Q3 FY2022

(Fiscal Year Ending March 31, 2023)

Financial Results Presentation

Eisai Co., Ltd.

February 6, 2023

hhc
human health care

Q3 FY2022 Consolidated Statement of Income (IFRS)

Steady growth in organic business and continuous investment in future growth

(Billions of yen, %)	April-December FY2021		April-December FY2022			Amount of forex impact
	Results	%	Results	%	YoY	
Revenue	565.3	100.0	546.2	100.0	97	53.6
Pharmaceutical Business	463.8	82.0	531.9	97.4	115	51.8
Other business	101.6	18.0	14.3	2.6	14	
Cost of sales	124.1	22.0	139.3	25.5	112	
Gross profit	441.2	78.0	406.9	74.5	92	46.9
R&D expenses	123.3	21.8	121.4	22.2	98	20.6
R&D expenses including partners reimbursement	175.9	31.1	175.1	32.1	100	
SG&A expenses	256.2	45.3	273.0	50.0	107	37.5
Expenses regarding shared profit of Lenvima paid to Merck	65.6	11.6	91.4	16.7	139	
SG&A expenses excluding the expenses regarding shared profit of Lenvima paid to Merck	190.6	33.7	181.6	33.2	95	20.5
Other income & expenses	12.6	2.2	1.3	0.2	10	
Operating profit	74.3	13.2	13.8	2.5	19	-10.8
Profit for the period	59.4	10.5	40.9*1	7.5	69	
Profit for the period (Attributable to owners of the parent)	60.2	10.6	39.1*1	7.2	65	

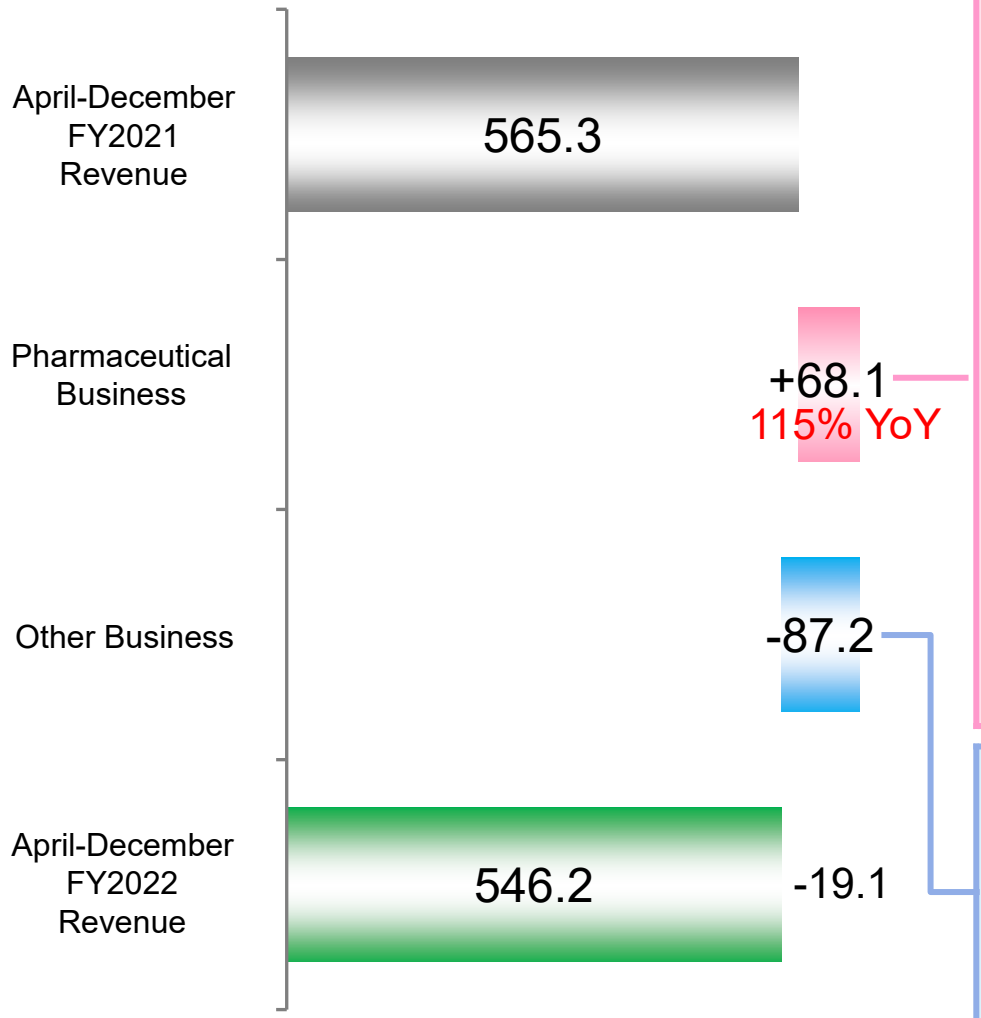
	End of March 2022	End of December 2022
Net DER*2 (times)	(0.32)	(0.18)
Ratio of equity attributable to owners of the parent (%)	60.4	61.9

The figures for FY2021 have been revised for retroactive application due to changes in accounting policies. Q3 FY2022 average exchange rates: 1 USD: 136.51 yen (+22.9% YoY), 1 EUR: 140.58 yen (+7.6% YoY), 1 GBP: 163.90 yen (+7.3% YoY), 1 RMB: 19.87 yen (+15.2% YoY) *1: Including the impact of repayment of paid-in capital from a consolidated U.S. subsidiary to the Company *2: "Net debt equity ratio (Net DER)" = ("Interest-bearing debt" ("Borrowings") - "Cash and cash equivalents" -"Time deposits exceeding three months, etc." - "Investment securities held by the parent") / "Equity attributable to owners of the parent"

Breakdown of Revenue Migration

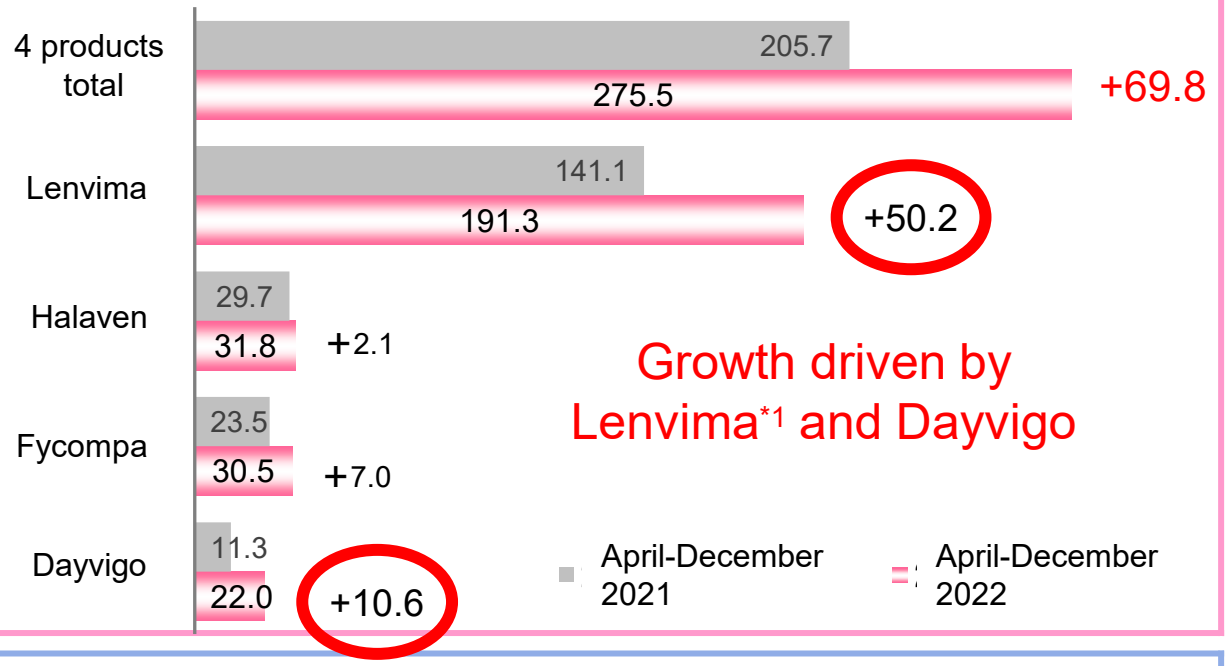
Pharmaceutical Business expanded, despite revenue decrease due to one-time income incurred in previous fiscal year

(Billions of Yen)



