INVESTOR CALL:
IZERVAY™ (AVACINCAPTAD PEGOL INTRAVITREAL SOLUTION)
GATHER2 2-YEAR DATA PRESENTED AT AAO 2023

November 6, 2023 (JST)

astellas

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

In this material, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas Pharma. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice. Information about investigational compounds in development does not imply established safety or efficacy of the compounds; there is no guarantee investigational compounds will receive regulatory approval or become commercially available for the uses being investigated.

注意事項

本資料には、医薬品に関する情報が含まれています。それらの医薬品は、すべての国で発売されているとは限らず、また、国によって商標、効能・効果、用法・用量等が異なる可能性もあります。ここに記載されている内容は、株主や投資家の皆さまのための情報開示を目的としており、開発品を含むいかなる医療用医薬品の宣伝広告、医学的アドバイスを意図するものではありません。

DHAVAL DESAI

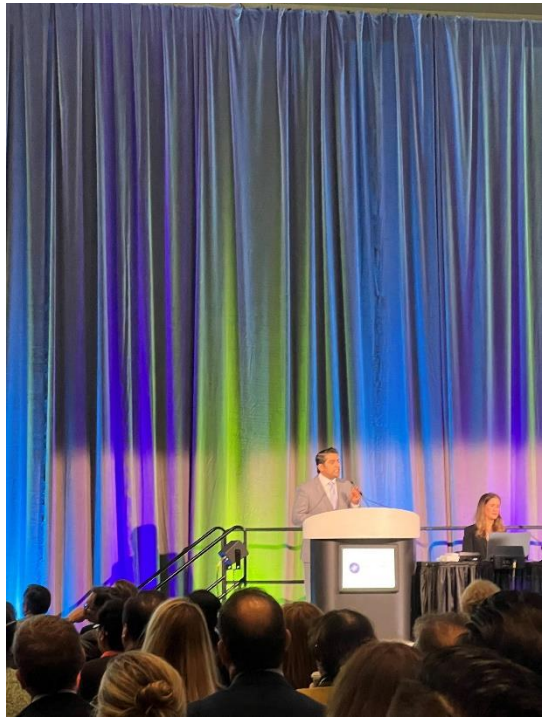
SENIOR VICE PRESIDENT AND CHIEF DEVELOPMENT OFFICER, IVERIC BIO, AN ASTELLAS COMPANY

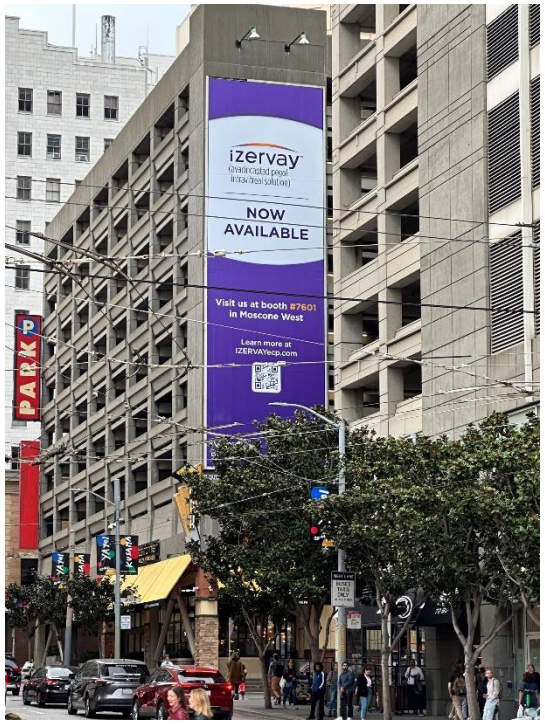
TODAY'S PRESENTATION CONTENTS

1. AAO Update and GATHER2 Summary and Background
   Dhaval Desai
2. GATHER2 2-Year Data
   Erin Henry
3. Lifecycle Management Update
   Dhaval Desai
4. Q&A

AAO UPDATE AND GATHER2 SUMMARY AND BACKGROUND

AAO UPDATE





Ophthalmology TIMES

STAT

OCULAR SURGERY NEWS

HCPLive®

eyetube®

SUMMARY OF GATHER2: 2-YEAR DATA

Both monthly (EM) and every other month (EOM) IZERVAY reduced GA growth vs sham

Treatment effect more than doubled over 2 years compared to 1 year for IZERVAY

IZERVAY was well tolerated: over 2 years, there was 1 case of non-serious IOI, 1 case of culture-positive endophthalmitis, and no cases of ION or retinal vasculitis

