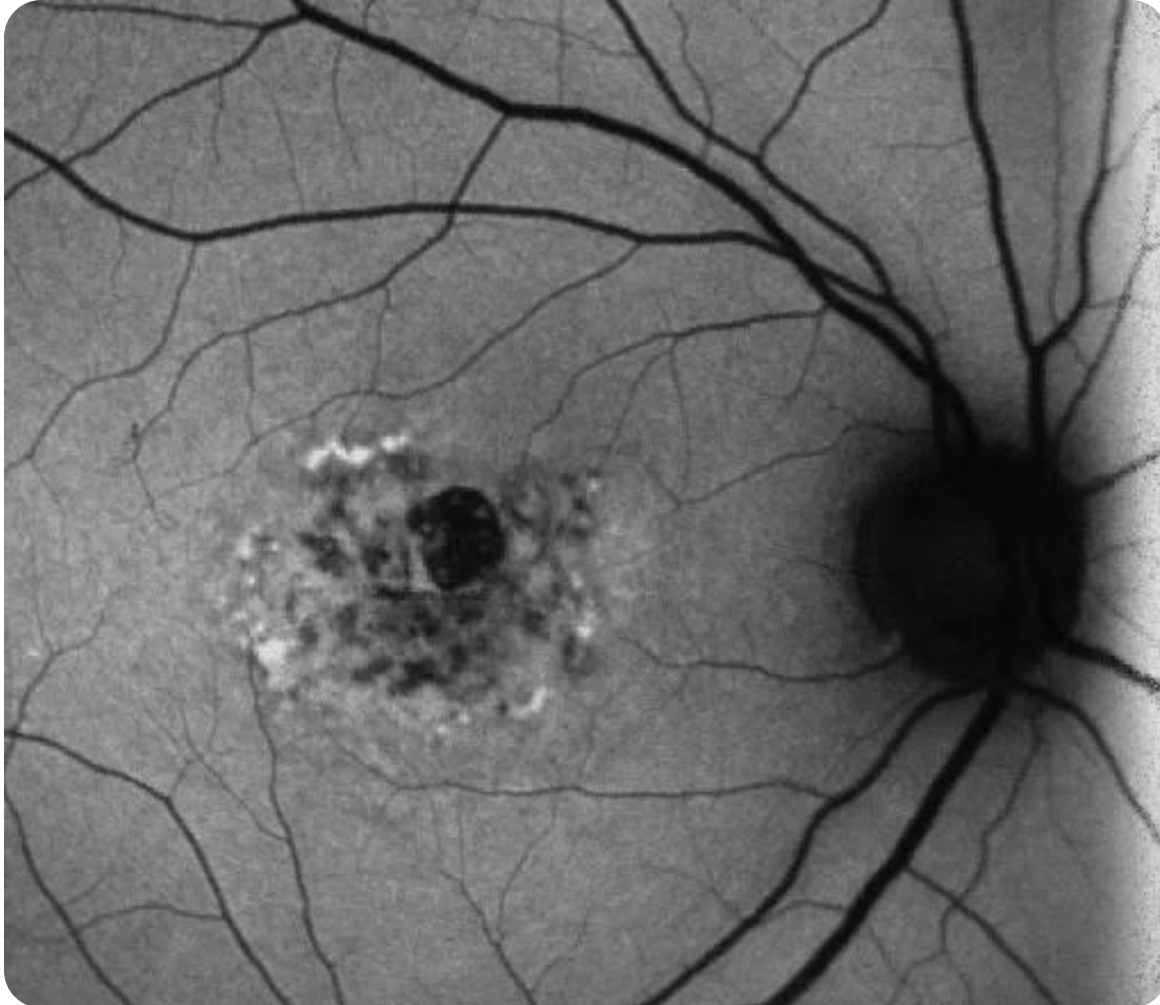
Ranking of Serious Health Conditions



Conditions With the Greatest Effect on Day-to-Day Life



DDAF Progression and Visual Loss in Stargardt Disease



Atrophy Progression over 4 Years

- **37-year-old male patient**
- **Compound heterozygous for mutations in *ABCA4***
 - Visual acuity (baseline): 20/40
 - Visual acuity (at 4Y): 20/80



