11. Major R&D Pipeline

NCT: Identification number of ClinicalTrials.gov, jRCT: Identification number of Japan Registry of Clinical Trials
JP: Japan, US: the United States, EU: Europe, CH: China, SK: South Korea, UK: United Kingdom, P: (Clinical trial) Phase
IIS: Investigator-initiated study ○: Development progress from April 2024 onwards, ◎: Development progress from October 2024

(1) Neurology

Development Code: **BAN2401** Generic Name: **lecanemab** Product Name: **Leqembi**				In-license (BioArctic AB)
Indications / Drug class: Treatment for Alzheimer's disease / anti-Aβ protofibril antibody				Injection (intravenous infusion, subcutaneous injection)
Description: An IgG1 antibody that primarily targets amyloid beta (Aβ) 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 Aβ protofibrils. For the treatment of early AD, it has been approved in Japan, the United States, China, South Korea, Hong Kong, Israel, the United Arab Emirates, United Kingdom, Mexico and Macao, and applications have been filed in European Union and other countries. Maintenance dosing by intravenous infusion has also been approved in the United States. Development underway for maintenance dosing by subcutaneous injection. Joint development with Biogen Inc.				
Early AD		Asia (SK) UK European Union	○ ○	Approval (April 2024) Approval (August 2024) Submission (accepted: January 2023)
Study 301 (Clarity AD)	NCT03887455			
Intravenous maintenance dosing for early AD (Additional Dosage and Administration)		US	◎	Approval (January 2025)
Study 201/301	NCT01767311/NCT03887455			
Maintenance dosing of a subcutaneous injection formulation for early AD (Additional Formulation)		US	◎	Submission (accepted: January 2025)
Study 301	NCT03887455			
Preclinical AD (Additional Indication)		JP/US/EU		PIII
Study 303 (AHEAD 3-45)	NCT04468659			

Development Code: **E2007** Generic Name: **perampanel** Product Name: **Fycompa**				In-house
Indications / Drug class: Antiepileptic agent / AMPA receptor antagonist				Oral / Injection
Description: Selectively inhibits the AMPA receptor (a glutamate receptor subtype) activation by glutamate. Approved as an adjunctive therapy for partial-onset seizures mainly in Japan, Europe, China and in Asia. Approved for monotherapy in Japan and China. Also approved as an adjunctive therapy for primary generalized tonic-clonic seizures mainly in Japan, Europe, China and Asia. An oral suspension formulation has been approved in Europe and China. Fine granule and injection formulations have been approved in Japan. In January 2023, the commercial rights in the United States were transferred.				
Adjunctive therapy for primary generalized tonic-clonic seizures (Additional Indication)		CH	○	Approval (April 2024)
Study 332	NCT01393743			

Development Code: **E2006** Generic Name: **lemborexant** 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 mainly in Japan, the United States and Asia.				
Insomnia disorder		CH		Submission (accepted: January 2024)
Study 311	NCT04549168			

Development Code: **E0302** Generic Name: **mecobalamin** Product Name: **Rozebalamin**				In-house
Indications / Drug class: Treatment for Amyotrophic lateral sclerosis (ALS)				Injection
Description: Ultrahigh-dose of mecobalamin that is 100 times the approved dose used for the treatment of peripheral neuropathy (as a single dose).				
ALS		JP	○	Approval (September 2024)
JETALS (IIS)	NCT03548311			

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 (Phase II/III study Tau NexGen).				
Dominantly inherited AD (in combination with lecanemab)		JP/US/EU		PII/III
Tau NexGen study	NCT05269394			
Dominantly inherited AD		US/EU		PIb/II
Study 103	NCT04971733			
Sporadic early AD (in combination with lecanemab)		JP/US	○	PII
Study 202	NCT06602258			

Development Code: **E2511**			In-house
Indications / Drug class: TrkA integrated synapse regenerant			Oral
AD	US		PI

Development Code: **E2025**			In-house
Indications / Drug class: Anti-EphA4 antibody			Injection
AD	US		PI

Development Code: **E2086**			In-house
Indications / Drug class: Orexin receptor agonist			Oral
Narcolepsy	US		PIb

◎ Regarding lorcaserin, the Phase III clinical study (Study 304) for Dravet syndrome in the United States has finished and therefore it was removed from this list.

◎ Regarding EA4017, EA Pharma has decided to discontinue the development at Phase I for chemotherapy-induced peripheral neuropathy in Japan and therefore it was removed from this list.

