

# ACQUISITION OF IVERIC BIO



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## Cautionary Notice Regarding Forward-Looking Statements

All statements in this press release, other than statements of historical fact, are statements that could be deemed “forward-looking statements” In some cases, forward-looking statements may be identified by terminology such as “believe,” “may,” “will,” “should”, “predict”, “goal”, “strategy”, “potentially,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “expect,” “seek” and similar expressions and variations thereof. Iveric Bio intends these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements in the U.S. Private Securities Litigation Reform Act of 1995.

This press release contains “forward-looking statements” relating to, among other things, the proposed acquisition of Iveric Bio by Astellas and the objectives of such proposed acquisition, Astellas’ and Iveric Bio’s beliefs and expectations regarding the potential benefits sought to be achieved by Astellas’ proposed acquisition of Iveric Bio, the potential effects of the proposed acquisition on both Astellas and Iveric Bio, the expected benefits and success of Iveric Bio’s product candidates, the potential for and anticipated timing for approval of ACP, the anticipated financing of the proposed acquisition, and the anticipated timing of completion of the proposed acquisition, each of which involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements.

Risks and uncertainties include, among other things, risks related to the ability of Iveric Bio and Astellas to complete the transactions contemplated by the merger agreement; the satisfaction or waiver of the conditions to closing the proposed acquisition set forth in the merger agreement (including the failure to obtain necessary regulatory approvals and failure to obtain the requisite vote by Iveric Bio stockholders) in the anticipated timeframe or at all, including the possibility that the proposed acquisition does not close; the timing and nature of regulatory filings for Iveric Bio’ product candidates, and the possibility of a termination of the merger agreement; the possibility that competing offers to acquire Iveric Bio may be made; risks related to the ability to realize the anticipated benefits of the proposed acquisition, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period; the risk that Iveric Bio’s business and products will not be integrated with those of Astellas successfully; the effects of disruption from the transactions contemplated by the merger agreement on Iveric Bio’s business and the fact that the announcement and pendency of the transactions may make it more difficult to establish or maintain relationships with employees, suppliers and other business partners; negative effects of this announcement or the consummation of the proposed acquisition on the market price of Astellas’ or Iveric Bio’s common stock and/or operating results; significant transaction costs; unknown liabilities; the risk of litigation and/or regulatory actions related to the proposed acquisition or Iveric Bio’s business; risks related to the financing of the acquisition; other business effects and uncertainties, including the effects of industry, market, business, economic, political or regulatory conditions; future exchange and interest rates; changes in tax and other laws, regulations, rates and policies; future business combinations or disposals; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data is subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when drug applications may be filed in any jurisdictions for Iveric Bio’s pipeline products; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product’s benefits outweigh its known risks and determination of the product’s efficacy and, if approved, whether any such products will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety or other matters that could affect the availability or commercial potential of such products; expectations regarding personnel and human capital matters; and competitive developments.

Moreover, Astellas and Iveric Bio operate in very competitive and rapidly changing environments, and new risks emerge from time to time. Astellas and Iveric Bio have based these forward-looking statements on their current expectations and projections about future events and trends that they believe may affect the financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs of Astellas and Iveric Bio, but they cannot guarantee future events, results, actions, levels of activity, performance or achievements, business and market conditions, the timing and results of biotechnology development and potential regulatory approval. The foregoing factors are not exhaustive. You should also carefully consider other risks and uncertainties that may affect the business of Iveric Bio, including those described in the “Forward-Looking Statements”, “Summary of Principal Risk Factors”, and “Risk Factors” sections of Iveric Bio’ Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other documents filed from time to time with the SEC, all of which are available on the SEC’s website at [www.sec.gov](http://www.sec.gov). These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements and Astellas and Iveric Bio assume no obligation to, and do not intend to, update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise, unless required by applicable law.

### **Additional Information and Where to Find It**

In connection with the proposed acquisition, Iveric Bio will be filing documents with the SEC, including preliminary and definitive proxy statements relating to the proposed acquisition. This press release is not a substitute for the proxy statement or any other document which Iveric Bio may file with the SEC. The definitive proxy statement will be mailed to Iveric Bio's stockholders in connection with the proposed acquisition. BEFORE MAKING ANY VOTING DECISION, IVERIC BIO'S INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PRELIMINARY AND DEFINITIVE PROXY STATEMENTS AND ANY OTHER DOCUMENTS TO BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED TRANSACTION OR INCORPORATED BY REFERENCE IN THE PROXY STATEMENT WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED ACQUISITION. Any vote in respect of resolutions to be proposed at Iveric Bio's stockholder meeting to approve the proposed transaction or other responses in relation to the proposed transaction should be made only on the basis of the information contained in Iveric Bio's proxy statement. Investors and security holders may obtain free copies of these documents (when they are available) and other related documents filed with the United States Securities and Exchange Commission ("SEC") at the SEC's web site at [www.sec.gov](http://www.sec.gov), and all documents filed by Iveric Bio with the SEC are available to all stockholders of Iveric Bio free of charge at [<https://investors.ivericbio.com/financial-information/sec-filings>]

### **Participants in the Solicitation**

Iveric Bio, and its directors, executive officers and other members of management and certain other people may be deemed to be participants in the solicitation of proxies in connection with the proposed acquisition. Information about Iveric Bio's directors and executive officers is included in the proxy statement for Iveric Bio's annual meeting of stockholders for 2023, filed with the SEC on April 5, 2023. Additional information regarding these persons and their interests in the merger will be included in the proxy statement relating to the proposed acquisition when it is filed with the SEC. These documents, when available, can be obtained free of charge from the sources indicated above.