Estimated Patient Population Sizes of STGD1



Europe



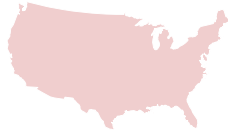
Australia



China



Japan



United States

gnomAD Ethnicity

European

European

East Asian

East Asian

Mixed

Population (N)

742,000,000

26,640,000

1,411,000,000

124,500,000

334,900,000

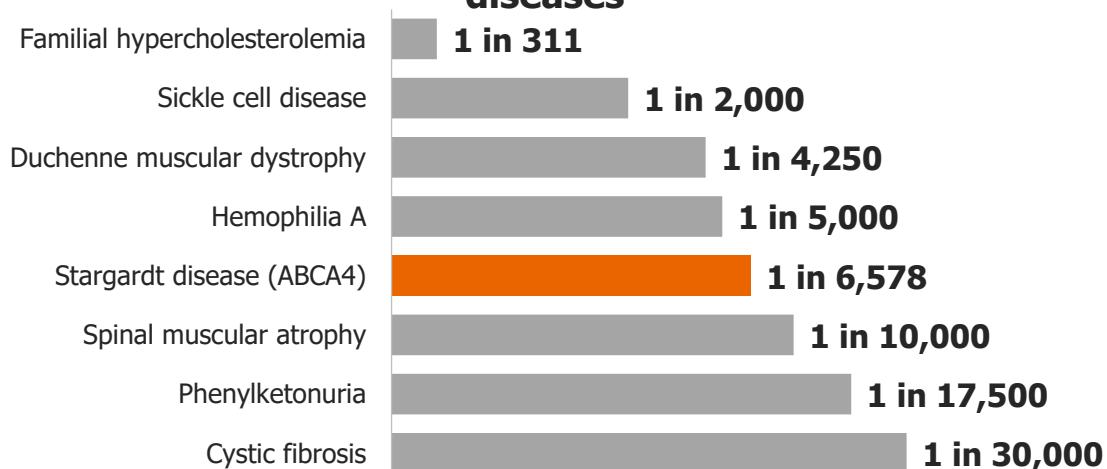
STGD1 Patients (N)	High Estimate	115,345	4,141	122,135	10,777	59,235
	Low Estimate	95,517	3,429	94,940	8,377	46,767

