

14. Major R&D Pipeline

1) R&D Pipeline (Japan, United States, Europe)

R&D Pipeline List

Product Name/Research Code	Additional Indication, etc.*	Development Stage	Therapeutic Area
New Approval			
<input type="radio"/> Halaven (Breast cancer)		(Japan, Switzerland) approved	Oncology and Supportive Care
<input checked="" type="radio"/> Lunesta (Insomnia)		(Japan) approved	Neurology
<input type="radio"/> Humira (Juvenile idiopathic arthritis)	AI	(Japan) approved	Vascular and Immunological Reaction
<input type="radio"/> Vasolan (Pediatric dosage and administration)	ADA	(Japan) approved	Vascular and Immunological Reaction
<input type="radio"/> Warfarin (Granules pediatric dosage and administration)	ADA	(Japan) approved	Vascular and Immunological Reaction
<input type="radio"/> Warfarin (Granules)	AF	(Japan) approved	Vascular and Immunological Reaction
<input type="radio"/> Inovelon (Oral suspension)	AF	(EU) approved	Neurology
Submitted/Preparing for Submission			
<input checked="" type="radio"/> E2007 (Partial-onset epilepsy)		(US/EU) submitted	Neurology
E7040 (Transcatheter arterial embolization (TAE) in patients with hepatocellular carcinoma (HCC))		(Japan) submitted	Oncology and Supportive Care
<input type="radio"/> T-614 (Rheumatoid arthritis)		(Japan) submitted	Vascular and Immunological Reaction
<input type="radio"/> ZONEGRAN (Monotherapy for epilepsy)	AI	(EU) submitted	Neurology
<input type="radio"/> Dacogen (Acute myeloid leukemia (AML))	AI	(US) submitted	Oncology and Supportive Care
<input type="radio"/> Humira (Inhibition of structural damage of joints)	AI	(Japan) submitted	Vascular and Immunological Reaction
<input checked="" type="radio"/> Humira (Ulcerative colitis)	AI	(Japan) submitted	Vascular and Immunological Reaction
<input type="radio"/> Aricept (Dry syrup)	AF	(Japan) submitted	Neurology
Clinical			
<input type="radio"/> E2007 (Partial-onset epilepsy)		(Japan) PIII	Neurology
<input type="radio"/> E2007 (Generalized epilepsy)		(Global) PIII	Neurology
E2080 (Lennox-Gastaut syndrome (LGS))		(Japan) PIII	Neurology
<input type="radio"/> E5501 (Idiopathic thrombocytopenic purpura (ITP))		(US/EU) PIII	Oncology and supportive care
E5564 (Severe sepsis)		(Global) PIII	Vascular and Immunological Reaction
E7080 (Thyroid cancer)		(Global) PIII	Oncology and Supportive Care
MORAb-003 (Platinum-sensitive ovarian cancer)		(Global) PIII	Oncology and Supportive Care
Halaven (Second-line treatment for breast cancer)	AI	(US/EU) PIII	Oncology and Supportive Care
<input type="radio"/> Halaven (Non small-cell lung cancer)	AI	(Global) PIII	Oncology and Supportive Care
Halaven (Sarcoma)	AI	(Global) PIII	Oncology and Supportive Care
Aricept (Lewy body dementia)	AI	(Japan) PIII	Neurology
Zonegran (Pediatric epilepsy)	AI	(EU) PIII	Neurology
<input type="radio"/> Aricept (Higher dose 23 mg tablet)	ADA, AF	(Japan) PIII	Neurology
E0302 (Amyotrophic lateral sclerosis (ALS))		(Japan) PII/III	Neurology
AS-3201 (Diabetic neuropathy)		(US/EU) PII/III	Neurology
<input type="radio"/> Pariet (Prevention of recurrence of gastric and duodenal ulcers during treatment with low-dosage aspirin)	AI	(Japan) PII/III	Gastrointestinal Disorders
E5501 (Thrombocytopenia in chronic liver disease requiring invasive surgery or diagnostic procedures)		(US) PII	Oncology and Supportive Care
<input type="radio"/> E5501 (Thrombocytopenia during antiviral therapy (both initiation and maintenance) with Interferon for Hepatitis C)		(US) PII	Oncology and Supportive Care
<input type="radio"/> E6005 (Atopic dermatitis)		(Japan) PII	Vascular and Immunological Reaction
E6201 (Psoriasis)		(US/EU) PII	Vascular and Immunological Reaction
E7080 (Endometrial cancer)		(US/EU) PII	Oncology and Supportive Care
E7080 (Melanoma)		(US/EU) PII	Oncology and Supportive Care
E7080 (Glioma)		(US) PII	Oncology and Supportive Care
<input checked="" type="radio"/> E7080 (Non-small cell lung cancer)		(US/EU) PII	Oncology and Supportive Care
E7820 (Colorectal cancer)		(US) PII	Oncology and Supportive Care
MORAb-003 (Non-small cell lung cancer)		(US/EU) PII	Oncology and Supportive Care
<input type="radio"/> MORAb-004 (Melanoma)		(US) PII	Oncology and Supportive Care
<input checked="" type="radio"/> MOBAb-004 (Colorectal cancer)		(US) PII	Oncology and Supportive Care
MORAb-009 (Mesothelioma)		(US/EU) PII	Oncology and Supportive Care
<input type="radio"/> Halaven (Sarcoma)	AI	(Japan) PII	Oncology and Supportive Care
Ontak (Melanoma)	AI	(US) PII	Oncology and Supportive Care
<input type="radio"/> Dacogen (Pediatric acute myeloid leukemia (AML))	AI	(US) PII	Oncology and Supportive Care
Pariet (Functional dyspepsia)	AI	(Japan) PII	Gastrointestinal Disorders
<input checked="" type="radio"/> E7080 (Hepatocellular carcinoma)		(Japan) PI/II	Oncology and Supportive Care

