

October 2020

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Precision Medicine for Genetically Defined Dry AMD



Correcting Factor H in
Patients with
Genetically Reduced
Function



#### **INVESTOR HIGHLIGHTS**

Precision medicine – genetically defined dry AMD – complement dysregulation

GEM103 – recombinant Complement Factor H

### Ph1 single dose – complete

Genetically defined patients with cGA

Safety endpoint met, no inflammation

Evidence of activity in ocular compartment

Sustained supraphysiological CFH in aqueous humor

Reduction in complement biomarkers

### Ph2a multi-dose escalation-enrolling-data 1H2021

Objectives: safety – dose selection via PK/biomarkers – specific CFH variants

### Precision approach in pipeline expansion

Selected wet AMD, anti-VEGF treated, w/GA & CFH-depleted-data 2021

AAV-CFH in intermediate AMD - IND enabled 2021

Potentiating Antibody for systemic indication



# Led by experienced management and backed by tier 1 investor syndicate

### Leadership Team



Jason Meyenburg, MBA
CEO, Orchard, Vtesse, Alexion



Scott Lauder, PhD
CTO, Merrimack, EMD Serono



Walter Strapps, PhD

VP Gene Therapy

Intellia, Merck, Sirna



Marc Uknis, MD, FACS
CMO, CSL-Behring, ViroPharma,
Achillion



**Suresh Katti, PhD**VP Research, Alexion,
Optherion, Bayer



Gregg Beloff, JD, MBA
Interim CFO

#### **Board of Directors**

Hannah Chang, MD, PhD
Wu Capital

**Jean George**Lightstone Ventures

Carl Gordon, PhD
OrbiMed

David Lubner
Independent

Jason Meyenburg

Tuyen Ong, MD
Biogen

Phil Reilly, MD, JD
Independent

Jason Rhodes
Atlas Venture

Steve Squinto, PhD
Chairman, OrbiMed

#### Investors





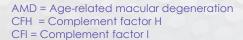






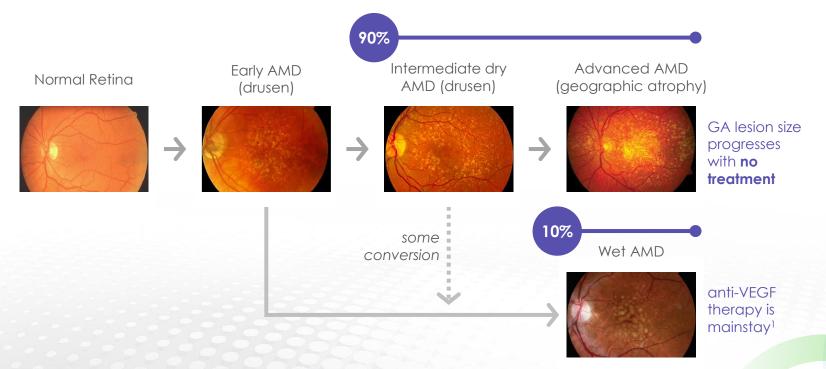
## Gemini pipeline

					Phase of De	velopment			
			Modality	Pre-Clinical	IND-Enabling	Phase 1	Phase 2	WW Rights	Milestone
		Dry	GEM103,				•		Ph 2a MD data 1H2021
	CFH	Wet: anti-VEGF treated w/GA	recombinant protein						Ph 1/2a data 2H2021
AMD		Dry	AAV						IND enabled 2H2021
		CFI	recombinant protein						
		CII	AAV						
Systemic Renal		CFH	potentiating antibody					0	IND ready 2H2021



