

Annual Flash Report (unaudited)

Fiscal Year ended March 31, 2009

ONO PHARMACEUTICAL CO., LTD.

May 13, 2009

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for the year ended March 31, 2009.

This Annual Flash Report 2009 (unaudited) is a summary information extracted from the financial statements announced, and the financial statements contained herein are prepared for reference only for the convenience of readers outside Japan with certain modifications and reclassifications made from the original financial statements presented in Japanese language.

Financial Highlights

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All yen amounts are rounded off to the nearest million yen.

	Millions of yen		Thousands of US\$	
	2009	2008	2009	
Net sales	¥ 136,557	¥ 145,898	\$ 1,393,439	
Net income	23,767	35,047	242,520	
Total Net assets	390,041	430,263	3,980,010	
Total assets	421,280	477,341	4,298,776	
	Yen		US\$	
Net income per common share	¥ 216.07	¥ 306.80	\$ 2.20	

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Ono Pharmaceutical Co., Ltd.
and Consolidated Subsidiaries

MESSAGE FROM THE MANAGEMENT

(1) Basic management policy

The Ono Pharmaceutical Group is "Dedicated to Man's Fight against Disease and Pain." Under this management philosophy, we are committed to fulfilling unmet medical needs. We aim to develop innovative new drugs that deliver true benefit to patients, and we strive to serve as an R&D-oriented, international pharmaceutical company specializing in defined areas.

We are highly aware of our responsibility as a pharmaceutical company dealing in medicinal drugs upon which human lives depend, and we are working to further strengthen our level of compliance to ensure that all our actions not only fully comply with all legal regulations but also are based on higher ethical standards.

In new drug research, our drug discovery activities focus on areas where we can fully benefit from the technologies and know-how we have accumulated and continue to exploit our strengths as well as on areas such as biotechnology based medicines where we can make effective use of genes we possess as our genetic assets. We are in active pursuit of the discovery and development of drugs that meet the unmet medical needs at the frontline of healthcare. The Global Discovery Research Alliance Headquarters established in our US base, Ono Pharma USA, Inc. (OPUS) in May 2008 is a powerful vehicle for promoting drug discovery alliances with bio-pharmaceutical companies in the US and Europe - plus research collaborations with universities and research institutions. Thus breakthrough drug discovery seeds and leading-edge technologies can be at our disposal to propel Ono's drug discovery research.

We are expanding our development pipeline by directing strong efforts into licensing activities including commercialization rights to new drug candidate compounds.

As for drug development, our first priority is in gaining licensing approval in Europe and the US in order to pursue approval of new drugs meeting global standard. Thus clinical development overseas is a key area of our endeavor.

For the purpose of further strengthening our global competitive position in new drug development, the Global Development Headquarters at OPUS was newly established in May 2008. Led by this US center, our international clinical development framework is ever strengthening.

Meanwhile, drug development in Japan focuses on obtaining early approval for compounds in late-stage development. We are also working on further speeding up the development speed of projects in their early development stage, filing by leveraging multinational clinical trials and global data for globally leading development programs.

The marketing division is actively working to further enhance product value of Ono's innovative pharmaceuticals through presenting its scientific data mainly at workshops and lecture meetings and through the dissemination of high-quality information that is always backed by the latest medical knowledge, aimed at fulfilling the diversifying needs of healthcare professionals.

We envision that the NHI price revision and implementation of various healthcare cost containment policies may significantly and adversely affect our business. However, we will strive to attain stable growth by launching new products and by enhancing sales of existing products.

With top priority given to the pursuit of quality assurance of our products, the manufacturing division is placing stronger emphasis on improving both its hardware, and software and on establishing an efficient production management system.

(2) Basic policy concerning dividends

Distribution of profits to all our shareholders is one of our key management policies, and we place great importance on the maintenance of stable dividends based on achievement.