* AI: Additional Indication, ADA: Additional Dosage & Administration, AF: Additional Formulation

P: Clinical phase

• The Phase II study (U.S. and Europe) evaluating the anticancer agent Halaven as a potential treatment for the additional indication of prostate cancer was temporarily terminated so that the Group can concentrate on development of the agent for selected indications.

• Development of the following pipeline products has been terminated for the respective indications: E6014 (Phase III development in the U.S. for oral mucositis); E7850 (Phase II development in the U.S. for prostate and other types of cancer); E2007 (Phase II development in the U.S. and Europe for neuropathic pain; Phase II development in Europe for multiple sclerosis; and Phase II development in the U.S. for migraine prophylaxis); and E5555 (Phase II development in Japan, the U.S. and Europe for acute coronary syndrome and atherothrombosis)

Development progress from April 2011 onwards Development progress from January 2012 onwards

(1) Oncology and Supportive Care

Product Name: **Halaven** Research Code: **E7389** Generic name: **eribulin mesylate** (Anticancer agent/microtubule dynamics inhibitor)

Description: A synthetic analog of halichondrin B derived from the marine sponge, *Halichondria okadai*. Believed to exert an antitumor effect by arresting the cell cycle through inhibition of the growth of microtubules. Currently being investigated as a potential treatment for breast cancer and various other solid tumors. Received approval in 35 countries including the United States, Singapore, European Union (EU) member states, Switzerland, and Japan. In addition, a Phase III study investigating the potential of the agent as a second-line treatment for recurrent and metastatic breast cancer is ongoing in the United States and Europe.

Breast cancer	<input type="radio"/> Japan: approved (April 2011) <input type="radio"/> Switzerland: approved (May 2011)	Inj.
Additional Indication: Second-line treatment for breast cancer	US/EU: PIII	Inj.
Additional Indication: Non-small cell lung cancer	<input type="radio"/> Global: PIII	Inj.
Additional Indication: Sarcoma	<input type="radio"/> Global: PIII <input type="radio"/> Japan: PII	Inj.

- The Phase II study evaluating Halaven as a potential treatment for the additional indication of prostate cancer was temporarily terminated so that the Group can concentrate on development of the agent for selected indications

Research Code: **E7820** (Anticancer agent/alpha 2 integrin suppressor)

Description: An angiogenesis inhibitor that suppresses the expression of alpha 2 integrin, a vascular endothelial cell adhesion molecule.

Colorectal cancer	US: PII	Oral
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Research Code: **E7080** Generic name: **lenvatinib** (Anticancer agent/VEGF receptor tyrosine kinase inhibitor/multi-kinase inhibitor)

Description: An anti-angiogenic agent that inhibits tyrosine kinase of the VEGF receptor, VEGFR2, and a number of other types of kinase involved in angiogenesis and tumor proliferation. Currently being investigated as a potential treatment for various solid tumors.

