

## Third Quarter (April 1 – December 31, 2014) Flash Report (unaudited)

Nine months ended December 31, 2014

# ONO PHARMACEUTICAL CO., LTD.

February 3, 2015

Ono Pharmaceutical Co., Ltd. ("The Company") has announced its consolidated financial results for nine months ended December 31, 2014.

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

This Third Quarter Flash Report 2015 (unaudited) is summary information extracted from the financial statements announced, and the financial statements and the figures 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.

The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan using the rate of 120 to \$1, the approximate rate of exchange at December 31, 2014.

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.

## Financial Highlights

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen			Thousands of US\$
	Nine months ended Dec. 31, 2013	Year ended Mar. 31, 2014	<b>Nine months ended Dec. 31, 2014</b>	<b>Nine months ended Dec. 31, 2014</b>
Revenue	¥ 111,424	¥ 143,247	¥ <b>107,267</b>	\$ <b>893,888</b>
Profit (Owners of the parent company)	19,883	20,344	<b>15,708</b>	<b>130,896</b>
Total equity	454,997	451,724	<b>463,873</b>	<b>3,865,607</b>
Total assets	489,546	486,141	<b>505,630</b>	<b>4,213,584</b>
		Yen		US\$
Basic earnings per share	¥ 187.55	¥ 191.90	¥ <b>148.17</b>	\$ <b>1.23</b>

**Third Quarter (April 1 – December 31, 2014) Flash Report (unaudited)**  
Nine months ended December 31, 2014

**Consolidated Financial Forecast for the Year Ending March 31, 2015**

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Year ending	
	March 31, 2015	
	Millions of yen	Thousands of US\$
Revenue	¥ 137,000	\$ 1,141,667
Operating profit	15,100	125,833
Profit before tax	17,700	147,500
Profit	12,000	100,000
(Owners of the parent company)		
	Yen	US\$
Basic earnings per share	¥ 113.20	\$ 0.94

(\*)The forecasts for the year ending March 31, 2015 are revised from November 5, 2014 for the following reasons.

The Company has estimated royalty income which had not originally been expected in its forecasts announced on November 5, 2014. On the other hand, the Company will not recognize a reduction of past service cost in fourth quarter due to a delay in pension scheme alteration, which will have retirement benefit expenses increased. For the above reasons, the Company has upwardly revised its forecasts for consolidated sales and each profit.

(\*)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.

## Third Quarter (April 1 – December 31, 2014) Flash Report (unaudited)

Nine months ended December 31, 2014

### Consolidated Statement of Financial Position

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

ASSETS	Millions of yen		Thousands of US\$
	As of March 31, 2014	As of December 31, 2014	As of December 31, 2014
<b>Current assets</b>			
Cash and cash equivalents	¥ 104,898	¥ 83,572	\$ 696,437
Trade and other receivables	42,240	58,058	483,813
Marketable securities	22,295	20,952	174,597
Other financial assets	905	806	6,719
Inventories	24,261	26,354	219,618
Other current assets	958	1,403	11,692
<b>Total current assets</b>	<b>195,557</b>	<b>191,145</b>	<b>1,592,876</b>
<b>Noncurrent assets</b>			
Property, plant and equipment	59,147	70,838	590,318
Intangible assets	22,690	34,120	284,335
Investment securities	188,360	197,589	1,646,574
Investments in associates	1,008	1,010	8,419
Other financial assets	5,913	6,183	51,524
Deferred tax assets	10,003	1,457	12,144
Retirement benefit assets	905	760	6,334
Other noncurrent assets	2,559	2,527	21,060
<b>Total noncurrent assets</b>	<b>290,585</b>	<b>314,485</b>	<b>2,620,708</b>
<b>Total assets</b>	<b>¥ 486,141</b>	<b>¥ 505,630</b>	<b>\$ 4,213,584</b>