### **Important Additional Information**

This communication is for informational purposes only and is not intended to and does not constitute, or form part of, an offer, invitation or the solicitation of an offer or invitation to purchase, otherwise acquire, subscribe for, sell or otherwise dispose of Iveric Bio common stock or any other securities, or the solicitation of any vote or approval in any jurisdiction, pursuant to the proposed acquisition or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law.

# AGENDA

I Transaction Summary

IV Financial Considerations

II Overview of Iveric Bio

III Strategic Rationale

# TRANSACTION SUMMARY

<b>Party</b>	<ul style="list-style-type: none"><li>• IVERIC bio, Inc. (New Jersey; listed on NASDAQ)</li></ul>
<b>Purchase Price</b>	<ul style="list-style-type: none"><li>• US\$40.00 per share in cash<ul style="list-style-type: none"><li>• Premium of 64% to Iveric Bio’s unaffected closing share price of US\$24.33 as of March 31, 2023</li><li>• Premium of 75% to Iveric Bio’s 30 trading day volume weighted average price as of March 31, 2023</li></ul></li><li>• Acquisition amount: approximately US\$5.9 billion*</li></ul>
<b>Acquisition Method</b>	<ul style="list-style-type: none"><li>• A wholly-owned subsidiary of Astellas US Holding, Inc. (Berry Merger Sub, Inc.) will acquire 100% of the outstanding shares of Iveric Bio</li></ul>
<b>Timing for Closure</b>	<ul style="list-style-type: none"><li>• The acquisition is expected to close during Q2 FY2023, subject to approval by Iveric Bio’s stockholders and other customary closing conditions</li></ul>

\*Acquisition amount includes the full amount required to purchase all outstanding options and restricted stock units.

# IVERIC BIO OVERVIEW

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## IVERIC bio, Inc. (NASDAQ: ISEE)

<b>Headquarters</b>	<ul style="list-style-type: none"><li>Parsippany, New Jersey, United States</li></ul>
<b>Business</b>	<ul style="list-style-type: none"><li>A biopharmaceutical company focusing on discovery and development of therapeutic drugs specialized in the field of ophthalmology</li></ul>
<b>Employees</b> (As of March 2023)	<ul style="list-style-type: none"><li>~260 (~90 in Commercial, ~60 in R&amp;D)*</li></ul>

## Clinical & Nonclinical Pipelines

Clinical Asset	MOA / modality	Target disease	Stage
<b>Avacincaptad Pegol (ACP)</b>	C5 inhibitor / RNA aptamer	Geographic Atrophy (GA) secondary to age-related macular degeneration (AMD)	NDA (US; PDUFA date: August 19, 2023)
		Stargardt disease	Phase 2b

Nonclinical Asset	MOA / modality	Target disease	Stage
<b>IC-500</b>	HtrA1 inhibitor / small molecule	GA secondary to AMD	Preclinical
<b>Mini-CEP290</b>	miniCEP290 gene replacement (AAV)	Leber's congenital amaurosis 10	Research
<b>Mini-ABCA4</b>	miniABCA4 gene replacement (AAV)	Stargardt disease type 1	Research
<b>Mini-USH2A</b>	miniUSH2A gene replacement (AAV)	Usher syndrome type 2	Research

\*Commercial includes Sales and Commercial Market Development & Reimbursement, R&D includes Research, Clinical Development, Medical Affairs and Regulatory/Pharmacovigilance  
MOA: Mechanism of action, NDA: New Drug Application, PDUFA: Prescription Drug User Fee Act, AAV: Adeno-associated virus



## 1. Avacincaptad Pegol (ACP): Potential as a New Revenue-generating Pillar

- Anticipated to enter geographic atrophy (GA) market with large patient population and significant unmet medical needs
- Opportunity to become standard of care for GA
- Anticipated to contribute to the mid-term revenue to help compensate for XTANDI LOE

## 2. Establishing Foundational Ophthalmology Capabilities for PF-BR

- Enhance commercial capabilities in ophthalmology
- Access to ophthalmology experts and medical institutes
- Acquire know-how in development and research platform

# AVACINCAPTAD PEGOL (ACP) OVERVIEW

**ACP has the potential to be an innovative medicine to address significant unmet medical needs in ophthalmology**

<b>MOA</b>	<ul style="list-style-type: none"><li>• Complement C5 inhibitor: Suppresses activity of complement system that causes retinal cell degeneration, leading to a decrease in the rate of geographic atrophy (GA) progression</li></ul>
<b>Modality</b>	<ul style="list-style-type: none"><li>• Pegylated RNA aptamer (Chemically synthesized)</li></ul>
<b>Administration method</b>	<ul style="list-style-type: none"><li>• Monthly or bi-monthly* intravitreal injections</li></ul>
<b>Target disease</b>	<ul style="list-style-type: none"><li>• Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)</li><li>• Stargardt disease</li></ul>
<b>Regulatory status</b>	<ul style="list-style-type: none"><li>• Breakthrough Therapy designation granted by FDA (November 2022)</li><li>• NDA filed (PDUFA date: August 19, 2023, under Priority Review)</li></ul>

\*Bi-monthly regimen is under investigation.

