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#### **Novel Treatment for Unmet Medical Need**

Lin BioScience, Inc. (TW TPEx: 6696) is a drug development company established in 2016 focusing on advancing novel therapies and first-inclass treatments for unmet medical needs in various therapeutic areas such as ophthalmology, oncology, and metabolic diseases. The Company's pipeline consists of RBP4 IP portfolio, CDC7 IP portfolio and 4 distinct small molecule drug candidates. LBS-008, targeted to treat Stargardt disease and dry age-related macular degeneration ("Dry AMD"), and LBS-009, targeted to treat NASH, derived from the RBP4 IP portfolio, are developed by Belite Bio, a subsidiary company of Lin BioScience. LBS-007, developed from the CDC7 platform technology and targeted to treat various cancers, and LBS-002, targeted to treat glioblastomas and metastatic brain tumors, are developed by Lin BioScience.

LBS-007 is a non-ATP competitive CDC7 inhibitor for the treatment of a broad array of cancers, especially for refractory/relapsed and late-stage cancers such as AML, ALL, ovarian cancer, pancreatic cancer, etc., which has entered phase 1 in 2022. LBS-007 treating ALL has been granted orphan drug designation (ODD) in the U.S..

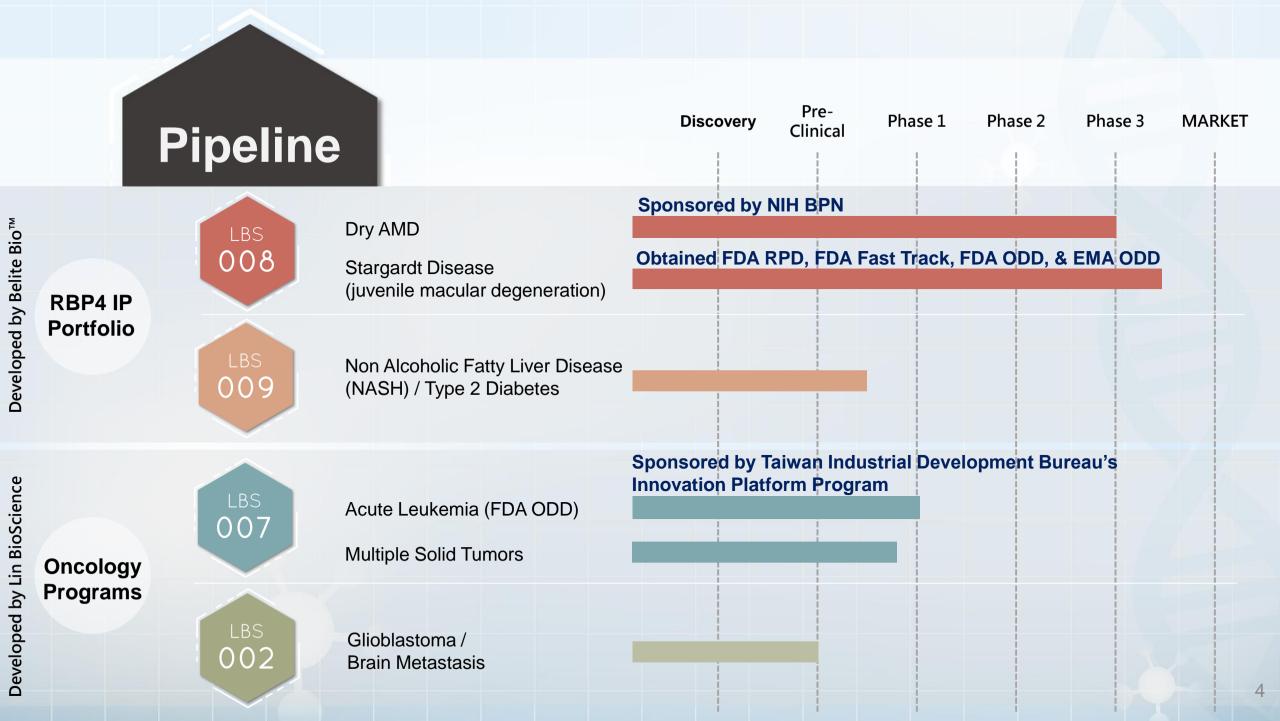
LBS-008 is the only drug candidate intended to treat dry AMD within the current drug development projects of the NIH Blueprint Program ("BPN"), whose mission is to foster small-molecule neurotherapeutic development. The mechanism of action utilized by LBS-008 has been recognized and recommended as a priority for clinical development in both STGD1 and dry AMD in a systematic review published by the U.K. National Institute for Health Research, or the NIHR, in 2018. LBS-008 phase 3 for Stargardt disease is currently ongoing and expected to complete its enrollment in 2023/H2. LBS-008 has initiated its phase 3 for GA (dry AMD) in 2023 and expected to start enrollment in mid-2023. LBS-008 has been granted fast track designation, rare pediatric disease designation (RPD) in the U.S., and orphan drug designation (ODD) in the U.S. and Europe.