(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 (PDGFRα), KIT, and RET. Discovered and developed in-house. As monotherapy indications, approved for use in the treatment of thyroid cancer and hepatocellular carcinoma (first-line) mainly in Japan, the United States, Europe, China and 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) mainly in the United States, Europe and Asia. As a combination therapy with pembrolizumab, approved for use in the treatment of renal cell carcinoma (first-line) mainly in Japan, the United States, Europe and Asia, and approved for use in the treatment of endometrial carcinoma (following prior systemic therapy) mainly in Japan, the United States, Europe and Asia, including conditional approval. The agent is marketed under the product name Kisplyx only for the 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)				
Hepatocellular carcinoma (in combination with transcatheter arterial chemoembolization)		JP/US/EU/CH		PIII
LEAP-012	NCT04246177			
Esophageal carcinoma (in combination with chemotherapy) / First-line		JP/US/EU/CH		PIII
LEAP-014	NCT04949256			
Gastric cancer (in combination with chemotherapy) / First-line		JP/US/EU/CH		PIII
LEAP-015	NCT04662710			
In combination with anti-PD-1 antibody nivolumab, joint development with Ono Pharmaceutical (Additional Indication)				
Hepatocellular carcinoma		JP		PIb

○ Based on the independent Data Monitoring Committee recommendation, the Phase II clinical study LEAP-009 for head and neck cancer (second-line) in the United States and Europe 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 *Halichondria okadai*. Shows an antitumor effect by arresting the cell cycle through inhibition of the growth of microtubules. Approved mainly in Japan, the United States, Europe, China and Asia for use in the treatment of breast cancer. Approved including Japan, the United States, Europe and 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		JP		PIb/II
Study 120	NCT04078295			

Development Code: **E7090** Generic Name: **tasurgratinib** Product Name: **Tasfygo**				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.				
Biliary tract cancer with *FGFR2* gene fusion		JP	○	Approval (September 2024)
Study 201	NCT04238715			
Breast cancer		JP		PIb

Development Code: **MORAb-202** Generic Name: **farletuzumab ecteribulin (FZEC)**				In-house
Indications / Drug class: Anticancer agent / Folate receptor α targeted antibody drug conjugate (ADC)				Injection
Description: ADC which combines anti-folate receptor α (FRα) antibody with approved anticancer drug eribulin via its linker. Expected to show an antitumor effect against FRα-positive tumors by concentrating eribulin on tumor; inclusive of endometrial, ovarian, lung and breast cancers. In June 2024, Eisai agreed to end its global strategic collaboration with Bristol Myers Squibb for co-development and co-commercialization, and moved to solo global development and commercialization.				
Non-small cell lung cancer		US/EU		PII
Study 203	NCT05577715			
Ovarian cancer, peritoneal cancer, fallopian tube cancer		JP/US/EU		PII
Study 205	NCT05613088			
Solid tumors		US/EU		PI/II
Study 201	NCT04300556			

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)		JP/US/EU		PIb/II
Study 201	NCT05091346			
Solid tumors (in combination with lenvatinib)		JP/US/EU		PIb/II
Study 102	NCT04008797			
Solid tumors		JP/US/EU		PI

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

Development Code: **E7130**				Collaboration (Harvard University)
Indications / Drug class: Anticancer agent				Injection
Solid tumors		JP		PI

Development Code: **E7766**				In-house
Indications / Drug class: Anticancer agent				Injection
Solid tumors		US/EU		PIb

◎ Eisai agreed with Bliss Biopharmaceutical Co., Ltd. ("BlissBio") that BlissBio will be solely responsible for future global development and commercialization of BB-1701, and decided not to exercise the option rights for a strategic collaboration. Therefore, BB-1701 was removed from this list.

(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. A Phase IIb/III clinical study was conducted in Sudan by DNDi and the Mycetoma Research Center of the University of Khartoum, Sudan. Currently, preparation for regulatory filing to the regulatory authorities (National Medicines and Poisons Board) in Sudan is underway. 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)	JP		PIII
Study CT3	jRCT2031230142		

Development Code: **AJM347**			In-house
Indications / Drug class: —			Oral
Inflammatory bowel disease (Joint development conducted by EA Pharma with Ensho Therapeutics, Inc)	EU		PI

Development Code: **EA1080**			In-house
Indications / Drug class: —			Oral
Inflammatory bowel disease (Joint development conducted by EA Pharma with Ensho Therapeutics, Inc)	EU		PI

Development Code: **EA3571**			In-house
Indications / Drug class: —			Oral
Metabolic dysfunction-associated steatohepatitis (Development conducted by EA Pharma)	JP		PI

(5) Other

Development Code: **FYU-981** Generic Name: **dotinurad** Product Name: **URECE**				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 with FUJI YAKUHIN concerning the development and distribution in China in February 2020, and in five ASEAN countries in August 2021.				
Gout, hyperuricemia		Asia (Thailand)	○	Approval (September 2024)
Gout		CH	◎	Approval (December 2024)
Study 301	NCT05007392			

Development Code: **E6742**				In-house
Indications / Drug class: Treatment for Systemic lupus erythematosus (SLE) / 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 SLE. 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.				
SLE		JP		PI/II
Study 101	NCT05278663			

Development Code: **E8001**				In-house
Indications / Drug class: —				Injection
Rejection reaction associated with organ transplantation		JP		PI