Pharmaceutical Business

- Achieved double-digit growth in Pharmaceutical Business revenue
- Revenue increased in all 5 regions



Growth driven by Lenvima*1 and Dayvigo

One-time income

<Factors in FY2022>

- Divestiture of rights of Myonal and Merislon in Asia (Q3 FY2022)

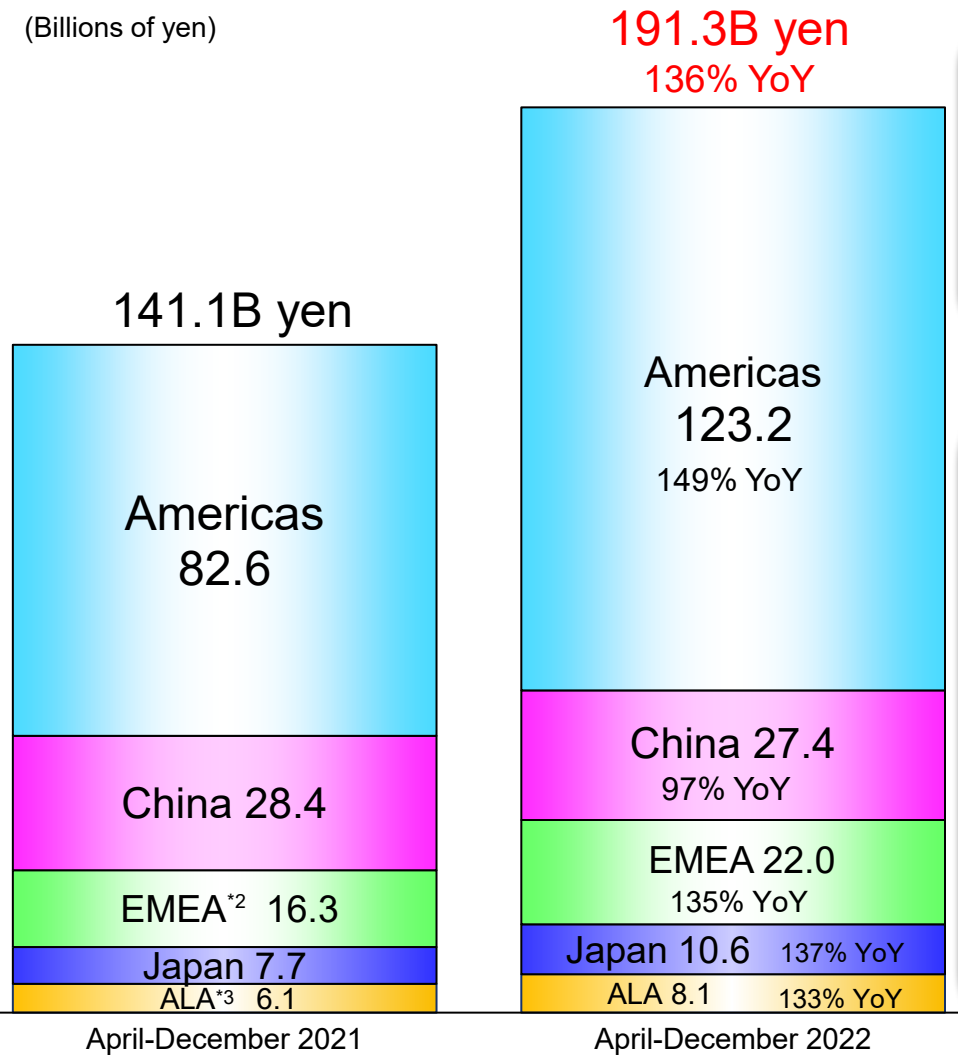
<Factors in FY2021>

- Upfront payment related to MORAb-202*2 (Q1 FY2021) -49.6
- Divestiture of rights of AcipHex (U.S.) and Neuquinon (China) (Q2 FY2021)
- Sales milestone payment related to Lenvima (Q3 FY2021) -34.5

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Rahway, N.J., U.S.A. Projects for Lenvima are under joint development with Merck & Co., Inc., Rahway, N.J., U.S.A.
*1: Includes Lenvima monotherapy and combination therapy with Keytruda® *2: Receipt of upfront payment associated with the strategic collaboration with Bristol Myers Squibb. Generic name for MORAb-202 is farletuzumab ecteribulin.

Lenvima

Achieved rapid growth in all regions by establishing position as backbone therapy with 6 indications in 5 cancer types*1



Growth driven by the Lenvima plus KEYTRUDA® combination therapy in aRCC and aEC

Increasing market shares in aEC in the biggest market, i.e. U.S., due to wide-spread of chemotherapy-free regimen position. Increasing new prescriptions in aRCC and aim to achieve highest shares in this fiscal year.

ESMO presentation of longer-term data from Phase III studies of aRCC and aEC, of which indications were approved*4

aRCC 1L*5: Updated data at 33.7 months (median) follow up from start of administration

- Continue to show clinically significant improvement in OS*6, PFS*7, and ORR*8 vs. sunitinib
- OS rate at 36 months after start of administration was 94.5%
- CR*9 rate increased from 16.1% (at the time of submission) to 17.2%

aEC FPST*10,*11: Updated data at 14.7 months (median) follow up from start of administration

- Continue to show clinically meaningful improvement in OS, PFS, and ORR vs. chemotherapy
- No new safety signals were observed, and safety results were consistent with the primary analysis of the study

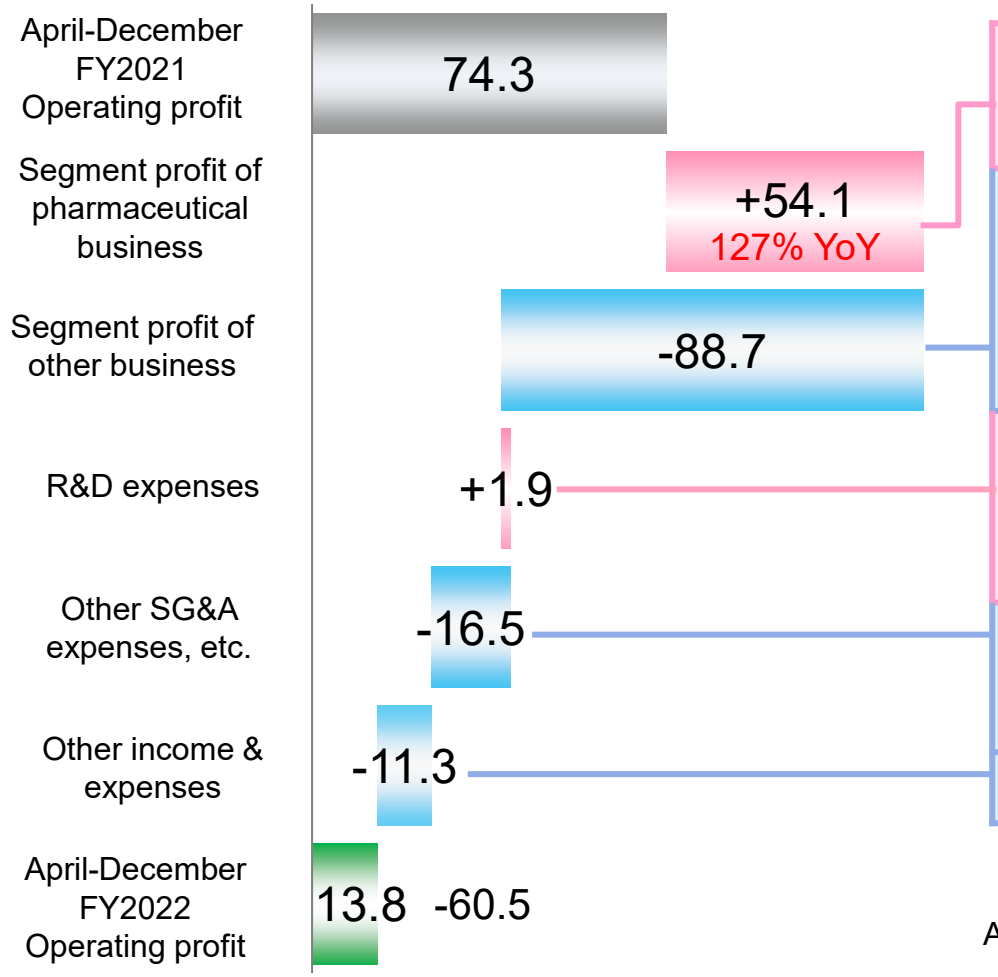
Aim to further increase contribution to patients as standard therapy

