

## First Quarter (April 1 – June 30, 2014) Flash Report (unaudited)

Three months ended June 30, 2014

# ONO PHARMACEUTICAL CO., LTD.

August 4, 2014

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for three months ended June 30, 2014.

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRS”).

This First Quarter Flash Report 2015 (unaudited) is 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

	Millions of yen			Thousands of US\$
	1st Quarter 3 months ended Jun. 30, 2014	1st Quarter 3 months ended Jun. 30, 2013	Annual 12 months ended Mar. 31, 2014	1st Quarter 3 months ended Jun. 30, 2014
Revenue	¥ 31,808	¥ 37,299	¥ 143,247	\$ 314,931
Profit (Owners of the parent company)	2,908	7,991	20,344	28,796
Total equity	450,730	441,164	451,724	4,462,677
Total assets	489,204	476,540	486,141	4,843,603
Basic earnings per share	¥ 27.43	¥ 75.38	¥ 191.90	\$ 0.27

**First Quarter (April 1 – June 30, 2014) Flash Report (unaudited)**

Three months ended June 30, 2014

**Consolidated Financial Forecast for the Six Months Ending  
September 30, 2014 and for the Year Ending March 31, 2015**

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Six months ending		Year ending	
	September 30, 2014		March 31, 2015	
	Millions of yen	Thousands of US\$	Millions of yen	Thousands of US\$
<b>Revenue</b>	¥ 68,100	\$ 674,257	¥ 139,000	\$ 1,376,238
<b>Operating profit</b>	10,300	101,980	19,200	190,099
<b>Profit before tax</b>	11,750	116,337	21,800	215,842
<b>Profit</b>	8,600	85,149	16,000	158,416
<b>(Owners of the parent company)</b>				
	Yen	US\$	Yen	US\$
<b>Basic earnings per share</b>	¥ 81.12	\$ 0.80	¥ 150.93	\$ 1.49

(\*)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.

## First Quarter (April 1 – June 30, 2014) Flash Report (unaudited)

Three months ended June 30, 2014

### Consolidated Statement of Financial Position

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

ASSETS	Millions of yen		Thousands of US\$
	1st Quarter June 30, 2014	Annual March 31, 2014	1st Quarter June 30, 2014
<b>Current assets</b>			
Cash and cash equivalents	¥ 91,117	¥ 104,898	\$ 902,146
Trade and other receivables	46,973	42,240	465,080
Marketable securities	22,160	22,295	219,404
Other financial assets	800	905	7,921
Inventories	27,283	24,261	270,131
Other current assets	1,041	958	10,304
<b>Total current assets</b>	<b>189,374</b>	<b>195,557</b>	<b>1,874,987</b>
<b>Noncurrent assets</b>			
Property, plant and equipment	60,030	59,147	594,356
Intangible assets	31,667	22,690	313,538
Investment securities	191,073	188,360	1,891,807
Investments in associates	1,009	1,008	9,987
Other financial assets	5,991	5,913	59,321
Deferred tax assets	6,912	10,003	68,433
Retirement benefit assets	636	905	6,296
Other noncurrent assets	2,513	2,559	24,880
<b>Total noncurrent assets</b>	<b>299,830</b>	<b>290,585</b>	<b>2,968,617</b>
<b>Total assets</b>	<b>¥ 489,204</b>	<b>¥ 486,141</b>	<b>\$ 4,843,603</b>