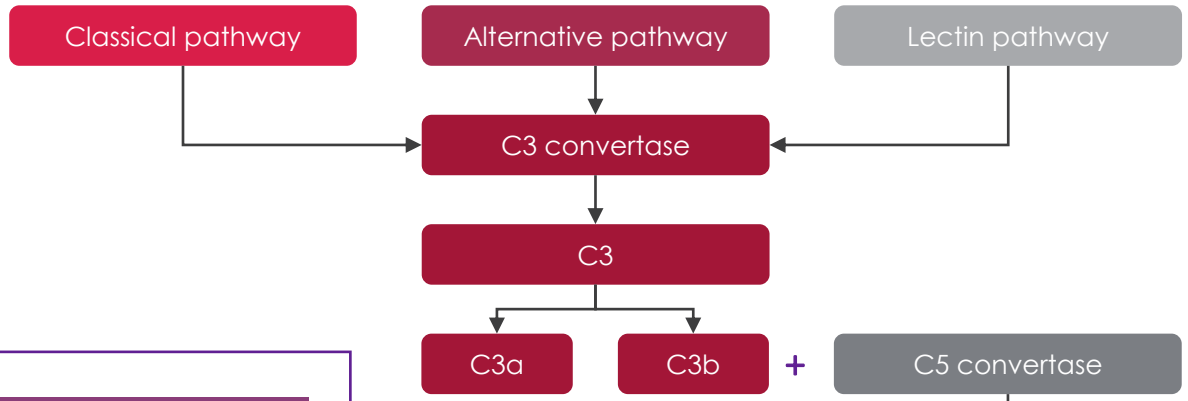
In year 2, incidence of CNV was similar for sham vs IZERVAY EOM

Over 2 years, only a slight increased incidence of CNV was observed for pooled IZERVAY vs sham (11.6% vs 9.0%, respectively)

CNV, choroidal neovascularization; GA, geographic atrophy; IOI, intraocular inflammation; ION, ischemic optic neuropathy.

astellas

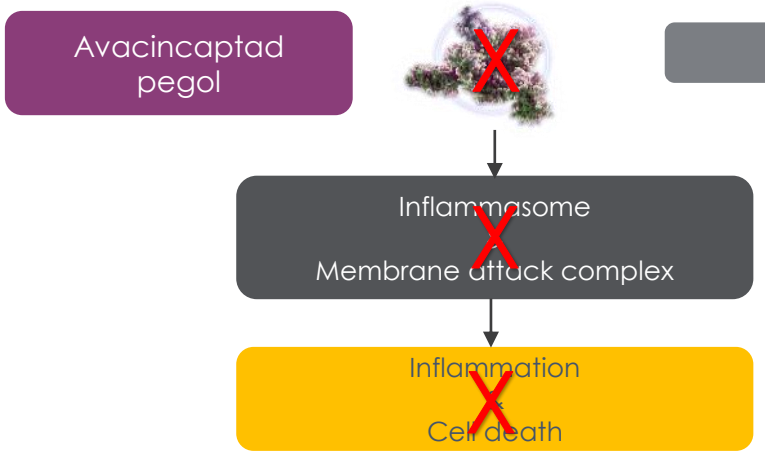
IZERVAY IS DESIGNED TO BE A SPECIFIC INHIBITOR OF COMPLEMENT C5



IZERVAY

Anti-C5 pegylated RNA aptamer

- Relatively small physical size
- Synthetic, as opposed to biological, production