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA. Projects for Lenvima are under joint development with Merck & Co., Inc., Rahway, NJ, USA. 1L: First line, 2L: Second line. Figures are approximate. Hong Kong was changed from Asia and Latin America pharmaceutical business to China pharmaceutical business from April 2022. This change has been reflected in the figures above. aEC: advanced endometrial carcinoma, Indications of aEC are: U.S.: For the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation. EU: For the treatment of patients with advanced or recurrent endometrial carcinoma who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and are not candidates for curative surgery or radiation. Japan: For the treatment of unresectable, advanced or recurrent endometrial carcinoma that progressed after cancer chemotherapy. Asia: For the treatment of patients with advanced endometrial carcinoma who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.
aRCC: advanced renal cell carcinoma *1:1L differentiated thyroid cancer, 1L RCC (combination with KEUTRUDA®), 2L RCC (combination with everolimus), 1L unresectable hepatocellular carcinoma, aEC FPST(following prior systemic therapy) and thymic carcinoma (Japan only)
*2: Europe, the Middle East, Africa, Russia, and Oceania *3: South Korea, Taiwan, India, ASEAN, Latin America, etc. *4: ESMO 2022. The updated data are for Lenvima plus KEYTRUDA. *5: ESMO Congress 2022 Abstract number: 1449MO. Safety data are consistent with the prescribing information, or previously reported results. *6: Overall Survival *7: Progression-Free Survival *8: Objective Response Rate *9: Complete Response *10: Following Prior Systemic Therapy *11: ESMO Congress 2022 Abstract number: 525MO

Breakdown of Operating Profit Migration

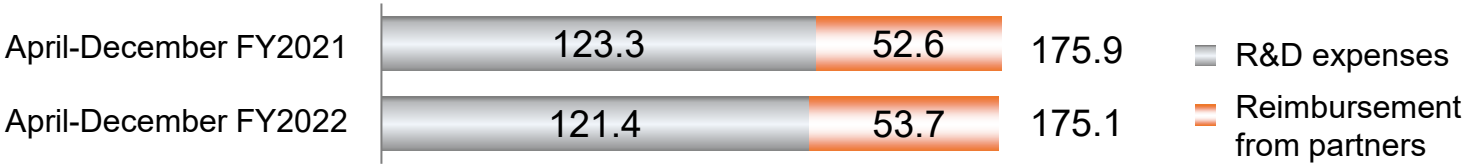
Pharmaceutical Business expanded, despite operating profit decrease due to one-time income incurred in previous fiscal year

(Billions of Yen)



Pharmaceutical business	• Achieved double-digit growth in segment profit for Pharmaceutical Business and significantly improved profitability • Profit increased in all 5 regions
Other business	<Factors in FY2022> • Divestiture of rights of Myonal and Merislon in Asia <Decrease due to factors in FY2021> • Upfront payment related to MORAb-202*1 - 49.6 • Sales milestone payment related to Lenvima - 34.5
R&D expenses*2	• Prioritized investment in R&D toward value maximization of LEQEMBI • Total R&D expenses decreased due to decrease in expenses related to Lenvima, ADUHELM®, and others • R&D ratio to sales including partnerships remains at a high level of 32.1%
Other SG&A expenses, etc.*3	• Increase of shared profit*4 of Lenvima due to revenue growth -25.8 • Decrease in ADUHELM® related expenses • Record of premium retirement benefits of EA Pharma*5 (Q3 FY2021) +2.5
Other profit & loss	• Divestiture of rights of Zonegran (Q1 FY2021)

Proactive investment in R&D leveraging partnership model



Figures shown in breakdown are approximate.
The figures from FY2021 have been revised for retroactive application due to changes in accounting policies. All relevant expenses related to ADUHELM®(selling, general and administrative expenses) that the Company should share and gains and losses on sale of non-current assets have been included in the "Group headquarters' management costs and other expenses" since FY2022. As a result, these changes from the FY 2021 have been reflected in Segment Information.
*1: Receipt of upfront payment associated with the strategic collaboration with Bristol Myers Squibb. Generic name for MORAb-202 is farletuzumab ecteribulin.
*2: Results of FY2021 include 8.3B yen reversal for the receipt of regulatory milestone payment for the approval of renal cell carcinoma indication in the U.S. (Q2) and impairment loss of 1.9B yen for the revision of development pipeline in EA Pharma (Q3). Results of FY2022 includes 3.2B yen reversal for the receipt of regulatory milestone payment for the approval and reimbursement for renal cell carcinoma in EU (Q1) *3: Group headquarters' management costs and other expenses (the costs and expenses covering Group-wide) – Other income & expenses *4: Shared profit of Lenvima paid by Eisai to Merck & Co., Inc., Rahway, NJ, USA *5: 0.2B yen for Cost of sales, 2.5B yen for SG&A expenses and 0.2B yen for R&D expenses

FY2022 Consolidated Financial Forecast (IFRS)

Further improve profitability of Pharmaceutical business and efficiency in R&D expenses, and aim to achieve the financial forecast by steadily implementing strategic options

(Billions of yen, %)	FY2021		FY2022		
	Results	%	Forecast	%	YoY
Revenue	756.2	100.0	760.0	100.0	100
Pharmaceutical business revenue	617.3	81.6	707.0	93.0	115
Other business revenue	139.0	18.4	53.0	7.0	38
Cost of sales	174.8	23.1	184.0	24.2	105
Gross profit	581.4	76.9	576.0	75.8	99
R&D expenses	171.7	22.7	166.5	21.9	97
SG&A expenses	366.4	48.5	361.5	47.6	99
Other income & expenses	10.5	1.4	7.0	0.9	67
Operating profit	53.7	7.1	55.0	7.2	102
Profit for the year	45.7	6.0	58.0*	7.6	127
Profit for the year (Attributable to owners of the parent)	48.0	6.3	57.0*	7.5	119
EPS (yen)	167.27		197.80		
ROE (%)	6.6		7.2*		
DOE (%)	6.3		5.8		
Dividend (yen)	160		160		

FY2022 Q3-Q4 expected average exchange rates: 1 USD: 143.00 yen, 1 EUR: 142.00 yen, 1 GBP: 162.00 yen, 1 RMB: 20.40 yen

The figures for FY2021 have been revised for retroactive application due to changes in accounting policies. * Including the impact of repayment of paid-in capital from a U.S. subsidiary to the Company

U.S. LEQEMBI*1 Label is Received as Highly Transparent and Informative

U.S. FDA*2 approved LEQEMBI for the treatment of AD under the Accelerated Approval (AA) pathway on January 6, 2023

- LEQEMBI has received many inquiries from a wide range of clinicians, including KOLs*3 and community neurologists, which are mostly focused on understanding patient selection, appropriate administration and monitoring in order to assist them in potentially prescribing LEQEMBI. Some HCPs*4 who were previously skeptical of anti-amyloid therapies, are now growing interest in LEQEMBI
- Providing clinical information especially important to physicians related to amyloid-related imaging abnormality (ARIA), such as incidence, classification criteria, monitoring and dose management guidelines for ARIA

Prescribing Information

---------- INDICATIONS AND USAGE----------

LEQEMBI is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with LEQEMBI. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial. (1)

---------- WARNINGS AND PRECAUTIONS ----------

- Amyloid Related Imaging Abnormalities (ARIA): Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment with LEQEMBI. Risk of ARIA, including symptomatic ARIA, was increased in apolipoprotein E ε4 homozygotes compared to heterozygotes and noncarriers. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI scanning if indicated. (2.3, 5.1)
- Infusion-Related Reactions: The infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy administered as clinically indicated. Consider pre-medication at subsequent dosing with antihistamines, non-steroidal anti-inflammatory drugs, or corticosteroids. (5.2)

Overall feedback on LEQEMBI label has been positive from HCPs, IDNs*5 and payers in the U.S.

*1: Antibody for Alzheimer's disease produced as the result of a strategic research alliance between Eisai and BioArctic. Collaboration with Biogen. Generic name is lecanemab.
*2: the U.S. Food and Drug Administration *3: Key opinion leaders *4: Healthcare professionals *5 Integrated delivery networks

LEQEMBI™ (lecanemab-irmb) INJECTION FOR INTRAVENOUS USE 100 mg/mL

Eisai

Reaction of Key Stakeholders in the U.S.