<b>LIABILITIES AND EQUITY</b>	Millions of yen		Thousands of US\$
	<b>1st Quarter June 30, 2014</b>	<b>Annual March 31, 2014</b>	<b>1st Quarter June 30, 2014</b>
<b>Current liabilities</b>			
Trade and other payables	¥ 15,481	¥ 11,288	\$ 153,274
Borrowings	492	508	4,869
Other financial liabilities	3,977	846	39,380
Income taxes payable	864	4,303	8,557
Provisions	670	1,063	6,629
Other current liabilities	10,798	10,264	106,912
<b>Total current liabilities</b>	<b>32,282</b>	<b>28,272</b>	<b>319,621</b>
<b>Noncurrent liabilities</b>			
Borrowings	393	468	3,896
Other financial liabilities	17	17	170
Retirement benefit liabilities	4,129	3,945	40,883
Provisions	88	87	867
Deferred tax liabilities	968	1,002	9,580
Other noncurrent liabilities	597	626	5,910
<b>Total noncurrent liabilities</b>	<b>6,192</b>	<b>6,146</b>	<b>61,305</b>
<b>Total liabilities</b>	<b>38,474</b>	<b>34,418</b>	<b>380,926</b>
<b>Equity</b>			
Share capital	17,358	17,358	171,864
Capital reserves	17,080	17,080	169,108
Treasury shares	(59,278)	(59,274)	(586,909)
Other components of equity	21,259	15,626	210,482
Retained earnings	449,877	456,537	4,454,228
Equity attributable to owners of the parent company	446,296	447,327	4,418,773
Non-controlling interests	4,434	4,397	43,904
<b>Total equity</b>	<b>450,730</b>	<b>451,724</b>	<b>4,462,677</b>
<b>Total liabilities and equity</b>	<b>¥ 489,204</b>	<b>¥ 486,141</b>	<b>\$ 4,843,603</b>

## First Quarter (April 1 – June 30, 2014) Flash Report (unaudited)

Three months ended June 30, 2014

### Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US\$
	1st Quarter 3 months ended June 30, 2014	1st Quarter 3 months ended June 30, 2013	1st Quarter 3 months ended June 30, 2014
<b>Revenue</b>	¥ 31,808	¥ 37,299	\$ 314,931
Cost of sales	(8,301)	(7,831)	(82,192)
<b>Gross profit</b>	<b>23,507</b>	<b>29,469</b>	<b>232,739</b>
Selling, general and administrative expenses	(11,412)	(9,027)	(112,993)
Research and development costs	(9,209)	(10,117)	(91,181)
Other income	28	29	277
Other expenses	(136)	(234)	(1,349)
<b>Operating profit</b>	<b>2,777</b>	<b>10,120</b>	<b>27,492</b>
Finance income	1,284	1,476	12,712
Finance costs	(115)	(123)	(1,140)
Share of profit from investments in associates	13	3	126
<b>Profit before tax</b>	<b>3,958</b>	<b>11,476</b>	<b>39,190</b>
Income tax expense	(1,002)	(3,449)	(9,924)
<b>Profit for the period</b>	<b>2,956</b>	<b>8,027</b>	<b>29,266</b>
<b>Profit for the period attributable to</b>			
Owners of the parent company	2,908	7,991	28,796
Non-controlling interests	48	36	471
<b>Profit for the period</b>	<b>2,956</b>	<b>8,027</b>	<b>29,266</b>
<b>Earnings per share:</b>		Yen	US\$
Basic earnings per share	27.43	75.38	0.27

## First Quarter (April 1 – June 30, 2014) Flash Report (unaudited)

Three months ended June 30, 2014

### Consolidated Statement of Comprehensive Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US\$
	<b>1st Quarter 3 months ended June 30, 2014</b>	1st Quarter 3 months ended June 30, 2013	<b>1st Quarter 3 months ended June 30, 2014</b>
<b>Profit for the period</b>	¥ 2,956	¥ 8,027	\$ 29,266
<b>Other comprehensive income</b>			
Items that will not be reclassified to profit or loss:			
Net gain on financial assets measured at fair value through other comprehensive income	5,678	141	56,214
Remeasurement of defined benefit plans	(28)	72	(273)
Share of net loss on financial assets measured at fair value through other comprehensive income of investments in associates	(11)	(1)	(109)
	<b>5,639</b>	212	<b>55,832</b>
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	(27)	148	(271)
Net fair value gain (loss) on cash flow hedges	(13)	49	(127)
	<b>(40)</b>	198	<b>(398)</b>
<b>Total other comprehensive income</b>	<b>5,599</b>	410	<b>55,434</b>
<b>Total comprehensive income for the period</b>	<b>8,555</b>	8,437	<b>84,700</b>
<b>Comprehensive income for the period attributable to:</b>			
Owners of the parent company	8,514	8,400	84,294
Non-controlling interests	41	37	406
<b>Total comprehensive income for the period</b>	<b>8,555</b>	8,437	<b>84,700</b>