#### Chairman

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



- •10+ years of executive management role in biotech, incl. 4 IPO (Lin BioScience & Belite)
- Multidisciplinary Specialization Clinical Training & Research in Neuroscience, Cardiovascular & Renal Medicine, Oncology, Immunology & Immunotherapy

- PhD in Medicine University of Sydney; Specialization: Neurology & Immunology
- o Treatment Strategies for Autoimmune Neuropathies
- Specialist Certificate in Clinical Neuroscience University of Melbourne; Specialization: Neurology
- Neurological Disorders, Neuroimaging & Diagnostics
- o Clinical Research & Design
- Master of Medicine University of Sydney; Specialization: Multidisciplinary Medicine and Surgery
- o Medicine: Cardiovascular & Renal Medicine, Neonatal Medicine
- o Surgery: Vascular & Endovascular Surgery, Transplant Surgery
- Cancer Therapeutics & Research Certificate Harvard Medical School
- Master of Business Administration Columbia University, London Business School, HK University
- Extensive Drug development from preclinical to global phase 3 trials
- o Phase 3 RBP4 Inhibitor for the Treatment of Atrophic Macular Degeneration & Stargardt Disease
- o Phase 2 Oubain Antagonist in the Treatment of Essential Hypertension
- Phase 2 SERCA2a Inhibitor in the Treatment of Acute Heart Failure
- o Phase 2 Pan-HER Inhibitor in the Treatment of HER2+ Breast Cancer and Gastric Cancer
- Phase 3 Anti-Glycan Active Immunotherapy in the Treatment of Metastatic Breast Cancer
- o Phase 3 Anti-α4 integrin Antibody in the Treatment of Resistant-Refractory Multiple Sclerosis
- o Phase 2 mTOR Immunosuppressant in the Treatment of Autoimmune Peripheral Neuropathies
- Co-invented and applied 64 patents

### **Management Team**

### Irene Wang, PhD, MBA (President & CSO)

- PhD in Biochemical Sciences, National Taiwan University,
   Trained at Scripps Research (TSRI), EMBA from University of California San Diego
- Co-invented and applied 125 patents and published 6 papers
- Extensive Drug development from preclinical to global phase 3 trials and 3 IPOs (including Lin BioScience and Belite Bio)



I've loved chemistry since
I was little. I was dedicated to
studying chemistry and scientific
research since middle school.
And now, I'm working on drug
development, doing significant
things to improve the lives
of human beings.

Irene Wang, PhD, MBA

President
LIN BIOSCIENCE



### **Management Team**

### Yvonne Chen (COO)



- Certified pharmacist & master in Science (Medicinal Chemistry) from National Taiwan University
- Served as Global Project Lead and Manager in Pfizer Taiwan
- Vast experience in clinical trial management and regulatory submissions with over 50 studies in various indications and 3 IPOs (including Lin BioScience and Belite Bio)

### Serena Chen, CPA (CFO)



- Certified Public Accountant & master in accounting from National Taipei University.
- Finance manager in a Taiwan biotech company and as assistant manager of audit department in Deloitte Taiwan
- Vast experience in auditing of listed companies and initial public offering (including Lin BioScience and Belite Bio)



