

Pharmaceutical Segment

Pharmaceutical Segment Overview

The Otsuka Group's pharmaceutical segment comprises four main businesses: pharmaceuticals, parenteral nutrition, diagnostics, and medical devices. In the core business of pharmaceuticals, Otsuka Pharmaceutical, which operates globally and focuses on the central nervous system and oncology, and Taiho Pharmaceutical, a leading company in the field of cancer treatments, are both involved in research and development, production and sales, with an emphasis on those diseases with high medical care needs. The parenteral nutrition business is conducted through Otsuka Pharmaceutical Factory, which continually strives to provide a steady supply of high-quality products and has the largest share of the domestic intravenous solution and clinical nutrition markets. The diagnostics and medical devices businesses are recognized as vital for future growth in our aim to provide comprehensive health care services that span from diagnostics to therapeutic treatments.



Pharmaceuticals	Otsuka Pharmaceutical	Highest priority areas	Central nervous system	Oncology
		Priority areas	Cardiovascular area Infectious disease	Gastroenterology Ophthalmology
	Taiho Pharmaceutical	Oncology	Allergies	Urology
Parenteral nutrition	Otsuka Pharmaceutical Factory	Intravenous solutions	Enteral nutrition	Contract manufacturing
Diagnostics	Otsuka Pharmaceutical	Influenza diagnostic agents	Helicobacter pylori test kit	Other products
Medical devices	JIMRO	Development of therapeutic systems for treating refractory diseases		
	Other affiliates	Manufacturing, sales and export of medical devices		

Marketing activities

Pharmaceutical Business

Otsuka Pharmaceutical and Taiho Pharmaceutical operate globally, primarily in the pharmaceutical business.



Core product groups

Brand name (generic name)	Therapeutic category	Major indications	Company
ABILIFY (aripiprazole)	Antipsychotic	Schizophrenia	Otsuka Pharmaceutical
Pletaal/Pletal (cilostazol)	Antiplatelet agent	Improvement of ischemic symptoms including ulcers, pain and coldness associated with chronic arterial obstruction, prevention of recurrent cerebral infarction	Otsuka Pharmaceutical
Mucosta (rebamipide)	Antigastritis and antigastric ulcer agent	Gastritis, gastric ulcers	Otsuka Pharmaceutical
TS-1 (tegafur, gimeracil, oteracil potassium)	Antimetabolite	Gastric cancer, head and neck cancer, colorectal cancer, non-small cell lung cancer, pancreatic cancer, bile duct cancer, inoperable or recurrent breast cancer	Taiho Pharmaceutical
UFT (tegafur, uracil)	Antimetabolite	Gastric cancer, head and neck cancer, colorectal cancer, liver cancer, pancreatic cancer, cancer of the gallbladder/bile duct, lung cancer, breast cancer, bladder cancer, prostate cancer, cervical cancer	Taiho Pharmaceutical
Uzel (calcium folinate)	Reduced folic acid formulation	Folinate and tegafur/uracil combination therapy enhances efficacy of tegafur-uracil in treating colorectal cancer	Taiho Pharmaceutical



[Central nervous system]

Sales of Otsuka Pharmaceutical's atypical antipsychotic *ABILIFY* have shown solid growth since the product was released in the United States in 2002. *ABILIFY* has been approved in more than 70 countries and FY2009 global sales totaled ¥374.5 billion (a 26% increase from FY2008). *ABILIFY* was developed as an antipsychotic with a new mode of action and its efficacy and superior stability mean that patients can continue using the drug for long periods of time. *ABILIFY* has therefore gained attention for its usefulness in preventing relapses and allowing patients to return to a fulfilling life. The contract with Bristol-Myers Squibb for the development and commercialization of *ABILIFY* was extended in April 2009 and further global growth is expected.

[Oncology]

Since releasing *Futraful* in 1974, Taiho Pharmaceutical has been a pioneer in the field of oral anticancer agents with products including *UFT* and *TS-1 Capsules*. Utilizing its many years of experience developing fluoropyrimidine anticancer agents, the company has continuously presented useful clinical data on gastric cancer, breast cancer, lung cancer, colorectal cancer, and other types of cancerous tumor. *TS-1 Capsules* in particular has become standard chemotherapy for gastric cancer, making it a core drug even in the age of polypharmacy.