<b>LIABILITIES AND EQUITY</b>	Millions of yen		Thousands of US\$
	As of March 31, 2014	As of December 31, 2014	As of December 31, 2014
<b>Current liabilities</b>			
Trade and other payables	¥ 11,288	¥ 18,644	\$ 155,369
Borrowings	508	321	2,673
Other financial liabilities	846	5,107	42,560
Income taxes payable	4,303	3,275	27,290
Provisions	1,063	924	7,699
Other current liabilities	10,264	7,058	58,820
<b>Total current liabilities</b>	<b>28,272</b>	<b>35,329</b>	<b>294,411</b>
<b>Noncurrent liabilities</b>			
Borrowings	468	337	2,808
Other financial liabilities	17	21	171
Retirement benefit liabilities	3,945	4,409	36,745
Provisions	87	87	725
Deferred tax liabilities	1,002	954	7,951
Other noncurrent liabilities	626	620	5,164
<b>Total noncurrent liabilities</b>	<b>6,146</b>	<b>6,428</b>	<b>53,566</b>
<b>Total liabilities</b>	<b>34,418</b>	<b>41,757</b>	<b>347,977</b>
<b>Equity</b>			
Share capital	17,358	17,358	144,652
Capital reserves	17,080	17,080	142,332
Treasury shares	(59,274)	(59,297)	(494,144)
Other components of equity	15,626	30,789	256,577
Retained earnings	456,537	453,440	3,778,664
Equity attributable to owners of the parent company	447,327	459,370	3,828,081
Non-controlling interests	4,397	4,503	37,526
<b>Total equity</b>	<b>451,724</b>	<b>463,873</b>	<b>3,865,607</b>
<b>Total liabilities and equity</b>	<b>¥ 486,141</b>	<b>¥ 505,630</b>	<b>\$ 4,213,584</b>

## Third Quarter (April 1 – December 31, 2014) Flash Report (unaudited)

Nine months ended December 31, 2014

### Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US\$
	Nine months ended Dec. 31, 2013	Nine months ended Dec. 31, 2014	Nine months ended Dec. 31, 2014
<b>Revenue</b>	¥ 111,424	¥ 107,267	\$ 893,888
Cost of sales	(25,137)	(26,753)	(222,943)
<b>Gross profit</b>	86,288	80,513	670,945
Selling, general and administrative expenses	(28,010)	(32,510)	(270,913)
Research and development costs	(32,462)	(29,995)	(249,960)
Other income	308	335	2,789
Other expenses	(534)	(1,869)	(15,575)
<b>Operating profit</b>	25,590	16,474	137,286
Finance income	3,143	3,367	28,060
Finance costs	(12)	(55)	(456)
Share of profit from investments in associates	(5)	12	102
<b>Profit before tax</b>	28,715	19,799	164,992
Income tax expense	(8,682)	(3,974)	(33,114)
<b>Profit for the period</b>	<u>20,033</u>	<u>15,825</u>	<u>131,878</u>
<b>Profit for the period attributable to :</b>			
Owners of the parent company	19,883	15,708	130,896
Non-controlling interests	149	118	982
<b>Profit for the period</b>	<u>20,033</u>	<u>15,825</u>	<u>131,878</u>
<b>Earnings per share:</b>			
Basic earnings per share	Yen <u>187.55</u>	<u>148.17</u>	US\$ <u>1.23</u>

**Third Quarter (April 1 – December 31, 2014) Flash Report (unaudited)**

Nine months ended December 31, 2014

**Consolidated Statement of Comprehensive Income**

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US\$
	Nine months ended Dec. 31, 2013	Nine months ended Dec. 31, 2014	Nine months ended Dec. 31, 2014
<b>Profit for the period</b>	¥ 20,033	¥ 15,825	\$ 131,878
<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	11,022	14,522	121,020
Remeasurement of defined benefit plans	319	379	3,156
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	4	(4)	(29)
	11,346	14,898	124,147
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	416	563	4,689
Net fair value gain (loss) on cash flow hedges	41	(28)	(234)
	457	535	4,454
<b>Total other comprehensive income</b>	11,802	15,432	128,601
<b>Total comprehensive income for the period</b>	31,835	31,258	260,479
<b>Comprehensive income for the period attributable to:</b>			
Owners of the parent company	31,682	31,148	259,564
Non-controlling interests	153	110	915
<b>Total comprehensive income for the period</b>	31,835	31,258	260,479