### Tinlarebant (LBS-008)

#### **Market Opportunity**

#### **STARGARDT**

**DRY AMD** 

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

1 in 10,000

The most common inherited retinal dystrophy

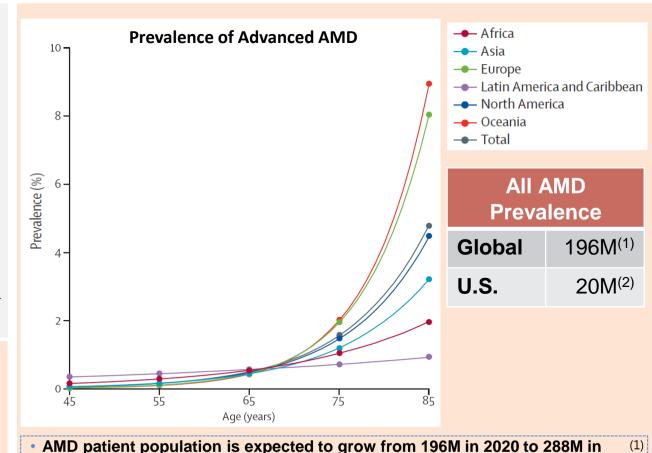
Patient population with Stargardt's Disease:

30k

146k

### **Columbia University + NIH Blueprint**

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



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

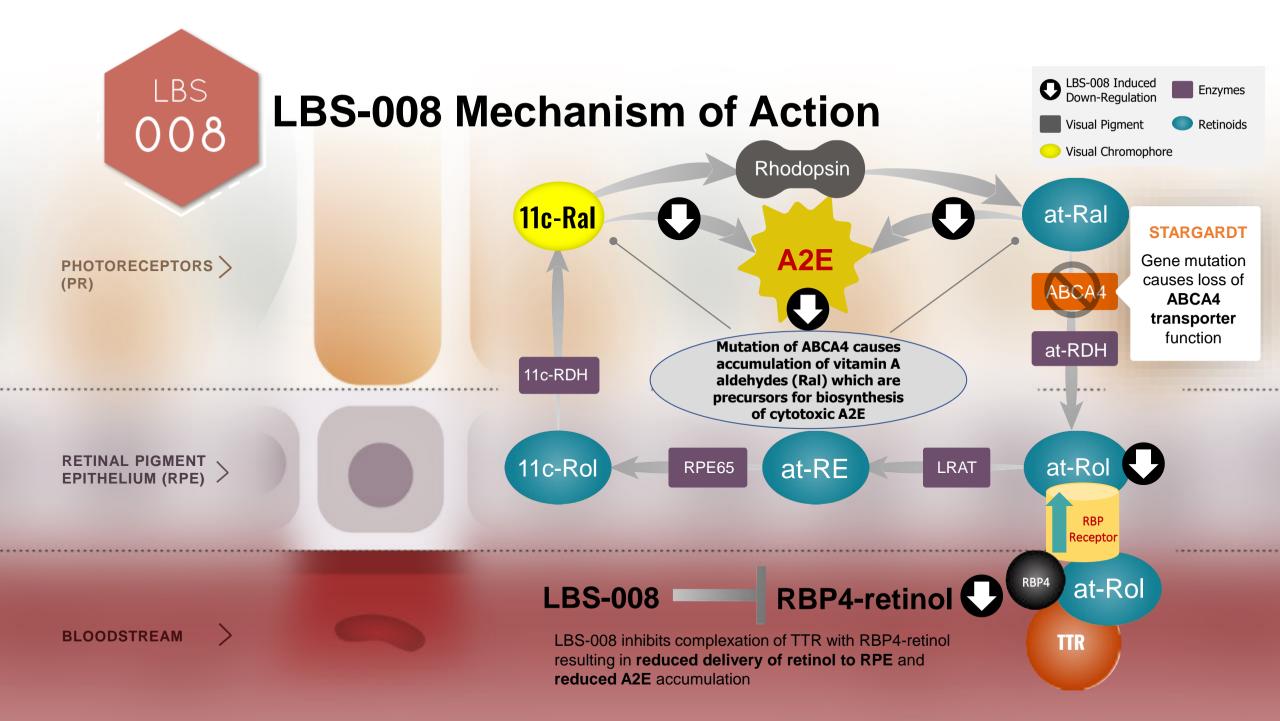
2040



#### **PRODUCT HIGHLIGHTS**

- Belite Bio's lead asset LBS-008 is a novel, orally administered, Retinol Binding Protein 4 ("RBP4") antagonist intended to slow or halt progression of vision loss in Stargardt disease (STGD1) and dry AMD.
- Currently no approved treatments for either STGD1 or dry AMD, significant market opportunity to become Standard of Care.
- Clinical development approach endorsed by US NIH, specifically to treat dry AMD.
- **UK NIHR's** 2018 systematic review of >7,000 publications recommends RBP4 antagonists as a **priority for clinical development to treat both STGD1 and dry AMD**.
- Dry AMD afflict 20 million patients in the US and 196 million patients worldwide.
- Without treatment, the continual increase in the size of the elderly population will worsen the impact of this disease.
- STGD1 is an orphan disease affecting approx. 1 in 10,000 children and adults.
- Granted Fast Track Designation, Rare Pediatric Disease in US / Orphan Drug Disease designation in US and EU for STGD1.
- Priority Review Voucher (PRV) eligible, vouchers have sold for \$95M-\$125M.

