

11. Major R&D Pipeline

(1) Neurology

Development Code: BAN2401 Generic Name: lecanemab Product Name: Leqembi				In-license (BioArctic AB)
Indications / Drug class: Treatment for Alzheimer's disease / anti-A β protofibril antibody				Injection
Description: An IgG1 antibody that targets amyloid beta (A β) protofibrils. Reduces the rate of disease progression and slows cognitive and functional decline in adults with Alzheimer's disease (AD) through the elimination of neurotoxic A β protofibrils. In July 2023, lecanemab was granted traditional approval in the United States as a treatment for AD by the U.S. Food and Drug Administration (FDA) after an application supporting the conversion of the accelerated approval to a traditional approval based on the Phase III clinical study Clarity AD. Applications have been submitted for use in the treatment of early AD in Japan, Europe, China, Canada, Great Britain, Australia, Switzerland, South Korea and Israel. The applications have been designated for priority review in Japan, China and Israel. In Great Britain, lecanemab has been designated for the Innovative Licensing and Access Pathway, which aims to reduce the time to market for innovative medicines. Development of subcutaneous injection formulation is underway to enhance convenience for patients. In addition, a study to determine a new dosing regimen for maintenance treatment after removal of brain A β is also underway. The Phase III clinical study AHEAD 3-45 for preclinical (asymptomatic) AD is underway in collaboration with the Alzheimer's Clinical Trials Consortium (ACTC). Joint development with Biogen Inc.				
Early AD	Study 301 (Clarity AD)	US EU JP CH Asia (SK)	⊙ ⊙	Traditional approval (July 2023) Submission (accepted: January 2023) Submission (January 2023) Submission (December 2022) Submission (June 2023)
Preclinical AD	Study 303 (AHEAD 3-45)	JP/US/EU		PIII
Development Code: E2007 Generic Name: perampanel Product Name: Fycompa				In-house
Indications / Drug class: Antiepileptic agent / AMPA receptor antagonist				Oral
Description: Selectively inhibits the AMPA receptor (a glutamate receptor subtype) activation by glutamate. Approved as an adjunctive therapy for partial-onset seizures in over 75 countries including Japan, China and countries in Europe and in Asia. Approved for monotherapy in Japan and China. Also approved as an adjunctive therapy for primary generalized tonic-clonic seizures in over 70 countries including Japan, and countries in Europe and in Asia. An oral suspension formulation has been approved in Europe and China. A fine granule formulation has been approved in Japan. In January 2023, the commercial rights in the United States were transferred.				
Injection formulation (Additional Formulation)	—	JP		Submission (August 2022)
Primary generalized tonic-clonic seizures (Additional Indication)	Study 332	CH		Submission (March 2023)
Lennox-Gastaut syndrome (Additional Indication)	Study 338	JP/US/EU		PIII
Development Code: E2006 Generic Name: lomborexant Product Name: Dayvigo				In-house
Indications / Drug class: Insomnia treatment / Orexin receptor antagonist				Oral
Description: An orexin receptor antagonist that blocks the receptors involved in the regulation of sleep and wakefulness. It is expected to alleviate wakefulness, thereby facilitating faster onset and maintenance of sleep. It has been approved for the treatment of insomnia in over 15 countries including Japan, the United States and countries in Asia. In addition, development for irregular sleep-wake rhythm disorder and Alzheimer's disease dementia is ongoing.				
Insomnia disorder	Study 311	CH		PIII
Irregular sleep-wake rhythm disorder and Alzheimer's disease dementia (Additional Indication)	Study 202	JP/US		PII
Development Code: E2023 Generic Name: lorcaserin				In-license (Arena Pharmaceuticals)
Indications / Drug class: Treatment for Dravet syndrome / serotonin 2C receptor agonist				Oral
Description: By selectively activating serotonin 2C receptors in the brain, through the activation GABAergic inhibitory interneuron, expected to suppress seizures of Dravet syndrome by increasing synaptic suppression from GABAergic. Although approval for the obesity indication has been voluntarily withdrawn, due to the request from Dravet syndrome patient groups, the extended access program has been continued in the United States, and the Phase III clinical study is underway for this indication. FDA has designated it as an orphan drug for Dravet syndrome.				
Dravet syndrome	Study 304	US		PIII

JP: Japan, US: the United States, EU: Europe, CH: China, SK: South Korea, P: (Clinical trial) Phase