The company has set 100% for total payout ratio as its target on free cash flow basis, aggregating dividends and acquisition of its own shares during the three year period from Fiscal 2007 to Fiscal 2009. The year-end dividend for Fiscal 2008 is projected to be JPY 90 per share, achieving the company's annual dividend for Fiscal 2008 of JPY 180 per share including the interim dividend of JPY 90 per share. The company has also acquired 4.63 million shares at the cost of JPY 26.5 billion during Fiscal 2008. Meanwhile the annual dividend for the next fiscal term is projected to be JPY 180 per share.

*Gyo Sagara
President, Representative
Director and CEO*

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Consolidated Financial Forecast for the Year Ending March 31,2010

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Year ending March 31,2010	
	Millions of yen	Thousands of US\$
Net sales	¥ 137,900	\$ 1,407,143
Operating income	40,500	413,265
Ordinary income	42,900	437,755
Net income	27,000	275,510
	Yen	US\$
Net income per common share	248.30	2.53

(*)The foregoing are forward-looking statements based on a number of assumptions and beliefs in light of the information currently available to management and are subject to risks and uncertainties. Actual financial results may differ materially depending on a number of economic factors, including conditions and currency exchange rate fluctuations.

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Fiscal Year ended March 31, 2009

Consolidated Balance Sheets

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest million yen.

ASSETS	Millions of yen		Thousands of US\$
	2009	2008	2009
Current assets			
Cash and bank deposits	¥ 14,103	¥ 14,256	\$ 143,908
Notes and accounts receivable	39,480	41,107	402,857
Marketable securities	102,908	130,599	1,050,082
Inventories	10,059	9,972	102,643
Deferred taxes	13,061	14,775	133,276
Others	956	1,358	9,755
Allowance for doubtful receivables	(10)	(10)	(102)
Total current assets	180,557	212,057	1,842,419
Property, plant and equipment			
Land	22,539	22,546	229,990
Buildings and structures	63,748	63,005	650,490
Machinery, equipment and others	24,796	24,844	253,020
Construction in progress	746	296	7,612
Accumulated depreciation	(61,289)	(59,429)	(625,398)
Net property, plant and equipment	50,540	51,262	515,714
Investments and other assets			
Investment securities	178,334	207,517	1,819,735
Deferred taxes	5,147	48	52,520
Intangible assets	1,033	1,042	10,541
Others	5,669	5,415	57,847
Total investments and other assets	190,183	214,022	1,940,643
Total assets	¥ 421,280	¥ 477,341	\$ 4,298,776

(Note) All amounts are rounded off to the nearest million yen.

LIABILITIES AND SHAREHOLDERS' EQUITY	Millions of yen		Thousands of US\$
	2009	2008	2009
Current liabilities			
Current portion of long-term debt	¥ 2	¥ 2	\$ 20
Notes and accounts payable	3,423	3,044	34,929
Income taxes payable	9,130	13,837	93,163
Others	12,905	12,527	131,685
Total current liabilities	25,460	29,410	259,797
Long-term liabilities			
Long-term debt, less current portion	16	17	163
Long-term payable	553	713	5,643
Liability for retirement benefits	2,240	8,668	22,857
Deferred tax liabilities	2,962	8,270	30,224
Others	8	—	82
Total long-term liabilities	5,779	17,668	58,969
Equity			
Shareholders' equity			
Common stock	17,358	17,358	177,122
Capital surplus	17,080	17,080	174,286
Retained earnings	422,565	421,279	4,311,888
Treasury stock	(63,425)	(36,861)	(647,194)
Total shareholders' equity	393,578	418,856	4,016,102
Other comprehensive income			
Unrealized gain on securities (*)	2,171	17,112	22,153
Land revaluation surplus	(8,923)	(8,919)	(91,051)
Foreign currency translation adjustments	(204)	(21)	(2,082)
Total other comprehensive income	(6,956)	8,172	(70,980)
Minority interests	3,419	3,235	34,888
Total equity	390,041	430,263	3,980,010
Total liabilities and equity	¥ 421,280	¥ 477,341	\$ 4,298,776

(*) Unrealized gain on securities classified as available for sale, net of tax

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Consolidated Statements of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest million yen.