ABCA4: One of the Largest Genetically Defined Rare Disease Opportunities

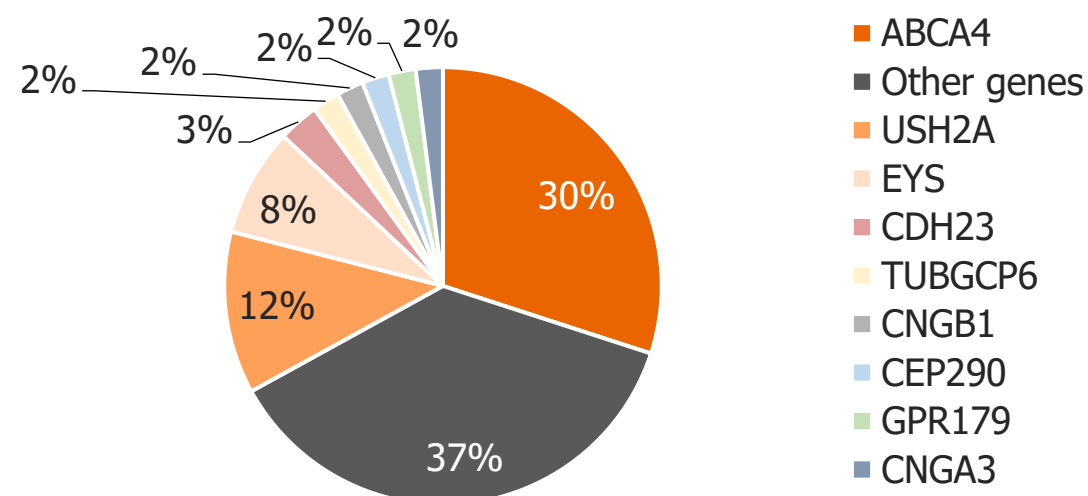


Illustrative comparison with selected commercially important monogenic diseases

Carrier frequency vs. selected monogenic diseases



Share of inherited retinal disease by gene



- *ABCA4* frequency: ~1 in 6,578 (Hanany M, Rivolta C, Sharon D, PNAS 2020)
- Largest inherited retinal disease gene worldwide (Hanany M, Rivolta C, Sharon D, PNAS 2020)
- Comparable patient population to several successful orphan-drug markets
- Normal life expectancy creates a large prevalent patient pool

Illustrative epidemiologic comparison; estimates represent published incidence/prevalence and are intended for order-of-magnitude benchmarking.

References:

Hanany M, Rivolta C, Sharon D (2020) Worldwide carrier frequency and genetic prevalence of autosomal recessive inherited retinal diseases. *Proc Natl Acad Sci U S A*. 117: 2710-2716.
Al-Khuzaei S, Broadgate S, Foster CR, et al. *Genes (Basel)*. 2021;12:1241. (ABCA4/Stargardt)
Hu P, Dharmayat KI, Stevens CAT, et al. *Circulation*. 2020;141:1742-1759. (Familial hypercholesterolemia)
Romitti PA, Zhu Y, Puzhankara S, et al. Prevalence of Duchenne and Becker muscular dystrophies in the United States. *Pediatrics*. 2015;135(3):513-521. doi:10.1542/peds.2014-2044.

U.S. Commercial



Kelly Kilpatrick

Chief Commercial Officer



Market Opportunity: There is a Strong Existing Diagnosed Patient Base



Stargardt Disease Type 1 is the most common inherited retinal disease (IRD).

~53,000

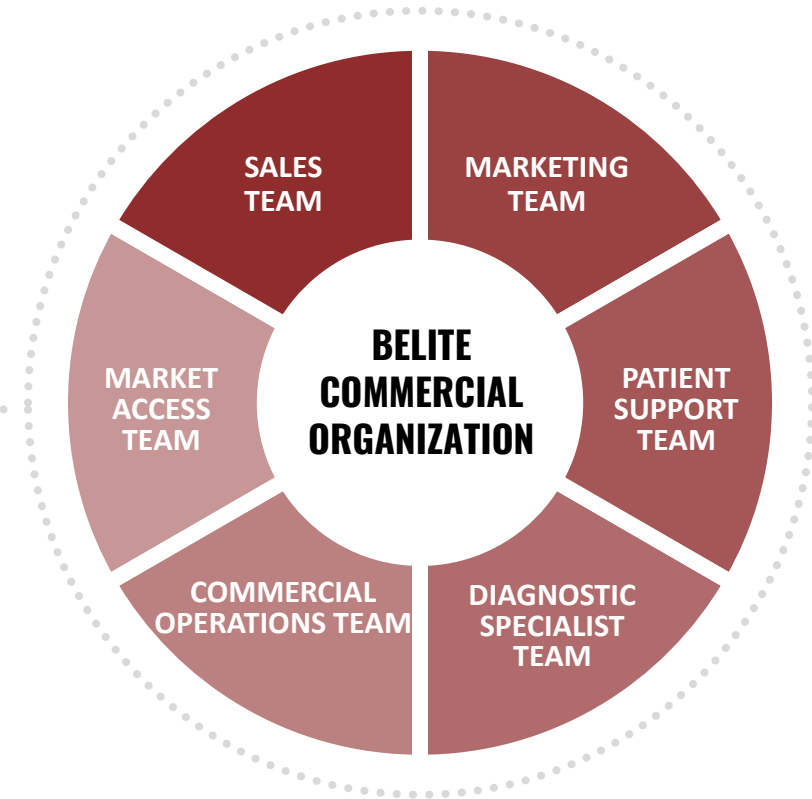
Estimated **Prevalent STGD1**
population in the U.S.