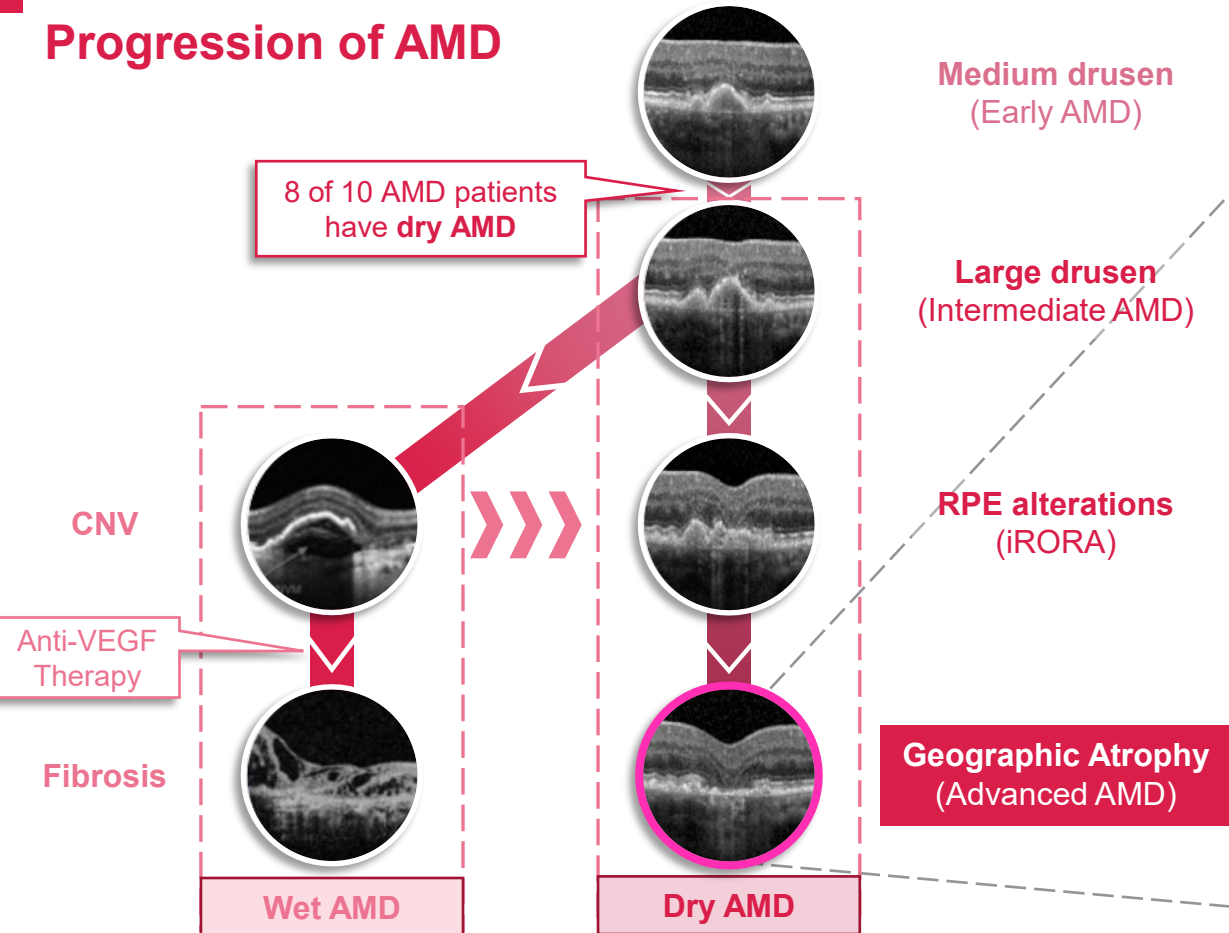
MOA: Mechanism of action, FDA: Food and Drug Administration, NDA: New Drug Application, PDUFA: Prescription Drug User Fee Act