	Millions of yen		Thousands of US\$
	2009	2008	2009
Net sales	¥ 136,557	¥ 145,898	\$ 1,393,439
Cost of sales	21,319	20,861	217,541
Gross profit	115,238	125,037	1,175,898
Selling, general and administrative expenses	71,766	72,750	732,306
Operating income	43,472	52,287	443,592
Other income (expenses)			
Interest and dividend income	3,319	3,060	33,867
Interest expenses	(1)	(1)	(10)
Other, net	(6,519)	4,167	(66,520)
	(3,201)	7,226	(32,663)
Income before income taxes and minority interests	40,271	59,513	410,929
Income taxes			
Current	16,217	24,738	165,480
Deferred	52	(697)	531
	16,269	24,041	166,011
Income before minority interests	24,002	35,472	244,918
Minority interests	(235)	(425)	(2,398)
Net income	¥ 23,767	¥ 35,047	\$ 242,520
		Yen	US\$
Amounts per common share			
Net income	¥ 216.07	¥ 306.80	\$ 2.20
Cash dividends applicable to the period	¥ 180.00	¥ 202.00	\$ 1.84

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Fiscal Year ended March 31, 2009

Consolidated Statements of Changes in Net Asset (Millions of yen)

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Year ended March 31 2009

(Note) All amounts are rounded off to the nearest million yen.

	Shareholder's Equity				
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total shareholder's equity
Balance at the end of previous period	17,358	17,080	421,279	(36,861)	418,856
Changes of items during the period					
Cash dividends paid			(22,485)		(22,485)
Net income			23,767		23,767
Purchase of treasury stock				(26,564)	(26,564)
Reversal of revaluation reserve for land			4		4
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	—	—	1,286	(26,564)	(25,278)
Balance at the end of current period	17,358	17,080	422,565	(63,425)	393,578

	Adjustments for valuation, foreign currency translation and others				Minority interests	Total net assets
	Unrealized gain on available-for-sale securities	Revaluation surplus of land	Foreign currency translation adjustments	Total Adjustments for valuation, foreign currency translation and others		
Balance at the end of previous period	17,112	(8,919)	(21)	8,172	3,235	430,263
Changes of items during the period						
Cash dividends paid						(22,485)
Net income						23,767
Purchase of treasury stock						(26,564)
Reversal of revaluation reserve for land						4
Net changes of items other than shareholder's equity during the period	(14,941)	(4)	(183)	(15,128)	184	(14,944)
Total changes of items during the period	(14,941)	(4)	(183)	(15,128)	184	(40,222)
Balance at the end of current period	2,171	(8,923)	(204)	(6,956)	3,419	390,041

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Fiscal Year ended March 31, 2009

Consolidated Statements of Changes in Net Asset

(Thousands of U.S. dollars)

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Year ended March 31 2009

(Note) All amounts are rounded off to the nearest thousands of US\$

	Shareholder's Equity				
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total shareholder's equity
Balance at the end of previous period	177,122	174,286	4,298,766	(376,133)	4,274,041
Changes of items during the period					
Cash dividends paid			(229,439)		(229,439)
Net income			242,520		242,520
Purchase of treasury stock				(271,061)	(271,061)
Reversal of revaluation reserve for land			41		41
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	—	—	13,122	(271,061)	(257,939)
Balance at the end of current period	177,122	174,286	4,311,888	(647,194)	4,016,102

	Adjustments for valuation, foreign currency translation and others				Minority interests	Total net assets
	Unrealized gain on available-for-sale securities	Revaluation surplus of land	Foreign currency translation adjustments	Total Adjustments for valuation, foreign currency translation and others		
Balance at the end of previous period	174,612	(91,010)	(214)	83,388	33,010	4,390,439
Changes of items during the period						
Cash dividends paid						(229,439)
Net income						242,520
Purchase of treasury stock						(271,061)
Reversal of revaluation reserve for land						41
Net changes of items other than shareholder's equity during the period	(152,459)	(41)	(1,868)	(154,368)	1,878	(152,490)
Total changes of items during the period	(152,459)	(41)	(1,868)	(154,368)	1,878	(410,429)
Balance at the end of current period	22,153	(91,051)	(2,082)	(70,980)	34,888	3,980,010

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Fiscal Year ended March 31, 2008

Consolidated Statements of Changes in Net Asset (Millions of yen)

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Year ended March 31 2008

(Note) All amounts are rounded off to the nearest million yen.