In Japan, sales of the serotonin 5-HT₃ receptor antagonist antiemetic agent *Aloxi* (approved in January 2010) began in April 2010. *Aloxi* has been approved in 63 countries and is the medication recommended by the National Comprehensive Cancer Network (NCCN)'s Antiemesis Guidelines. Sales of the antineoplastic agent *Abraxane* (approved in July 2010 for breast cancer) also commenced in Japan in September 2010. *Abraxane* has been approved for breast cancer treatment in 41 countries including the U.S. and Europe.

Otsuka Pharmaceutical has seen solid U.S. sales of *IV Busulfex*, a conditioning regimen prior to bone marrow transplantation surgery to treat chronic myeloid leukemia. In addition, Otsuka and Bristol-Myers Squibb entered into an oncology collaboration for the two products, *SPRYCEL* and *IXEMPRA*. Co-promotion activities for *SPRYCEL* will start from 2010 in the U.S. and Japan, and 2012 in Europe.

[Cardiovascular]

Otsuka Pharmaceutical's antiplatelet agent *Pletaal* is marketed in 25 countries including Japan, the U.S. and Europe. The prescription of *Pletaal* has shown steady growth as a result of research and development to identify new possible uses for the drug and efforts to proactively provide information. The selective V₂-vasopressin antagonist *SAMSCA* (tolvaptan) received U.S. Food and Drug Administration (FDA) approval in May 2009 as an effective treatment for hyponatremia, including in patients with heart failure, cirrhosis, and the syndrome of inappropriate antidiuretic hormone (SIADH). The European Commission (EC) also approved *SAMSCA* in August 2009 for indication of hyponatremia resulting from SIADH, and sales are showing steady growth.

[Gastroenterology]

Strong sales of Otsuka Pharmaceutical's anti-gastritis and antigastric ulcer agent *Mucosta* continued due to the ongoing validation and proactive provision of data supporting the product's efficacy. Taiho's H₂-receptor antagonist *PROTECADIN* received approval in March 2010 for the additional indication of reflux esophagitis.

[Ophthalmology]

Sales of *Mikelan LA*, a new formulation of Otsuka Pharmaceutical's *Mikelan* ophthalmic solution for treatment of glaucoma and ocular hypertension, were boosted by the new permission granted for long-term prescriptions. Sales of the broad-spectrum antibacterial ophthalmic solution *OZEX* Ophthalmic Solution, which has now also been approved for treatment in children, remained solid based on a more precise description in the drug's unique profile.

[Allergies, urology]

Taiho Pharmaceutical's antiallergenic drug *IPD* recorded solid sales. In December 2009, the urinary incontinence/frequency urination agent *BUP-4* received additional approval for the indication of overactive bladder. In addition, Taiho terminated a co-marketing contract for *BUP-4* with UCB Japan and began exclusive sales in August 2010. In July 2009, Taiho and GlaxoSmithKline K.K. entered into a co-promotion arrangement for the benign prostatic hyperplasia treatment agent *Avo/ve*.



Parenteral Nutrition (clinical nutrition) Business

Core product groups

Brand name	Category	Company
NEOPAREN (No. 1 and No. 2 Injection)	Carbohydrate, electrolyte, amino acid and multivitamin injection for central vein infusion	Otsuka Pharmaceutical Factory
B-FLUID for IV infusion	Amino acid and glucose injection with electrolytes and vitamin B1	Otsuka Pharmaceutical Factory
RACOL	Enteral nutrition formula (for either enteral or oral administration)	Otsuka Pharmaceutical Factory

The parenteral nutrition business is carried out primarily by Otsuka Pharmaceutical Factory, which has contributed to quality parenteral management by developing a full lineup of products to meet the needs of physicians, based on its advanced sterilization technology. These products include Japan's first plastic bottle pack and the world's first aseptically prepared antibiotic kit.