# GEOGRAPHIC ATROPHY (GA) OVERVIEW

## Progression of AMD



## GA Market

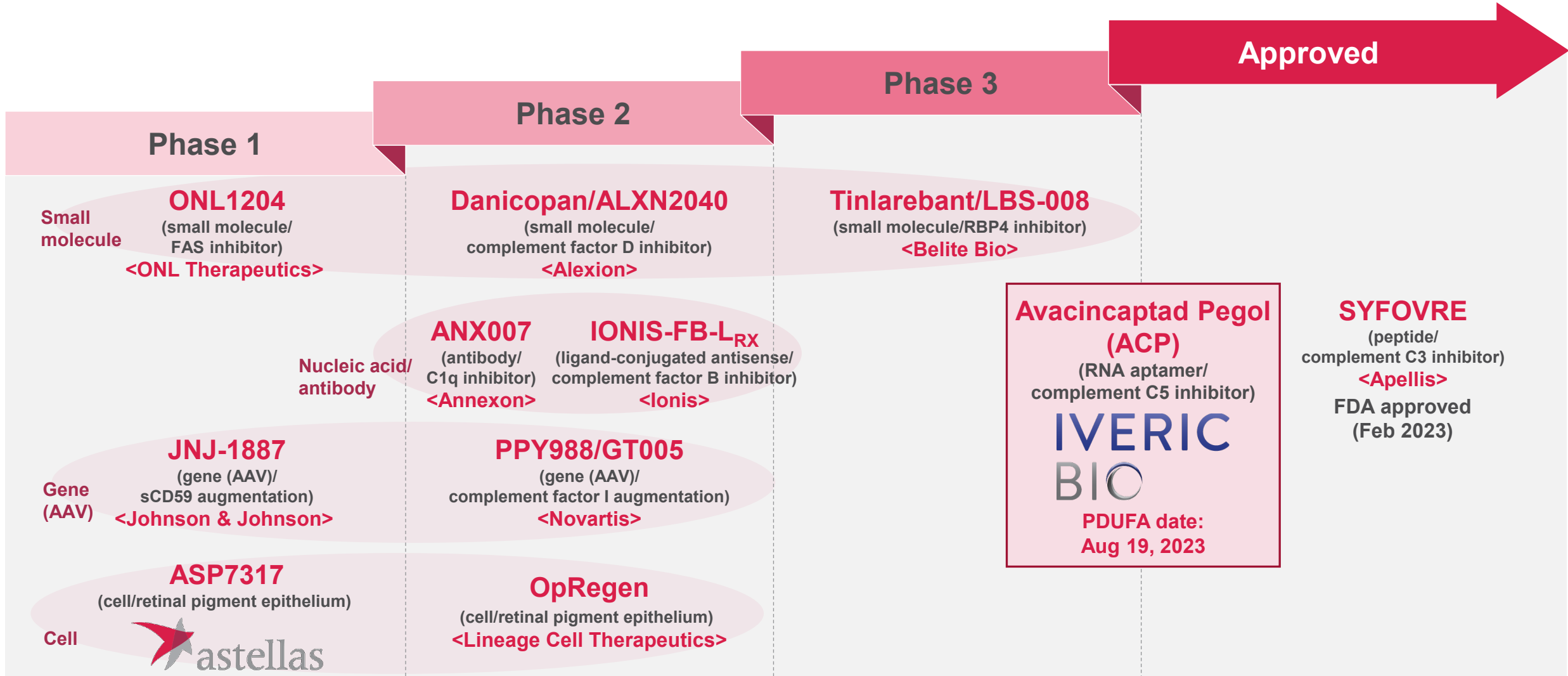
- ~40% of eyes with GA are blinded
- Leading cause of increasing irreversible blindness
- ~50% of patients are affected bilaterally
- Severely underdiagnosed, with exact cause unknown
- ~1.6M patients in the U.S. <sup>1</sup>
- Currently only one FDA approved treatment

**Long-standing need for effective treatment**

1. Arch Ophthalmol. 129:75-80 (2011)

AMD: Age-related macular degeneration, CNV: Choroidal neovascularization, VEGF: Vascular endothelial growth factor, RPE: Retinal pigment epithelial, iRORA: Incomplete retinal pigment epithelial and outer retinal atrophy

# SELECTED CLINICAL PIPELINE ASSETS TARGETING GEOGRAPHIC ATROPHY (GA)



AAV: Adeno-associated virus, PDUFA: Prescription Drug User Fee Act, FDA: Food and Drug Administration