First Quarter (April 1 – June 30, 2014) Flash Report (unaudited)  
Three months ended June 30, 2014

Consolidated Statement of Changes in Equity

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen								
	Equity attributable to owners of the parent company							Non-controlling interests	Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company			
Balance at April 1, 2013	17,358	17,080	(59,231)	8,198	454,681	438,086	4,190	442,276	
Profit for the period					7,991	7,991	36	8,027	
Other comprehensive income				409		409	1	410	
Total comprehensive income for the period	–	–	–	409	7,991	8,400	37	8,437	
Purchase of treasury shares			(4)			(4)		(4)	
Cash dividends					(9,541)	(9,541)	(3)	(9,545)	
Transfer from other components of equity to retained earnings				(71)	71	–		–	
Total transactions with the owners	–	–	(4)	(71)	(9,470)	(9,546)	(3)	(9,549)	
Balance at June 30, 2013	17,358	17,080	(59,235)	8,535	453,202	436,940	4,224	441,164	

	Millions of yen								
	Equity attributable to owners of the parent company							Non-controlling interests	Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company			
Balance at April 1, 2014	17,358	17,080	(59,274)	15,626	456,537	447,327	4,397	451,724	
Profit for the period					2,908	2,908	48	2,956	
Other comprehensive income				5,605		5,605	(6)	5,599	
Total comprehensive income for the period	–	–	–	5,605	2,908	8,514	41	8,555	
Purchase of treasury shares			(3)			(3)		(3)	
Cash dividends					(9,541)	(9,541)	(4)	(9,545)	
Transfer from other components of equity to retained earnings				28	(28)	–		–	
Total transactions with the owners	–	–	(3)	28	(9,569)	(9,544)	(4)	(9,548)	
Balance at June 30, 2014	17,358	17,080	(59,278)	21,259	449,877	446,296	4,434	450,730	

	Thousands of US \$								
	Equity attributable to owners of the parent company							Non-controlling interests	Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company			
Balance at April 1, 2014	171,864	169,108	(586,876)	154,711	4,520,171	4,428,978	43,536	4,472,514	
Profit for the period					28,796	28,796	471	29,266	
Other comprehensive income				55,498		55,498	(64)	55,434	
Total comprehensive income for the period	–	–	–	55,498	28,796	84,294	406	84,700	
Purchase of treasury shares			(33)			(33)		(33)	
Cash dividends					(94,465)	(94,465)	(38)	(94,503)	
Transfer from other components of equity to retained earnings				273	(273)	–		–	
Total transactions with the owners	–	–	(33)	273	(94,738)	(94,499)	(38)	(94,537)	
Balance at June 30, 2014	171,864	169,108	(586,909)	210,482	4,454,228	4,418,773	43,904	4,462,677	

## First Quarter (April 1 – June 30, 2014) Flash Report (unaudited)

Three months ended June 30, 2014

### Consolidated Statement of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US\$
	1st Quarter 3 months ended June 30, 2014	1st Quarter 3 months ended June 30, 2013	1st Quarter 3 months ended June 30, 2014
<b>Cash flows from operating activities</b>			
Profit before tax	¥ 3,958	¥ 11,476	\$ 39,190
Depreciation and amortization	1,487	1,207	14,722
Impairment losses	—	1	—
Interest and dividend income	(1,282)	(1,327)	(12,692)
Interest expense	4	2	36
Increase in inventories	(3,022)	(1,512)	(29,919)
Increase in trade and other receivables	(4,733)	(6,940)	(46,860)
Increase in trade and other payables	3,156	1,786	31,252
Increase in retirement benefit liabilities	139	131	1,381
Decrease in retirement benefit assets	271	252	2,681
Other	2,375	1,981	23,510
Subtotal	2,353	7,058	23,301
Interest received	128	190	1,268
Dividends received	1,172	1,175	11,601
Interest paid	(4)	(2)	(36)
Income taxes paid	(4,450)	(5,688)	(44,058)
Net cash provided by (used in) operating activities	(800)	2,733	(7,923)
<b>Cash flows from investing activities</b>			
Purchases of property, plant and equipment	(1,609)	(1,074)	(15,935)
Purchases of intangible assets	(8,777)	(3,073)	(86,905)
Purchases of investments	—	(11,595)	—
Proceeds from sales and redemption of investments	6,120	18,201	60,594
Other	(124)	(335)	(1,228)
Net cash provided by (used in) investing activities	(4,391)	2,123	(43,474)
<b>Cash flows from financing activities</b>			
Dividends paid to owners of the parent company	(8,490)	(8,697)	(84,059)
Dividends paid to non-controlling interests	(4)	(3)	(37)
Repayments of long-term borrowings	(128)	(118)	(1,263)
Net increase in short-term borrowings	23	141	223
Purchases of treasury shares	(3)	(4)	(31)
Net cash used in financing activities	(8,602)	(8,681)	(85,166)
Net decrease in cash and cash equivalents	(13,793)	(3,825)	(136,563)
Cash and cash equivalents at the beginning of the period	104,898	89,117	1,038,592
Effects of exchange rate changes on cash and cash equivalents	12	21	117
Cash and cash equivalents at the end of the period	¥ 91,117	¥ 85,313	\$ 902,146