In September 2009, Otsuka Pharmaceutical Factory released *ELNEOPA No. 1 Injection* and *ELNEOPA No. 2 Injection*, the world's first high-calorie total parenteral nutrition (TPN) solutions formulated with five trace elements, containing glucose, electrolytes, amino acids, multi-vitamins and trace elements. *HINE Jelly AQUA*, which adds hydration, was added to the *HINE* and *HINE Jelly* lineup of concentrated liquid nutrition products in November 2009, further promoting nutritional management that corresponds to the patient's condition.



Diagnostics Business

Core product groups

Brand name	Category	Company
UBIT	Diagnostic agent for H.pylori	Otsuka Pharmaceutical
Quick Navi-Flu	Influenza virus test kit	Otsuka Pharmaceutical
Uropaper III 'Eiken'	Urinalysis test strip	Otsuka Pharmaceutical

The diagnostics business focuses on the development and sales of intracorporeal and extracorporeal diagnostic agents for clinical use and research-use reagents. In the field of infectious diseases, sales of Otsuka Pharmaceutical's influenza virus test kit *Quick Navi-Flu*, an agent for in vitro diagnosis, have shown significant growth in part due to influenza epidemics.



Medical Devices Business

Core product groups

Brand name	Category	Company
Adacolumn	Apheresis device for leukocyte adsorption	JIMRO
Firebird	Drug-eluting stent	MicroPort Medical

JIMRO is the primary company for Otsuka Group medical devices. Using JIMRO's *Adacolumn*, an apheresis device for leukocyte adsorption that helps in the treatment of intractable inflammatory bowel disorder, a new granulocyte removal treatment method that absorbs unusually active leukocytes from the blood has been established. In addition to the original approval for ulcerative colitis, approval was received in January 2009 for the treatment of Crohn's disease under health insurance coverage.

Shanghai-based MicroPort Medical is a market leader in China in drug-eluting stents (DES) and is steadily expanding, primarily in China but also in the rest of Asia.



Research and Development Activities



Otsuka Pharmaceutical Co., Ltd.

Driven by *JISSHO* “proof through execution” and Creativity, we create useful medicines for patients.

What is “uniquely Otsuka” in Otsuka’s research and development?

Under the corporate philosophy, “Otsuka-people creating new products for better health worldwide,” that is posted all around our research laboratories, Otsuka Pharmaceutical’s motto is based in originality, not imitation. We aim for originality. That is the starting point for Otsuka’s research and development.

Another aspect that may be “uniquely Otsuka” is that we obtain many insights into drug development from actual medical needs. Research staff meet directly with doctors around the world to get a first-hand feel for whether their research is actually useful in medical care. Making the effort to gain this first-hand experience is important.

What are some representative examples of Otsuka’s unique drug development?

ABILIFY, in the central nervous system (CNS) area of focus, is one. Most antipsychotics to date have been based on suppression of dopamine, but we took a new idea and, through trial and error, created a partial agonist based on partial dopamin activation. The idea is to control the amount of dopamine. On another occasion, a professor at a local university spoke of the need for “a diuretic that increases the excretion of free water only,” and this led to the creation of *SAMSCA*, which was released in Europe and the U.S. last year. Both of these are examples of researchers’ efforts to fulfill unmet medical needs.

What are the special features of Otsuka Pharmaceutical’s research and development?

Each researcher takes the initiative in carrying out research and pursuing unique themes of investigation. At the annual Kawauchi Conference, an internal research seminar, researchers from around the world gather in Tokushima, Otsuka’s birthplace, bringing unique ideas and research themes. Recently, many of the presentations have been in the fields of the CNS and oncology. Although speed is required in the clinical area, in

the research area we emphasize originality.

Many of our research successes have been based on carbostyryl. *Mikelan* was the starting point and led to major success with *Meptin*, *Pletaal*, *Mucosta* and *ABILIFY*. We have also created new drugs like *SAMSCA* which do not have a carbostyryl structure. Our research methods are not at all standardized. We carry out research using the latest technologies and give importance to the various reactions that take place in living organisms.