	Shareholder's Equity				
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total shareholder's equity
Balance at the end of previous period	17,358	17,002	404,062	(24,709)	413,713
Changes of items during the period					
Cash dividends paid			(17,157)		(17,157)
Change of scope of equity method			(673)		(673)
Net income			35,047		35,047
Purchase of treasury stock				(12,167)	(12,167)
Disposal of treasury stock		78		15	93
Net changes of items other than shareholder's equity during the period					
Total changes of items during the period	—	78	17,217	(12,152)	5,143
Balance at the end of current period	17,358	17,080	421,279	(36,861)	418,856

	Adjustments for valuation, foreign currency translation and others				Minority interests	Total net assets
	Unrealized gain on available-for-sale securities	Revaluation surplus of land	Foreign currency translation adjustments	Total Adjustments for valuation, foreign currency translation and others		
Balance at the end of previous period	39,161	(8,919)	50	30,292	2,800	446,805
Changes of items during the period						
Cash dividends paid						(17,157)
Change of scope of equity method						(673)
Net income						35,047
Purchase of treasury stock						(12,167)
Disposal of treasury stock						93
Net changes of items other than shareholder's equity during the period	(22,049)	—	(72)	(22,121)	436	(21,685)
Total changes of items during the period	(22,049)	—	(72)	(22,121)	436	(16,542)
Balance at the end of current period	17,112	(8,919)	(21)	8,172	3,235	430,263

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Fiscal Year ended March 31, 2009

Consolidated Statements of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest million yen.

	Millions of yen		Thousands of US\$
	2009	2008	2009
Cash flows from operating activities:			
Income before income taxes and minority interests	¥ 40,271	¥ 59,513	\$ 410,929
Adjustments:			
Depreciation and amortization	3,005	3,384	30,663
Decrease in allowance for doubtful receivables	(0)	(12)	(5)
Increase (decrease) in provision for retirement benefits, net	(6,436)	186	(65,673)
Contribution to retirement benefits trust	10,000	—	102,041
Interest and dividend income	(3,319)	(3,060)	(33,867)
Interest expenses	1	1	10
Gain on sales of investment securities	(1,327)	(5,393)	(13,541)
Loss on valuation of investment securities	7,808	—	79,673
Decrease in notes and accounts receivable	1,649	925	16,827
Others	204	666	2,085
Interest and dividend income received	3,560	3,302	36,327
Interest paid	(1)	(1)	(10)
Payments for contribution to retirement benefits trust	(10,000)	—	(102,041)
Income taxes paid	(20,890)	(22,989)	(213,163)
Net cash provided by operating activities	24,525	36,522	250,255
Cash flows from investing activities:			
Payments for purchases of marketable securities	(93,655)	(109,282)	(955,663)
Proceeds from sales and redemption of marketable securities	158,963	147,991	1,622,071
Payments for purchases of property, plant and equipment	(1,509)	(1,592)	(15,398)
Payments for purchases of investment securities	(34,969)	(42,441)	(356,827)
Proceeds from sales and redemption of investment securities	2,205	13,308	22,500
Other payments	(307)	(550)	(3,132)
Net cash generated from (used in) investment activities	30,728	7,434	313,551
Cash flows from financing activities:			
Repayment of current portion of long-term debt	(2)	(2)	(20)
Payments for obtaining treasury stock	(26,563)	(12,165)	(271,052)
Proceeds from sales of treasury stock	—	120	—
Cash dividends	(22,448)	(17,119)	(229,061)
Cash dividends to minority shareholders	(5)	(5)	(51)
Net cash used in financing activities	(49,018)	(29,171)	(500,184)
Foreign currency translation adjustments			
on cash and cash equivalents	(207)	(21)	(2,112)
Net increase in cash and cash equivalents	6,028	14,764	61,510
Cash and cash equivalents, beginning	47,433	32,669	484,010
Cash and cash equivalents, ending	¥ 53,461	¥ 47,433	\$ 545,520