Thyroid cancer	Global: PIII	Submission Target FY2013	Oral
Endometrial cancer	US/EU: PII		Oral
Melanoma	US/EU: PII		Oral
Glioma	US: PII		Oral
⊙ Non-small cell lung cancer	US/EU: PII		Oral
⊙ Hepatocellular carcinoma	Japan: PI/II		Oral

Research Code: **MORAb-003** Generic name: **farletuzumab** (Anticancer agent/monoclonal antibody)

Description: A humanized IgG1 monoclonal antibody that targets folate receptor alpha (FRA). Expected to exhibit an antitumor effect against carcinomas that over-express FRA.

Platinum-sensitive ovarian cancer	Global: PIII	Submission Target FY2012	Inj.
Non-small cell lung cancer	US/EU: PII		Inj.

- In December 2012, the Phase III study that was being conducted in the United States and Europe for MORAb-003 in patients with platinum-resistant ovarian cancer was terminated based on the results of an interim analysis conducted by an Independent Data Monitoring Committee (IDMC) that determined the study was unlikely to meet its statistically defined efficacy endpoints.

Research Code: **MORAb-004** Generic name: **ontecizumab** (Anticancer agent/monoclonal antibody)

Description: A humanized IgG1 monoclonal antibody that targets Tumor Endothelial Marker 1 (TEM-1/endsialin). Expected to exhibit an antitumor effect against carcinomas that express endsialin.

<input type="radio"/> Melanoma	US: PII	Inj.
⊙ Colorectal cancer	US: PII	Inj.

Research Code: **MORAb-009** Generic name: **amatuximab** (Anticancer agent/monoclonal antibody)

Description: A chimeric IgG1 monoclonal antibody that blocks the function of mesothelin. Expected to exhibit an antitumor effect against carcinomas that express mesothelin.

Mesothelioma

US/EU: PII

Inj.

Product Name: **Dacogen** Research Code: **E7373** Generic name: **decitabine** (DNA methylation inhibitor)

Description: Induces cell differentiation by inhibiting DNA methylation. Currently approved in the United States for the treatment of myelodysplastic syndromes (MDS). In March 2012, Eisai received a Complete Response Letter from the FDA concerning the supplemental New Drug Application (sNDA) for Dacogen in acute myeloid leukemia. The Company is currently considering next steps.

Additional Indication: Acute myeloid leukemia (AML) US: submitted (May 2011), accepted (July 2011) Inj.

Additional Indication : Pediatric acute myeloid leukemia (AML) US: PII Inj.

Research Code: **E5501/AKR-501** Generic name: **avatrombopag** (Treatment for thrombocytopenia/thrombopoietin receptor agonist)

Description: A novel, oral thrombopoietin receptor agonist that stimulates platelet production. Expected to exhibit effects against conditions that are associated with thrombocytopenia.

Idiopathic thrombocytopenic purpura (ITP) US/EU: PIII Submission Target FY2013 Oral

Thrombocytopenia in chronic liver disease requiring invasive surgery or diagnostic procedures

US: PII

Oral

Thrombocytopenia during antiviral therapy (both initiation and maintenance) with Interferon for Hepatitis C

US: PII

Oral

Product Name: **Ontak** Research Code: **E7272** Generic name: **denileukin diftitox** (Anticancer agent/interleukin-2 diphtheria toxin fusion protein)

Description: A fusion protein that combines the interleukin-2 (IL-2) receptor binding domain with diphtheria toxins. It specifically binds to IL-2 receptors on the cell surface, causing diphtheria toxins that have entered cells to inhibit protein synthesis. The agent is already approved in the United States as a treatment for CD25 (a component of the IL-2 receptor) positive cutaneous T-cell lymphoma.

Additional Indication: Melanoma

US: PII

Inj.

• During the second quarter of Fiscal 2011 (fiscal year ending March 1, 2012), a Phase III study of Ontak for the additional indication of peripheral T-cell lymphoma (PTCL) was terminated to prioritize development of a new improved formulation.