⊙ : Development progress from April 2023 onwards

Development Code: E2027				In-house
Indications / Drug class: Treatment for dementia with Lewy bodies, Parkinson's disease dementia / PDE9 inhibitor				Oral
Description: A selective phosphodiesterase (PDE) 9 inhibitor that reduces the degradation of cyclic GMP, which is critical to signal transduction among cells. Expected to be a new treatment for dementia with Lewy bodies and Parkinson's disease dementia by helping to maintain the concentration of cyclic GMP in the brain.				
Dementia with Lewy bodies, Parkinson's disease dementia	Study 203	US		PII

Development Code: E2814				Collaboration (University College London)
Indications / Drug class: anti-MTBR tau antibody				Injection
Description: An anti-microtubule binding region (MTBR) tau antibody that was discovered as part of the research collaboration between Eisai and University College London. Expected to prevent the spreading of tau seeds within the brain. Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU) has selected E2814 as the first investigational medicine among anti-tau drugs for their DIAN-TU tau study, and Phase Ib/II study and Phase II/III study Tau NexGen for dominantly inherited AD are underway.				
AD	Tau NexGen study Study103	JP/US/EU US/EU		PII/III PI/II

Development Code: E2511				In-house
Indications / Drug class: Synapse regenerant				Oral
Description: Expected to promote recovery and synaptic remodeling of damaged cholinergic neurons, and to suppress cerebral atrophy caused by neurodegeneration.				
AD	—	US		PI

Development Code: E2025			In-house	Injection
AD	—	US		PI

Development Code: E2086			In-house	Oral
Narcolepsy	—	US		PI

Development Code: EA4017			In-house	Oral
Chemotherapy-induced peripheral neuropathy (Development conducted by EA Pharma)	—	JP		PI

(2) Oncology

Development Code: E7080 Generic Name: lenvatinib Product Name: Lenvima				In-house
Indications / Drug class: Anticancer agent / kinase inhibitor				Oral
Description: An orally available multiple kinase inhibitor that selectively inhibits kinase activities vascular endothelial growth factor receptors (VEGFR): VEGFR1, VEGFR2 and VEGFR3, and fibroblast growth factor receptors (FGFR): FGFR1,FGFR2, FGFR3 and FGFR4, in addition to pathogenic angiogenesis, tumor growth and cancer progression related receptor tyrosine kinases such as the platelet derived growth factor receptor alpha (PDGFR α), KIT, and RET. Discovered and developed in-house. As monotherapy indications, approved for use in the treatment of thyroid cancer in over 80 countries including Japan, the United States, China and countries in Europe and in Asia. Approved for use in the treatment of hepatocellular carcinoma (first-line) in over 80 countries including in Japan, the United States, China and countries in Europe and in Asia. Also approved for use in the treatment of thymic carcinoma in Japan. As a combination therapy with everolimus, approved for use in the treatment of renal cell carcinoma (second-line) in over 65 countries including the United States, countries in Europe and in Asia. As a combination therapy with pembrolizumab, approved for use in the treatment of renal cell carcinoma in over 45 countries including in Japan, the United States, and countries in Europe and in Asia, and approved for use in the treatment of endometrial carcinoma in over 50 countries including in Japan, the United States, and countries in Europe and in Asia, including conditional approval. The agent is marketed under the product name Kisplyx only for renal cell carcinoma indication in Europe. Joint development with Merck & Co., Inc., Rahway, NJ, USA, through an affiliate.				
In combination with anti-PD-1 therapy pembrolizumab, joint development with Merck & Co., Inc., Rahway, NJ, USA, through an affiliate (Additional Indication)				
Endometrial carcinoma / First-line	LEAP-001	JP/US/EU/CH		PIII
Non-small cell lung cancer (nonsquamous) (in combination with chemotherapy) / First-line	LEAP-006	JP/US/EU/CH		PIII
Non-small cell lung cancer / Second-line	LEAP-008	JP/US/EU		PIII
Head and neck cancer / First-line	LEAP-010	JP/US/EU/CH		PIII
Hepatocellular carcinoma (in combination with transcatheter arterial chemoembolization) / First-line	LEAP-012	JP/US/EU/CH		PIII
Esophageal carcinoma (in combination with chemotherapy) / First-line	LEAP-014	JP/US/EU/CH		PIII
Gastric cancer (in combination with chemotherapy) / First-line	LEAP-015	JP/US/EU/CH		PIII
Colorectal cancer (non MSI-H / pMMR) / Third-line	LEAP-017	US/EU		PIII
Melanoma / Second-line	LEAP-004	US/EU		PII
Selected solid tumors (Gastric cancer, colorectal cancer, glioblastoma, biliary tract cancers and pancreatic cancer)	LEAP-005	US/EU		PII
Head and neck cancer / Second-line	LEAP-009	US/EU		PII
In combination with anticancer agent everolimus, joint development with Merck & Co., Inc., Rahway, NJ, USA, through an affiliate (Additional Indication)				
Renal cell carcinoma / First-line	Study 307	JP/US/EU		PIII
In combination with anti-PD-1 antibody nivolumab, joint development with Ono Pharmaceutical (Additional Indication)				
Hepatocellular carcinoma	—	JP		PI

