

Topline Results from the CATALINA Phase 2 Trial of NGM621 in Patients with Geographic Atrophy Secondary to AMD

### **Safe Harbor Statement**

The following presentation contains forward-looking statements, including, but not limited to, statements regarding: NGM Bio's expectation that additional analyses from the Phase 2 CATALINA trial (CATALINA) showed potentially encouraging findings that NGM Bio believes warrant further evaluation or exploration; NGM Bio's beliefs as to the factors that may have contributed to CATALINA not meeting its primary endpoint; the therapeutic potential of NGM Bio's other product candidates; NGM Bio's program milestones in 2022 and other anticipated milestones, including those relating to enrollment in and reporting data from various trials of its product candidates and the anticipated timing thereof; NGM Bio's expectation of sharing initial data from Phase 1 trials of NGM831 and NGM438 next year; NGM120's potential anti-cancer activity; NGM Bio's expectation that it will report that it had approximately \$300 million of cash, cash equivalents and short-term marketable securities as of September 30, 2022; NGM Bio's expectation regarding the sufficiency of its cash runway to fund planned activities; and other statements that are not historical fact. Because such statements deal with future events and are based on NGM Bio's current expectations, they are subject to various risks and uncertainties, and actual results, performance or achievements of NGM Bio could differ materially from those described in or implied by the statements in this presentation. These forward-looking statements are subject to risks and uncertainties, including, without limitation, risks and uncertainties associated with: the costly and time-consuming pharmaceutical product development process and the uncertainty of clinical success, including the risks that NGM621 may be unable to demonstrate future clinical benefit in patients with geographic atrophy (GA), particularly in light of the failure to achieve the primary endpoint in CATALINA, and that NGM Bio's other product candidates may not be tolerable and effective treatments in their planned indications; failure or delays in successfully initiating, enrolling, reporting data from or completing clinical studies, as well as the risks that results obtained in preclinical or clinical trials to date may not be indicative of results obtained in future trials and that post-hoc analyses performed after unmasking trial results can result in the introduction of bias, have other limitations and may not be predictive of results obtained in future trials; NGM Bio's reliance on its amended collaboration with Merck, including the risks that if Merck fails to exercise its option to license NGM621, NGM Bio would need to partner the NGM621 program and/or raise substantial additional capital in order to further clinical development of NGM621, if any, which NGM Bio may be unable to do in a timely manner or at all, which could delay or preclude the further development of and/or commercialization of NGM621; the ongoing COVID-19 pandemic, which has adversely affected, and could materially and adversely affect in the future, NGM Bio's business and operations, including NGM Bio's ability to timely supply, initiate, enroll and complete its ongoing and future clinical trials; the time-consuming and uncertain regulatory approval process; NGM Bio's reliance on third-party manufacturers for its product candidates and the risks inherent in manufacturing and testing pharmaceutical products; the sufficiency of NGM Bio's cash resources, including to fund its wholly-owned programs, and NGM Bio's need for additional capital; and other risks and uncertainties affecting NGM Bio and its development programs, including those discussed in the section titled "Risk Factors" in NGM Bio's quarterly report on Form 10-Q for the quarter ended June 30, 2022 filed with the Securities and Exchange Commission (SEC) on August 4, 2022 and future filings and reports that NGM Bio makes from time to time with the SEC. In addition, this presentation includes NGM Bio's expectation that it will report that it had approximately \$300 million of cash, cash equivalents and short-term marketable securities as of September 30, 2022. NGM Bio has not yet completed its financial close process for the quarter and nine-month period ended September 30, 2022. This estimate of our cash, cash equivalents and short-term marketable securities as of September 30, 2022 is preliminary and is subject to change upon completion of NGM Bio's financial statement closing procedures and the review of its unaudited condensed consolidated financial statements. Additional information and disclosures would be required for a more complete understanding of NGM Bio's financial position and results of operations as of September 30, 2022. Except as required by law, NGM Bio assumes no obligation to update these forward-looking statements, or to update the reasons if actual results differ materially from those anticipated in the forward-looking statements.