Research Code: **E7040** (Embolic bead/medical device)

Description: A hydrophilic microspherical particle produced from a polyvinyl alcohol polymer. An embolic bead that is injected through a catheter to physically and selectively embolize targeted blood vessels. Microscopic and uniformly spherical in shape, it allows for precise embolization of targeted vessels based on vascular diameter and tumor size.

Transcatheter arterial embolization (TAE) in patients with hepatocellular carcinoma (HCC)

Japan: submitted (December 2010)

Embolic Agent

*The Group decided to terminate development of the oral mucositis treatment E6014 (Phase III development in the U.S. for oral mucositis) and the anticancer agent E7850 (Phase II development in the U.S. for prostate cancer) for the respective indications.

(2) Neurology

Product Name: **Aricept** Research Code: **E2020** Generic name: **donepezil** (Anti-Alzheimer's agent)

Description: Increases levels of the neurotransmitter acetylcholine in the brain by inhibiting its breakdown by the enzyme acetylcholinesterase, thereby slowing the overall progression of symptoms associated with Alzheimer's disease (AD). Currently approved in more than 90 countries around the world for the treatment of mild to moderate AD. It is also approved as a treatment for patients with severe AD in numerous countries including the United States, Canada, Japan, and some Asian and South/Central American countries.

Additional Formulation: Dry Syrup Japan: submitted (December 2011) Oral

Additional Indication: Lewy body dementia

Japan: PIII

Submission Target FY2012

Oral

Additional Dosage & Administration, Formulation: Higher dose 23 mg tablet

Japan: PIII

Oral

Development progress from April 2011 onwards

Development progress from January 2012 onwards

Research Code: **E2007** Generic name: **perampanel** (AMPA receptor antagonist)

Description: A selective antagonist against the AMPA receptor (a glutamate receptor subtype), it is expected to be effective in the treatment of various neurological disorders. Clinical studies investigating the potential of the agent as an adjunctive treatment for partial-onset seizures as well as a treatment for generalized seizures in patients with epilepsy are currently underway. Further studies are also planned to evaluate perampanel as a monotherapy for partial-onset seizures and as a treatment for other forms of epilepsy such as Lennox-Gastaut syndrome (LGS).

Partial-onset epilepsy	<input type="radio"/> EU: submitted (May 2011), accepted (June 2011) <input checked="" type="radio"/> US: submitted (December 2011), accepted (March 2012) <input type="radio"/> Japan: PIII	Oral
Generalized epilepsy	<input type="radio"/> Global: PIII	Oral

- The Group decided to terminate development of perampanel for neuropathic pain (Phase II development in the U.S. and Europe), multiple sclerosis (Phase II development in the Europe) and migraine prophylaxis (Phase II development in the U.S.) to concentrate on developing the agent for epileptic disorders.

Research Code: **AS-3201** Generic name: **ranirestat** (Treatment for diabetic complications/aldose reductase inhibitor)

Description: An aldose reductase inhibitor that is believed to reduce intracellular accumulation of sorbitol. Currently being investigated as a potential treatment for diabetic neuropathy, one of the most common diabetic complications.

Diabetic neuropathy	US/EU: PII/III	Oral
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Product Name: **Zonegran** Research Code: **E2090** Generic name: **zonisamide** (Anti-epileptic agent)

Description: Believed to exhibit a broad anti-epileptic spectrum and is well-tolerated. Currently indicated as an adjunctive therapy in the treatment of patients with partial-onset seizures.

<input type="radio"/> Additional Indication: Monotherapy for epilepsy	EU: submitted (June 2011), accepted (July 2011)	Oral
Additional Indication: Pediatric epilepsy	EU: PIII	Submission Target FY2012
		Oral

Research Code: **E0302** Generic name: **mecobalamin** (Amyotrophic lateral sclerosis)

Description: A mecobalamin (vitamin B₁₂ coenzyme) formulation. Restores damaged peripheral nerves and is widely used for the treatment of peripheral neuropathy. Currently being investigated as a potential treatment for amyotrophic lateral sclerosis (ALS).