# PIVOTAL TRIALS (GATHER1 AND GATHER2): OVERVIEW

## GATHER1

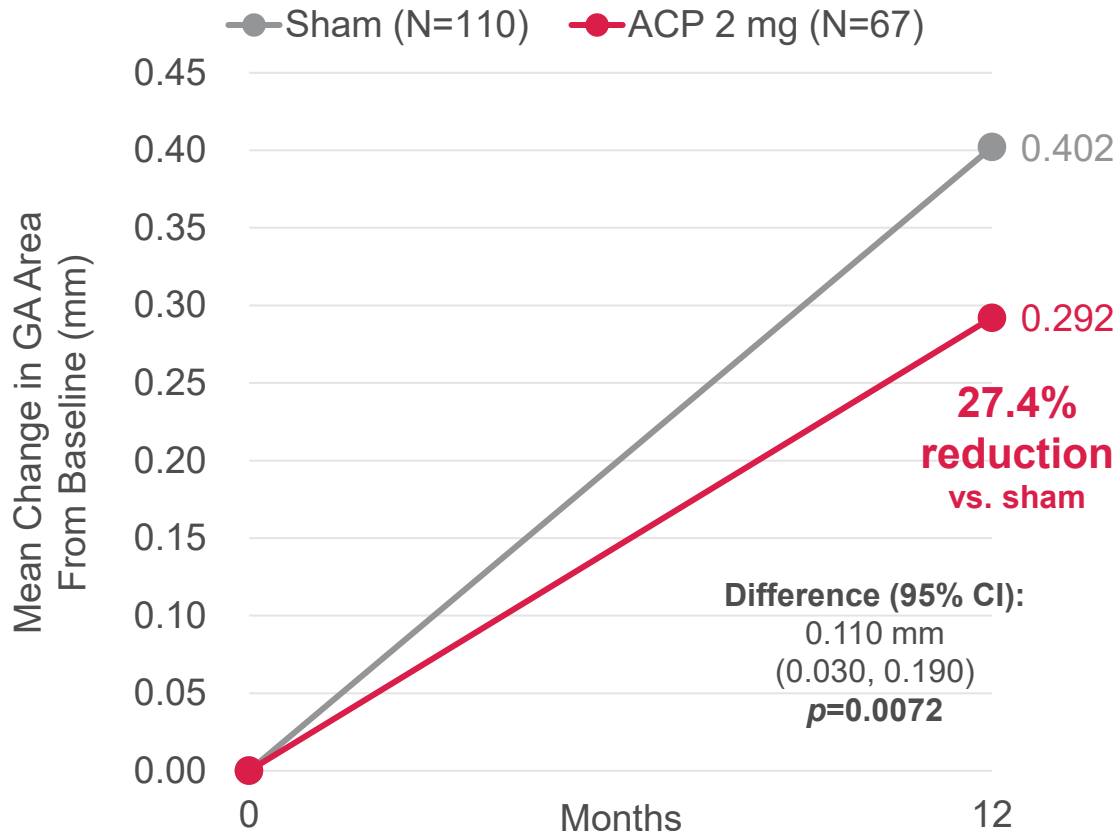
## GATHER2

<b>Design</b>	<ul style="list-style-type: none"> <li>Randomized, double masked, sham controlled, multicenter</li> </ul>	
<b>Phase</b>	<ul style="list-style-type: none"> <li>Phase 2/3</li> </ul>	<ul style="list-style-type: none"> <li>Phase 3</li> </ul>
<b>Dosing Interval</b>	<ul style="list-style-type: none"> <li>Monthly</li> </ul>	<ul style="list-style-type: none"> <li>Monthly (first 12 months)</li> <li>Monthly or bi-monthly (after 13 months)</li> </ul>
<b>Primary Endpoint</b>	<ul style="list-style-type: none"> <li>Mean change in GA area from baseline to month 12 measured by fundus autofluorescence (square root transformation)</li> </ul>	<ul style="list-style-type: none"> <li>Mean rate of growth (slope) in GA area from baseline to month 12 measured by fundus autofluorescence (square root transformation)</li> </ul>
<b>Patients Enrolled</b>	<ul style="list-style-type: none"> <li>286</li> </ul>	<ul style="list-style-type: none"> <li>448</li> </ul>
<b>Cohort</b>	<ul style="list-style-type: none"> <li>Part 1: 1 mg, 2 mg, Sham (N=77)</li> <li>Part 2: 2 mg, 4 mg, Sham (N=209)</li> </ul>	<ul style="list-style-type: none"> <li>2 mg, Sham (N=448)</li> </ul>