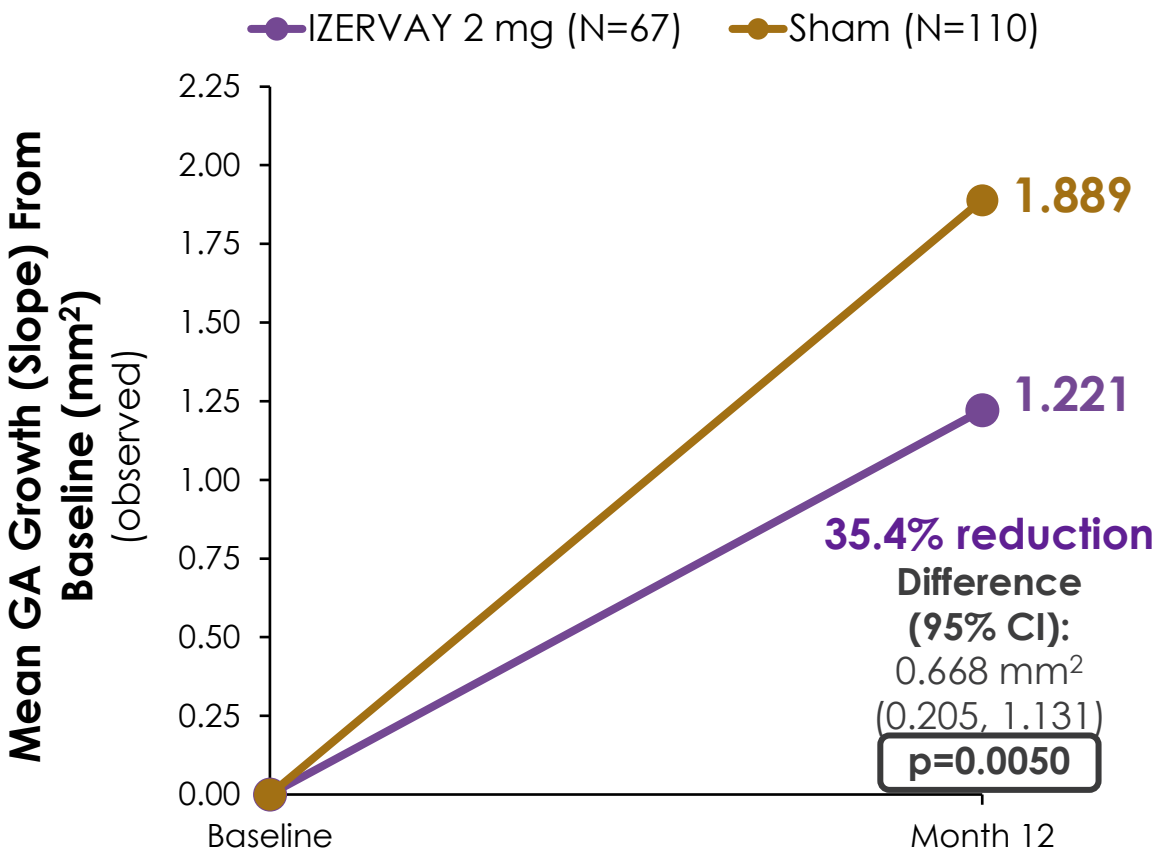
Inhibition of C5 slows inflammation and cell death associated with development and progression of GA

GA, geographic atrophy.

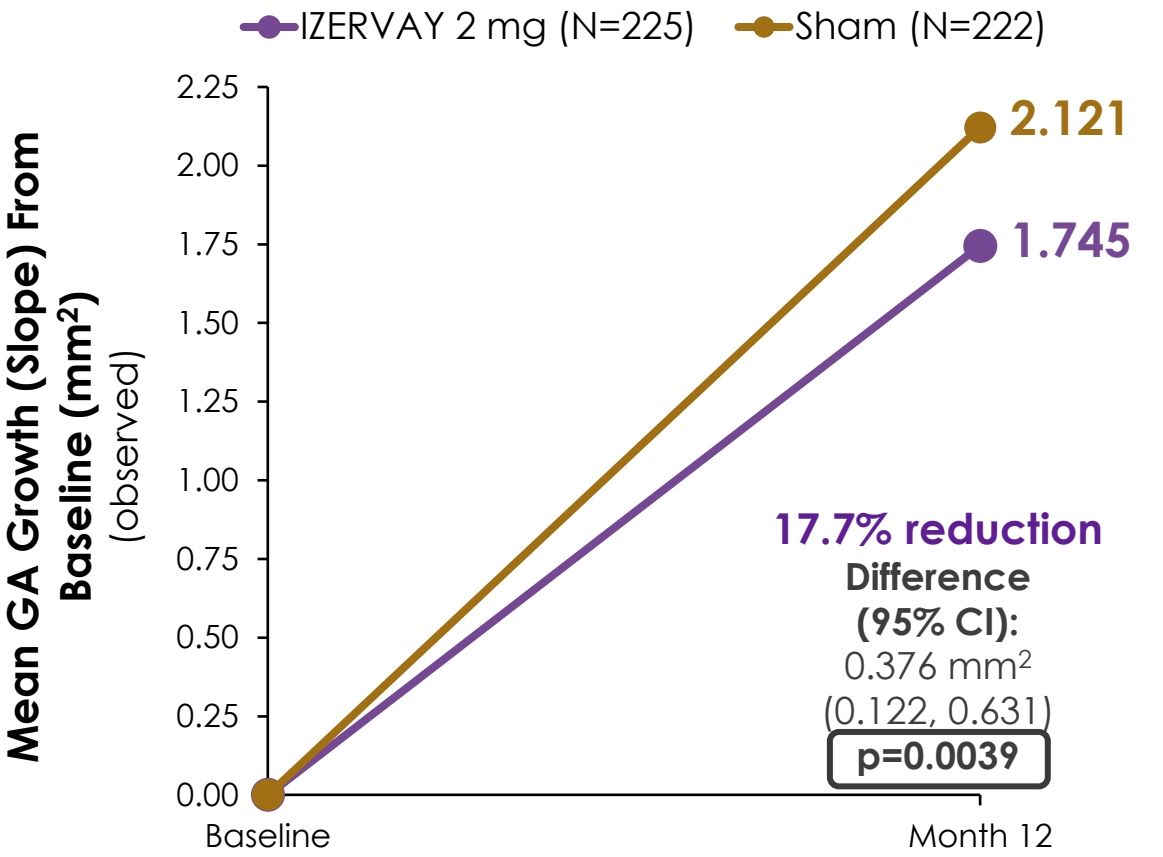
Khanani AM, et al. Presented at: Retina Society; November 2-5, 2022; Pasadena, CA.