Otsuka’s progress in oncology

Research is progressing in small-molecular cancer treatments at the Fujii Memorial Research Institute and in peptides and immunology systems at the Microbiological Research Institute. Our anticancer agents, developed at the Fujii Memorial Research Institute, are currently undergoing Phase I testing in the U.S. and Asia. A therapeutic cancer vaccine in-licensed from OncoTherapy Science Inc. is at the clinical trial stage in Japan, and in clinical diagnostic agents, we have released for sale the *WT1 mRNA Assay Kit*, a diagnostic and prognostic agent for acute myeloid leukemia and myelodysplastic syndromes. We are also aggressively pursuing research in antibody drugs.

“10th Research Center” (Drug Discovery Research Building) commencing operations

Medical care itself in recent years has tended to focus on individual internal organs and the area of research has also failed to look at the patient’s overall condition. In order to eliminate walls around researchers in different fields, the biological system research building and the synthesis research building in Tokushima were consolidated in April 2010 with the establishment of the 10th Research Center. This promotes communication in the workplace that crosses organizational divisions. Through ongoing discussions among researchers engaged in studies of the CNS, the cardiovascular system, gastroenterology, and inflammation, insights can be offered across areas of specialization, leading to the creation of groundbreaking new drugs which patients anxiously await.





Taiho Pharmaceutical Co., Ltd.

We aim to create innovative new drugs as experts in cancer treatment.

Taiho's activities in the field of anticancer agents

Taiho Pharmaceutical focuses its research and development activities on three areas: oncology, its foremost field of activity, immunology/allergy and urology.

The company is well recognized among medical professionals in Japan, particularly in the area of cancer, and has gained significant trust and market share as a leading company in the field of antimetabolites. Taiho Pharmaceutical began the development of anticancer agents in 1969 with the in-licensing of the *FT-207* (later called *Futraful*) from the former Soviet Union. As an anticancer agent available for oral use, it made outpatient treatment possible, significantly reducing the burden on patients compared with the intravenous drip infusion available at the time. The company has continued to grow mainly due to successful launching of the next generation of anticancer agents, *UFT* and *TS-1*. Research and development is currently focused on the effective clinical application of *UFT* and *TS-1* employing recent advances in pharmacogenetics and on their successor drugs; for instance, molecular-targeted drugs that target tumor cell growth at the molecular level, as well as supportive drugs to control side effects and palliative care. In this way, our goal is to provide total care to cancer patients.

Challenges in developing new anticancer agents

Progress continues in the development of anticancer agents that inhibit the enzymes needed for cancer cell proliferation, anticancer agents that inhibit DNA and RNA synthesis in cancer cells, and angiogenesis inhibitors that work to starve cancer cells by inhibiting the production of new blood vessels that would allow them to gain nutrients and oxygen.

Strength and unique features of Taiho Pharmaceutical's research and development

Over our long history, we have built strong and trustful relationships with leading physicians and medical professionals, to the point that Taiho has become synonymous with oncology. In clinical settings, multiple drugs are being used for cancer treatment, with antimetabolites playing a crucial role in

the treatment. Recently, the prescription of molecular-targeted drugs has been added for cancer treatment. Our research and development devotes equal resources to the creation of both antimetabolites and molecular-targeted drugs. Our employees, from researchers to individual medical representatives, are cancer treatment experts, and our strength lies in our ability to incorporate a wealth of data into comprehensive solutions.

Establishment of Tsukuba Research Institute

We purchased the facilities of the former Banyu Pharmaceutical's Tsukuba Research Institute in August 2009 and set it up as our new Research Laboratory for Molecular-Targeted Drugs. The fact that we consequently have acquired top-level researchers and superior basic technologies is a major benefit. We plan to consolidate the drug discovery function of our Hanno Research Center by moving it to the Tsukuba Research Institute by March 2011, thereby accelerating research through application of the newest cutting-edge technologies, including molecular design, bioinformatics, and biomarkers. Researchers with different backgrounds will work together under the banner of "Quickly delivering innovative new drugs to patients affected by cancer." This is Taiho Pharmaceutical's new strength.

Current status and future plans for overseas development

Our proprietary injectable antibiotic *Zosyn/Tazocin* is marketed in more than 90 countries by Taiho's local partner, Pfizer Inc. Concurrently, our own overseas development is on the right track. *TS-1 Capsules* has recorded strong sales in Korea, and was launched in China and Singapore last year. An application has also been filed for the indication of gastric cancer treatment in Europe, while Phase III clinical trials are in progress in the U.S.