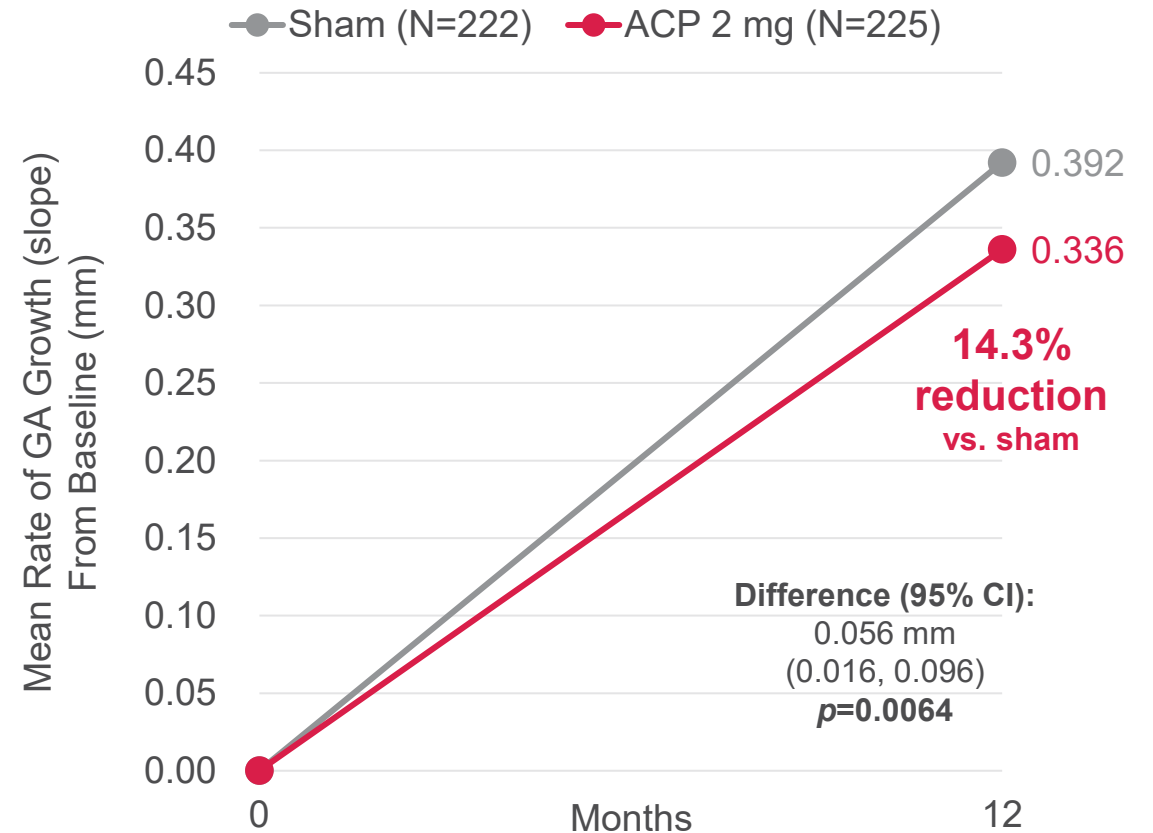
# PIVOTAL TRIALS (GATHER1 AND GATHER2): EFFECT ON GA AREA

Significant reduction in progression of GA by ACP treatment

## GATHER 1



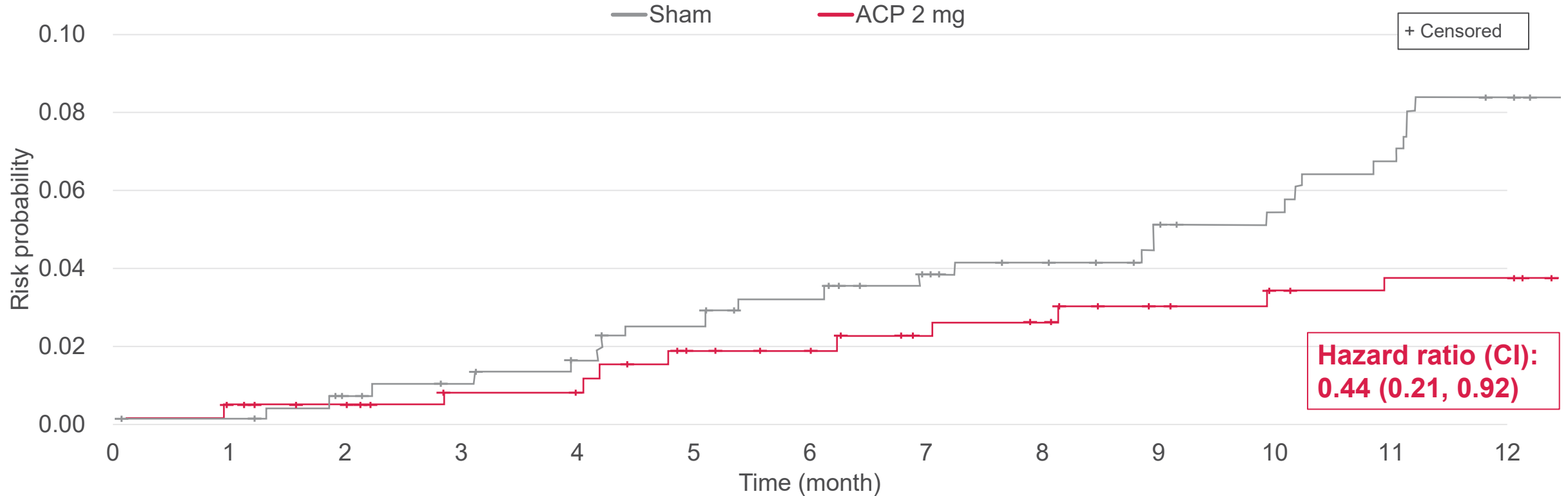
## GATHER 2



Khanani AM, et al. Presented at: Retina Society: November 2-5, 2022.  
Changes in GA area are determined using the square root transformation (mm).  
CI: Confidence interval

# PIVOTAL TRIALS (GATHER1 AND GATHER2): EFFECT ON VISION LOSS

**56% risk reduction in rate of vision loss by ACP treatment**



Number of patients at risk (events)

ACP 2 mg:	292 (0)	288 (1)	281 (1)	277 (2)	276 (2)	269 (5)	264 (5)	258 (6)	256 (7)	251 (8)	248 (9)	246 (10)	246 (10)
Sham:	332 (0)	329 (0)	323 (2)	320 (3)	316 (5)	312 (8)	307 (10)	300 (12)	296 (13)	289 (16)	285 (17)	281 (21)	275 (26)

Post hoc time-to-event analysis.

Vision loss: a loss of  $\geq 15$  letters in Best Corrected Visual Acuity (BCVA) from baseline measured at any two consecutive visits up to month 12

CI: Confidence interval

# PIVOTAL TRIALS (GATHER1 AND GATHER2): SAFETY

**ACP group showed a consistent safety profile with Sham group with no intraocular inflammation and infectious endophthalmitis events**