~20,000

Estimated **Clinically**
diagnosed STGD1 patients
in the U.S. since 2016

The Commercial Organization is Built to Directly Engage with Key Stakeholders



50+ combined rare disease product launches amongst the commercial organization's current team members

Market Research Insights



HCP Insights

Patient and
Caregiver Insights

UNMET NEED



There is a high unmet need in the Stargardt Disease Type 1 space

AWARENESS



Disease awareness and genetic testing rates are high among retinal specialists

PERCEPTION



Tinlarebant profile is very well received

PRESCRIBER



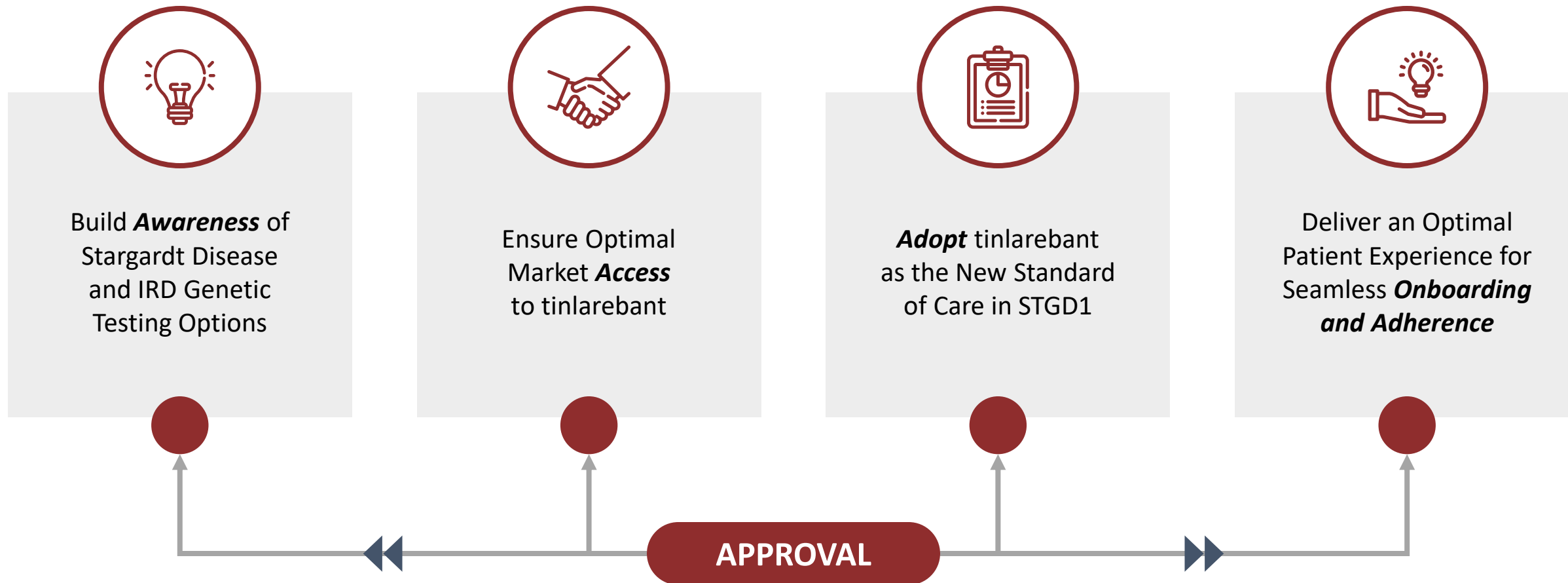
Retinal specialists will be the primary prescribers and managers of tinlarebant

PATIENT JOURNEY



The patient journey is convoluted and emotionally frustrating for patients

U.S. Commercial Focus Areas





Build Awareness of Stargardt Disease



Partner with Advocacy Groups

Unbranded awareness campaign through patient advocacy organizations

Disease Education

Educate stakeholders to recognize, understand, and address Stargardt disease

Pre-Approval Information Exchange

Strengthen market awareness of Stargardt disease, its biology and unmet needs with payer audience