The worldwide adoption of an effective anticancer agent developed in Japan is of great importance. In China and the rest of Asia in particular, we are able to utilize a great deal of our existing clinical database because of the similar genomic background their populations share with the Japanese. Along with Otsuka Pharmaceutical, we are working to become a global specialty pharmaceutical company, with a special focus on oncology as well as immunology/allergy and urology.

Overseas R&D Facilities



Pipeline Information (As of September 30, 2010)

Code/Brand name	Generic name	Origin	Category	Indication/Dosage form	Country/Region	Development Status
Central nervous system						
OPC-14597 (ABILIFY*)	aripiprazole	Otsuka Pharmaceutical	Dopamine partial agonist	Schizophrenia/Depot injection Manic episode associated with bipolar I disorder/Oral Adjunctive therapy for major depressive disorder/Oral Tic disorder/Oral Major depression/Combination of aripiprazole and antidepressants Tourette syndrome/Once-weekly tablet	Global JP JP Korea US US	Phase III Phase III Phase III Phase III Phase III Phase I
L059 (KEPPRA*)	levetiracetam	UCB	Anti-epileptic drug	Epilepsy (partial onset seizures)/Oral	JP	Approved Jul 2010
SPM-962 (NEUPRO*)	rotigotine	UCB	Dopamine agonist	Parkinson's disease/Patch Restless legs syndrome/Patch	JP JP	Phase III Phase III
OPC-34712		Otsuka Pharmaceutical	Dopamine partial agonist	Adjunctive therapy for major depressive disorder/Oral Schizophrenia/Oral ADHD/Oral	US Global US	Phase II Phase II Phase II
Cardiovascular						
OPC-41061 (SAMSCA*)	tolvaptan	Otsuka Pharmaceutical	Vasopressin V ₂ -receptor antagonist	Cardiac edema/Oral Autosomal dominant polycystic kidney disease/Oral Hepatic edema/Oral Hyponatremia/Oral Hepatic edema/Oral	JP Global JP China China	Filed Phase II-III** Phase III Filed Phase II
Anti-cancer and cancer-supportive care						
ABI-007(Abraxane)	paclitaxel protein-bound particle for injectable suspension	Abraxis Bioscience	Anti-cancer (nanoparticle)	Breast cancer/Injection NSCLC/Injection Gastric cancer/Injection	JP JP JP	Approved Jul 2010 Phase III Phase II
OVF	fentanyl	Cephalon	Narcotic analgesic	Cancer pain/Oral	JP	Phase III
S-1 TS-1(Korea) TS-ONE(Singapore) 愛欺万(China)		Taiho Pharmaceutical	Anti-cancer (Anti-metabolite)	Gastric cancer/Oral Gastric cancer/Oral Uterocervical cancer/Oral Hepatocellular carcinoma/Oral Pancreatic cancer, NSCLC/Oral Prostatic, renal cell cancer/Oral	US EU JP, Asia JP US JP	Phase III Filed Phase III Phase III Phase II Phase II
TSU-68		SUGEN	Anti-cancer (Molecular targeted drug)	Hepatocellular carcinoma/Oral Breast cancer/Oral	JP JP, Asia	Phase II Phase II



Hi-Z Tower, Tokushima Research Institute (Otsuka Pharmaceutical)



Tsukuba Research Institute (Taiho Pharmaceutical)



10th Research Center, Tokushima Research Institute (Otsuka Pharmaceutical)



Otsuka Shanghai Research Institute



Otsuka Maryland Medicinal Laboratories, Inc.