## Oral treatment for an unmet market



#### **Symptoms of STGD1 & Dry AMD**





#### Reference:

https://makariwellness.com/stargardt-disease/

https://www.ncbi.ie/supporting-you/everyday-living/eye-conditions/age-related-macular-degeneration-amd/



#### **CLINICAL DEVELOPMENT PATHWAY**

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

2021 2022 2023

## Ph1b/2 Adolescent STGD1 (2-year treatment)

- Dose finding Phase 1b completed; open label Phase 2 ongoing
- Ph1b (1-mo, Australia/Taiwan):11 subjects completed
- Ph2 (2-yr, AU/TW): 13 subjects (11 from Ph1b enrolled)
- Top line data expected in Q4 2023
- Observed a mean RBP4 reduction of > 70% without severe adverse events in Ph2

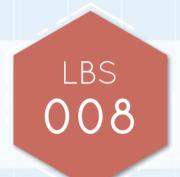
## Ph3 Adolescent STGD1 (2-year treatment)

- Initiated in June 2022, recruiting
- Randomized, double-masked, global study: 90 subjects (2:1, active, placebo)
- Expect to complete enrollment in 2023/H2
- Primary Endpoint: Lesion growth rate

## Ph3 GA (2-year treatment)

- Phase 3 study in early-stage Geographic Atrophy
- Randomized, double-masked, global study: 430 subjects targeted (2:1, active, placebo)
- Endpoints same as in STGD1 trial
- Expect to begin enrollment in mid 2023



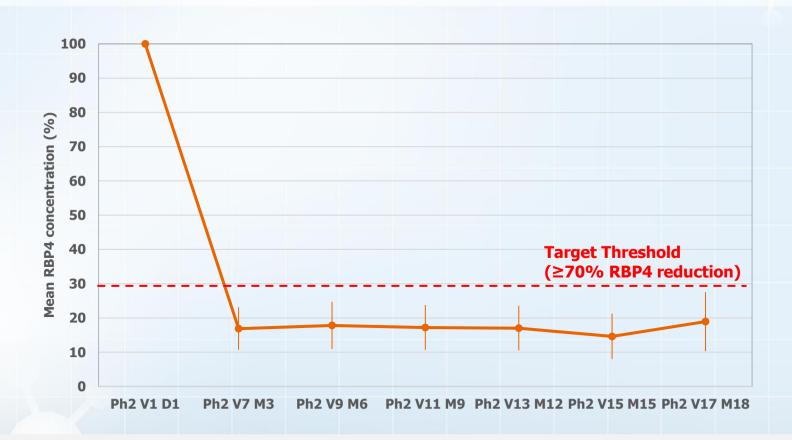


#### **CLINICAL TRIAL DESIGN OVERVIEW IN STGD1**

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

	STGD1 Phase 2 "LBS-008-CT02" (Preliminary 18-Month Interim Data Available)	STGD1 "Dragon" Phase 3* (Enrolling)	
Enrollment	13 subjects (QDAF, no DDAF)	At least 90 subjects targerted (must 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	12-20 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 mm²), a BCVA of 20/200 or better	