**Third Quarter (April 1 – December 31, 2014) Flash Report (unaudited)**

Nine months ended December 31, 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					19,883	19,883	149	20,033	
Other comprehensive income				11,799		11,799	3	11,802	
Total comprehensive income for the period	–	–	–	11,799	19,883	31,682	153	31,835	
Purchase of treasury shares			(28)			(28)		(28)	
Cash dividends					(19,083)	(19,083)	(3)	(19,086)	
Transfer from other components of equity to retained earnings				(318)	318	–		–	
Total transactions with the owners	–	–	(28)	(318)	(18,765)	(19,111)	(3)	(19,114)	
Balance at December 31, 2013	¥17,358	¥17,080	(¥59,259)	¥19,679	¥455,799	¥450,657	¥4,340	¥454,997	

	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					15,708	15,708	118	15,825	
Other comprehensive income				15,440		15,440	(8)	15,432	
Total comprehensive income for the period	–	–	–	15,440	15,708	31,148	110	31,258	
Purchase of treasury shares			(23)			(23)		(23)	
Cash dividends					(19,082)	(19,082)	(4)	(19,086)	
Transfer from other components of equity to retained earnings				(277)	277	–		–	
Total transactions with the owners	–	–	(23)	(277)	(18,805)	(19,105)	(4)	(19,109)	
Balance at December 31, 2014	¥17,358	¥17,080	(¥59,297)	¥30,789	¥453,440	¥459,370	¥4,503	¥463,873	

	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	\$144,652	\$142,332	(\$493,954)	\$130,215	\$3,804,477	\$3,727,723	\$36,643	\$3,764,366	
Profit for the period					130,896	130,896	982	131,878	
Other comprehensive income				128,668		128,668	(67)	128,601	
Total comprehensive income for the period	–	–	–	128,668	130,896	259,564	915	260,479	
Purchase of treasury shares			(191)			(191)		(191)	
Cash dividends					(159,016)	(159,016)	(32)	(159,048)	
Transfer from other components of equity to retained earnings				(2,306)	2,306	–		–	
Total transactions with the owners	–	–	(191)	(2,306)	(156,710)	(159,206)	(32)	(159,238)	
Balance at December 31, 2014	\$144,652	\$142,332	(\$494,144)	\$256,577	\$3,778,664	\$3,828,081	\$37,526	\$3,865,607	

### Third Quarter (April 1 – December 31, 2014) Flash Report (unaudited)

Nine months ended December 31, 2014

## Consolidated Statement of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US\$
	Nine months ended Dec. 31, 2013	Nine months ended Dec. 31, 2014	Nine months ended Dec. 31, 2014
<b>Cash flows from operating activities</b>			
Profit before tax	¥ 28,715	¥ 19,799	\$ 164,992
Depreciation and amortization	3,647	4,478	37,317
Impairment losses	1,901	559	4,657
Interest and dividend income	(2,441)	(2,397)	(19,979)
Interest expense	10	10	86
Increase in inventories	(903)	(2,091)	(17,423)
Increase in trade and other receivables	(8,296)	(15,812)	(131,766)
Increase in trade and other payables	2,897	4,646	38,715
Increase in retirement benefit liabilities	401	385	3,209
Decrease in retirement benefit assets	757	812	6,769
Other	(1,178)	(1,086)	(9,049)
Subtotal	25,510	9,303	77,526
Interest received	516	351	2,922
Dividends received	2,022	2,093	17,440
Interest paid	(10)	(10)	(86)
Income taxes paid	(10,893)	(4,615)	(38,462)
<b>Net cash provided by operating activities</b>	<b>17,145</b>	<b>7,121</b>	<b>59,340</b>
<b>Cash flows from investing activities</b>			
Purchases of property, plant and equipment	(2,917)	(12,109)	(100,909)
Purchases of intangible assets	(6,802)	(13,420)	(111,832)
Purchases of investments	(27,221)	(1,036)	(8,637)
Proceeds from sales and redemption of investments	44,324	16,814	140,119
Other	(256)	(197)	(1,642)
<b>Net cash provided by (used in) investing activities</b>	<b>7,127</b>	<b>(9,948)</b>	<b>(82,901)</b>
<b>Cash flows from financing activities</b>			
Dividends paid to owners of the parent company	(18,575)	(18,174)	(151,448)
Dividends paid to non-controlling interests	(3)	(4)	(34)
Repayments of long-term borrowings	(384)	(372)	(3,102)
Net increase in short-term borrowings	(47)	(45)	(374)
Purchases of treasury shares	(27)	(22)	(183)
<b>Net cash used in financing activities</b>	<b>(19,036)</b>	<b>(18,617)</b>	<b>(155,142)</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>5,236</b>	<b>(21,444)</b>	<b>(178,703)</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>89,117</b>	<b>104,898</b>	<b>874,148</b>
<b>Effects of exchange rate changes on cash and cash equivalents</b>	<b>108</b>	<b>119</b>	<b>992</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>¥ 94,461</b>	<b>¥ 83,572</b>	<b>\$ 696,437</b>