## **First Quarter (April 1 – June 30, 2014) Flash Report (unaudited)**

Three months ended June 30, 2014

### **Notes to Consolidated Financial Statements**

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

- Note 1 This First Quarter Flash Report 2015 (unaudited) is a summary information extracted from the financial statements announced by the Company on August 4, 2014. The financial statements announced have been prepared and stated in accordance with International Financial Reporting Standards (“IFRS”). The financial statements and figures contained in this First Quarter Flash Report 2015 (unaudited) are prepared for the 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 Amounts of less than one million yen and one thousand U.S. dollars have been rounded to the nearest million yen and one thousand U.S. dollars in the presentation of the accompanying consolidated financial statements.
- 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 101 = US\$ 1, the approximate exchange rate prevailing on June 30, 2014.

## First Quarter (April 1 – June 30, 2014) Flash Report (unaudited)

Three months ended June 30, 2014

### Sales of Major Products

Supplemental Data

For information purpose only

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

		1st Quarter 3 months ended Jun 30, 2014			Year ending March 31,2015
		Results	Increase/Decrease		Forecast
<b>Glactiv</b>	Agent for type II diabetes	¥ 78	¥ Δ 18	Δ 18.3 %	¥ 320
<b>Opalmon</b>	Circulatory system agent	65	Δ 22	Δ 25.0 %	285
<b>Onon</b>	Agent for bronchial asthma and allergic rhinitis	25	Δ 9	Δ 26.7 %	105
<b>Recalbon</b>	Agent for osteoporosis	22	Δ 4	Δ 14.3 %	120
<b>Emend/Proemend</b>	Agent for Chemotherapy-induced nausea and vomiting	20	Δ 2	Δ 10.0 %	105
<b>Foipan</b>	Agent for chronic pancreatitis and postoperative reflux esophagitis	17	Δ 5	Δ 23.0 %	70
<b>Rivastach</b>	Agent for Alzheimer's disease	15	+1	+5.1 %	80
<b>Kinedak</b>	Agent for diabetic peripheral neuropathy	14	Δ 6	Δ 30.9 %	60
<b>Onon dry syrup</b>	Agent for pediatric bronchial asthma and allergic rhinitis	14	Δ 3	Δ 16.8 %	60
<b>Forxiga</b>	Agent for type II diabetes	12	—	—	30
<b>Staybla</b>	Agent for overactive bladder (pollakiuria and urinary incontinence)	12	Δ 4	Δ 25.4 %	65
<b>Onoact</b>	Agent for tachyarrhythmia during and post operation	11	+1	+9.1 %	60
<b>Elaspol</b>	Agent for acute lung injury associated with SIRS	7	Δ 2	Δ 25.4 %	30
<b>Orencia SC</b>	Agent for rheumatoid arthritis	5	—	—	30

Note: 1 Sales of products are shown in a gross sales basis.