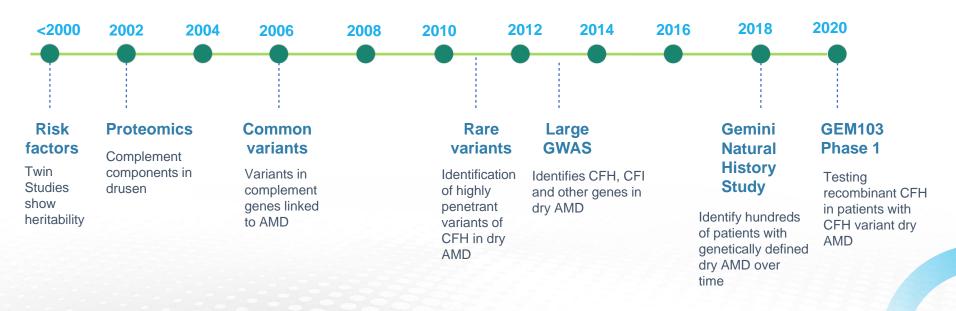


# Dry AMD represents ~90% of all AMD cases and leads to vision loss due to geographic atrophy





# Our Understanding Of AMD Genetics Has Advanced Significantly

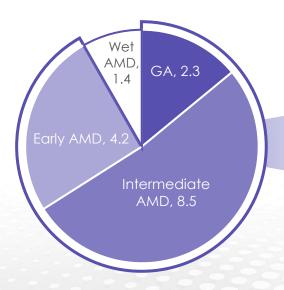


Seddon et al (1997) AJO \*Hageman et al (2001) PRER, Anderson et al (2002) AJO \*\* Rivera et al (2005) Hum Mol Gen, Jakobsdottr (2005) Am J Hum Gen, Weeks et al (Am J Hum Gen), Hageman et al (PNAS) 2005, Haines et al (2005) Science, Klein et al (2005) Science, Edwards et al (2005) Science, DeWan et al (2006), Yang et al (2006) Science \*\*\*\*\*\*Halgeman et al (2006) Ann Med, Gold et al (2006) Nat Gen, Hughes et al (2006) Nat Gen \*\*\*\*\*\*Maller te al (2007) Nat Gen, Yates et al NEJM (2007) Fagerness et al (2009) Eur J Hum Gen \*\*Neale et al (2010) PNAS, Chen et al (PNAS) 2010 \*\*\*Seddon et al (2013) Nat Gen. Helgasen et al (2013) Nat Gen, Zhan et al (Nat Gen) \*\*\*\*Triebwasser et al (2015) IOVS Kavanagh et al (2015) Hum Mol Gen, Fritsche et al (2015) Nat Gen



## Dry AMD market large – no approved therapies

#### ~16M AMD Patients in US



Dry AMD represents ~90% (15M) of AMD patients

Irreversible progression to blindness

Source: Doherty et al (2018)

## Targeting the ~6 M dAMD Patients that have CFH gene variants



**40% (6M)** patients with dAMD variants in CFH gene

**37% (5.5M)** dAMD one common variant, homozygous

3% (0.5M) patients carry high-risk rare variants

## Dysfunctional CFH directly involved in AMD pathogenesis



Mutations include complement Factor H dysregulation<sup>1</sup>



CFH risk variant unable to prevent MAC deposition on RPE<sup>5</sup>



High risk CFH variants associated with early onset<sup>2,3</sup>



CFH risk variants are functionally impaired<sup>6</sup>



Factor H insufficiency leads to AMD phenotype in preclinical models<sup>4</sup>



Impaired lipid trafficking function on RPEs<sup>7</sup>



<sup>&</sup>lt;sup>1</sup> Geerlings et al, Mol Immunol (2017) 84:65-76 <sup>2</sup> Ferrara et al, JAMA Ophthalmol (2015) 133:785; <sup>3</sup> Wagner et al, Sci Rep (2016) 6:31531; <sup>4</sup>Ding et al, Am J Pathol (2015) 185:29; <sup>5</sup>Radu et al JBC 2014 289:9113; <sup>6</sup>Gemini data on file; <sup>7</sup>Weismann et al, (2011) Nature 478:76