**GATHER1**

12 months\*

**GATHER2**

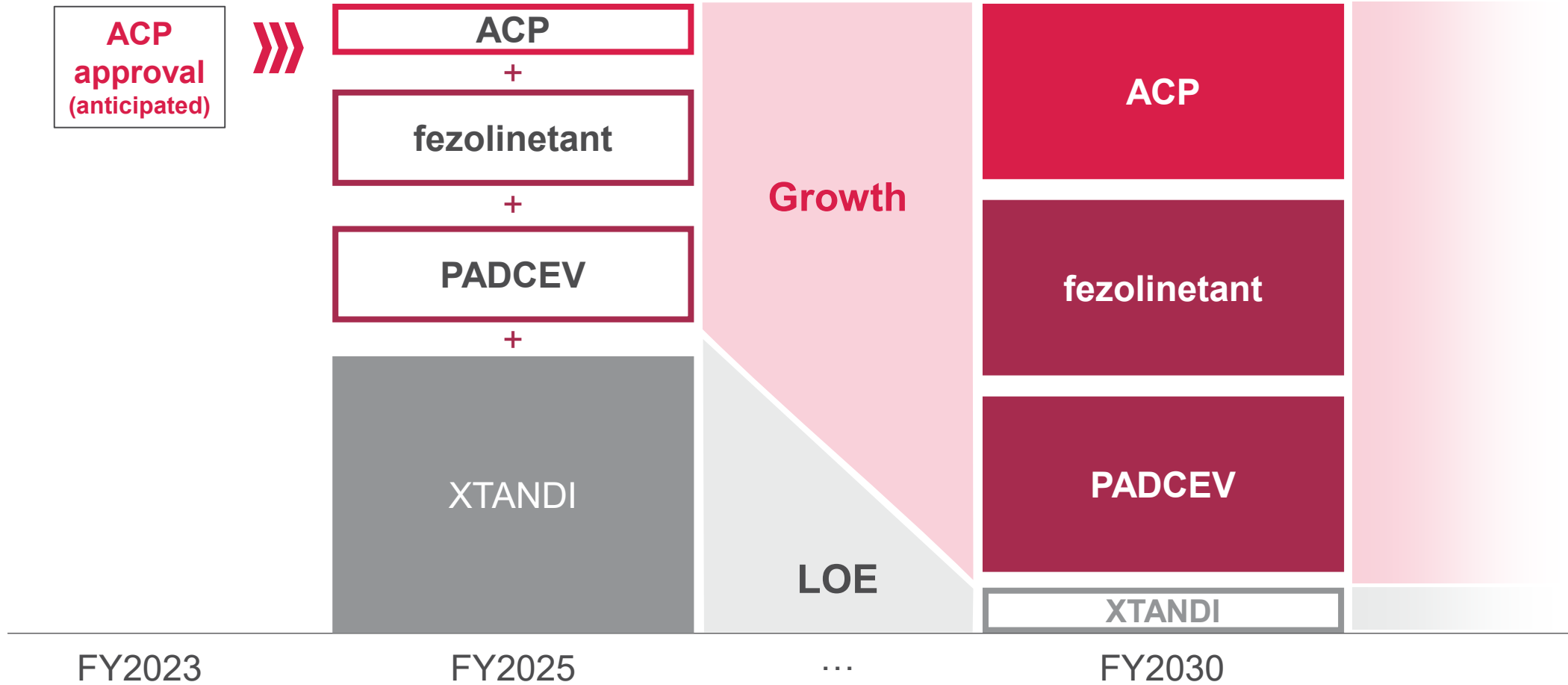
12 months

	<b>ACP 2 mg (N=67)</b>	<b>Sham (N=110)</b>	<b>ACP 2 mg (N=225)</b>	<b>Sham (N=222)</b>
<b>TEAEs, N (%)</b>	<b>50 (74.6)</b>	<b>77 (77.0)</b>	<b>178 (79.1)</b>	<b>157 (70.7)</b>
Ocular in study eye	35 (52.2)	38 (34.5)	110 (48.9)	83 (37.4)
Non-ocular	39 (58.2)	60 (54.5)	125 (55.6)	127 (57.2)
<b>Serious TEAEs, N (%)</b>	<b>7 (10.4)</b>	<b>20 (18.2)</b>	<b>30 (13.3)</b>	<b>37 (16.7)</b>
Ocular in study eye	0	0	2 (0.9)	2 (0.9)
Non-ocular	7 (10.4)	20 (18.2)	29 (12.9)	35 (15.8)
<b>TEAEs leading to study drug discontinuation, N (%)</b>	<b>0</b>	<b>1 (1.9)</b>	<b>6 (2.7)</b>	<b>2 (0.9)</b>
Ocular in study eye	0	0	2 (0.9)	0
Non-ocular	0	1 (0.9)	4 (1.8)	2 (0.9)
<b>CNV** (%)</b>	<b>9.0</b>	<b>2.7</b>	<b>6.7</b>	<b>4.1</b>
<b>Intraocular inflammation*** (%)</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
<b>Infectious endophthalmitis (%)</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>

\*Both ACP and sham groups are a combination of Part 1 and Part 2. \*\*Choroidal neovascularization. \*\*\*Excluding those reported as related to injection procedure.  
 Note: N = study eyes with events. A patient with multiple occurrences of an AE under one treatment is counted only once. TEAE: Treatment-emergent adverse event  
 Kaiser PK, et al. Presented at: Retina Society: November 2-5, 2022.