# PH2 18-MONTH: REDUCTION OF PLASMA RBP4 LEVELS



• Plasma RBP4 was reduced by approximately **80%** relative to baseline during daily dosing at **5 mg** over 18 months

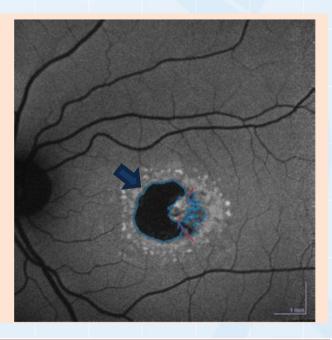


#### PH2 18-MONTH: CHANGE IN QDAF + DDAF LESION SIZE



QDAF in STGD1 patient as measured by retinal imaging.

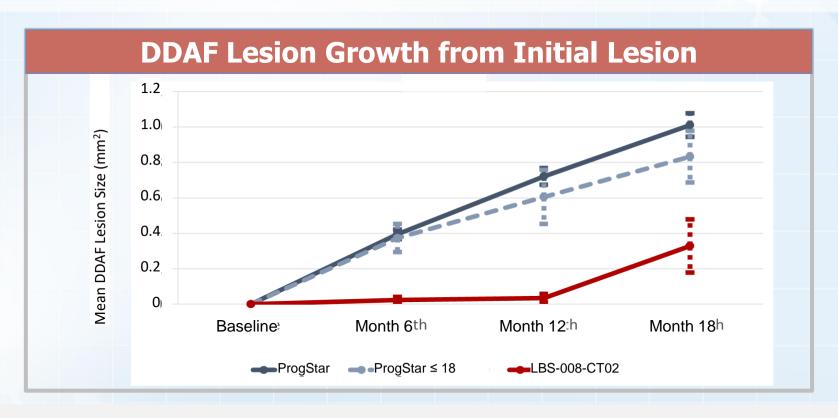
DDAF, or lesion ("dead retina") in STGD1 patient as measured by retinal imaging. This is the area where retinal cells and vision are lost.



Sources	Mean lesion growth rate (DAF=DDAF+QDAF <sup>(1)</sup> )
The Prospective Cohort Study of Childhood-Onset STGD1 by Georgiou et al. 2020	0.69 ± 0.72 mm <sup>2</sup> /year, n=53
Belite Bio 18-month data	0.28 ± 0.28 mm²/year, n=12

Note: (1) The combined QDAF + DDAF lesion size area is referred to as decreased autofluorescence (DAF). Georgiou et al. Am J Ophthalmol. 2020 Mar;211:159-175.

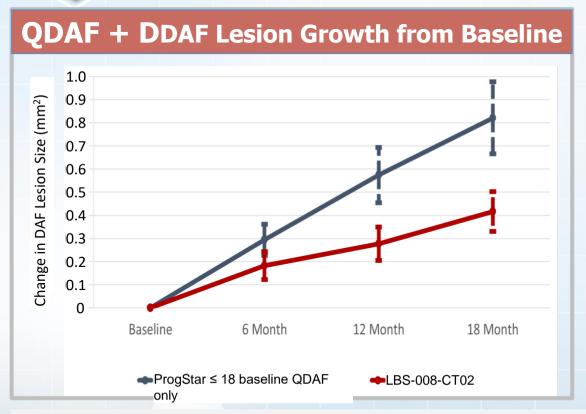
# PH2 18-MONTH: COMPARISON WITH SUBJECTS IN PROGSTAR (≤18 WITH DDAF AT BASELINE)