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Notes to Consolidated Financial Statements

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

- Note 1 This Annual Flash Report 2009 (unaudited) is summary information extracted from the financial statements announced by the Company on May 13, 2009.
The financial statements announced have been prepared and stated in accordance with accounting principles generally accepted in Japan.
The financial statements and figures contained in this Annual Flash Report 2009 (unaudited) are prepared for reference only for the convenience of readers outside Japan with certain modifications and reclassifications made from the original financial statements presented in Japanese language.
- Note 2 All amounts expressed herein in millions of Japanese yen are rounded off to the nearest million yen.
- Note 3 U.S. Dollar amounts herein are given solely for the convenience of readers outside Japan and are stated, as a matter of arithmetical computation only, at the rate of Japanese yen 98 = US\$ 1, the approximate exchange rate prevailing on March 31, 2009.

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Ono Pharmaceutical Co., Ltd. and
Consolidated Subsidiaries

Sales of Major Products

Supplemental Data

For information purpose only

(Note) All amounts are rounded down to the nearest hundred million yen.

		Hundred Millions of yen	
		2009	2008
Opalmon	Circulatory system agent	¥ 381	¥ 373
Onon	Agent for bronchial asthma and allergic rhinitis	244	271
Kinedak	Agent for diabetic peripheral neuropathy	158	174
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	121	134
Onon dry syrup	Agent for pediatric bronchial asthma	89	110
Elaspol	Agent for acute lung injury associated with SIRS	50	54
Onoact	Agent for tachyarrhythmia during and post operation	27	19
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	22	5

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Ono Pharmaceutical Co., Ltd. and
Consolidated Subsidiaries

Supplemental Information

Status of Development Pipeline

as of May 13, 2009

Developments in Japan

NDA filed (New Chemical Entities):

- **Emend® Capsules (ONO-7436 / MK-0869)**
(in-licensed from Merck & Co., Inc.)

Chemotherapy-induced nausea and vomiting
[NK1 antagonist]

- **Glactiv® Tablets (ONO-5435 / MK-0431)**
(co-development with Banyu Pharmaceutical Co., Ltd.)
Type II diabetes [DPP-IV inhibitor]

Ongoing clinical studies (New Chemical Entities):

- **ONO-2540 / ENA713D (transdermal patch)**
(co-development with Novartis Pharma K.K.)
Alzheimer's disease (Phase III)
[dual inhibitor of AChE and BuChE]
- **ONO-7643 / RC-1291 (tablet)**
(in-licensed from Helsinn Therapeutics (U.S.), Inc.)
Cancer anorexia / cachexia (Phase I)
[ghrelin mimetic]
- **ONO-5334 (tablet)**
Osteoporosis (Phase I) [cathepsin K inhibitor]
- **ONO-8539 (tablet)**
Overactive bladder (Phase I) [EP 1 antagonist]
- **ONO-7847 / MK-0517 (injection)**
(in-licensed from Merck & Co., Inc.)
Chemotherapy-induced nausea and vomiting (Phase I)
[NK1 antagonist]
- **ONO-4641 (tablet)**
Multiple sclerosis (Phase I) [S1P receptor agonist]
- **ONO-4538 / MDX-1106 (injection)**
Cancer (Phase I)
[fully human anti-PD-1 antibody]
- **ONO-3849 (injection)**
(in-licensed from Progenics Pharmaceuticals, Inc.)
Opioid-induced constipation (Phase I)
[mu-opioid receptor antagonist]

Ongoing clinical studies (Additional Indications):