### Third Quarter (April 1 – December 31, 2014) Flash Report (unaudited)

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Supplemental Information

## Sales of Major Products

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

Products	Indications	Nine months ended December 31, 2014			Year ending March 31, 2015
		Results	Change over the same period of the previous year		Forecasts
Glactiv	Agent for type II diabetes	¥ 248	¥ Δ 40	Δ 13.9 %	¥ 320
Opalmon	Circulatory system agent	197	Δ 59	Δ 23.0 %	250
Recalbon	Agent for osteoporosis	79	Δ 3	Δ 3.2 %	115
Onon	Agent for bronchial asthma and allergic rhinitis	72	Δ 25	Δ 25.6 %	100
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	67	Δ 0	Δ 0.3 %	90
Rivastach	Agent for Alzheimer's disease	52	+5	+10.5 %	70
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	49	Δ 15	Δ 23.5 %	60
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	43	Δ 9	Δ 17.3 %	60
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	41	Δ 8	Δ 15.8 %	55
Onoact	Agent for tachyarrhythmia during and post operation, or tachyarrhythmia in left ventricular dysfunction.	37	+3	+8.6 %	50
Kinedak	Agent for diabetic peripheral neuropathy	41	Δ 17	Δ 29.5 %	50
Orencia SC	Agent for rheumatoid arthritis	29	+25	+681.0 %	35
Forxiga	Agent for type II diabetes	13	—	—	30
Elaspol	Agent for acute lung injury associated with SIRS	22	Δ 6	Δ 21.6 %	25
Opdivo	Agent for treatment of unresectable melanoma	15	—	—	20

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

2 Forxiga and Opdivo were launched in Fiscal year 2014, and year-on-year changes in value and percentage are therefore not available.

## Third Quarter (April 1– December 31, 2014) Flash Report (unaudited)

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### Supplemental Information

## Status of Development Pipeline

as of February 3, 2015

### I. Main Pipelines Other than ONO-4538

#### i. Developments Status in Japan

##### Filed

- **Onoact<sup>®</sup> Intravenous Infusion 150 mg (ONO-1101)**

- **Additional formulation**
- Intraoperative tachyarrhythmia
- Post operative tachyarrhythmia under monitoring hemodynamics, tachyarrhythmia in low cardiac function [Short acting beta 1 blocker]
- Injection
- *In-house*

- **Rivastach<sup>®</sup> Patch (ONO-2540 / ENA713D) \*1**

- **Additional Dosing Regimen**
- Alzheimer's disease [dual inhibitor of AChE and BuChE]
- Transdermal patch
- *In-license (Novartis Pharma AG)*

##### Ongoing clinical studies

- **Proemend<sup>®</sup> for i.v. infusion (ONO-7847 / MK-0517)**

- **Additional indication for pediatric use**
- Chemotherapy-induced nausea and vomiting in pediatric patients [NK1 receptor antagonist]/Phase III
- Injection

*In-license (Merck & Co., Inc.)*

- **Orencia<sup>®</sup> IV (ONO-4164 / BMS-188667)**

- **Additional indication**
- Juvenile Rheumatoid Arthritis [T-cell activation inhibitor] / Phase III
- Injection
- *In-license (Bristol-Myers Squibb Company)*