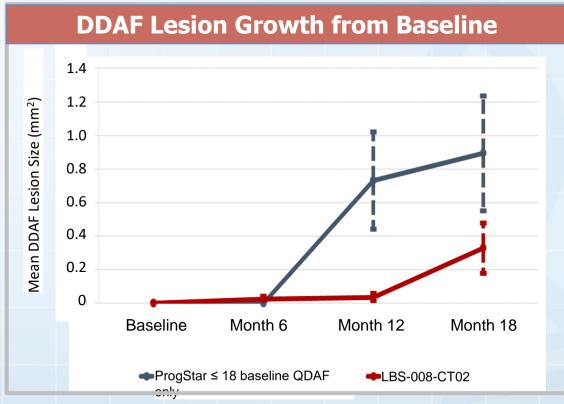


- No development of DDAF in 7 out of 12 (58.3%) subjects in LBS-008-CT02 trial
- Comparing to ProgStar subjects, including subjects with DDAF and no DDAF at baseline, LBS-008-CT02 subjects showed reduced expansion in "DDAF" lesion from initial lesion

Note: Preliminary data and is subject to data verification and clean-up. Eyes are combined to produce an integral value for the purpose of comparison.

# PH2 18-MONTH: COMPARISON WITH MATCHING SUBJECTS IN PROGSTAR (≤18 AND QDAF ONLY AT BASELINE)



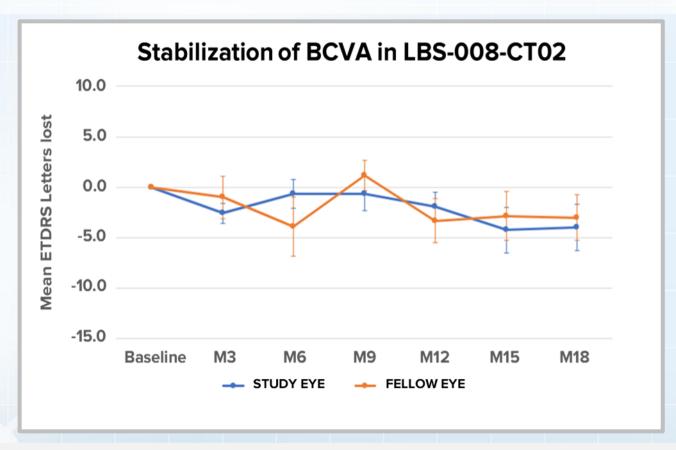


- No development of DDAF in 7 of 12 subjects (58.3%) at the 18-month timepoint
- Comparing to ProgStar subjects ≤ 18 years old with no DDAF at baseline, LBS-008-CT02 subjects showed reduced expansion in both "QDAF + DDAF" and "DDAF" lesion from baseline

Note: Preliminary data and is subject to data verification and clean-up. Eyes are combined to produce an integral value for the purpose of comparison.



#### PH2 18-MONTH: VISUAL ACUITY DATA



- A trend for maintaining BCVA in a majority of subjects was observed following 18 months of treatment
- Mean change in BCVA (ETDRS letters lost) within the study cohort over 18 months of treatment was -3 ± 1 letters in the Study eye and -2 ± 2 letters in the Fellow eye

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



## PH2 18-MONTH: WELL-TOLERATED DRUG-RELATED ADVERSE EVENTS

Adverse Events	Severity	Frequency (#patients)	% Recovered
Xanthopsia/Chromatopsia	Mild	9/12 (75%)	6/9 (66.7%)
Delayed Dark Adaptation	Mild	9/12 (75%)	1/9 (11.1%)
Night Vision Impairment	Mild	9/12 (75%)	6/9 (66.7%)