- **Glactiv® Tablets (ONO-5435 / MK-0431)**
(co-development with Banyu Pharmaceutical Co., Ltd.)
Type II diabetes: combination therapy [DPP-IV inhibitor]
 - with alpha-glucosidase inhibitor (Phase III)
 - with insulin (Phase III)
- **Onoact® for Injection**
Improvement of multislice CT coronary imaging ability
(Phase II) [short-acting β1 blocker]
- **Elaspol® for Injection**
Acute respiratory failure associated with community-acquired pneumonia (Phase II)
[neutrophil elastase inhibitor]

Ongoing clinical studies (New Dosage Regimen):

- **ONO-5920 / YM529 (tablet)**
(co-development with Astellas Pharma Inc.)
Osteoporosis (Phase II / III)
[bone resorption inhibitor (bisphosphonate)]

Developments abroad

Ongoing clinical studies (New Chemical Entities):

- **ONO-5334 (tablet)**
Osteoporosis (Phase II) [cathepsin K inhibitor]
- **ONO-8539 (tablet)**
Overactive bladder (Phase II) [EP 1 antagonist]
- **ONO-4538 / MDX-1106 (injection)**
(co-development with Medarex, Inc.)
Cancer (Phase I)
Hepatitis C (Phase I)
[fully human anti-PD-1 antibody]
- **ONO-4641 (tablet)**
Multiple sclerosis (Phase I) [S1P receptor agonist]

Changes from the Third Quarter Flash Report for the Fiscal Year ended March 2009 announced on February 5, 2009

(In Japan)

- Ono commenced Phase III studies of Glactiv® Tablets (ONO-5435 / MK-0431), a drug for the treatment of type II diabetes, one for combination therapy with alpha-glucosidase inhibitor and another for that with insulin.
- Ono commenced Phase I study of ONO-3849 injection, a drug for opioid-induced constipation.

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Ono Pharmaceutical Co., Ltd. and
Consolidated Subsidiaries

Supplemental Information

New Drugs in Development

Development status as of May 13, 2009

In our ongoing effort to create products that will promote the health of more people worldwide, Ono has many new drug formulations under development, including the following major drugs:

Emend® Capsules (ONO-7436 / MK-0869)

Emend® is the first neurokinin (NK) 1 antagonist in the world. The drug is effective not only for acute phase of chemotherapy-induced nausea and vomiting, but also for delayed phase (24 hours or later after start of chemotherapy) of nausea and vomiting caused by chemotherapy for which there was no effective drug.

Japan: NDA filed / Chemotherapy-induced nausea and vomiting

Overseas: Marketed (Merck & Co., Inc.)

Glactiv® Tablets (ONO-5435 / MK-0431)

Glactiv®, a dipeptidyl-peptidase (DPP) IV inhibitor, is a new class of drug for type II diabetes and is expected to be useful for control of postprandial hyperglycemia with low risks of hypoglycemia and/or weight gain in type II diabetes patients.

Japan: NDA filed / Type II diabetes (co-development with Banyu Pharmaceutical Co., Ltd.)

Japan: Phase III / Type II diabetes: combination therapy (co-development with Banyu Pharmaceutical Co., Ltd.)

- with alpha-glucosidase inhibitor
- with insulin

Overseas: Marketed (Merck & Co., Inc.)

ONO-2540 / ENA713D (transdermal patch)

ONO-2540 or rivastigmine patch is a drug for the treatment of Alzheimer's disease with an inhibitory action on both acetylcholinesterase (AChE) and butyrylcholinesterase (BuChE). The drug inhibits not only AChE which is known as an enzyme deeply involved in Alzheimer's disease, but also BuChE which reportedly increases as the disease progresses. Therefore, the drug is expected to have an effect in patients who do not respond to existing drugs. The rivastigmine patch is the first transdermal system developed for the disease and is expected to provide greater convenience, e.g. caregivers can easily confirm the administration of the drug.

Japan: Phase III / Alzheimer's disease (co-

development with Novartis Pharma K.K.)