IZERVAY ACHIEVED THE 12-MONTH PRESPECIFIED PRIMARY OBJECTIVE IN 2 PIVOTAL PHASE 3 STUDIES[1,2]

GATHER1



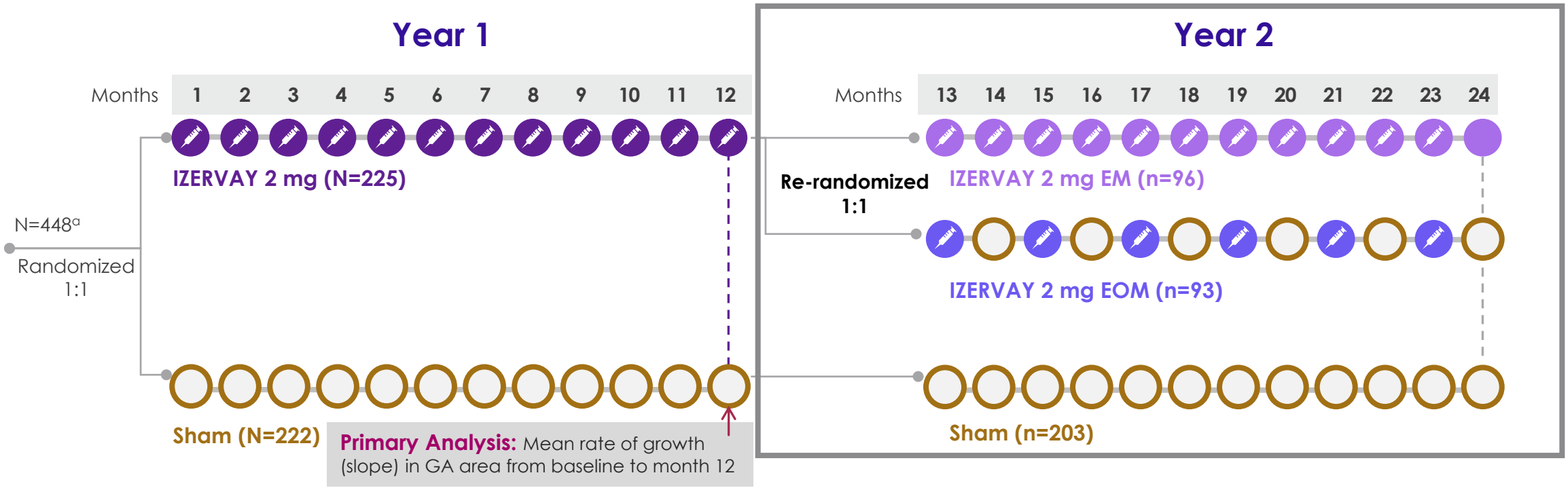
GATHER2



CI, confidence interval; GA, geographic atrophy. 1. Iveric Bio press release; 2. Khanani AM, et al. *Lancet.* 2023;402(10411):1449-1458.

astellas

GATHER2 IS A 2-YEAR, PHASE 3, INTERNATIONAL, MULTICENTER, PROSPECTIVE, RANDOMIZED, DOUBLE-MASKED, SHAM-CONTROLLED STUDY (NCT04435366)



Year 2 Objectives:

Evaluate efficacy and safety of re-randomized population of IZERVAY monthly (EM) and every other month (EOM) through year 2

Statistical Methodology:

To control for multiplicity, year 2 statistical significance was conducted sequentially on prespecified outcomes:

1. Reduction in GA growth for IZERVAY EM vs sham
2. Reduction in rate of persistent vision loss for IZERVAY pooled vs sham
3. Reduction in GA growth for IZERVAY EOM vs sham

GA, geographic atrophy.
Khanani AM, et al. *Lancet*. 2023;402(10411):1449-1458.
Note: The 24-month objective used observed data. [a] 448 randomized, with 447 treated (1 patient in sham did not receive treatment after randomization).