- **Orencia<sup>®</sup> IV (ONO-4164 / BMS-188667)**

- **Additional indication**
- Lupus nephritis[T-cell activation inhibitor] /Phase III
- Injection
- *In-license (Bristol-Myers Squibb Company)*

- **ONO-7057 / Carfilzomib**

- **New chemical entities**
- Multiple Myeloma [Proteasome inhibitor] /Phase III
- Injection
- *In-license (Onyx Pharmaceuticals, Inc.)*

- **ONO-5163 / AMG-416**

- **New chemical entities**
- Secondary hyperparathyroidism [Calcium sensing receptor agonist] / Phase III
- Injection
- *In-license (Amgen Inc.)*

- **ONO-7643 / RC-1291**

- **New chemical entities**
- Cancer anorexia/cachexia [Ghrelin mimetic]/Phase II
- Tablet
- *In-license (Helsinn Healthcare, S.A.)*

- **ONO-1162 / Ivabradine**

- **New chemical entities**
- Chronic heart failure [If channel inhibitor] /Phase II
- Tablet
- *In-license (Les Laboratoires Servier)*

##### Ongoing clinical studies

- **ONO-6950 \*2**

- **New chemical entities**
- Bronchial asthma [LT receptor antagonist]/ Phase II
- Tablet
- *In-house*

- **ONO-4053 \*3**

- **New chemical entities**
- Allergic rhinitis [PGD2 receptor antagonist]/Phase II
- Tablet
- *In-house*

- **ONO-7056 / Salirasib**

- **New chemical entities**
- Solid tumor [Ras signal inhibitor] / Phase I
- Tablet
- *In-license (Kadmon Corporation LLC)*

- **ONO-7268 MX1**

- **New chemical entities**
- Hepatocellular carcinoma [Therapeutic cancer peptide vaccines] /Phase I
- Injection
- *In-license (OncoTherapy Science, Inc.)*

- **ONO-7268 MX2**

- **New chemical entities**
- Hepatocellular carcinoma [Therapeutic cancer peptide vaccines]/ Phase I
- Injection
- *In-license (OncoTherapy Science, Inc.)*

- **ONO-2160/CD**

- **New chemical entities**
- Parkinson's disease [levodopa pro-drug]/ Phase I
- Tablet
- *In-house*

- **ONO-2370 / Opicapone**

- **New chemical entities**
- Parkinson's disease [Long acting COMT inhibitor] / Phase I
- Tablet
- *In-license (Bial)*

- **ONO-4059**

- **New chemical entities**
- B cell lymphoma [Bruton's tyrosine kinase (Btk) inhibitor] /Phase I
- Capsule
- *In-house*

- **ONO-5371 / Metirosine \*4**

- **New chemical entities**
- Pheochromocytoma [Tyrosine hydroxylase inhibitor] /Phase I
- Capsule
- *In-license (Valeant Pharmaceuticals North America LLC.)*

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2015 announced on November 5, 2014

\*1: Application was filed for the approval of partial changes in the manufacturing and marketing authorization of transdermal patch therapy "Rivastach Patch" to treat mild-to-moderate Alzheimer's disease in order to add dosage and administration in which the dose is increased to the maintenance dose by one step.

\*2: Phase II of ONO-6950 (LT receptor antagonist) was initiated for the treatment of bronchial asthma.

\*3: Phase II of ONO-4053 (PGD2 receptor antagonist) was initiated for the treatment of allergic rhinitis.

\*4: Phase I of ONO-5371 / Metirosine (Tyrosine hydroxylase inhibitor) was initiated in healthy adult volunteers.