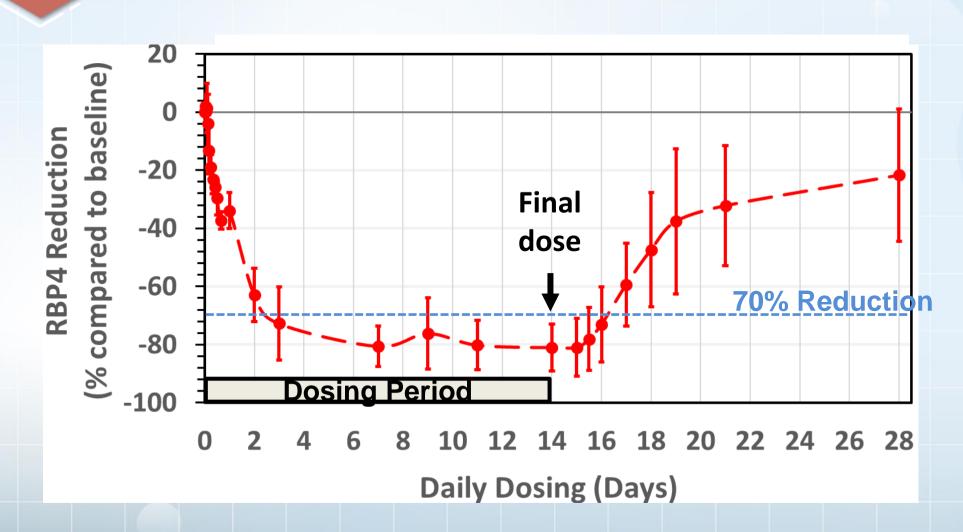
- Tinlarebant (5 mg p.o., daily) continues to be **safe** and **well tolerated** in adolescent STGD1 patients
- Tinlarebant treatment produced a mean 80% reduction of RBP4 (from baseline) throughout the study
- Delayed Dark Adaptation and Xanthopsia/Chromatopsia are the most common drug related ophthalmic 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 clinical significant findings in relation to vital signs, physical exams, cardiac health, or organ functions





#### **TINLAREBANT: ≥ 70% REDUCTION OF RBP4**

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





#### 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 or halt 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"*	
Approximately 430 subjects targeted (Expected to begin enrolling in mid-2023)	
Global	
Double Blind	
2:1 ratio (Tinlarebant : Placebo)	
2 years	
Efficacy as measured through DDAF lesion growth rate, safety & tolerability	
QDAF, BCVA, SD-OCT, microperimetry	
Yes	



#### Non-ATP CDC7 Inhibitor

for treatment of Broad Variety of Cancer types

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



**KEY OPPORTUNITY** 

**Novel Anti-Cancer** 

#### Target Therapy



for Acute Lymphoblastic Leukemia or ALL (US)

**MARKET** 

\$5B

Expected 2026 market size of AML & ALL

\$55B

Expected 2023 market size of pancreatic, lung, ovarian cancers

1.7 in 100k

Acute lymphoblastic leukemia (orphan disease)

\$6B

Estimated global market

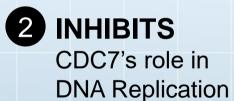
Reference: Globaldata, Marketwatch, NIH National Cancer Institute