### ngmbio

# **Summary of Phase 2 CATALINA Trial Topline Findings**

<sup>7</sup> Trial did not meet primary endpoint of statistically significant rate of change in GA lesion area using slope analysis over 52 weeks vs. sham

In a pre-specified secondary MMRM analysis, NGM621 Q4W showed a treatment effect at 24 weeks (nominal p<0.05) that diminished by 52 weeks

Additional post-hoc analysis that adjusted for large lesion variability showed potentially encouraging findings warranting further evaluation

NGM621 showed no evidence of increased CNV conversion vs. sham and was well-tolerated with no treatment-related SAEs



# **Geographic Atrophy (GA) Unmet Need**

- GA is an age-related, progressive retinal degenerative disease associated with **irreversible loss of vision**
- Over time, GA robs patients of their central vision, which can lead to a loss of independence, social isolation, depression and an increased risk of falls and fractures<sup>1</sup>
- GA currently has **no FDA-approved treatments**<sup>2</sup> and is a **leading cause of blindness** in the developed world<sup>3,4</sup>
- GA prevalence is similar to wet AMD in the U.S.; both rise exponentially with age<sup>5,6</sup>



#### **Neurodegenerative Disease of the Retina**





<sup>1</sup>Chakravarty U et al. Ophthalmology. 2018 Jun;125(6):842-849; <sup>2</sup> On 7/19/22 Apellis announced FDA acceptance and priority review of its NDA for pegcetacoplan for the treatment of GA, PDUFA 11/26/22 <sup>3</sup>Eye Vis (Lond). 2016; 3: 34; <sup>4</sup>Wong et al. Lancet 2014; <sup>5</sup>Fleckenstein, 2018; <sup>6</sup>Friedman, 2004; BrightFocus® Foundation; <sup>7</sup> Boyer DS et al., Retina 2017. AMD = Advanced Macular Degeneration



# Phase 2 CATALINA Study Design





# **CATALINA Key Inclusion and Exclusion Criteria**

### **KEY INCLUSION CRITERIA**

- ≥ 55 years of age
- BCVA > 34 ETDRS letters (20/200 or better Snellen equivalent)
- Clinical diagnosis of GA secondary to AMD
  - Foveal and non-foveal lesions allowed
- Study Eye GA requirements:
  - − Total GA area between ≥2.5 mm<sup>2</sup> and  $\leq$ 17.5 mm<sup>2</sup>
  - If multifocal, at least one lesion must be  $\geq$ 1.25mm<sup>2</sup>
  - Presence of banded or diffuse junctional hyperautofluorescence
  - No evidence of current or prior CNV

### **KEY EXCLUSION CRITERIA**

- GA secondary to a condition other than AMD in either eye
- Any history or active ocular infection in either eye within 3 months of randomization
- PDR or DME in either eye

Fellow (non-study) eye CNV permitted if clinical diagnosis was <u>></u> 2 years prior; capped at not more than 25% of study population



# **Patient Disposition and Exposure**

	NGM621 Q4W	NGM621 Q8W	Sham Pooled <sup>1</sup>	Total
Patient disposition				
Subjects randomized, n	108	105	107	320
Subjects treated, n	108	104	106	318
Exposure <sup>2</sup>				
Total number of injections received per subject, mean (SD)	11.5 (2.76)	6.3 (1.59)	9.1 (3.24)	9.0 (3.38)

### **Overall treatment compliance rate of 98-99%**



<sup>1</sup>Sham Pooled combines subjects receiving sham in the Q4W and Q8W arm <sup>2</sup>Exposure based on safety population SD = standard deviation



## Patient Demographics and Baseline Ocular Characteristics

	Q4 weeks NGM621 15 mg (N = 108)	Q8 weeks NGM621 15 mg (N = 104)	Sham Pooled (N = 106)	Total (N = 318 <sup>2</sup> )
Age, mean (SD)	78.5 (8.17)	79.1 (7.51)	77.6 (8.42)	78.4 (8.04)
Female, n (%)	67 (62.0)	63 (60.6)	68 (64.2)	198 (62.3)
White, n (%)	107 (99.1)	102 (98.1)	101 (95.3)	310 (97.5)
GA area, mean (SD) mm <sup>2</sup>	7.02 (3.964)	7.62 (3.968)	7.75 (4.007)	7.46 (3.980)
Square Root GA area, mean (SD) mm <sup>2</sup>	2.56 (0.699)	2.67 (0.708)	2.69 (0.710)	2.64 (0.706)
Foveal Involved GA (%)	62 (57.4%)	65 (62.5%)	66 (62.3%)	193 (60.7%)
Multifocal lesions (%)	58 (53.7%)	56 (53.8%)	51 (48.1%)	165 (51.9%)
BCVA, mean (SD) ETDRS letters	62.8 (14.73)	58.4 (15.33)	60.6 (14.20)	60.6 (14.82)
Snellen Equivalent	20/63	20/80	20/63	20/63
LLD (BCVA - LLVA), mean ETDRS letters	29.9 (16.82)	29.4 (16.60)	27.1 (16.10)	28.8 (16.50)
Bilateral GA, n (%)	99 (91.7)	88 (84.6)	95 (89.6)	282 (88.7)
CNV in Fellow Eye, n (%) <sup>1</sup>	22 (20.4)	17 (16.3)	20 (18.9)	59 (18.6)