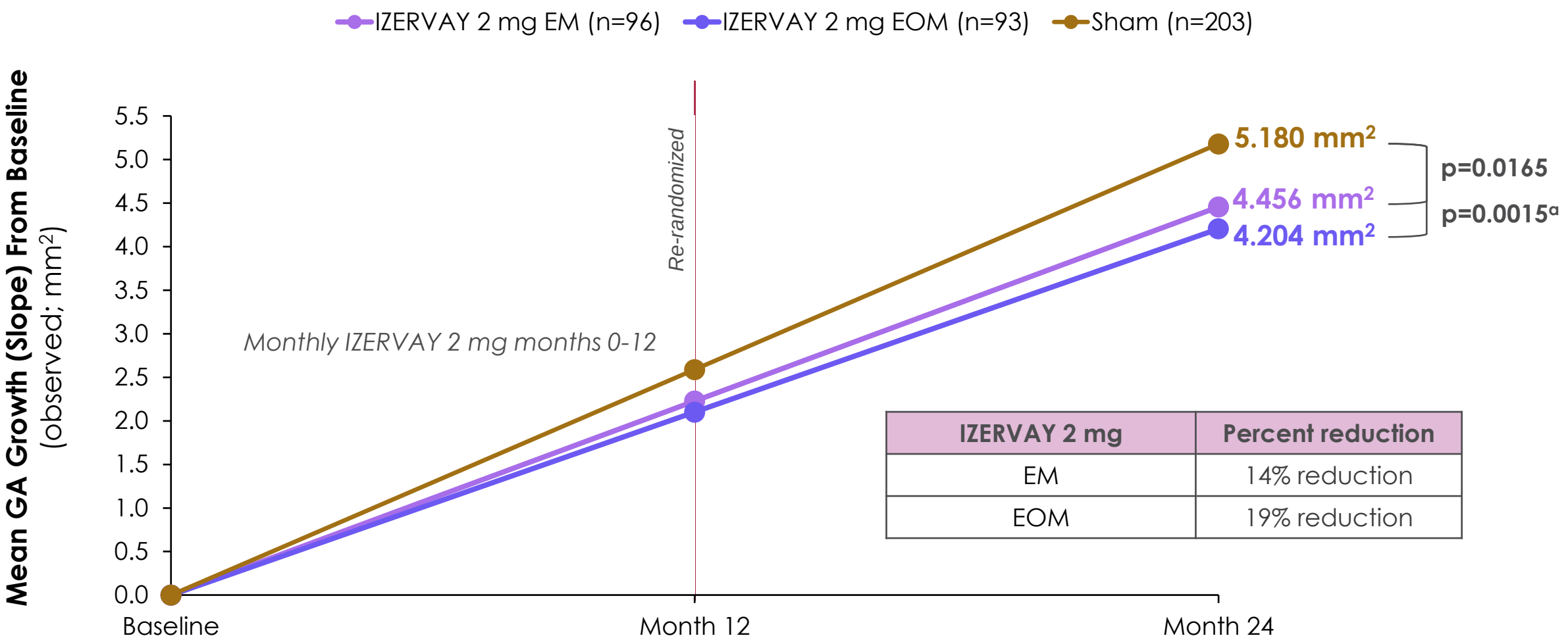
GATHER2 2-YEAR DATA

ERIN HENRY

VICE PRESIDENT, PRODUCT STRATEGY AND INNOVATION,
IVERIC BIO, AN ASTELLAS COMPANY

astellas

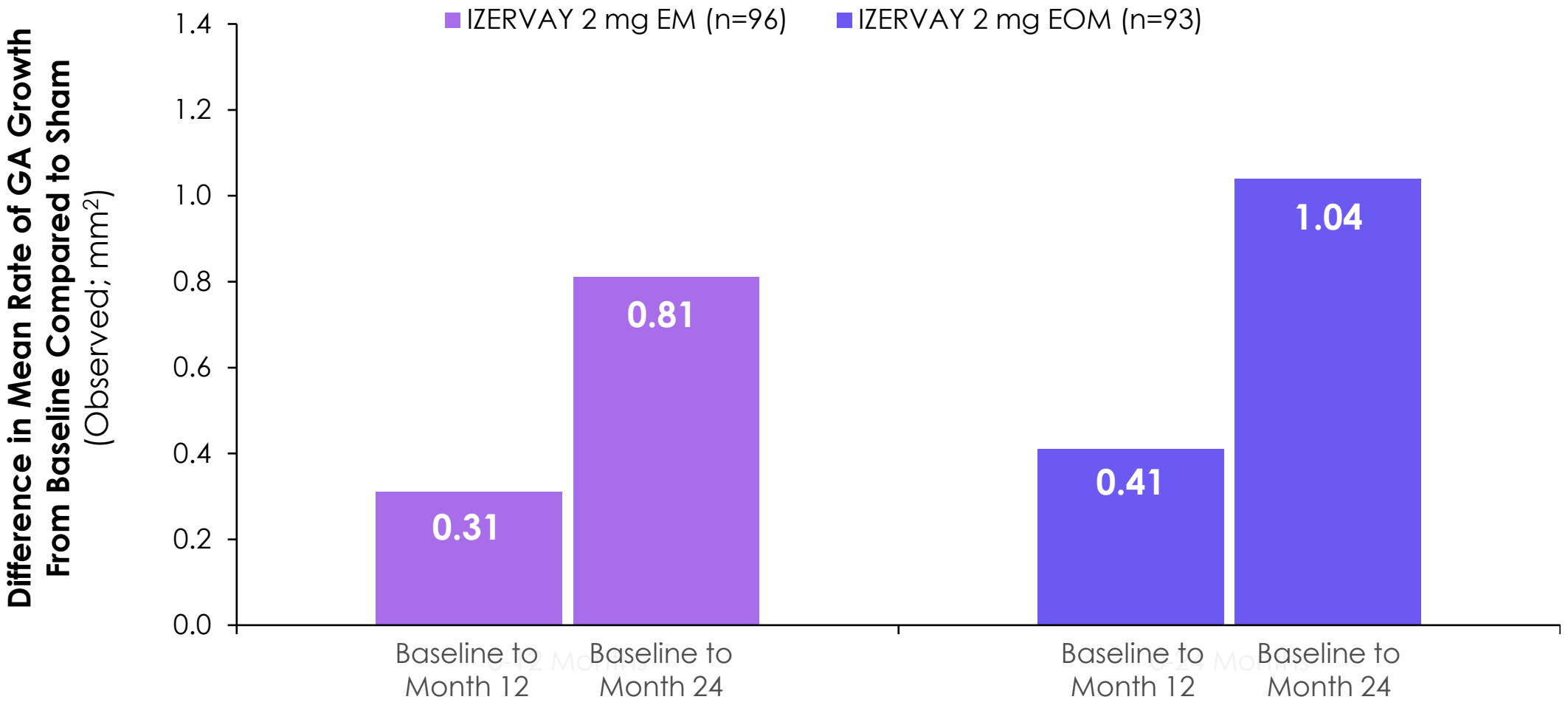
IZERVAY REDUCED GA GROWTH WHEN DOSED EM AND EOM VS SHAM



IZERVAY 2 mg	Percent reduction
EM	14% reduction
EOM	19% reduction

ª P-value is nominal. Note: This analysis is based on a mixed model assuming constant growth rate from baseline to month 24.
CI, confidence interval; EM, every month; EOM, every other month.