January 6, 2023

Statement from FDA*1 at the time of Accelerated Approval

Billy Dunn, M.D., Director of the Office of Neuroscience in the FDA's Center for Drug Evaluation and Research, mentioned the significance of LEQEMBI*2 to people living with AD at the time of Accelerated Approval in a statement*3

"Alzheimer's disease immeasurably incapacitates the lives of those who suffer from it and has devastating effects on their loved ones.

This treatment option is the latest therapy to target and affect the underlying disease process of Alzheimer's, instead of only treating the symptoms of the disease."

Billy Dunn, M.D.
Director of the Office of Neuroscience
FDA Center for Drug Evaluation and Research

*1: the U.S. Food and Drug Administration *2: Antibody for Alzheimer's disease produced as the result of a strategic research alliance between Eisai and BioArctic. Collaboration with Biogen. Generic name is lecanemab.
*3: https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-disease-treatment

LEQEMBI™ (lecanemab-irmb) INJECTION FOR INTRAVENOUS USE 100 mg/mL

Reaction of Key Stakeholders in the U.S.

January 6, 2023

Statement from CMS[*1] on the day of Accelerated Approval

Within hours of accelerated approval of LEQEMBI[*2], Chiquita Brooks-LaSure, Administrator of CMS, issued a statement[*3] that mentions a wider coverage will potentially be considered at the time of full approval

"At CMS, we will continue to expeditiously review the data on these products as they become available and are committed to timely access to treatments, including drugs, that improve clinically meaningful outcomes.

If lecanemab subsequently receives traditional FDA approval, CMS would provide broader coverage using the framework we announced last year, under coverage with evidence development, on the same day."

Chiquita Brooks-LaSure
Administrator of CMS

*1: Centers for Medicare & Medicaid Services *2: Antibody for Alzheimer's disease produced as the result of a strategic research alliance between Eisai and BioArctic. Collaboration with Biogen. Generic name is lecanemab.
*3: https://www.cms.gov/newsroom/press-releases/cms-statement-fda-accelerated-approval-lecanemab

LEQEMBI™ (lecanemab-irmb) INJECTION FOR INTRAVENOUS USE 100 mg/mL

Completed Global Regulatory Submissions Soon After Receiving Accelerated Approval (AA) in the U.S.

Eisai

Expect regulatory approvals in early timing of FY2023

Jan 6, 2023

U.S. FDA*1

Approved LEQEMBI*2 under AA pathway for the treatment of early AD

Submitted supplemental BLA*3 to FDA for full approval

Jan 9, 2023

Europe EMA*4

Submitted marketing authorization application as a treatment for early AD

Jan 16, 2023

Japan PMDA*5

Filed marketing authorization application as a treatment for early AD

Jan 26, 2023

Japan MHLW*6

Priority Review was granted

Dec 21, 2022

China NMPA*7 Initiated submission of data for BLA

The registration category of lecanemab was designated as a Category 1 drug*8

The dates of submission/regulatory communication are based on local time

*1: the U.S. Food and Drug Administration *2: Antibody for Alzheimer's disease produced as the result of a strategic research alliance between Eisai and BioArctic. Collaboration with Biogen. Generic name is lecanemab.

*3: Biologics License Application *4: European Medicines Agency *5: Pharmaceuticals and Medical Devices Agency *6: Ministry of Health, Labour and Welfare *7: National Medical Products Administration

*8: Innovative biologics that have not been approved in China or any other countries

LEQEMBI™ (lecanemab-irmb) INJECTION FOR INTRAVENOUS USE 100 mg/mL

Eisai

Pricing based on Societal Value Concept with Detailed and Transparent Explanation including Rationale and Formula as Industry-first Approach*1

LEQEMBI*2 launched in the U.S.
Industry-first detailed and transparent explanation made based on societal value concept.
Launch price (WAC*3) set at $26,500*4 per person per year while projected societal value was $37,600*4.

- Over 10 years cumulatively, the gradual adoption of LEQEMBI treatment at this pricing approach could bring potential positive social impact of several tens of billion dollars to the U.S. society and about 60% of which could give back to patients, families, caregivers, healthcare providers and payers.
- Remainder, about 40% of the potential positive social impact, will be accrued by employees and shareholders in the form of product sales, from which we are committed to re-invest in future research and development to create new AD therapies and new innovations such as establishing ecosystems toward inclusive AD communities

Value-based pricing for multi-stakeholders is being highly evaluated

- Payers discussions have been focused more on clinical and safety topics as the pricing was transparent and value based
- The published AD ACE*5 model evaluating long-term health outcomes was appreciated, and contained similar aligned findings to the ICER*6 model

Planning to take approaches leveraging AD ACE model using Clarity AD*7 data in more countries

*1: Based on an internal research *2: Antibody for Alzheimer's disease produced as the result of a strategic research alliance between Eisai and BioArctic. Collaboration with Biogen. Generic name is lecanemab.
*3: Wholesale Acquisition Cost *4: Estimated annual price based on 10mg/kg IV biweekly for average U.S. patient weight of 75kg based on Study 201 and Clarity AD
*5: AD Archimedes condition-event simulation model *6: Institute for Clinical and Economic Review. ICER is a non-profit research organization in the U.S. that evaluates the evidence on the clinical and economic value of prescription drugs, medical tests, devices and health system delivery innovations *7: Phase III study in early AD for lecanemab

LEQEMBI™ (lecanemab-irmb) INJECTION FOR INTRAVENOUS USE 100 mg/mL

Accelerating Engagements with Payers in the U.S.

Eisai

Engagements with payers is steadily ongoing towards insurance coverage

- Strong stakeholders' interest and engagement continue following accelerated approval of LEQEMBI*1 with requests for clinical presentation of the Clarity AD*2 data. Payers appreciate data transparency.
- Frequent questions are raised around safety (understanding of ARIA*3 profile), efficacy and clinical meaningfulness.

CMS*4	VHA*5	Commercial/Private Plans
• Communication is steadily ongoing with the aim for broad and simple coverage to label upon full approval • Within hours of approval of LEQEMBI, CMS issued a statement regarding the status of Medicare coverage	• Explanation of clinical study results and communication are steadily ongoing with VHA, one of the largest integrated health systems in the U.S.	• Completed presentation of Clarity AD data to major payers, which cover people under 65 years old • Several U.S. healthcare providers are advancing their formulary discussions based on the Clarity AD data and Eisai's transparent pricing philosophy, and they seek to understand inclusion and exclusion criteria, and how to monitor patient response (efficacy and safety)

*1: Antibody for Alzheimer's disease produced as the result of a strategic research alliance between Eisai and BioArctic. Collaboration with Biogen. Generic name is lecanemab.
*2: Phase III study in early AD for lecanemab *3: Amyloid related imaging abnormality *4: Centers for Medicare & Medicaid Services *5: The U.S. Veteran's Health Administration. VHA operates 1,298 health care facilities, including 171 medical centers and 1,113 outpatient sites of care of varying complexity (VHA outpatient clinics), serving 9 million enrolled Veterans each year

LEQEMBI™ (lecanemab-irmb) INJECTION FOR INTRAVENOUS USE 100 mg/mL

Reaction of Key Stakeholders in the U.S.
December 19, 2022
Letter to CMS*1 from Alzheimer's Association (U.S.)

Prior to Accelerated Approval of LEQEMBI*2, Alzheimer's Association (U.S.) filed a letter*3 for CMS to provide unrestricted and full coverage for FDA*4-approved AD treatments

At that time, a joint letter "Treating Alzheimer's: A New Era Begins with Lecanemab*5" signed by 220 AD researchers and physicians was enclosed

alzheimer's association

December 19, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

RE: Final and Formal Request for Reconsideration of National Coverage Determination (NCD) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N)

Dear Administrator Brooks-LaSure:

The Alzheimer's Association formally requests a reconsideration of the Centers for Medicare & Medicaid Services' (CMS') coverage policy established in National Coverage Analysis (NCA) CAG-00460N.[1] Specifically, we respectfully request that CMS remove the

Re: Final and Formal Request for Reconsideration of National Coverage Determination (NCD) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N)

Treating Alzheimer's: A New Era Begins with Lecanemab

Few diagnoses in medicine are more devastating than Alzheimer's disease (AD). Barely known to the public four decades ago, the number of people living with dementia – estimated to stand at 55 million in 2019 – is expected to rise to 139 million in 2050[1], and 75% of these individuals have not been diagnosed. The toll on patients, families, and society of this ubiquitous and ultimately fatal disorder is staggering. The number affected more than doubles if one includes the millions of cognitively normal older people who do not yet know the disease is underway in their brains. But breaking news from the Clinical Trials in Alzheimer's Disease (CTAD) Conference late November 2022 suggests this bleak outlook is changing. A disease-modifying treatment for Alzheimer's has finished a highly successful trial (called Clarity AD), the results of which will soon be reviewed by the U.S Food and Drug Administration, with approval widely expected to follow.