Amyotrophic lateral sclerosis (ALS)	Japan: PII/III	Inj.
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Product Name: **Lunesta** Research Code: **SEP-190** Generic name: **eszopiclone** (Treatment for insomnia/GABA_A receptor agonist)

Description: A non-benzodiazepine GABA_A receptor agonist that is believed to enhance GABA activity while exerting hypnotic and sedative effects. Results from clinical studies conducted in both Japan and overseas demonstrated that the agent is effective in treating those patients who have trouble falling asleep or wake up often during the night, two major symptoms of insomnia. Moreover, a distinctive feature of the agent is that patients do not experience clinically problematic issues such as dependency or carry-over effects, or develop a tolerance (experience diminished efficacy) with long-term use. Currently approved for the treatment of insomnia.

<input checked="" type="radio"/> Insomnia	Japan: approved (January 2012)	Oral
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Product Name: **Inovelon(EU)/Banzel(US)** Research Code: **E2080** Generic name: **rufinamide** (Anti-epileptic agent)

Description: A triazole derivative that is structurally unrelated to currently marketed antiepileptic drugs (AEDs). It is believed to regulate the activity of sodium channels in the brain that carry excessive electrical charges. The agent is approved in Europe (under the brand name Inovelon) and the United States (under the brand name Banzel) as an adjunctive therapy for Lennox-Gastaut syndrome (LGS).

<input type="radio"/> Additional Formulation: Oral suspension	EU: approved (November 2011)	Oral
Adjunctive therapy for LGS	Japan: PIII	Submission Target FY2012
		Oral

(3) Vascular and Immunological Reaction

Product Name: **Humira** Research Code: **D2E7** Generic name: **adalimumab** (Fully human anti-TNF-alpha monoclonal antibody)

Description: A fully human anti-TNF-alpha monoclonal antibody that neutralizes the activity of tumor necrosis factor alpha (TNF-alpha), a type of cytokine that plays a central role in inflammatory reactions in patients with autoimmune diseases. Approved in Japan for the treatment of rheumatoid arthritis, psoriasis, Crohn's disease, ankylosing spondylitis, and juvenile idiopathic arthritis.

<input type="radio"/>	Additional Indication: Juvenile idiopathic arthritis	Japan: approved (July 2011)	Inj.
<input type="radio"/>	Additional Indication: Inhibition of structural damage of joints	Japan: submitted (September 2011)	Inj.
<input checked="" type="radio"/>	Additional Indication: Ulcerative colitis	Japan: submitted (March 2012)	Inj.

Research Code: **E5564** Generic name: **eritoran** (Severe sepsis/endotoxin antagonist)

Description: Exhibits endotoxin antagonist effects that inhibit isolation of inflammatory cytokines. Suppresses various clinical conditions caused by endotoxins.

Severe sepsis	Global: PIII	Inj.
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Research Code: **E6201** (Novel MEK-1/MEKK-1 kinase inhibitor)

Description: A novel MEK-1/MEKK-1 kinase inhibitor. Expected to inhibit inflammatory cellular signaling as well as overgrowth of epidermal cells in patients with psoriasis.

Psoriasis	US/EU: PII	Topical
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Research Code: **E6005** (Phosphodiesterase 4 inhibitor)

Description: Inhibits the action of phosphodiesterase 4, a cyclic AMP-degrading enzyme that acts as an intracellular messenger. It is expected to be effective as a treatment to suppress the various symptoms associated with atopic disease.

<input type="radio"/>	Atopic dermatitis	Japan: PII	Topical
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Research Code: **T-614** Generic name: **iguratimod** (Rheumatoid arthritis)

Description: Suppresses inflammatory cytokine and immunoglobulin production. Expected to exhibit effects against rheumatoid arthritis.

<input type="radio"/>	Rheumatoid arthritis	Japan: submitted (August 2011)	Oral
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Product Name: **Warfarin** Generic name: **warfarin potassium** (Oral anticoagulant)

Description: Exhibits anticoagulant effects by antagonizing vitamin K and inhibiting the production of blood clotting factors. Widely used for the treatment and prevention of thromboembolisms in adults. An application seeking approval for pediatric use of the new granules formulation was approved in Japan after the Japanese Ministry of Health, Labour and Welfare' Study Group on Unapproved and Off Label Drugs of High Medical Need designated the agent as a drug that can provide significant clinical benefits to pediatric patients.