© Based on the independent Data Monitoring Committee recommendation, Phase III clinical study of LEAP-003 for melanoma / First-line in the United States, Europe and China, has been decided to be discontinued and therefore was removed from this list.

Development Code: E7389 Generic Name: eribulin Product Name: Halaven				In-house
Indications / Drug class: Anticancer agent / microtubule dynamics inhibitor				Injection
Description: A synthetic analog of halichondrin B derived from the marine sponge <i>Halichondria okadae</i> . Shows an antitumor effect by arresting the cell cycle through inhibition of the growth of microtubules. Approved in over 85 countries including Japan, the United States, China and countries in Europe and in Asia for use in the treatment of breast cancer. Approved in over 80 countries including Japan, the United States and countries in Europe and in Asia for use in the treatment of liposarcoma (soft tissue sarcoma in Japan).				
Monotherapy (Additional Formulation)				
Liposomal formulation	—	JP/EU		PI
In combination with anti-PD-1 antibody nivolumab, joint development with Ono Pharmaceutical (Additional Formulation)				
Liposomal formulation	Study 120	JP		PI/II

Development Code: H3B-6545				In-house
Indications / Drug class: Anticancer agent / ER α inhibitor				Oral
Description: An orally administered selective estrogen receptor (ER) α covalent antagonist that inhibits ER α wild type / ER α mutant. Expected to show an antitumor effect against ER positive / HER2 negative breast cancers.				
Breast cancer	Study 101	US/EU		PI/II
Breast cancer (in combination with CDK4/6 inhibitor palbociclib)	—	US/EU		PI

Development Code: E7090 Generic Name: tasurgratinib				In-house
Indications / Drug class: Anticancer agent / FGFR1, FGFR2, FGFR3 inhibitor				Oral
Description: An orally administered fibroblast growth factor receptors (FGFR1, FGFR2, FGFR3) selective tyrosine kinase inhibitor. Phase II clinical study for unresectable cholangiocarcinoma (one of biliary tract cancers) with <i>FGFR2</i> gene fusion is ongoing. It has been granted the orphan drug designation with a prospective indication for unresectable biliary tract cancer with <i>FGFR2</i> gene fusion by the Ministry of Health, Labour and Welfare (MHLW) in Japan.				
Cholangiocarcinoma	Study 201	JP/CH		PII
Breast cancer	—	JP		PI

Development Code: MORAb-202 Generic Name: farletuzumab ecteribulin (FZEC)				In-house
Indications / Drug class: Anticancer agent / Folate receptor α targeted antibody drug conjugate				Injection
Description: An antibody drug conjugate (ADC) with approved anticancer drug eribulin. Expected to show an antitumor effect against folate receptor α -positive tumors by concentrating eribulin on tumor; inclusive of endometrial, ovarian, lung and breast cancers. Joint development with Bristol Myers Squibb.				
Non-small cell lung cancer	Study 203	US/EU		PII
Ovarian cancer, peritoneal cancer, fallopian tube cancer	Study 205	JP/US/EU		PII
Solid tumors	Study 201	US/EU		PI/II
Solid tumors	—	JP		PI

Development Code: E7386				Collaboration (PRISM BioLab)
Indications / Drug class: Anticancer agent / CBP/ β -catenin interaction inhibitor				Oral
Description: A CREB-binding protein (CBP) / β -catenin inhibitor that blocks the protein-protein interaction between CBP and β -catenin, and regulates Wnt signaling-dependent gene expression. Expected inhibition of Wnt signaling-dependent tumor growth.				
	Solid tumors (in combination with pembrolizumab)	Study 201	JP/US/EU	PI/II
	Solid tumors	—	JP/US/EU	PI
	Solid tumors (in combination with lenvatinib)	—	JP/US/EU	PI

Development Code: E7130			Collaboration (Harvard University)	Injection
	Solid tumors	—	JP	PI