## Factor H critical regulatory complement component necessary for retinal health

## CFH – endogenous complement regulator and...



Selectively binds & protects self-tissues

Prevents damage from terminal complement pathway mediators



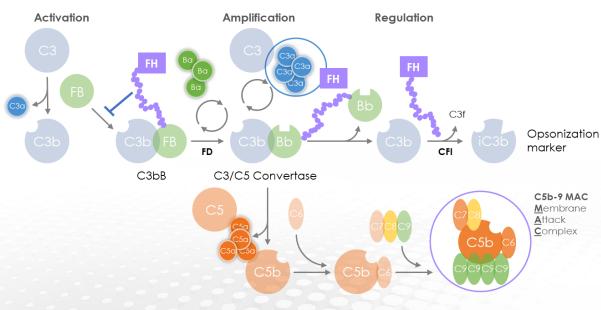
Efficient, inhibitor of complement pathways



Critical to maintain retinal health



# Functional Factor H supplementation can downregulate pathogenic complement activation and amplification



C3a, C5a & MAC
pathogenic mediators in dry AMD

### **Factor H**

Prevents Factor B association with C3b

Accelerates C3/C5 convertase decay

Inactivates free C3b

Prevents formation of the C5b-9 MAC

A reduction in **Ba** levels is a sensitive marker of Factor H activity



## GEM103 – full-length recombinant Factor H



1<sup>st</sup> ever recombinant, native complement regulator



Ideal for intravitreal administration



Distribution & retention in all relevant ocular tissues at endogenous levels

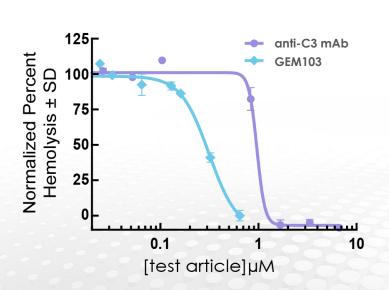


Targeted restoration of function lost in CFH mutations

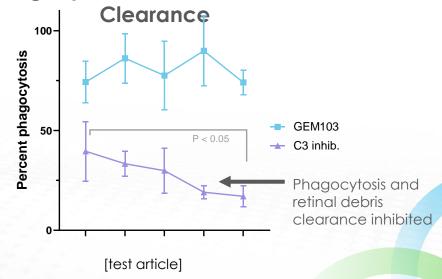


# GEM103 restores physiologic complement activity...without unintended consequences of current inhibitory approaches

### **More Efficient Inhibition**



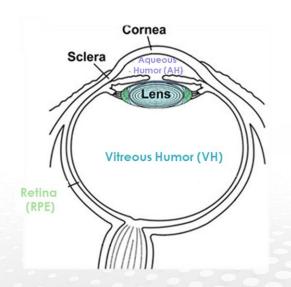
## Preserves Beneficial Phagocytosis and Retinal Debris





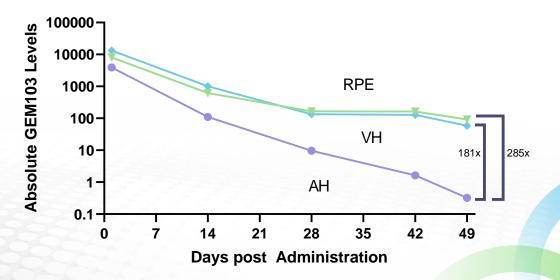
15

## After IVT administration GEM103 present at high levels in RPE



## NHP Biodistribution (I-125)

Aqueous Humor CFH levels underestimates CFH levels on retina (RPE)







GEM103
Recombinant Human CFH
- Precision Ophthalmology
for Dry AMD



## Strategic development of GEM103: precision ophthalmology

#### Gene-Variant Targeted Therapeutic, Enriched Population

## Preclinical Complete

- Functional study of CFH variants
- GMP manufacturing GEM103
- Established complement and non complement related CFH role
- Biodistribution of GEM103 in NHP

## CLARITY

Natural History Study Ongoing

- Genotype mutation frequency confirmed
- Characterize Phenotypic progression
- Clinical Biomarker (AH) characterization in dAMD

### Phase 1 Complete

- Safety Tolerability: No DLTs
- •PK: **supraphysiological CFH** at each dose
- Dose response, Time CFH supraphysiologic
- PD: AH C3a, Ba confirms functional activity of GEM103

## Phase 2a Enrolling

- Topline data: 1H2021
- N = 40, 3mos, dose escalation
- Enriched CFH variant population
- Safety & Tolerability
- Dose Selection