<input type="radio"/>	Additional Formulation: Granules	Japan: approved (July 2011)	Oral
<input type="radio"/>	Additional Dosage & Administration: Granules pediatric dosage & administration	Japan: approved (October 2011)	Oral

Product Name: **Vasolan** Generic name: **verapamil** (Calcium channel blocking anti-arrhythmic agent)

Description: Slows cardiac excitation and regulates tachyarrhythmia by blocking calcium channels. Also exhibits coronary dilating and peripheral vasodilator action and is widely used as a treatment for ischemic heart disease and tachyarrhythmia in adults. An application seeking approval for pediatric dosage and administration was approved in Japan after the Japanese Ministry of Health, Labour and Welfare's Study Group on Unapproved and Off Label Drugs of High Medical Need designated the agent as a drug that can provide significant clinical benefits to pediatric patients.

<input type="radio"/>	Additional Dosage & Administration: Pediatric dosage & administration	Japan: approved (May 2011)	Oral Inj.
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* The Group terminated development of the thrombin receptor antagonist E5555, which was under Phase II development in Japan, the U.S. and Europe for acute coronary syndrome and atherothrombosis.

(4) Gastrointestinal Disorders

Product Name: **Pariet/Aciphex** Research Code: **E3810** Generic name: **rabeprazole** (Proton pump inhibitor)

Description: A proton pump inhibitor approved for the treatment of gastric and duodenal ulcers, reflux esophagitis and eradication of *Helicobacter pylori* infections, etc.

○	Additional Indication: Prevention of recurrence of gastric and duodenal ulcers during treatment with low-dosage aspirin	Japan: PII/III	Oral
	Additional Indication: Functional dyspepsia	Japan: PII	Oral

- In September 2011, Eisai decided to terminate the development of the proton pump inhibitor Pariet/Aciphex extended-release 50mg formulation in the United States and Europe, and subsequently withdrew the marketing authorization applications it had submitted to the regulatory authorities in the two regions.

2) R&D Pipeline (Asia)

Product Name: **Glufast** Generic name: **mitiglinide** (Rapid-acting insulin secretagogue agent)

Description: By selectively binding to sulfonylurea receptors in pancreatic beta cells, it accelerates insulin release, resulting in the reduction of blood glucose. (In-licensed from Kissei Pharmaceutical Co., Ltd.)

	currently marketed: ○Thailand		
Type 2 diabetes mellitus	approved: Philippines		Oral
	submitted: Indonesia		

- The development of Glufast was terminated in Malaysia following careful consideration by Eisai after the Malaysian regulatory authorities failed to approve the drug.

Product Name: **Gasmotin** Generic name: **mosapride** (Gastroprokinetic agent)

Description: A selective serotonin 5-HT₄ receptor agonist that exhibits gastroprokinetic and gastric evacuation effects by enhancing acetylcholine release. (In-licensed from Dainippon Sumitomo Pharma Co., Ltd.)

Gastroprokinetic agent	currently marketed: Thailand, ○Philippines, ○Vietnam		Oral
	submitted: Malaysia, Myanmar, Laos, Cambodia		

Generic name: **clevudine** (Anti-chronic hepatitis B agent)

Description: An antiviral drug that exerts an anti-HBV effect by inhibiting DNA polymerase. (In-licensed from Bukwang Pharmaceutical Co., Ltd.)

Chronic hepatitis B	currently marketed: Philippines (Product Name: Revovir)		Oral
	submitted: Indonesia, Thailand, ○Vietnam, India, China		

Product Name: **Urief** Generic name: **silodosin** (Treatment for dysuria associated with benign prostatic hyperplasia)

Description: A selective alpha 1A-adrenergic receptor antagonist. By selectively blocking alpha 1A-adrenergic receptors that are found primarily in the prostate gland, it reduces urethral resistance by relaxing certain prostate gland muscles, thereby improving dysuria associated with benign prostatic hyperplasia (BPH). (In-licensed from Kissei Pharmaceutical Co., Ltd.)

Dysuria associated with BPH	submitted: Singapore, ○Malaysia, ○Thailand		Oral
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Generic name: **cinitapride** (Gastroprokinetic agent)

Description: By stimulating 5-HT₂ and 5-HT₄ receptors found in the gastrointestinal tract, the agent increases acetylcholine release and improves upper gastrointestinal motility. Its antidopaminergic effects also help stimulate the release of acetylcholine by blocking dopamine receptors, thereby improving upper gastrointestinal function. (In-licensed from Almirall, S.A.)

Functional dyspepsia	submitted: ○China		Oral
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