Europe & US: Marketed (Novartis AG)

ONO-7643 / RC-1291 (tablet)

ONO-7643 is a small molecule ghrelin mimetic and the development is underway in cancer anorexia / cachexia. The drug is a low molecular weight substance having similar pharmacological actions to ghrelin, which is a circulating peptide hormone that has multiple physiological actions, including appetite stimulation, muscle-building (anabolic) and gastrointestinal function modulating effects. The compound is therefore expected to be a breakthrough drug that would improve patient quality of life (QOL) impaired by exhausted general conditions based on anorexia and loss of body fat and muscle mass associated with progression of cancer

Japan: Phase I / Cancer anorexia / cachexia

US, etc.: Phase II / Cancer anorexia / cachexia (Helsinn Therapeutics (U.S.), Inc.)

ONO-5334 (tablet)

ONO-5334, a cathepsin K inhibitor, is being developed for osteoporosis with a novel mechanism of action. Unlike bisphosphonates, the drug only inhibits bone resorption without having impact on bone formation.

Japan: Phase I / Osteoporosis

Europe: Phase II / Osteoporosis

ONO-8539 (tablet)

ONO-8539 is a selective antagonist of EP1, one of subtype receptors of prostaglandin E2, and overactive bladder is the first indication for its clinical development program. It is expected that the drug can be given to the patients who are complicated with glaucoma for which use of anticholinergics is limited due to its mechanism of actions and with lower urinary obstruction including benign prostatic hypertrophy.

Japan: Phase I / Overactive bladder

Europe: Phase II / Overactive bladder

ONO-7847 / MK-0517 (injection)

ONO-7847 is a neurokinin (NK) 1 antagonist, and is the prodrug of ONO-7436 (Emend® Capsules) available in injectable form. The development for prevention of chemotherapy-induced nausea and vomiting has been pursued.

Japan: Phase I / Chemotherapy-induced nausea and vomiting

Overseas: Phase III / Chemotherapy-induced nausea and vomiting (Merck & Co., Inc.)

ONO-4641 (tablet)

ONO-4641 is a sphingosine-1-phosphate (S1P) receptor agonist, being developed for the treatment of multiple sclerosis. The drug is a low molecular weight substance that keeps lymphocytes in lymph nodes and reduces the lymphocyte count in the blood, as a result inhibiting the infiltration of lymphocytes into lesions. The compound is therefore expected to be an innovative drug for the treatment of autoimmune diseases such as multiple sclerosis, which is regarded as an intractable diseases.

Japan: Phase I / Multiple sclerosis

US: Phase I / Multiple sclerosis

ONO-4538 / MDX-1106 (injection)

ONO-4538, a fully human anti-PD-1 antibody, is expected to be a potential treatment for cancer and other diseases. PD-1 is one of the receptors expressed on activated lymphocytes, and is involved in the negative regulatory system to suppress the activated lymphocytes. It has been reported that tumor cells utilize this system to escape from the host immune responses. It is anticipated that blockade of the negative regulatory signal mediated by PD-1 will promote the host's immune response, in which tumor cells and viruses are recognized as foreign and eliminated.

Japan: Phase I / Cancer

US: Phase I / Cancer and hepatitis C (co-development with Medarex, Inc.)

ONO-3849 (injection)

ONO-3849 is a peripherally acting mu-opioid receptor antagonist, and is developed for opioid-induced constipation. Opioid pain medications are mainly used for the treatment of pain in cancer and other advanced illnesses, but often cause constipation in many of these patients. ONO-3849 is expected to decrease the constipating effects of opioid pain medications in the gastrointestinal tract without affecting their ability to relieve pain.

Japan: Phase I / Opioid-induced constipation

Overseas: Marketed / Opioid-induced constipation (Wyeth)

<New Dosage Regimen>

ONO-5920 / YM529 (tablet)

ONO-5920 is a drug for the treatment of osteoporosis, and is intermittently administered oral formulation of Recalbon® Tablets.

Japan: Phase II / III / Osteoporosis (co-development with Astellas Pharma Inc.)

<Additional Indications>

Onoact® for Injection

Japan: Phase II / Improvement of multislice CT coronary imaging ability

Elaspol® for Injection

Japan: Phase II / Acute respiratory failure associated with community-acquired pneumonia