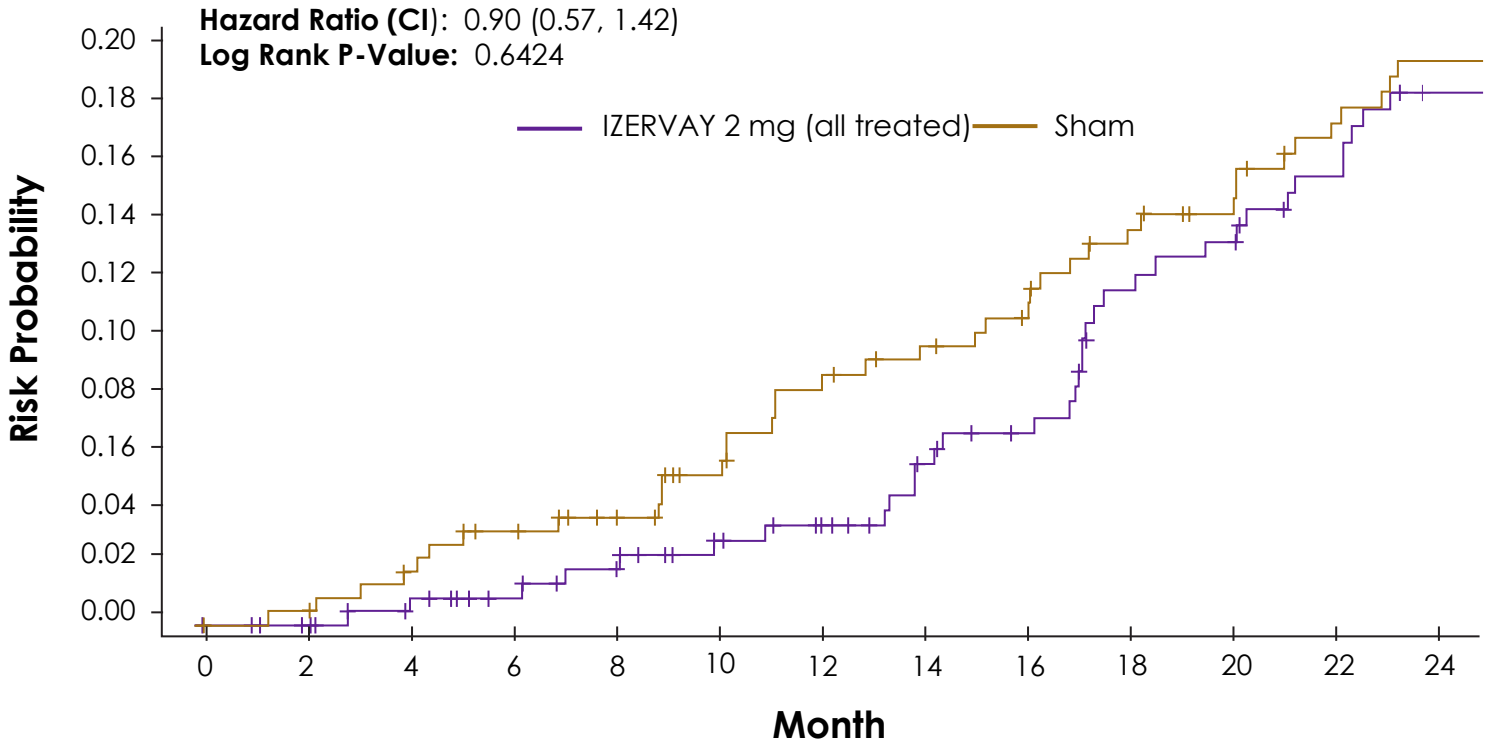
TREATMENT EFFECT MORE THAN DOUBLED WITH IZERVAY OVER 2 YEARS COMPARED TO 1 YEAR



Note: This is a simplified piecewise slope spline Mixed model with Repeated Measures analysis. The analysis is based on a mixed effects model for repeated measures assuming a piecewise linear growth slope every 6 months. The EOM group received monthly IZERVAY in the first year.
EM, every month; EOM, every other month

NO STATISTICALLY SIGNIFICANT DIFFERENCE IN ≥15-LETTER PERSISTENT VISION LOSS BETWEEN IZERVAY AND SHAM

~ Mean change in BCVA and LL-BCVA from baseline between IZERVAY and sham was similar at two-years



Number of Patients at Risk (Events)

IZERVAY 2 mg	225(0)	219(0)	214(1)	207(2)	203(4)	194(6)	189(7)	179(11)	174(13)	161(22)	158(25)	149(29)	142(34)
Sham	222(0)	220(1)	215(4)	209(7)	203(8)	195(11)	188(17)	183(20)	179(22)	171(28)	166(29)	157(35)	152(39)

Note: Persistent vision loss was defined as loss ≥15 letters in BCVA at 2 consecutive visits. Mean BCVA change from baseline at month 24 was -7.309 for ACP 2 mg (N=225) and -6.475 for sham (N=222).
Mean LL-BCVA change from baseline at month 24 was -10.583 for ACP 2 mg (N=225) and -9.096 for sham (N=222).
BCVA, best-corrected visual acuity; CI, confidence interval; LL-BCVA, low-luminance BCVA.

astellas

TREATMENT EMERGENT ADVERSE EVENTS (TEAES) OVER 2 YEARS WERE SIMILAR AND CONSISTENT WITH YEAR 1[1]

	IZERVAY (N=225)	Sham (N=222)
TEAEs, n (%)	**208 (92.4)**	**184 (82.9)**
Ocular in study eye	144 (64.0)	107 (48.2)
Non-ocular	172 (76.4)	160 (72.1)
Serious TEAEs, n (%)	**60 (26.7)**	**51 (23.0)**
Ocular in study eye	4 (1.8)	2 (0.9)
Non-ocular	55 (24.4)	49 (22.1)
TEAEs leading to study drug discontinuation, n (%)	**11 (4.9)**	**9 (4.1)**
Ocular in study eye	4 (1.8)	0
Non-ocular	7 (3.1)	9 (4.1)

Note: n = study eyes with events.