...The many undersigned AD clinicians and other experts know this terrible disease all too well from witnessing it up close. We herald the foundational advance represented by the advent of lecanemab therapy. Now, we must build on the success of science to translate these gains into even better outcomes for patients and families. Autonomy and justice dictate that our patients have equitable access and the opportunity to make informed choices regarding reasonable treatments that can impact their lives and well-being. No barrier can be allowed to stand between our patients and a treatment that has a reasonable risk-benefit ratio and significantly reduces the causative pathology. *[Excerpt from the letter "Treating Alzheimer's: A New Era Begins with Lecanemab"]*

*1: Centers for Medicare & Medicaid Services *2: Antibody for Alzheimer's disease produced as the result of a strategic research alliance between Eisai and BioArctic. Collaboration with Biogen. Generic name is lecanemab.
*3: https://alz.org/media/Documents/final-NCD-reconsideration-request.pdf *4: the U.S. Food and Drug Administration *5: https://www.alz.org/media/Documents/joint-letter-alzheimers-scientists-lecanemab.pdf

LEQEMBI™ (lecanemab-irmb) INJECTION FOR INTRAVENOUS USE 100 mg/mL

Reaction of Key Stakeholders in the U.S.

February 2, 2023

Letter[*1] to CMS[*2] from American Academic of Neurology (AAN)

AAN, the world's largest professional association of neurologists sent a letter to CMS to request reconsideration for NCD[*3]

...To summarize, the AAN believes that the phase III data from the CLARITY AD trial indicating a direct clinical benefit warrants a focused expedited reconsideration of the existing coverage policy as it applies to lecanemab, as it would have been impossible for CMS to consider this highly relevant data at the time that the NCD was published.

AMERICAN ACADEMY OF NEUROLOGY®

February 2, 2023

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease [CAG-00460N]

Dear Ms. Syrek Jensen,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 38,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the

We believe to promote patient access to therapy, that it would be appropriate for this reconsideration to occur so that a revised decision can be released with an effective date concurrent with a potential traditional approval of lecanemab. Furthermore, the AAN believes that a similar approach could be applied to future products which meet the standard set by the phase III data published in NEJM.

[Excerpt from the letter "Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease"]

*1: https://www.aan.com/siteassets/home-page/policy-and-guidelines/advocacy/comment-letters/lecanemab-ncd-reconsideration-request.pdf *2: Centers for Medicare & Medicaid Services *3: National Coverage Determination

Reaction of Key Stakeholders in the U.S.

January 10, 2023

FDA*1 Commissioner's comments at an interview

Robert Califf, M.D., Commissioner of FDA spoke about CMS*2 policy on NCD*3 at CNBC interview*4

He commented that he expects CMS limiting coverage of Alzheimer's drug is not a fixed policy

"The company just submitted their data for full approval, not the accelerated approval. That's going to be coming up. So I don't expect the CMS policy to be a totally fixed policy, we have a lot of communication and I think they'll reach a good spot.

It is important for me to always point FDA has a mission. We don't tell CMS what to do. CMS doesn't tell us what to do. I liken it to a relay race, where we need to make the baton handoff a lot smoother. That's not a new problem. But this has really brought it to public attention and I don't think that's a bad thing."

Robert M. Califf M.D., MACC
Commissioner of FDA

*1: the U.S. Food and Drug Administration *2: Centers for Medicare & Medicaid Services *3: National Coverage Determination
*4: https://www.cnbc.com/video/2023/01/10/cms-limiting-coverage-of-alzheimers-drug-not-a-fixed-policy-says-fdas-robert-califf.html

LEQEMBI™ (lecanemab-irmb) INJECTION FOR INTRAVENOUS USE 100 mg/mL

Initial Operation After Accelerated Approval in the U.S.

Eisai

Initiated Patient Assistance Program (PAP) on January 6, 2023

- LEQEMBI[*1] is provided at no cost to eligible uninsured and underinsured patients, including Medicare beneficiaries, who meet financial need and other programs criteria. PAP eligibility criteria are easy to understand and consistent with industry standards.
- LEQEMBI Patient Navigator to provide support

Patient Navigators are assigned to patients and physicians

- Registration
- Assistance for insurance coverage
- Provide information on financial support
- Continuously provide education and support

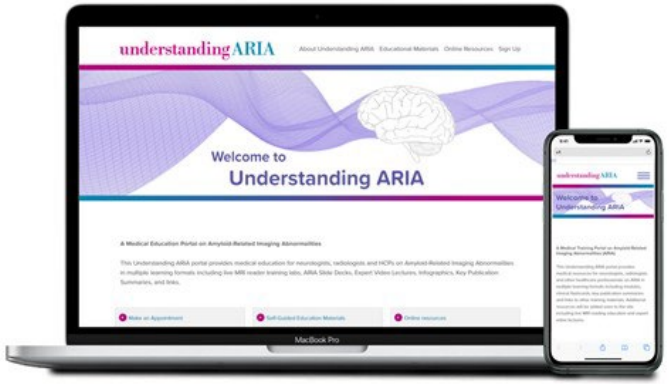
Eisai Patient Support

Achieved the first sales in the U.S. on January 18, 2023

Confirmed that the first prescription was written on January 23 and administration initiated on February 3

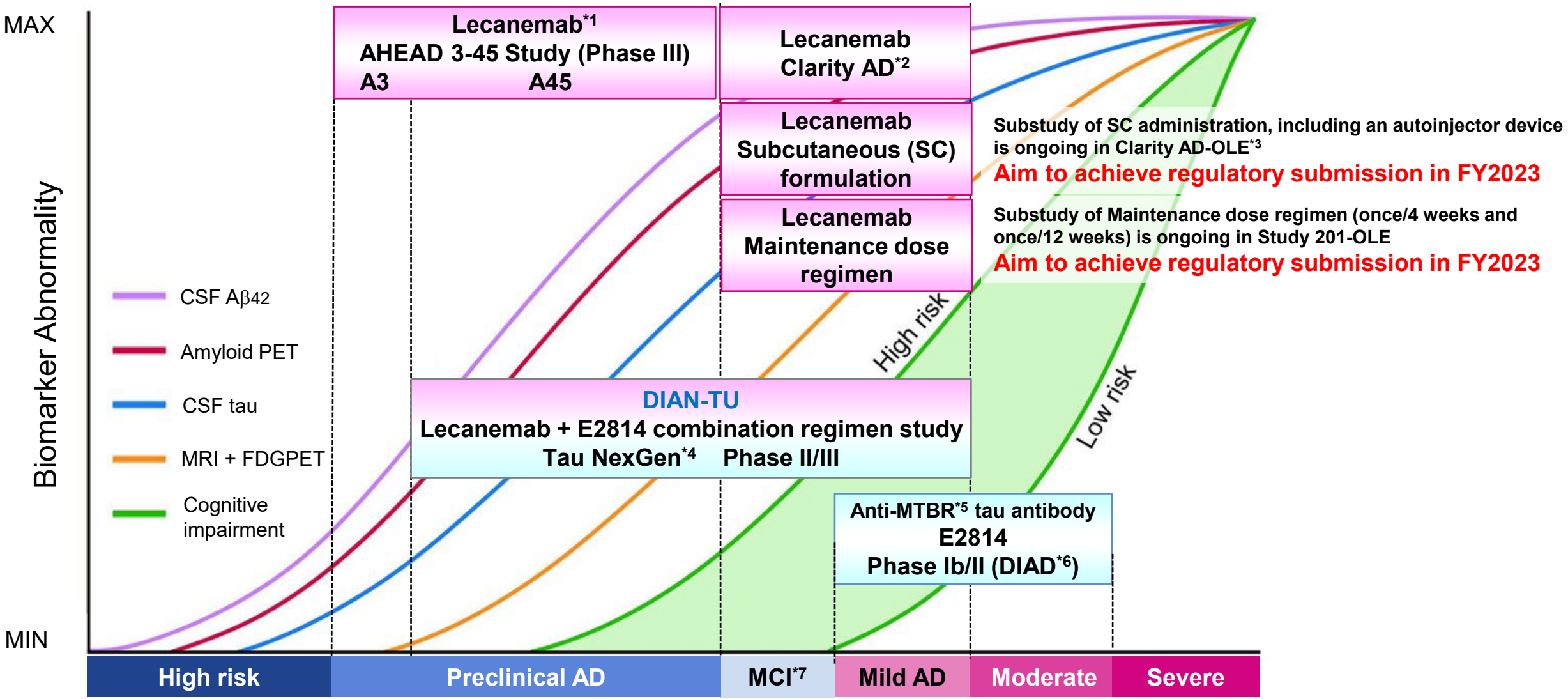
Initiated unbranded educational website on ARIA[*2] "Understanding ARIA" on January 25, 2023