<sup>1</sup>Fellow Eye CNV is defined as a history of CNV or neovascular AMD <sup>2</sup>The mITT analysis set includes all randomized and treated (with at least one study treatment) patients LLD = low luminance deficit; LLVA = low luminance visual acuity



# **Primary Endpoint Analysis**

#### Rate of Change (Slope Analysis) in GA Lesion Area over 52 Weeks





Slope is generated from all available timepoints (Baseline, 24 weeks, 52 weeks) The Least Square (LS) mean is estimated from a random coefficients linear growth model The mITT analysis set includes all randomized and treated (with at least one study treatment) patients SE = standard error



# **Pre-specified Secondary Analysis (MMRM)**



Change from Baseline in GA Lesion Area (MMRM) over 52 Weeks



The Least Square (LS) means is estimated from a mixed model for repeated measures (MMRM) The mITT analysis set includes all randomized and treated (with at least one study treatment) patients



### **Representative Baseline Large GA Lesion Cases**



Patient is a protocol violation as it did not meet eligibility criteria at baseline with GA >17.5 mm<sup>2</sup>

### **Exploratory Post-Hoc Subgroup Analysis (MMRM and Slope): Excluding** Quartile of Patients with Largest Lesions (>9.64 mm<sup>2</sup>) at Baseline





<sup>3</sup>The Least Square (LS) mean is estimated from a random coefficients linear growth model <sup>4</sup> All p values are nominal



### Study Eye CNV Conversions Over 56 Weeks<sup>1</sup>

	NGM621 Q4W (N = 108)	NGM621 Q8W (N = 104)	Sham Pooled (N = 106)
Study Eye CNV Conversions	3 (2.8%)	2 (1.9%)	4 (3.8%) <sup>2</sup>
Reading Center Confirmed CNV Conversions	3 (2.8%)	2 (1.9%)	4 (3.8%)

### Fellow eye CNV conversion rate was 4.2% (N = 11)<sup>3</sup> over 56 weeks



<sup>1</sup>Events include preferred terms of CNV and neovascular AMD <sup>2</sup>There was a coding error for 1 additional CNV patient in the sham arm which was removed from this table <sup>3</sup>259 = number of patients that did not have medical history of CNV or neovascular AMD in fellow eye at baseline



# Intraocular Inflammation (IOI) in the Study Eye

	NGM621 Q4W (N = 108)	NGM621 Q8W (N = 104)	Sham Pooled (N = 106)
Number of subjects with IOI <sup>1</sup> :	2 (1.9%)	1 (1.0%)	1 (0.9%)
Anterior Chamber Cells	1 (0.9%)	1 (1.0%)	1 (0.9%)
Vitreous Cells	0	0	0
Eye Inflammation	1 (0.9%)	0	0
Endophthalmitis	0	0	0
Retinal Vasculitis	0	0	0
Retinal Vein Occlusion	0	0	0





## **Ocular SAEs in the Study Eye**

	NGM621 Q4W (N = 108)	NGM621 Q8W (N = 104)	Sham Pooled (N = 106)
Number of subjects with $\geq 1$ Ocular SAE <sup>1</sup>	8 (7.4%)	8 (7.7%)	3 (2.8%)
Eye Disorders	8 (7.4%)	8 (7.7%)	3 (2.8%)
Visual Acuity Reduced	2 (1.9%)	3 (2.9%)	0
Dry AMD	4 (3.7%)	3 (2.9%)	1 (0.9%)
Visual Impairment	1 (0.9%)	2 (1.9%)	1 (0.9%)
Neovascular AMD	1 (0.9%)	0	1 (0.9%)
Retinal Artery Occlusion	1 (0.9%)	1 (1.0%)	0