Build Awareness of IRD Genetic Testing Options

How Genetic Testing Is Obtained



Sources for IRD Genetic Testing

-  **Academic and Private Labs**
e.g., UCSF, MUSC, UCLA, OSU
-  **Advocacy/Non-Profit Sponsored Program**
e.g., My Retina Tracker (Foundation Fighting Blindness)
-  **Commercial Testing Labs**
e.g., Blueprint Genetics, Prevention Genetics, GeneDx
-  **Manufacturer-Sponsored Program**
e.g., Genentech, Opus

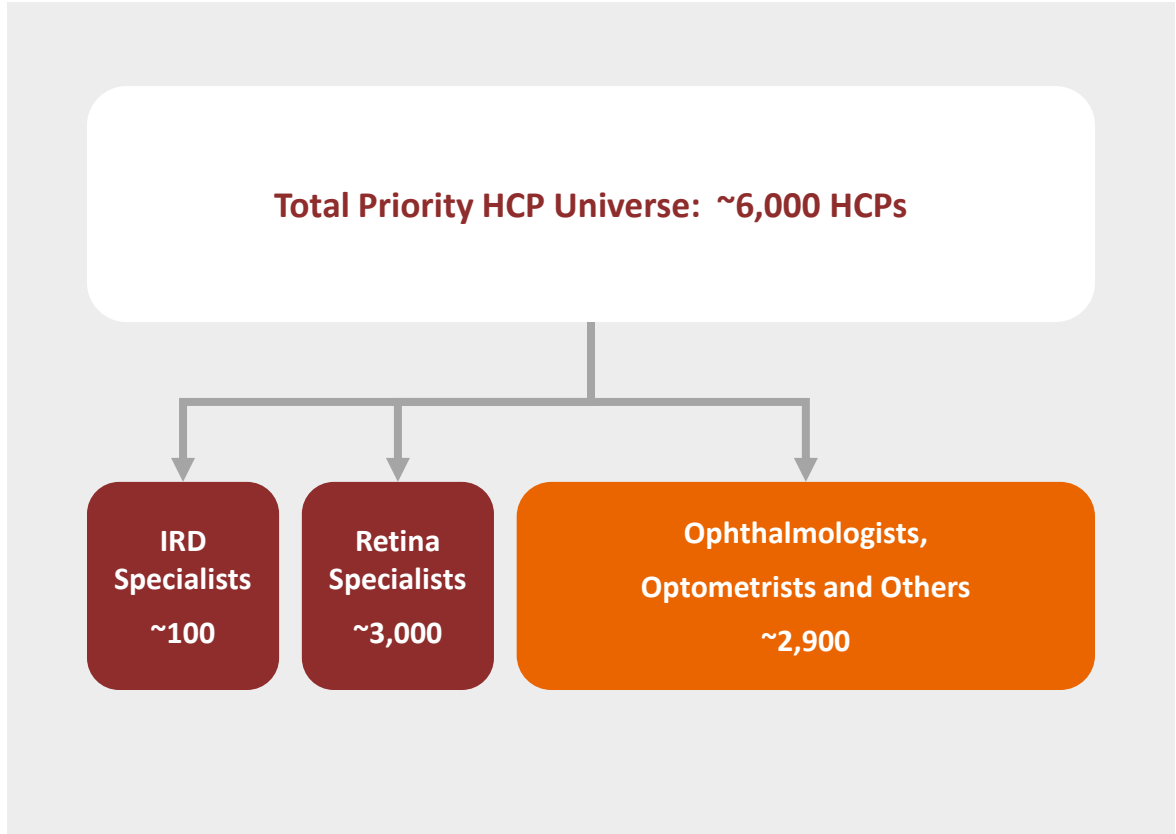
Ensuring Optimal Market Access to tinlarebant