Code/Brand name	Generic name	Origin	Category	Indication/Dosage form	Country/Region	Development Status
Anti-cancer and cancer-supportive care						
TAS-102		Taiho Pharmaceutical	Anti-cancer (Anti-metabolite)	Colorectal cancer/Oral	JP	Phase II
TAS-106		Taiho Pharmaceutical	Anti-cancer (Anti-metabolite)	NSCLC/Injection	US, Asia	Phase II
ET-743	trabectedin	PharmaMar	Anti-cancer	Malignant soft tissue tumors/Injection	JP	Phase I/II
OTS102		OncoTherapy Science	Therapeutic cancer vaccine	Pancreatic cancer/Injection Biliary tract cancer/Injection	JP	Phase II/III
OIF	interferon α	Hayashibara Biochemical Labs	Natural interferon α	Highly advanced hepatocellular carcinoma(combination with 5-FU)/Injection	JP	Phase II
SATIVEX*	nabiximols	GW Pharmaceuticals	Cannabinoid (THC, CBD)	Cancer pain/Oral spray	US	Phase II
OPB-31121		Otsuka Pharmaceutical	Anti-cancer	Anti-cancer/Oral	US, Asia	Phase I
OPB-51602		Otsuka Pharmaceutical	Anti-cancer	Anti-cancer/Oral	US, Asia	Phase I
OTS11101		OncoTherapy Science	Therapeutic cancer vaccine	Pancreatic cancer/Injection	JP	Phase I
Other areas						
CDP870 (CIMZIA*)	certolizumab pegol	UCB	PEGylated anti-TNF α drug	Crohn's disease/Injection Rheumatoid arthritis/Injection	JP	Filing in process
OPC-12759E	rebamipide	Otsuka Pharmaceutical	Mucin-production enhancing agent	Dry eyes/Eye drops	JP	Filing in process
ACU-4429		Acucela	Visual cycle modulator	Dry AMD/Oral	US	Phase II
ONGLYZA*	saxagliptin	Bristol-Myers Squibb	DPP-IV inhibitor	Type2 diabetes mellitus/Oral	JP	Phase II/III
OPC-67683		Otsuka Pharmaceutical	Anti-tuberculosis agent	Multidrug-resistant tuberculosis/Oral	Global	Phase II
OPC-6535	tetomilast	Otsuka Pharmaceutical	Anti-inflammatory agent	Crohn's disease/Oral COPD/Oral	JP, Korea JP, US, China, Korea	Phase II/III Phase II
YP-18	piperacillin, tazobactam	Taiho Pharmaceutical	β -lactamase inhibitor-antibiotic agent	*Peritonitis, intra-abdominal abscess, liver abscess, cholecystitis, cholangitis/Injection*	JP	Phase III
TAC-201		Meiji Dairies Corporation	Recombinant peptide for immunotherapy of Japanese cedar pollinosis	Cedar pollen allergy/Injection	JP	Phase II
NST-141		Nippon Shinyaku	Anti-pruritus agent	Pruritus in atopic dermatitis/external	JP	Phase I/II
Diagnostics						
ODK-0501 (Rapirun pneumococcus)		Otsuka Pharmaceutical	Diagnostic agent of pneumococcus infection	Extracorporeal diagnostic agent	JP	Approved May 2010
ODK-0702 (Rapirun H.pylori stick)	H.pylori antibody kit	Otsuka Pharmaceutical	Diagnostic agent of H.pylori infection	Extracorporeal diagnostic agent	JP	Approved Jun 2010
ODK-0801 (WT1 mRNA assay kit)	Wilms tumor gene-1(WT1) mRNA Assay kit	Otsuka Pharmaceutical	Diagnostic and prognostic agent of MDS (myelodysplastic syndrome)	Extracorporeal diagnostic agent	JP	Filed

Note 1: In general, we disclose compounds that are in Phase II or later stage of development, although some compounds in Phase I are disclosed in the above table.

Note 2: Product names with asterisk '*' are the names used outside Japan.

Note 3: ** Preparation for additional study.





R&D Topics

[Central nervous system]

The antipsychotic *ABILIFY* was approved in Europe for the additional indication of schizophrenia (in young patients) in September 2009. *ABILIFY* also received additional approval from FDA in November 2009 for the indication of treatment of irritability associated with autistic disorder in pediatric patients (ages 6 to 17 years). *SPM-962*, which is being developed to treat Parkinson's disease and restless leg syndrome, has entered Phase III clinical trials in Japan.