#### Inhibits CDC7 in Cell Cycle Regulation



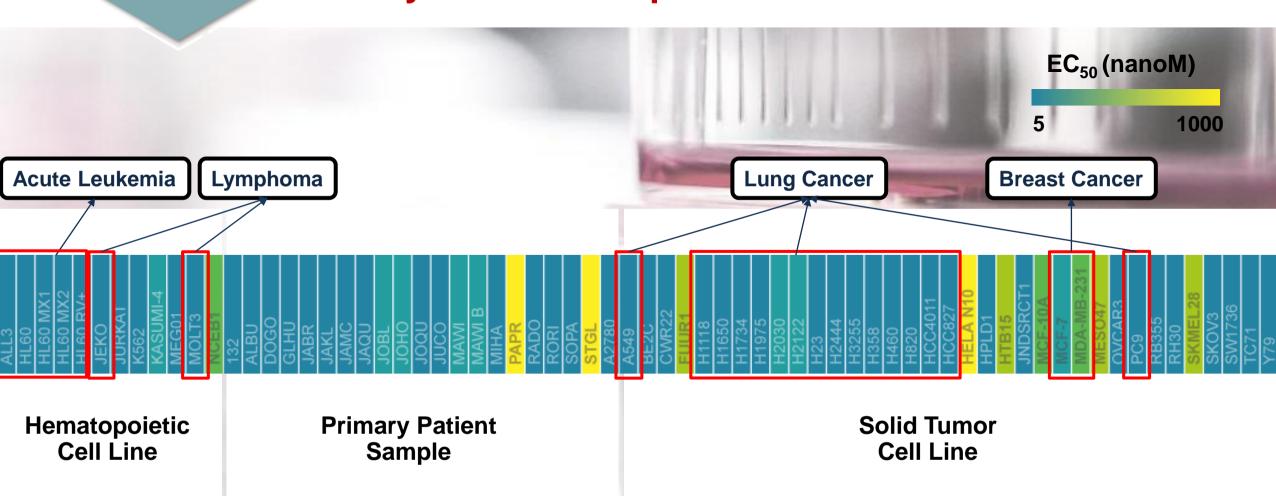






3 PREVENTS
Cell Division

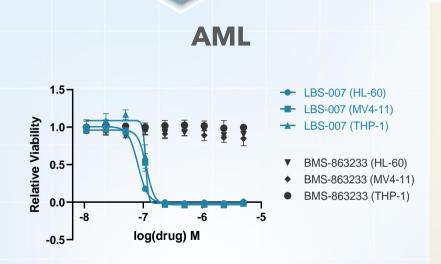
# Potently Inhibits Multiple Cancer Cell Lines & Primary Patient Samples of Blood Cancers



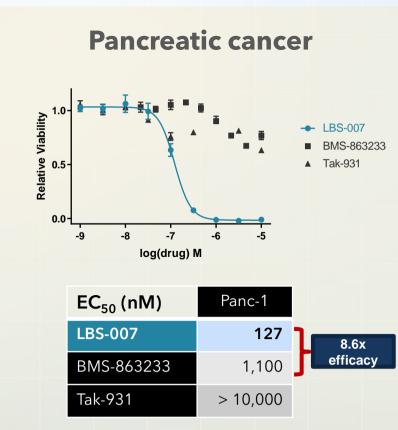


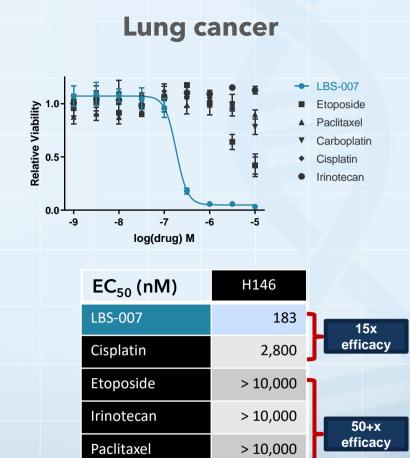
#### SUPERIOR EFFICACY AT NANOMOLAR POTENCY

Approx. 0.15µ molar of LBS-007 can achieve therapeutic effect on cancer cells



EC <sub>50</sub> (nM)	HL-60	MV4-11	THP-1
LBS-007	83.8	71.5	108
BMS-863233	> 10,000	5,400	> 10,000





> 10,000

Carboplatin

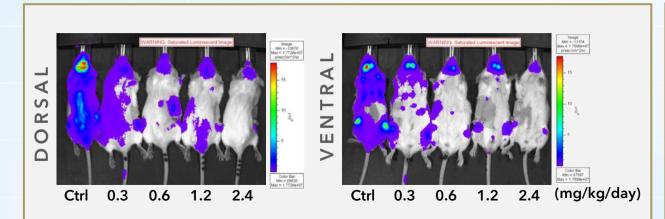
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#### IN VIVO EFFICACY DEMONSTRATED IN ANIMAL MODELS

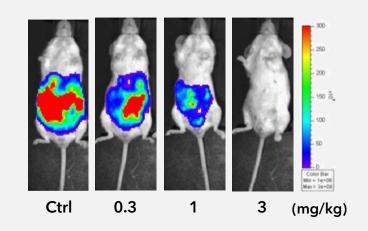
Potent tumor reduction in various cancer mouse models

#### **Acute Lymphoblastic Leukemia (ALL)**



- ✓ In vivo dose responsive efficacy
- √ 95% tumor removal at 2.4 mg/kg/day
- ✓ No significant organ dysfunction or toxicity at therapeutic dose

#### **Ovarian Cancer**



- ✓ In vivo dose responsive efficacy
- ✓ Inhibits ovarian cancer growth in mice
- ✓ Significant improvement in long-term survival