PK/PD (Biomarkers)

- Clinical data collected GA progression Drusen volume BCVA/LLVA
- Study and fellow eyes

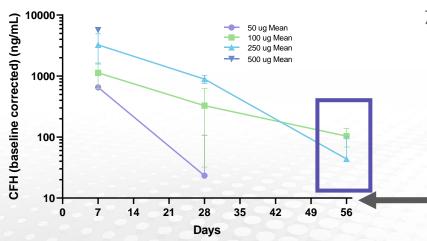
## Phase 2b/3 POC → Pivotal

- •FDA Alignment 2H 2021
- Ph2b: powered shamcontrol
- Enriched StudyPopulation
- •Ph2b interim result (6mos) → pivotal Ph3 (12mos)
- Confirms Safety
- Potential to Reduce dosing frequency



## GEM103 IVT dose results in sustained supraphysiological CFH in AH correlates to supraphysiologic RPE concentrations

Phase 1
CFH in Aqueous Humor (ng/mL)



CFH levels significantly above baseline

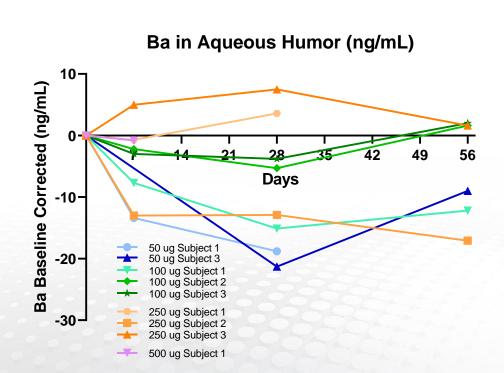
7 days post dose – irrespective of dose level

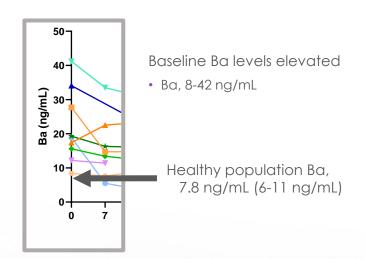
Healthy population CFH Levels average 68 ng/mL (27 to 113 ng/mL)

Baseline corrected by patient



## Decrease in Ba after single GEM103 dose confirms functionality







20

## GEM103 achieves safety endpoint in central GA patients

- Substantial baseline disease
  - Central GA, BCVA 27-43, 70-95yo

### In presence of persistent supraphysiological CFH (GEM103)

- No dose-limiting toxicity (DLT) no adverse drug reactions
- No ocular inflammation
- No CNV
- Visual acuity maintained
- Independent safety review committee confirmation
  - All patients in 3 cohorts, 50-250 µg single dose IVT
  - 500 µg single dose IVT: no DLTs



## Strategic development of GEM103: precision ophthalmology

#### Gene-Variant Targeted Therapeutic, Enriched Population

## Preclinical Complete

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- GMP manufacturing GEM103
- Established complement and non complement related CFH role
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22

# Ph2a open-label dose escalation in enriched CFH variant GA population to confirm PK and complement PD effect

#### Phase 2a, Open-Label Dose Escalation Study

Minimum 3mos exposure at MTD

N = 40

Population: 402H homozygous (N=30), rare variants (N=10)

250µg N = 10, q30d for 12wks



Escalate based on Safety

GEM103 Exposure

Pts 1-10, 3X 250µg, 3X 500µg over 6mos

Pts 11-40, 3X 500µg over 3mos

#### **Open-Label Extension**

Cumulative ≥ 12mos exposure at MTD

500µg

g30d for 52wks, interim analysis 6 &12mos exposure

Topline data: 1H2021

Safety & Tolerability

**Dose Selection:** PK/PD (Biomarkers)

Clinical data collected: GA progression,

BCVA/LLVA (study and fellow eye)