Development Code: E7766			In-house	Injection
	Solid tumors	—	US/EU	PI

(3) Global Health

Development Code: E1224 Generic Name: fosravuconazole				In-house
Indications / Drug class: Antifungal agent / ergosterol synthesis inhibitor				Oral
Description: An ongoing collaboration with the Drugs for Neglected Diseases initiative (DNDi) for a new treatment for eumycetoma, a fungal form of mycetoma with a particularly high unmet medical need, and one of the world's most neglected diseases. Eisai is mainly responsible for non-clinical studies and the provision of the investigational drug. The Phase IIb/III clinical study is being conducted in Sudan by DNDi and the Mycetoma Research Center of the University of Khartoum, Sudan. Supported by the Global Health Innovative Technology Fund (GHIT Fund).				

Development Code: SJ733				Co-development (University of Kentucky)
Indications / Drug class: Antimalarial agent / ATP4 inhibitor				Oral
Description: Expected to be suitable for treatment in malaria-endemic areas, with rapid efficacy and safety, and providing lasting protection against reinfection. The treatment might potentially solve the problem of increased resistance faced by current antimalarial medicines. In the ongoing collaboration with the University of Kentucky, Eisai is responsible for the provision of drug substance and formulation manufacturing. The Phase II clinical study is being conducted in Peru by the University of Kentucky. Supported by the GHIT Fund.				

Development Code: AWZ1066S				Co-development (Liverpool School of Tropical Medicine)
Indications / Drug class: Antifilarial agent / antiwolbachia mechanism				Oral
Description: An ongoing collaboration with the Liverpool School of Tropical Medicine and the University of Liverpool to jointly identify new drugs effective against lymphatic filariasis and onchocerciasis (river blindness), both major types of filariasis. Eisai is responsible for the provision of drug substance and formulation manufacturing. The Phase I clinical study is being conducted in the United Kingdom (UK) by the Liverpool School of Tropical Medicine. Supported by the GHIT Fund and Medical Research Council in the UK.				

(4) Gastrointestinal Disorders

Development Code: AJG555 Product Name: MOVICOL				In-license (Norgine)
Indications / Drug class: Chronic constipation treatment / polyethylene glycol preparation				Oral
Description: An orally available constipation treatment consisting of a polyethylene glycol preparation which facilitates bowel movement by regulating osmolality in the intestines. Approved for chronic constipation treatment for children of 2 years and above and adult patients in Japan. Development conducted by EA Pharma.				
©	Chronic constipation in children under 2 years of age (Additional Dosage and Administration)	Study CT3	JP	PIII

Development Code: AJM347		In-house		Oral
	Inflammatory bowel disease (Development conducted by EA Pharma)	—	EU	PI

Development Code: EA1080		In-house		Oral
	Inflammatory bowel disease (Development conducted by EA Pharma)	—	EU	PI

Development Code: EA3571		In-house		Oral
	Nonalcoholic steatohepatitis (Development conducted by EA Pharma)	—	JP	PI

(5) Other

Development Code: FYU-981 Generic Name: dotinurad				In-license (FUJI YAKUHIN)
Indications / Drug class: Treatment for Hyperuricemia and Gout / selective URAT1 inhibitor				Oral
Description: Dotinurad selectively inhibits URAT1, one of the uric acid transporters, thus preventing reabsorption of uric acid by kidneys and promoting uric acid excretion in urine. In addition, it has a small effect on other transporters affecting uric acid secretion, so it reduces serum uric acid levels at lower doses. Therefore, dotinurad is expected to have a low risk of side effects and drug interaction. In Japan, FUJI YAKUHIN obtained manufacturing and marketing approval for dotinurad in January 2020. Eisai entered into a license agreement concerning the development and distribution in China in February 2020, and in five ASEAN countries in August 2021 with FUJI YAKUHIN.				
	Gout	Study 301	CH	PIII

Development Code: E6742		In-house		
Indications / Drug class: Treatment for Systemic lupus erythematosus / TLR 7/8 inhibitor		Oral		
Description: Toll-Like Receptors (TLRs) are receptors of the innate immune system, and activated TLRs initiate an inflammatory reaction or an antiviral response. E6742 is the inhibitor of oral and selective TLR7/8 which is associated with the pathogenesis of systemic lupus erythematosus. This project has been selected by the Japan Agency for Medical Research and Development (AMED) for its Cyclic Innovation for Clinical Empowerment (CiCLE) grant program.				
	Systemic lupus erythematosus	Study 101	JP	PI/II

Development Code: E8001		In-house		Injection
	Rejection reaction associated with organ transplantation	—	JP	PI