1. Khanani AM, et al. *Lancet.* 2023;402(10411):1449-1458.

astellas

SERIOUS OCULAR TEAEs – NO NEW SAFETY SIGNALS IN YEAR 2

	Year 1[1]		Year 2			Total	
	IZERVAY 2 mg (N=225)	Sham (N=222)	IZERVAY 2 mg EM (n=96)	IZERVAY 2 mg EOM (n=93)	Sham (n=203)	IZERVAY 2 mg (N=225)	Sham (N=222)
Serious ocular TEAEs in study eye, n (%)	**2 (0.9)**	**2 (0.9)**	**2 (2.1)**	**0 (0.0)**	**0 (0.0)**	**4 (1.8)**	**2 (0.9)**
Choroidal neovascularization	2 (0.9)	1 (0.5)	0	0	0	2 (0.9)	1 (0.5)
Visual acuity reduced	0	1 (0.5)[a]	0	0	0	0	1 (0.5)[a]
Visual acuity reduced transiently	0	1 (0.5)[a]	0	0	0	0	1 (0.5)[a]
Endophthalmitis	0	0	1 (1.0)[b]	0	0	1 (0.4)[b]	0
Subluxated intraocular lens	0	0	1 (1.0)	0	0	1 (0.4)	0

[a] Occurred in the same patient; [b] Culture positive.
Note: Choroidal neovascularization = eMNV, neMNV, peripapillary NV.
EM, every month; eMNV, exudative macular neovascularization; MNV, macular neovascularization; EOM, every other month; neMNV, nonexudative MNV; NV, neovascularization; TEAE, treatment emergent adverse event.
1. Khanani AM, et al. *Lancet.* 2023;402(10411):1449-1458.

astellas

CHOROIDAL NEOVASCULARIZATION (CNV)

	Year 1[1]		Year 2			Total	
	IZERVAY 2 mg (N=225)	Sham (N=222)	IZERVAY 2 mg EM (n=96)	IZERVAY 2 mg EOM (n=93)	Sham (n=203)	IZERVAY 2 mg (N=225)	Sham (N=222)
CNV in study eye, n (%)	15 (6.7)	9 (4.1)	7 (7.3)	4 (4.3)	11 (5.4)	26 (11.6)	20 (9.0)

Incidence of CNV in year 2 was similar for sham and the IZERVAY groups

Note: Choroidal neovascularization = eMNV, neMNV, peripapillary NV.
EM, every month; eMNV, exudative macular neovascularization; MNV, macular neovascularization; EOM, every other month; neMNV, nonexudative MNV; NV, neovascularization.
1. Khanani AM, et al. *Lancet.* 2023;402(10411):1449-1458.

astellas

ADVERSE EVENTS OF SPECIAL INTEREST

	Year 1[1]		Year 2			Total	
	IZERVAY 2 mg (N=225)	**Sham** (N=222)	**IZERVAY 2 mg EM** (n=96)	**IZERVAY 2 mg EOM** (n=93)	**Sham** (n=**203**)	**IZERVAY 2 mg** (N=225)	**Sham** (N=222)
Intraocular inflammation	0	0	1 (1.0)	0	0	1 (0.4)	0
Endophthalmitis	0	0	1 (1.0)[a]	0	0	1 (0.4)[a]	0
Ischemic optic neuropathy	0	0	0	0	0	0	0

Over 2 years

- 1 case of non-serious intraocular inflammation, reported as trace vitreous cells
- 1 case of culture-positive endophthalmitis
- No cases of ischemic optic neuropathy and occlusive or non-occlusive retinal vasculitis

[a] Culture positive.
EM, every month; EOM, every other month.
1. Khanani AM, et al. *Lancet.* 2023;402(10411):1449-1458.

SUMMARY OF GATHER2: 2-YEAR DATA

Both monthly (EM) and every other month (EOM) IZERVAY reduced GA growth vs sham

Treatment effect more than doubled over 2 years compared to 1 year for IZERVAY

IZERVAY was well tolerated: over 2 years, there was 1 case of non-serious IOI, 1 case of culture-positive endophthalmitis, and no cases of ION or retinal vasculitis

In year 2, incidence of CNV was similar for sham vs IZERVAY EOM

Over 2 years, only a slight increased incidence of CNV was observed for pooled IZERVAY vs sham (11.6% vs 9.0%, respectively)

CNV, choroidal neovascularization; GA, geographic atrophy; IOI, intraocular inflammation; ION, ischemic optic neuropathy.

astellas

LIFECYCLE MANAGEMENT UPDATE

GATHER2

Ongoing open-label study capturing long-term safety data

LABEL

Anticipate FDA filing submission for label update on treatment duration and regimen in Q4 FY2023

EMA

The Marketing Authorization Application for ACP was accepted on 17 Aug 2023

FDA, Food and Drug Administration; EMA, European Medicines Agency; ACP, avacincaptad pegol.

Q&A