- Developing a multifaceted educational initiative for the AD healthcare community on the management and monitoring of ARIA in clinical practice
- Materials and programs are provided, including peer-to-peer education, individual and group education, and expert hypothetical case reviews, and conducted in collaboration with medical imaging experts and leading professional societies
- First material became available on January 25, 2023



*1: Antibody for Alzheimer's disease produced as the result of a strategic research alliance between Eisai and BioArctic. Collaboration with Biogen. Generic name is lecanemab. *2: Amyloid related imaging abnormality

Eisai Therapeutic Pipeline that Supports AD Patient Journey



Adopted from *Lancet Neurol*. 2013 Feb;12(2):207-16. All projects are investigational except for Clarity AD for lecanemab.
*1: Antibody for Alzheimer's disease produced as the result of a strategic research alliance between Eisai and BioArctic. Collaboration with Biogen. *2: Phase III study for lecanemab targeting early Alzheimer's disease
*3: Open Label Extension *4: Tau NexGen: Study name (Tau Next Generation).Phase II/III study in DIAD conducted by Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU) *5: MTBR: microtubule binding region
*6: DIAD: Dominantly inherited Alzheimer's disease *7: Mild cognitive impairment

A new chapter has begun

We will make every effort towards
the realization of “Innovation and Access”,
a fundamental strategic mission
of a modern pharmaceutical company

Reference Data

Revenue by Reporting Segment

(Billions of yen, %)

	April-December FY2021		April-December FY2022			FY2022
	Results	%	Results	%	YoY	Forecast
Japan	163.4	28.9	169.4	31.0	104	217.5
Americas*1	120.8	21.4	161.9	29.6	134	229.5
China	80.0	14.2	91.5	16.8	114	117.0
EMEA*2	44.3	7.8	52.5	9.6	118	69.5
Asia and Latin America*3	36.6	6.5	37.8	6.9	103	49.0
OTC and others (Japan)	18.7	3.3	18.7	3.4	100	24.5
Pharmaceutical business total	463.8	82.0	531.9	97.4	115	707.0
Other business*4	101.6	18.0	14.3	2.6	14	53.0
Consolidated revenue	565.3	100.0	546.2	100.0	97	760.0

Indicates revenue from external customers. The figures for FY2021 have been revised for retroactive application due to changes in accounting policies.
From FY2022, Hong Kong was changed from Asia and Latin America pharmaceutical business to China pharmaceutical business. *1: North America *2: Europe, Middle East, Africa, Russia and Oceania
*3: Primarily South Korea, Taiwan, India, ASEAN, Central and South America *4: Income mainly from license and the pharmaceutical ingredient business of the parent company. From FY2022, upfront payments and other factors received as consideration for license grants have been included in “Other business”. These changes for the FY2021 have been reflected in Segment Information.

Profit by Reporting Segment

(Billions of yen, %)

	April-December FY2021			April-December FY2022			
	Results	%	% of revenue	Results	%	% of revenue	YoY
Japan	47.2	15.8	28.9	56.6	21.5	33.4	120
Americas*1	67.4	22.6	55.8	98.9	37.6	61.1	147
China	43.8	14.7	54.7	49.1	18.7	53.7	112
EMEA*2	23.7	8.0	53.5	29.5	11.2	56.2	125
Asia and Latin America*3	15.8	5.3	43.1	17.6	6.7	46.6	112
OTC and others in Japan	4.3	1.4	23.0	4.5	1.7	23.9	104
Pharmaceutical business total	202.1	67.9	43.6	256.2	97.3	48.2	127
Other business*4	95.7	32.1	94.3	7.1	2.7	49.3	7
Reporting segment total	297.9	100.0	52.7	263.3	100.0	48.2	88
R&D expenses and Group headquarters' management costs and other expenses*5	(223.5)	-	-	(249.5)	-	-	112
Consolidated operating profit	74.3	-	13.2	13.8	-	2.5	19

The figures for FY2021 have been revised for retroactive application due to changes in accounting policies.
All relevant expenses related to ADUHELM®(selling, general and administrative expenses) that the Company should share and gains and losses on sale of non-current assets have been included in the "Group headquarters' management costs and other expenses" since FY2022. As a result, these changes for the FY 2021 have been reflected in Segment Information. The amount of shared profit of Lenvima paid by Eisai to Merck & Co., Inc., Rahway, NJ, USA was 65.6B yen in Q3 FY2021 and 91.4B yen in Q3 FY2022. Of 110 million USD (for April 2022 - December 2022), which is the remaining amount of Eisai's share of Alzheimer's disease treatment ADUHELM® related expenses capped at 335 million USD, 110 million USD is recorded in selling, general and administrative expenses, and research and development expenses in Q3 FY2022. From January 2023, the Company will not bear any expenses related to ADUHELM®.*1: North America *2: Europe, Middle East, Africa, Russia and Oceania *3: Primarily South Korea, Taiwan, India, ASEAN, Central and South America *4: Income mainly from license and the pharmaceutical ingredient business of the parent company *5: Including the amounts of profits and expenses shared with partners under strategic collaborations.

Revenue of Major Products

(Billions of yen, %)

	April-December FY2021		April-December FY2022				FY2022
	Results	%	Results	%	YoY		Forecast
Lenvima	141.1	100.0	191.3	100.0	136	[114]	262.0
Japan	7.7	5.5	10.6	5.5	137	[137]	14.5
Americas	82.6	58.5	123.2	64.4	149	[121]	174.0
China	28.4	20.1	27.4	14.3	97	[84]	33.0
EMEA	16.3	11.5	22.0	11.5	135	[120]	30.0
Asia and Latin America	6.1	4.3	8.1	4.2	133	[116]	10.5
Halaven	29.7	100.0	31.8	100.0	107	[94]	43.0
Japan	6.3	21.3	6.5	20.5	103	[103]	8.5
Americas	10.4	35.1	11.0	34.6	105	[86]	14.5
China	1.3	4.4	1.7	5.3	128	[110]	2.5
EMEA	9.9	33.3	10.2	32.2	104	[92]	14.5
Asia and Latin America	1.7	5.8	2.3	7.3	135	[117]	3.0
Fycompa	23.5	100.0	30.5	100.0	130	[113]	42.0
Japan	4.1	17.2	4.7	15.4	116	[116]	6.5
Americas	10.8	45.9	14.1	46.1	130	[106]	19.5
China	0.8	3.5	1.9	6.2	227	[197]	2.5
EMEA	6.8	28.7	8.5	27.9	126	[114]	11.5
Asia and Latin America	1.1	4.6	1.3	4.3	122	[110]	2.0
Dayvigo	11.3	100.0	22.0	100.0	194	[188]	31.0
Japan	8.6	76.2	18.1	82.6	210	[210]	25.0
Americas	2.7	23.5	3.6	16.2	134	[110]	6.0
Asia and Latin America	-	-	0.1	0.6	-	-	-

[ ] based on local currency

Performance of Japan Pharmaceutical Business

(Billions of yen, %)

	April-December FY2021		April-December FY2022			FY2022
	Results	%	Results	%	YoY	Forecast
Revenue(Prescription medicines)	163.4	100.0	169.4	100.0	104	217.5
Humira	38.7	23.7	37.5	22.1	97	46.5
Dayvigo	8.6	5.3	18.1	10.7	210	25.0
Lenvima	7.7	4.7	10.6	6.2	137	14.5
Methycobal	8.2	5.0	8.2	4.8	99	10.0
Halaven	6.3	3.9	6.5	3.8	103	8.5
Elental *1	5.2	3.2	5.5	3.3	106	6.5
Jyseleca	0.9	0.5	5.3	3.2	612	-
Goofice *1	4.6	2.8	5.1	3.0	111	7.0
Fycompa	4.1	2.5	4.7	2.8	116	6.5
Pariet *1,2	5.5	3.3	4.5	2.6	82	6.0
Movicol *1	3.7	2.3	4.4	2.6	121	5.5
Aricept	5.6	3.4	3.4	2.0	62	-
Segment profit	47.2	28.9	56.6	33.4	120	