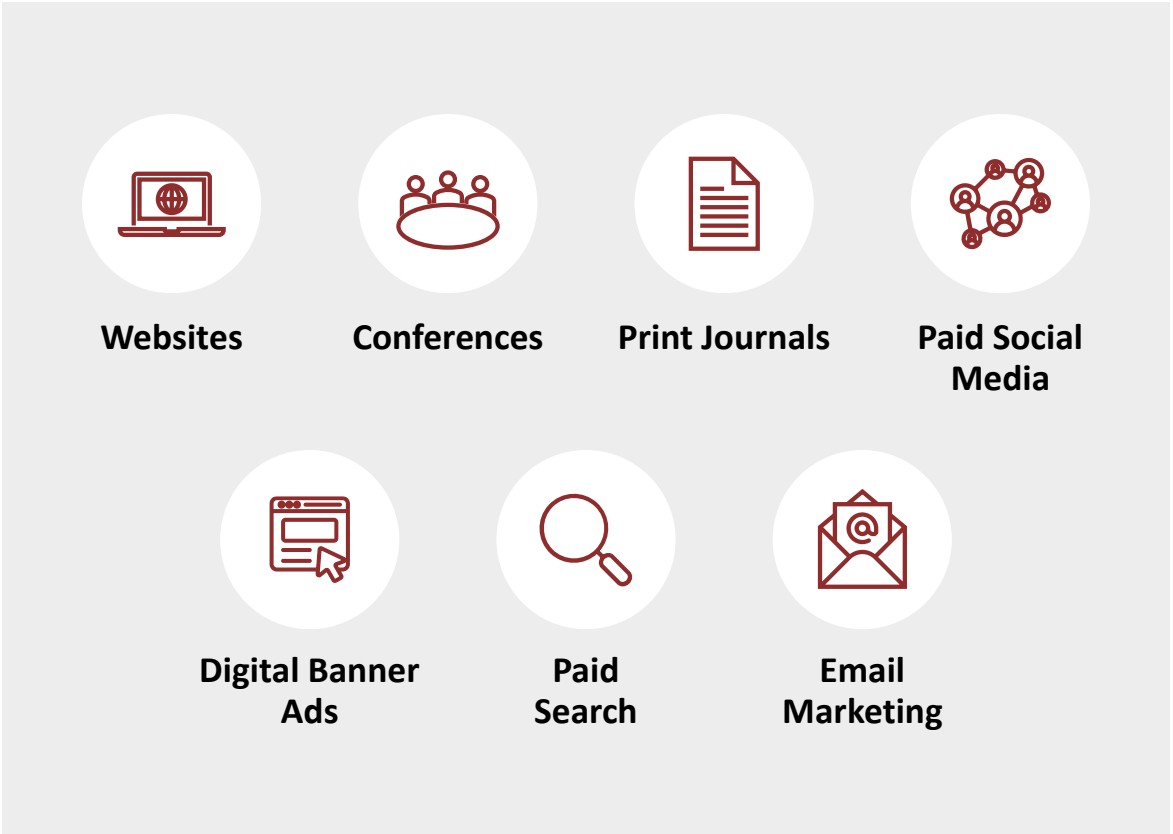


Adopt tinlarebant as the New Standard of Care in STGD1

Personal Promotion



Non-Personal Promotion



Prioritize top centers and key HCPs. Engage across every channel. Establish the standard of care.



Deliver Optimal Patient Experience for Seamless Onboarding and Adherence

Ideal Post Rx Patient Journey



HCP Writes Prescription
Diagnosis to treatment decision



Specialty Pharmacy
Prescription routed for fulfillment



Patient Services
Onboarding into support programs

Patient Support Pillars



Seamless Onboarding
Frictionless start to treatment



Financial Support Programs for Eligible Patients
Cost should not be the reason a patient does not receive treatment



Access Continuity
Treatment continues without interruption



Adherence
Daily treatment is the key to success

Belite Bio Has Been Preparing for This Moment ... And We Are Prepared to Launch



*We have done the work,
developed the plan, built
the team...*

NDA Submission
June 12, 2026



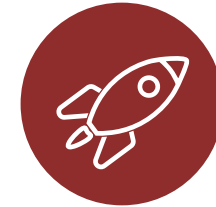
**NDA Acceptance
and Priority Review**
August 11, 2026



PDUFA
February 2027



Launch
March 2027



*... and we are excited to potentially
bring the first-in-class treatment for
STGD1 patients to market!*

Live Q&A





Thank you!