**Note:** "In-house" compounds include a compound generated from collaborative research.

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

## ii . Developments Status outside Japan

### *Ongoing clinical studies*

- **ONO-6950**
  - **New chemical entities**
  - Bronchial asthma [LT receptor antagonist]/ Phase II
  - Tablet
  - USA
  - *In-house*
- **ONO-4053**
  - **New chemical entities**
  - Allergic rhinitis [PGD2 receptor antagonist]/Phase II
  - Tablet
  - Europe
  - *In-house*
- **ONO-2952**
  - **New chemical entities**
  - Irritable bowel syndrome [TSPO antagonist]/Phase II
  - Tablet
  - USA
  - *In-house*
- **ONO-9054**
  - **New chemical entities**
  - Glaucoma, ocular hypertension [PG receptor (FP / EP3) agonist] /Phase II
  - Eye drop
  - USA
  - *In-house*
- **ONO-4059**
  - **New chemical entities**
  - B cell lymphoma [Bruton's tyrosine kinase (Btk) inhibitor] /Phase I
  - Capsule
  - Europe
  - *In-house*
- **ONO-8055**
  - **New chemical entities**
  - Underactive bladder [PG receptor (EP2 / EP3) agonist]/Phase I
  - Tablet
  - Europe
  - *In-house*
- **ONO-8539**
  - **New chemical entities**
  - Gastroesophageal reflux disease (GERD) [PG receptor (EP1) antagonist]/Phase I
  - Tablet
  - Europe
  - *In-house*
- **ONO-1266**
  - **New chemical entities**
  - Portal hypertension [S1P receptor antagonist]/Phase I
  - Capsule
  - USA
  - *In-house*
- **ONO-4232**
  - **New chemical entities**
  - Acute heart failure [PG receptor (EP4) agonist] /Phase I
  - Injection
  - USA
  - *In-house*

**Note:** "In-house" compounds include a compound generated from collaborative research. In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

## II. Main Pipelines ONO-4538 (BMS-936558)

### i . Developments Status in Japan

#### Opdivo® Intravenous Infusion 20mg, 100mg (ONO-4538 / BMS-936558)

[human anti-human PD-1 monoclonal antibody]

*In-house (Co-development with Bristol-Myers Squibb Company)*

#### *Ongoing clinical studies*

Development Indications	Clinical Stage
Renal cell cancer	Phase III
Non-small cell lung cancer	Phase III
Head and neck cancer	Phase III
Gastric cancer	Phase III
Esophageal cancer	Phase II
Hodgkin's lymphoma *1	Phase II

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2015 announced on November 5, 2014

\*1: Phase II of ONO-4538 was initiated in Japan for the treatment of Hodgkin lymphoma.

### ii . Developments Status outside Japan

#### ONO-4538 / BMS-936558

[human anti-human PD-1 monoclonal antibody]

*In-house (Co-development with Bristol-Myers Squibb Company)*

#### *Approved*

Development Indications	Area
Melanoma *2	USA

#### *Filed*

Development Indications	Area
Non-small cell lung cancer	USA, Europe
Melanoma	Europe
Melanoma	South Korea, Taiwan *3

#### *Ongoing clinical studies*

Development Indications	Clinical Stage	Area
Renal cell cancer	Phase III	USA, Europe
Non-small cell lung cancer	Phase III	South Korea*4, Taiwan
Head and neck cancer	Phase III	USA, Europe
	Phase III	South Korea*5, Taiwan
Glioblastoma	Phase III	USA, Europe
Gastric cancer *6	Phase III	South Korea, Taiwan
Diffuse large B cell lymphoma	Phase II	USA, Europe
Follicular lymphoma	Phase II	USA, Europe
Hodgkin's lymphoma	Phase II	USA, Europe
Solid tumors (triple negative breast cancer, gastric cancer, pancreatic cancer, small cell lung cancer, bladder cancer)	Phase I/II	USA, Europe
Colon cancer	Phase I/II	USA, Europe
Hepatocellular carcinoma	Phase I	USA, Europe
Chronic myeloid leukemia	Phase I	USA, Europe
Hepatitis C	Phase I	USA, Europe

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2015 announced on November 5, 2014

\*2: Approval of ONO-4538/ BMS-936558 was obtained in USA for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor.

\*3: Application for the indication of melanoma was filed in Taiwan.

\*4: Phase III of ONO-4538/BMS-936558 was initiated for the treatment of non-small cell lung cancer in South Korea.

\*5: Phase III of ONO-4538/BMS-936558 was initiated for the treatment of head and neck cancer in South Korea.

\*6: Phase III of ONO-4538/BMS-936558 was initiated for the treatment of gastric cancer in South Korea and Taiwan.

**Note:** "In-house" compounds include a compound generated from collaborative research.

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