*1: EA Pharma product *2: Includes sales of triple formulation *Helicobacter pylori* eradication packs (Rabecure Pack 400/800 and Rabefine Pack)

Performance of Americas* Pharmaceutical Business

(Billions of yen, %)

	April-December FY2021		April-December FY2022				FY2022
	Results	%	Results	%	YoY		Forecast
Revenue	120.8	100.0	161.9	100.0	134	[109]	229.5
Lenvima	82.6	68.4	123.2	76.1	149	[121]	174.0
Fycompa	10.8	9.0	14.1	8.7	130	[106]	19.5
Halaven	10.4	8.6	11.0	6.8	105	[86]	14.5
Banzel	6.2	5.1	3.7	2.3	59	[49]	-
Dayvigo	2.7	2.2	3.6	2.2	134	[110]	6.0
Segment profit	67.4	55.8	98.9	61.1	147	[125]	

* North America

[ ] based on local currency

Performance of China Pharmaceutical Business

(Billions of yen, %)

	April-December FY2021		April-December FY2022				FY2022
	Results	%	Results	%	YoY		Forecast
Revenue	80.0	100.0	91.5	100.0	114	[99]	117.0
Lenvima	28.4	35.5	27.4	30.0	97	[84]	33.0
Methycobal	10.0	12.4	12.0	13.2	121	[105]	-
Pariet	6.8	8.5	7.1	7.8	106	[92]	-
Stronger Neo-Minophagen C and Glycyron Tablets	7.3	9.1	6.4	7.0	88	[77]	-
Aricept	4.1	5.2	5.2	5.7	125	[109]	-
Fycompa	0.8	1.0	1.9	2.1	227	[197]	2.5
Halaven	1.3	1.6	1.7	1.8	128	[110]	2.5
Segment profit	43.8	54.7	49.1	53.7	112	[96]	

[ ] based on local currency

Performance of EMEA* Pharmaceutical Business

(Billions of yen, %)

	April-December FY2021		April-December FY2022				FY2022
	Results	%	Results	%	YoY		Forecast
Revenue	44.3	100.0	52.5	100.0	118	[106]	69.5
Lenvima/Kisplyx	16.3	36.7	22.0	41.9	135	[120]	30.0
Halaven	9.9	22.3	10.2	19.5	104	[92]	14.5
Fycompa	6.8	15.3	8.5	16.2	126	[114]	11.5
Inovelon	2.0	4.6	2.3	4.4	113	[104]	-
Segment profit	23.7	53.5	29.5	56.2	125	[109]	

* Europe, Middle East, Africa, Russia and Oceania

[ ] based on local currency

Performance of Asia and Latin America* Pharmaceutical Business

(Billions of yen, %)

	April-December FY2021		April-December FY2022				FY2022
	Results	%	Results	%	YoY		Forecast
Revenue	36.6	100.0	37.8	100.0	103	[92]	49.0
Aricept	8.9	24.4	10.0	26.3	112	[102]	-
Lenvima	6.1	16.7	8.1	21.4	133	[116]	10.5
Pariet	2.9	8.0	3.5	9.2	118	[105]	-
Methycobal	2.6	7.2	3.0	8.0	115	[101]	-
Halaven	1.7	4.7	2.3	6.1	135	[117]	3.0
Fycompa	1.1	2.9	1.3	3.5	122	[110]	2.0
Segment profit	15.8	43.1	17.6	46.6	112	[98]	

* Primarily South Korea, Taiwan, India, ASEAN, Central and South America

[ ] based on local currency

Performance of OTC and Others in Japan

(Billions of yen, %)

	April-December FY2021		April-December FY2022			FY2022
	Results	%	Results	%	YoY	Forecast
Revenue	18.7	100.0	18.7	100.0	100	24.5
Chocola BB Group*	11.3	60.2	11.1	59.1	98	14.5
Segment profit	4.3	23.0	4.5	23.9	104	

* Vitamin B preparations, “Chocola BB Plus” and others

Overview of Anti-Aβ Antibody Clinical Trial Designs (Phase II & Beyond)

Drug (Sponsor)	Study name (phase), NCT number	Target population (Enrollment number)	Dose	Inclusion criteria (excerpt)	Primary endpoints (for core study)
lecanemab[*1] (Eisai, Biogen)	**Phase II** (Bayesian adaptive design) NCT01767311	Early AD (856)	Core study: 2.5mg/kg, 5mg/kg (biweekly, monthly), 10mg/kg (biweekly, monthly), placebo (IV) OLE: 10 mg/kg biweekly, Q4W or Q3M	Core study: MCI due to AD and mild AD-D（NIA-AA） CDR 0.5-1, CDR memory box ≧0.5, MMSE 22-30, WMS-IV LM II:≧1 SD below age-adjusted mean, amyloid positive OLE: Participants who have received OLE for at least 18 months may opt to enter the Q4W or Q3M dosing regimen substudy	ADCOMS (12 months)
lecanemab[*1] (Eisai, Biogen)	**Clarity AD** (Phase III) NCT03887455	Early AD (1906[*2,3])	Core study: 10mg/kg biweekly, Placebo OLE: 10 mg/kg biweekly (IV) 720mg weekly(SC substudy)	Core study: MCI due to AD, mild AD-D (NIA-AA), CDR: 0.5-1, CDR memory box ≧0.5, amyloid positive, MMSE≧22, WMS-IV LMII: ≧1 SD below age-adjusted mean SC substudy: All participants must have an amyloid PET scan within 4 weeks before starting subcutaneous BAN2401	CDR-SB (18 months)
lecanemab[*1] (Eisai, Biogen, ACTC, NIA)	**AHEAD 3-45** (Phase III) NCT04468659	Preclinical AD (1400)	5mg/kg + 10mg/kg, Placebo	CDR: 0, MMSE≧27, WMS-R LM II≧6 A3: Intermediate levels of brain amyloid pathology A45: Elevated brain amyloid pathology	A3: Amyloid PET SUVr (216 weeks) A45: Preclinical Alzheimer Cognitive Composite 5 (PACC 5) (216 weeks)
E2814[*4]**/lecanemab** (Washington University School of Medicine, Eisai)	**DIAN-TU** (Phase II/III) NCT05269394	DIAD[*5], cognitively normal or with MCI or mild dementia (168)	E2814, lecanemab, matching placebo (E2814)	Individuals who know they have an AD-causing mutation and are within -10 to + 10 years of the predicted or actual age of cognitive symptom onset. Cognitively normal or with mild cognitive impairment or mild dementia, CDR 0-1 (inclusive)	Change in tau PET from Week 24 to 104 (interim analysis), and Week 208 (final analysis)
aducanumab （Biogen, Eisai）	**ENVISION** (Phase IIIb/IV) NCT05310071	Early AD (1512)	10mg/kg monthly placebo	Amyloid positive, MCI due to AD or mild AD(NIA-AA)、MMSE: 22-30, CDR memory score>0.5, CDR-Global Score: 0.5 or 1.0, RBANS[*6]≦85	CDR-SB (78 weeks)
donanemab (Eli Lilly)	**TRAILBLAZER-ALZ** (Phase II) NCT03367403	Prodromal to mild AD (272)	700mg Q4W x3, 1400mg Q4W up to 72W, placebo	MMSE: 20-28, meet ^{18}F flortaucipir PET scan criteria and ^{18}F florbetapir PET scan (central read) criteria	Integrated Alzheimer's Disease Rating Scale (iADRS) (18 months)
	TRAILBLAZER-ALZ 2 (Phase III) NCT04437511	Early AD (Prodromal to mild) (1800)	donanemab, placebo	MMSE: 20-28, meet ^{18}F flortaucipir and ^{18}F florbetapir PET scan (central read) criteria	iADRS (76 weeks)
	TRAILBLAZER-ALZ 3 (Phase III) NCT05026866	Preclinical AD (3300)	donanemab, placebo	Telephone Interview for Cognitive Status-modified (TICS-M) score reflective of intact cognitive functioning. Has a phosphorylated tau (p-tau) result consistent with the presence of amyloid and early-tau pathology	Time to clinical progression by Clinical Dementia Rating-Global Score (CDR-GS) (up to 182 weeks)
	TRAILBLAZER-ALZ 5 （Phase III） NCT05508789	Early AD (Prodromal to mild) (1500)	donanemab placebo	MMSE: 20-28, meet ^{18}F flortaucipir and ^{18}F florbetapir PET scan (central read) criteria	iADRS (76 weeks)
remternetug LY3372993 (Eli Lilly)	**TRAILRUNNER-ALZ 1** (Phase III) NCT05463731	Early AD（600）	Remternetug (IV) Remternetug (SC) placebo	MMSE 20-28, has p-tau and amyloid PET scan results consistent with the presence of amyloid pathology	Percentage of participants who reach amyloid plaque clearance on amyloid PET scan (52 weeks)