[Oncology]

Otsuka Pharmaceutical concluded an agreement with Fuso Pharmaceutical Industries for the manufacture and commercialization of the therapeutic cancer vaccine *OTS102* in January 2010, which is in Phase II/III clinical trials for advanced pancreatic cancer and in Phase II trials for biliary tract cancer in Japan. The therapeutic cancer vaccine *OTS11101* has also begun Phase I trials in Japan for advanced pancreatic cancer. The novel/anticancer agent *OPB-51602* is in Phase I trials in the U.S. and Asia. Otsuka Pharmaceutical also established a global oncology collaboration with Bristol-Myers Squibb for two anticancer compounds in April 2009.

At Taiho Pharmaceutical, an application was filed in October 2009 for *TS-1* to treat gastric cancer in Europe. The Phase III trials of *TS-1* for gastric cancer in the U.S. are now in process. As new evidence for *TS-1*, the combination of *TS-1* and irinotecan has been proven to not be inferior to FOLFIRI (one of the standard therapies for secondary treatment of colorectal cancer). This result was announced at the European Society for Medical Oncology (ESMO) Congress in September 2009 and published in *The Lancet Oncology* in August 2010. In addition, the combination of *TS-1* and carboplatin has shown noninferiority to the combination of paclitaxel and carboplatin as a standard treatment for non-small cell lung cancer, and this finding was presented at the annual meeting of the American Society of Clinical Oncology (ASCO) in June 2010.

The 5-HT₃ receptor antagonist antiemetic agent *Aloxi* was approved in Japan in January 2010, and launched in April. The anticancer agent *Abraxane* was approved in Japan for breast cancer in July 2010 and sales commenced in September.

The novel antimetabolite *TAS-102* is in Phase II trials in Japan and the U.S., while the novel antineoplastic agent *TSU-68* is in Phase II trials in Japan for hepatocellular carcinoma.

[Cardiovascular]

The antiplatelet agent *Pletal* (*cilostazol*) was launched in Spain in June 2009. The results of a large-scale clinical trial in patients with cerebral infarction, Cilostazol Stroke Prevention Study II (CSPS II),

were announced at the International Stroke Conference. CSPS II showed that *Pletal* had a greater effect than aspirin in preventing relapse strokes (cerebral infarction, cerebral hemorrhage, subarachnoid hemorrhage) and serious hemorrhaging in patients with cerebral infarction. *SAMSCA*, approved for hyponatremia, was launched in the U.S. in June 2009, in Germany, the U.K., Sweden, Norway, and Finland in September 2009, and in Australia in November 2009. In Japan, an application was filed for cardiac edema in July 2009, Phase III trials for hepatic edema are currently in progress.

[Other Fields]

(Ophthalmology)

ACU-4429, which is being co-developed with Acucela Inc. for the dry form of age-related macular degeneration (AMD), began Phase II trials in the U.S. *OPC-12759E*, which is being developed to treat dry eye, is in Phase III in Japan.

(Gastroenterology)

The H₂-receptor antagonist *PROTECADIN* was approved in Japan for the additional indication of reflux esophagitis in March 2010.

(Urology)

BUP-4, a therapeutic drug for urinary incontinence/frequent urination, received additional approval in Japan in December 2009 for such indications as urgency urination, frequent urination, and urge incontinence associated with overactive bladder.

(Others)

The antiinflammatory agent *OPC-6535* began Phase II/III trials for Crohn's disease in Korea following Japan. The DPP-4 inhibitor *saxagliptin*, which is being developed as a therapeutic drug for diabetes, began Phase II/III trials in Japan.

[Clinical nutrition]

Otsuka Pharmaceutical Factory launched *ELNEOPA No. 1 Injection* and *ELNEOPA No. 2 Injection* in September 2009 in Japan.

[Diagnostics]

In the field of infectious diseases, Otsuka Pharmaceutical released the research reagent *Flu-Sw AH1pdm*, used to detect novel strains of influenza virus for survey and research purposes, in November 2009, and the in vitro diagnostic norovirus antigen kit *Quick Navi-Noro* in January 2010. An application has also been filed for the *Wilms tumor gene-1 (WT1) mRNA Assay Kit*.