### No SAEs were deemed related to NGM621 by the Investigator

**NEW BIO**<sup>1</sup>Protocol defined sight threatening events (a decrease of visual acuity of >30 letters in any post-baseline visit; severe intraocular inflammation; adverse events that require surgical or medical intervention to prevent permanent loss of sight; any decrease to light perception or worse lasting more than an hour) were reported as serious adverse events



- CATALINA trial did not meet its primary endpoint
- Pre-specified secondary MMRM analysis showed reduction in lesion growth rate at 24 weeks with a nominal p-value of < 0.05 for the Q4W arm, that diminished at 52 weeks
- Additional post-hoc analyses that adjusted for large lesion variability showed potentially encouraging findings warranting further evaluation
- NGM621 showed no evidence of increased CNV conversion
- Overall NGM621 appears to have been well-tolerated with no treatmentrelated SAEs





Drs. Ashkan Abbey, Prema Abraham, Sean Adrean, Payam Amini, Andrew Antoszyk, Irene Barbazetto, Ivan Batlle, Sumit Bhatia, Robert Bhisitkul, David Boyer, William Bridges, Harold Brooks, David Brown, Brandon Busbee, David Callanan, Jorge Calzada, Alessandro Castellarin, Margaret Chang, Nauman Chaudhry, Sanford Chen, Karl Csaky, Amr Dessouki, Christopher Devine, Dilsher Dhoot, Kimberly Drenser, David Eichenbaum, Michael Elman, Robert Engstrom, Robert Feldman, Philip Ferrone, Diane Fiander, Sunir Garg, Alan Gordon, Shailesh Gupta, Sunil Gupta, Jeffrey Heier, Vrinda Hershberger, Allan Hunter, Atul Jain, Randy Katz, Arshad Khanani, Rahul Khurana, Erik Kruger, Eleonora Lad, Seong Young Lee, Jennifer Lim, Mimi Liu, Raj Maturi, Katrina Mears, David Wilkin Parke, Stephen Perkins, Michael Samuel, Rishi Singh, Raymond Sjaarda, Robert Stoltz, Aleksandra Rachitskaya, Michael Rauser, Ryan Rich, Steven Schwartz, Veeral Sheth, Yevgeniy Shildkrot, Lawrence Singerman, Eduardo Uchiyama, Robert Wirthlin, Charles Wykoff, Nicolas Yannuzzi

#### THANK YOU TO THE CATALINA STUDY SITES, INVESTIGATORS AND PATIENTS



# Looking Forward to Multiple Program Milestones in 2022

Program	Mechanism	Status	Milestones	
NGM621 Geographic Atrophy	Anti-Complement C3 Antibody	CATALINA trial completed	Topline Ph2 CATALINA data readout in 4Q22	$\checkmark$
<b>NGM707</b> Advanced Solid Tumors	ILT2/ILT4 Dual Antagonist Antibody	Ph1/2 trial enrolling	Initial Ph1a clinical data readout in 4Q22	
NGM831 Advanced Solid Tumors	ILT3 Antagonist Antibody	Enrolling	Initiation of Ph1 trial in 1Q22	$\checkmark$
NGM438 Advanced Solid Tumors	LAIR1 Antagonist Antibody	Enrolling	Initiation of Ph1 trial in 2Q22	$\checkmark$
NGM120 Cancer and Cachexia	GFRAL Antagonist Antibody	Ph1a/1b trial ongoing Ph2 trial enrolling	Additional Ph1a/1b clinical data readouts in 3Q22	$\checkmark$
Aldafermin Cirrhotic NASH	FGF19 Analog	Ph2b ALPINE 4 trial fully enrolled	Last Patient In (LPI) in 1Q22	$\checkmark$
MK-3655 Non-cirrhotic NASH	FGFR1c/KLB Agonist Antibody	Merck-led global Ph2b trial enrolling	Ongoing enrollment	

#### 3Q22 \$300M cash balance funds planned activities through data readouts in 2023 across oncology portfolio<sup>1</sup>

**NEW BIO**<sup>1</sup>Based upon preliminary estimates and information currently available to the Company, the Company expects to report that it had approximately \$300 million of cash, cash equivalents and short-term marketable securities as of September 30, 2022





David Woodhouse, Ph.D. Chief Executive Officer, NGM Bio



**Erin Henry, Ph.D.** Head of Ophthalmology, NGM Bio



Hsiao Lieu, M.D. Chief Medical Officer, NGM Bio



**Siobhan Nolan Mangini** President and Chief Financial Officer, NGM Bio