Study design overview for Phase II and beyond in this chart was edited by Eisai based on ClinicalTrials.gov as of January 28, 2023. All projects are investigational except for aducanumab and lecanemab in the U.S.
OLE: Open level extension IV: intravenous injection SC: subcutaneous injection *1: Investigational antibody for Alzheimer's disease produced as the result of a strategic research alliance between Eisai and BioArctic. *2: Includes 111 subjects in China *3: SC substudy plans to enroll an additional 40 de novo participants (those that did not participate in the core study) with early AD *4: Anti-MTBR tau antibody. Discovered as part of the research collaboration between Eisai and University College London. *5: Dominantly Inherited Alzheimer's Disease *6: Repeatable Battery for the Assessment of Neuropsychological Status

Pipeline that Supports AD Patient Journey

ATN+[*1] comprehensive AD pipeline		Target Indication	Non-Clinical	Phase I	Phase II	Phase III	Sub-mission	Approval, Launch
A	Lecanemab[*2] (Anti-Aβ[*3] protofibril antibody)	Early AD AA[*4] (US) LEQEMBI	U.S., Jan. 2023 Approved based on AA and launched					
		Early AD Full Approval (US)	U.S., Jan. 2023 Submitted sBLA[*5] for Full Approval					
		Early AD (EU)	Europe, Jan. 2023 Filed MAA[*6]					
		Early AD (Japan)	Japan, Jan. 2023 Filed J-NDA[*7] (Priority Review)					
		Early AD (China)	China, Dec. 2022 Initiated BLA submission of data					
		Preclinical AD	Phase III ongoing with ACTC[*8]					
		Subcutaneous formulation (New dosage form)	Substudies in 301-OLE		Aim to achieve regulatory submission in FY2023			
		Maintenance dosing regimen	Substudy in 201-OLE		Aim to achieve regulatory submission in FY2023			
T	E2814[*9] (Anti-MTBR[*10] tau antibody)	Tau NexGen[*11] DIAD[*12] *Combination Regimen with lecanemab*	Phase II/III ongoing					
		103 study in DIAD *Investigation of TE[*13] with new biomarkers*	Phase Ib/II ongoing					
N	E2511 (TrkA[*14]binding synapse regenerant)	AD	Phase I (MAD[*15]) ongoing					
	E2025 (Anti-EphA4[*16] antibody)	AD	Phase I initiated					

*1: ATN: Amyloid, Tau, Neurodegeneration *2: Antibody for AD produced as the result of a strategic research alliance between Eisai and BioArctic. Collaboration with Biogen *3: Amyloid beta *4: Accelerated Approval
*5: Biologics License Application *6: Marketing Authorization Application *7: Japan-New Drug Application, *8: Alzheimer's Clinical Trials Consortium *9: Discovered as part of the research collaboration between Eisai and University College London *10: MTBR: microtubule binding region *11: Tau NexGen: Study name (Tau Next Generation). Phase II/III study in DIAD conducted by Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU)
*12: Dominantly inherited Alzheimer's disease *13: Target Engagement *14: Tropomyosin receptor kinase A *15: Multiple Ascending Dose *16: Erythropoietin-producing hepatocellular receptor A4

Pipeline in Oncology Area

Oncology pipeline			Non-clinical trials	Phase I	Phase II	Phase III	Submission	Approved
Lenvima	Combination with KEYTRUDA®	Endometrial carcinoma following prior systemic therapy (Study 309)	Approved (Japan, U.S. and EU)					
		1L Endometrial carcinoma (LEAP-001)[*1]	Achieved LPI[*2]					
		1L Hepatocellular carcinoma (LEAP-002)	Achieved LPI					
		1L Melanoma (LEAP-003)[*1]	Achieved LPI					
		1L Non-small cell lung cancer[*3] (LEAP-006)[*1]	Achieved LPI					
		2L Non-small cell lung cancer (LEAP-008)	Achieved LPI					
		1L Head and neck cancer (LEAP-010)[*1]	Achieved LPI					
		1L Hepatocellular carcinoma (combination with TACE[*4], LEAP-012)						
		1L Esophageal carcinoma (LEAP-014)						
		1L Gastric cancer (LEAP-015)						
		3L Colorectal cancer (LEAP-017)[*1]	Achieved LPI					
		2L Melanoma (LEAP-004)	Achieved LPI					
		Basket trial[*5] (LEAP-005)	Expanding sample size					
		2L Head and neck cancer (LEAP-009)						
	Combination with KEYTRUDA or everolimus	1L Renal cell carcinoma (Study 307)	Combination with KEYTRUDA: Approved (Japan, U.S. and EU)					
	Combination with nivolumab[*6]	Hepatocellular carcinoma (Study 117)						
E7090 FGFR1,2,3 inhibitor		Biliary tract cancer						
		Breast cancer						
H3B-6545 ERα inhibitor		Breast cancer	Phase I/II study					
E7389-LF Liposomal formulation		Solid tumors	Phase Ib/II study					
		Solid tumors (combination with nivolumab)[*6]	Phase Ib/II study					
E7386[*7] CBP/β-catenin inhibitor		Solid tumors						
		Hepatocellular carcinoma, Solid tumors (combination with Lenvima)						
		Solid tumors (combination with KEYTRUDA)	Phase Ib/II study					
E7130[*8] Next-generation drug improving tumor microenvironment		Solid tumors						
MORAb-202[*9] Antibody-drug conjugate (ADC)		Folate receptor α (FRA) positive solid tumors	Phase I/II study					
E7766 STING agonist		Solid tumors						
Splicing modulator		Solid tumors						
Protein degrader		Solid tumors						

All projects are investigational unless stated "Approved". KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.
Projects for Lenvima are under joint development with Merck & Co., Inc., Rahway, NJ, USA. 1L: First line, 2L: Second line, 3L: Third line *1: Expanding sample size in China *2: Last Patient In
*3: Non-squamous cell carcinoma, combination with chemotherapy *4: Transcatheter arterial chemoembolization *5: Gastric cancer, colorectal cancer, glioblastoma, biliary tract cancer, and pancreatic cancer
*6: Development in collaboration with Ono Pharmaceutical Co., Ltd. *7: Collaboration with PRISM BioLab *8: Compound co-created with Harvard University *9: Co-development with Bristol Myers Squibb. Generic name for MORAb-202 is farletuzumab ecteribulin.

Achievement of Milestones with Merck & Co., Inc., Rahway, NJ, USA

FY2020 results
335 million USD (34.6 billion yen)

- Sales milestone payment recognized upon achievement of 1.2 billion USD revenue from January to December 2020: 200 million USD (20.7 billion yen)
- Regulatory milestone payment for the approval of thyroid cancer indication in China: 10 million USD (1.0 billion yen) Reversal of R&D expenses
- One-time option payment associated with certain option rights: 125 million USD (12.9 billion yen)

FY2021 results
700 million USD (80.3 billion yen)

- Sales milestone payment recognized upon achievement of 1.5 billion USD revenue FY2021: 300 million USD (34.7 billion yen)
- Sales milestone payment recognized upon achievement of 1.4 billion USD revenue from January to December 2021: 300 million USD (34.5 billion yen)
- Regulatory milestone payment for the approval of renal cell carcinoma indication in Japan: 25 million USD (2.9 billion yen) Reversal of R&D expenses
- Regulatory milestone payment for the approval of renal cell carcinoma indication in US: 75 million USD (8.3 billion yen) Reversal of R&D expenses

Q3 FY2022 cumulative results
25 million USD (3.2 billion yen)

- Regulatory milestone payment for the approval of renal cell carcinoma in EU: 25 million USD (3.2 billion yen) Reversal of R&D expenses (1Q)

Chart not to scale

Safe Harbor Statement

- Forecast or target figures in this material are not official earnings guidance but represent midterm strategies, goals, and visions. Official earnings guidance should be referred to in the disclosure of the annual financial report (Consolidated Financial Statement) in accordance with the rules set by Tokyo Stock Exchange.
- Materials and information provided during this presentation may contain so-called “forward-looking statements.” These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties that could cause actual outcomes and results to differ materially from these statements.
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