2 Orencia SC was launched in Fiscal 2013, and year-on-year changes in value and percentage are therefore not available.

3 Forxiga was launched in Fiscal 2014, and year-on-year changes in value and percentage are therefore not available.

## First Quarter (April – June 30, 2014) Flash Report (unaudited)

Three months ended June 30, 2014

### Supplemental Information

## Status of Development Pipeline

as of August 4, 2014

### Developments in Japan

#### *NDA approved (New Chemical Entities):*

- **Opdivo® Intravenous Infusion 20mg, 100mg(ONO-4538 / BMS-936558) \*1**  
Treatment of unresectable melanoma [human anti-human PD-1 monoclonal antibody]

#### *NDA approved (Additional Indication):*

- **Glactiv® Tablets (ONO-5435 / MK-0431) \*2**  
(Co-development with Merck & Co., Inc.)  
Type 2 diabetes: combination therapy with a rapid-acting insulin secretagogue [DPP-4 inhibitor]

#### *NDA filed (New Formulation):*

- **Opalmon® Tablets (OP-1206 •  $\alpha$ -CD)**  
(Co-development with Sumitomo Dainippon Pharma Co., Ltd.)  
Thromboangitis obliterans and lumbar spinal canal stenosis [Blood vessel dilation]

#### *NDA filed (Additional Formulation):*

- **Onoact® Intravenous Infusion 150 mg (ONO-1101)**  
Post operative tachyarrhythmia under monitoring hemodynamics, tachyarrhythmia in low cardiac function [Short acting beta 1 blocker]

#### *Ongoing clinical studies (New Chemical Entities):*

- **ONO-7057 / Carfilzomib (injection)**  
(In-licensed from Onyx Pharmaceuticals, Inc.)  
Multiple Myeloma (Phase III) [Proteasome inhibitor]
- **ONO-2745 / CNS 7056 (injection)**  
(In-licensed from PAION AG)  
Short acting general anesthetic (Phase II / III)  
[GABA<sub>A</sub> receptor modulator]
- **ONO-7165 / EMD531444 (injection)**  
(Co-development with Merck KGaA)  
Non-small cell lung cancer (Phase II) [Therapeutic cancer peptide vaccine targeting the tumor antigen MUC-1]
- **ONO-7643 / RC-1291 (tablet)**  
(In-licensed from Helsinn Healthcare S.A.)  
Cancer anorexia / cachexia (Phase II)  
[Ghrelin mimetic]
- **ONO-1162 / Ivabradine (tablet)**  
(In-licensed from Les Laboratoires Servier)  
Chronic heart failure (Phase II) [If channel inhibitor]
- **ONO-5163 / AMG-416 (injection)**  
(In-licensed from Amgen Inc.)  
Secondary hyperparathyroidism (Phase I / II) [Calcium sensing receptor agonist]
- **ONO-6950 (tablet)**  
Bronchial asthma (Phase I) [LT receptor antagonist]

- **ONO-7056 / Salirasib (tablet)**  
(In-licensed from Kadmon Corporation LLC)  
Solid tumor (Phase I) [Ras signal inhibitor]
- **ONO-7268 MX1 (injection)**  
(In-licensed from OncoTherapy Science, Inc.)  
Hepatocellular carcinoma (Phase I) [Therapeutic cancer peptide vaccines]
- **ONO-7268 MX2 (injection)**  
(In-licensed from OncoTherapy Science, Inc.)  
Hepatocellular carcinoma (Phase I) [Therapeutic cancer peptide vaccines]
- **ONO-2160/CD (tablet)**  
Parkinson's disease (Phase I) [levodopa pro-drug]
- **ONO-4053 (tablet)**  
Allergic rhinitis (Phase I) [PGD2 receptor antagonist]
- **ONO-2370 (tablet) / Opicapone \*3**  
(In-licensed from Bial)  
Parkinson's disease (Phase I) [Long acting COMT inhibitor]