# REVENUE CONTRIBUTION OF ACP (ILLUSTRATIVE)

Potential to help compensate for XTANDI LOE as the “third pillar”



Note: The figure above is for illustrative purposes only, and does not represent the exact figures of each drugs' sales  
LOE: Loss of exclusivity

# ESTABLISHING FOUNDATIONAL OPHTHALMOLOGY CAPABILITIES

The acquisition of Iveric Bio is expected to provide capabilities as a leader at the forefront of ophthalmology field

## Commercial and Market Access

- Enhance commercial capabilities in ophthalmology to maximize ACP's value
- Advance market access proficiencies with payers
- Build a foundation to support the future launch and commercialization of PF-BR assets

## Medical and R&D

- Access to network of ophthalmology experts and medical institutes
- Acquire the know-how that succeeded in clinical development in GA
- Acquire research platform and assets in retinal gene therapy



## Transaction financing

- Bridge financing through CPs and short-term loans (total approx. 800 billion yen), and cash on hand
- Afterwards, consider corporate bonds and long-term loans



**Possible to complete repayments within the next five to seven years through robust cash flow**

## Capital allocation policy

- 1 Top priority is investment for business growth
- 2 Raise dividend level aligned with profit / cashflow plan and actual performance throughout CSP2021 period
- 3 Flexibly execute share buyback with excess cash

- ✓ **No change in capital allocation policy is anticipated due to the acquisition**
- ✓ **Diligently control financial structure to allow for future opportunistic investments**
- ✓ **Dividends to be paid out in line with CSP2021**

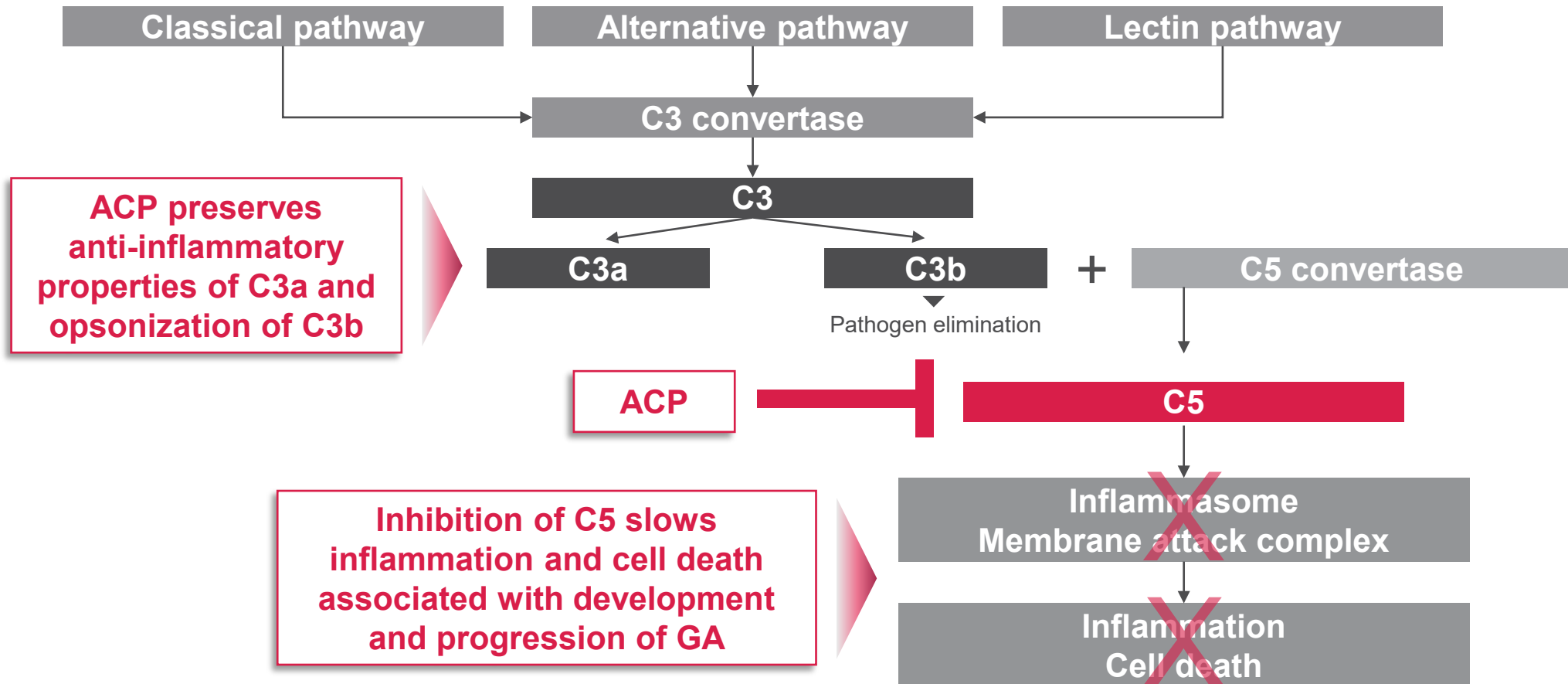
# APPENDIX



# MECHANISM OF ACTION

Complement pathway associated with the pathogenesis of AMD, which has been demonstrated by genetic analysis<sup>1</sup>

Complement hyperactivity leading to overactivation of the immune system and chronic inflammation in the macula is a hypothesized contributing factor to GA<sup>2</sup>



1: Nature Genetics 45: 433-439 (2013). 2: Eye (Lond) 36: 294-302 (2022)

# ON THE FOREFRONT OF HEALTHCARE CHANGE