Alignment with FDA on Ph2b/3

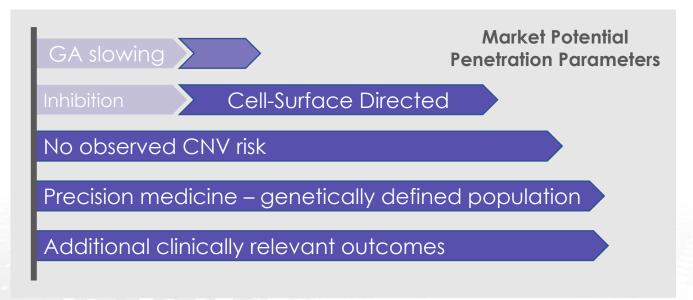






# Precision and Complement Regulation – differentiated and improved market potential in dry AMD

■ Differentiation relevant to payers, prescribers, patients

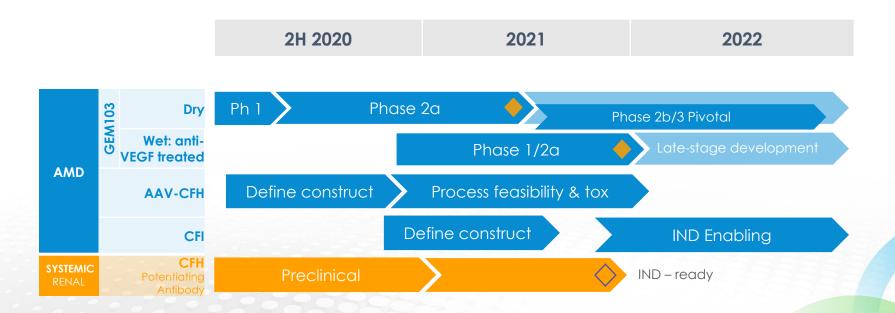








# \$200 mln funds pipeline through 2022 and the completion of anticipated GEM103 dry AMD pivotal studies in 2023





27

## **Transaction Overview**

## Transaction Summary

- Gemini and FS Development Corp. (FSDC) have entered into a definitive merger agreement
- Expected post transaction equity value of approximately \$465 million
- Expected to be completed by January 2021

# Premier Healthcare Investor Base

- PIPE investors include lead investor Foresite Capital, as well as Fidelity Management & Research Company LLC, Wellington Management, Boxer Capital of Tavistock Group, Alyeska Investment Group, L.P., Suvretta Capital Management, CVF, DAFNA Capital, and Acorn Bioventures
- Existing Gemini shareholders, including Orbimed Healthcare Fund Management, Atlas Venture, Lightstone Ventures and Wu Capital

## Use of Proceeds

- At the time of closing, expected to have approximately \$200 million in cash and cash equivalents
- Funding expected to generate multiple data readouts across its pipeline
- Expected to provide cash runway into 2023

## Key Management and Board

- Combined company to be led by Jason Meyenburg
- Anticipated directors\*: Jason Meyenburg, Jim Tananbaum

\* BOD will include 5 members of Gemini's current BOD



## Terms of Transaction

Shares and \$ in millions (other than share price)

Pro Forma Valua	tion
Pro Forma Shares Outstanding <sup>(1)</sup>	46.5
Implied Share Price	\$10.00
Pro Forma Equity Value	\$465.4
Less: Pro Forma Cash	(\$199.8)
Plus: Pro Forma Debt	-
Pro Forma Valuation <sup>(1)</sup>	\$265.6

Sources of Funds	S
Cash Held in Trust <sup>(1)</sup>	\$120.8
Gemini Shareholder Equity Rollover	\$215.0
PIPE Proceeds	\$95.0
Sources	\$430.8

Uses of Funds	
Equity Issued to Gemini Shareholders Estimated Transaction Fees &	\$215.0
Expenses Remaining Cash (Balance Sheet) (1)	\$199.8
Uses	\$430.8

	Shares	% Ownership
FSDC Sponsor (Foresite)	5.0	11%
Sponsor Shares	3.5	7%
PIPE Shares	1.5	3%
Public Shareholders <sup>(1)</sup> (excl. FSDC Sponsor)	12.1	26%
Current Gemini Shareholders	21.5	46%
PIPE Investors (excl. FSDC Sponsor)	8.0	17%
Total	46.5	100%



#### **INVESTOR HIGHLIGHTS**

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