#### *Ongoing clinical studies (Additional Indications):*

- **Proemend® for i.v. infusion (ONO-7847 / MK-0517)**  
(In-licensed from Merck & Co., Inc.)  
Chemotherapy-induced nausea and vomiting in pediatric patients (Phase III) [NK1 receptor antagonist]
- **Opdivo® Intravenous Infusion (ONO-4538 / BMS-936558)**  
Renal cell cancer (Phase III) [human anti-human PD-1 monoclonal antibody]
- **Orencia® IV (ONO-4164 / BMS-188667)**  
(Co-development with Bristol-Myers Squibb Company)  
Juvenile Rheumatoid Arthritis (Phase III) [T-cell activation inhibitor]
- **Orencia® IV (ONO-4164 / BMS-188667)**  
(Co-development with Bristol-Myers Squibb Company)  
Lupus nephritis (Phase III) [T-cell activation inhibitor]
- **Opdivo® Intravenous Infusion (ONO-4538 / BMS-936558)**  
Esophageal cancer (Phase II) [human anti-human PD-1 monoclonal antibody]
- **Opdivo® Intravenous Infusion (ONO-4538 / BMS-936558)**  
Non-small cell lung cancer (Phase II) [human anti-human PD-1 monoclonal antibody]

#### *Ongoing clinical studies (Additional Dosing Regimen):*

- **Rivastach® Patch (ONO-2540 / ENA713D)**  
(Co-development with Novartis Pharma AG)  
Alzheimer's disease (Phase III) [dual inhibitor of AChE and BuChE]

*In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.*

## Developments abroad

### *Ongoing clinical studies (New Chemical Entities):*

- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Renal cell cancer (Phase III) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Non-small cell lung cancer (Phase III) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Melanoma (Phase III) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection) \*4**  
(Out-licensed to Bristol-Myers Squibb Company)  
Head and neck cancer (Phase III) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Glioblastoma (Phase II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Diffuse large B cell lymphoma (Phase II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Follicular lymphoma (Phase II) [human anti-human PD-1 monoclonal antibody]
- **ONO-6950 (tablet)**  
Bronchial asthma (Phase II) [LT receptor antagonist]
- **ONO-4053 (tablet)**  
Allergic rhinitis (Phase II) [PGD2 receptor antagonist]
- **ONO-2952 (tablet)**  
Irritable bowel syndrome (Phase II) [TSPO antagonist]
- **ONO-9054 (eye drop)**  
Glaucoma, ocular hypertension (Phase II) [PG receptor (FP / EP3) agonist]
- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Solid tumors (triple negative breast cancer, stomach cancer, pancreatic cancer, small cell lung cancer, bladder cancer (Phase I/II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Colon cancer (Phase I/II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Hepatocellular carcinoma (Phase I) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection) \*5**  
(Out-licensed to Bristol-Myers Squibb Company)  
Chronic myeloid leukemia (Phase I) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Hepatitis C (Phase I) [human anti-human PD-1 monoclonal antibody]

- **ONO-4059 (capsule)**  
B cell lymphoma (Phase I) [Bruton's tyrosine kinase (Btk) inhibitor]
- **ONO-8055 (tablet)**  
Underactive bladder (Phase I) [PG receptor (EP2 / EP3) agonist]
- **ONO-8539 (tablet)**  
Gastroesophageal reflux disease (GERD) (Phase I) [PG receptor (EP1) antagonist]
- **ONO-1266 (capsule)**  
Portal hypertension (Phase I) [S1P receptor antagonist]
- **ONO-4232 (injection)**  
Acute heart failure (Phase I) [PG receptor (EP4) agonist]

*In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.*

### **Changes from Flash Report for the Fiscal Year ending March 2014 announced on May 13, 2014**

- \*1: Marketing authorization of ONO-4538, human anti-human PD-1 monoclonal antibody was obtained for the treatment of unresectable melanoma.
- \*2: Glactive® has obtained the approval of the partial change in the indications of "type 2 diabetes".
- \*3: Phase I clinical study of ONO-2370 (long acting COMT inhibitor) was initiated in Japanese healthy male volunteers.
- \*4: Phase III clinical study of ONO-4538/BMS-936558 (human anti-human PD-1 monoclonal antibody) was initiated for the treatment of head and neck cancer.
- \*5: Phase I clinical study of ONO-4538/BMS-936558 (human anti-human PD-1 monoclonal antibody) was initiated for the treatment of chronic myeloid leukemia.
- \*: Phase II clinical study of ONO-4641 (S1P receptor agonist) for the treatment of multiple sclerosis was terminated due to the change of external environment.
- \*: The development of ONO-3849,  $\mu$ -opioid receptor antagonist was terminated due to strategic reasons.