First Quarter (April 1 – June 30, 2015) Flash Report (unaudited)

Three months ended June 30, 2015

ONO PHARMACEUTICAL CO., LTD.

August 4, 2015

Ono Pharmaceutical Co., Ltd. ("The Company") has announced its consolidated financial results for three months ended June 30, 2015.
The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRSs”).

This First Quarter Flash Report 2016 (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 122 to $1, the approximate rate of exchange at June 30, 2015.

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$
	1st Quarter 3 months ended Jun. 30, 2014	Annual 12 months ended Mar. 31, 2015	**1st Quarter 3 months ended Jun. 30, 2015**	**1st Quarter 3 months ended Jun. 30, 2015**
Revenue	¥ 31,808	¥ 135,775	**¥ 35,696**	**$ 292,587**
Profit (Owners of the parent company)	2,908	12,976	**9,453**	**77,485**
Total equity	450,730	475,213	**478,045**	**3,918,401**
Total assets	489,204	524,588	**527,832**	**4,326,496**
	Yen			US$
Basic earnings per share	¥ 27.43	¥ 122.40	**¥ 89.17**	**$ 0.73**

Consolidated Financial Forecast for the Six Months Ending September 30, 2015 and for the Year Ending March 31,2016

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Six months ending September 30, 2015		Year ending March 31, 2016	
	Millions of yen	Thousands of US$	Millions of yen	Thousands of US$
Revenue	¥ 64,100	$ 525,410	¥ 135,100	$ 1,107,377
Operating profit	7,500	61,475	14,000	114,754
Profit before tax	8,800	72,131	16,500	135,246
Profit	6,200	50,820	11,600	95,082
(Owners of the parent company)				
	Yen	US$	Yen	US$
Basic earnings per share	¥ 58.49	$ 0.48	¥ 109.43	$ 0.90

(*) 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.

(*) Revisions to the consolidated financial forecast most recently announced: None

Consolidated Statement of Financial Position

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

ASSETS	Millions of yen		Thousands of US$
	As of March 31, 2015	**As of June 30, 2015**	**As of June 30, 2015**
Current assets			
Cash and cash equivalents	¥ 104,222	¥ **103,178**	$ **845,722**
Trade and other receivables	41,960	**46,876**	**384,229**
Marketable securities	22,746	**20,951**	**171,726**
Other financial assets	820	**901**	**7,381**
Inventories	25,805	**25,796**	**211,447**
Other current assets	2,311	**2,010**	**16,476**
Total current assets	197,865	**199,712**	**1,636,980**
Non-current assets			
Property, plant, and equipment	70,754	**74,102**	**607,392**
Intangible assets	33,913	**33,622**	**275,590**
Investment securities	212,162	**210,035**	**1,721,601**
Investments in associates	1,023	**1,011**	**8,287**
Other financial assets	6,314	**6,392**	**52,397**
Deferred tax assets	45	**46**	**374**
Retirement benefit assets	–	**456**	**3,734**
Other non-current assets	2,512	**2,457**	**20,142**
Total non-current assets	326,723	**328,121**	**2,689,516**
Total assets	¥ 524,588	¥ **527,832**	$ **4,326,496**

LIABILITIES AND EQUITY	Millions of yen		Thousands of US$
	As of March 31, 2015	**As of June 30, 2015**	**As of June 30, 2015**
Current liabilities			
Trade and other payables	¥ 13,745	¥ **17,167**	$ **140,716**
Borrowings	287	**297**	**2,435**
Other financial liabilities	2,585	**3,825**	**31,352**
Income taxes payable	6,587	**4,145**	**33,973**
Provisions	684	**743**	**6,090**
Other current liabilities	11,109	**12,153**	**99,614**
Total current liabilities	34,997	**38,330**	**314,180**
Non-current liabilities			
Borrowings	317	**341**	**2,792**
Other financial liabilities	21	**21**	**172**
Retirement benefit liabilities	5,426	**1,941**	**15,913**
Provisions	89	**92**	**753**
Deferred tax liabilities	1,156	**1,912**	**15,674**
Long-term advances received	6,724	**6,548**	**53,675**
Other non-current liabilities	645	**602**	**4,935**
Total non-current liabilities	14,378	**11,458**	**93,914**
Total liabilities	49,375	**49,788**	**408,095**
Equity			
Share capital	17,358	**17,358**	**142,281**
Capital reserves	17,080	**17,080**	**139,999**
Treasury shares	(59,308)	**(59,315)**	**(486,188)**
Other components of equity	45,756	**49,503**	**405,764**
Retained earnings	449,690	**448,734**	**3,678,144**
Equity attributable to owners of the parent company	470,575	**473,360**	**3,880,000**
Non-controlling interests	4,638	**4,685**	**38,402**
Total equity	475,213	**478,045**	**3,918,401**
Total liabilities and equity	¥ 524,588	¥ **527,832**	$ **4,326,496**

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, 2015**	**1st Quarter 3 months ended June 30, 2015**
Revenue	¥ 31,808	¥ **35,696**	$ **292,587**
Cost of sales	(8,301)	**(9,227)**	**(75,635)**
Gross profit	23,507	**26,468**	**216,952**
Selling, general, and administrative expenses	(11,412)	**(6,832)**	**(55,996)**
Research and development costs	(9,209)	**(7,835)**	**(64,224)**
Other income	28	**36**	**294**
Other expenses	(136)	**(164)**	**(1,341)**
Operating profit	2,777	**11,674**	**95,685**
Finance income	1,284	**1,779**	**14,579**
Finance costs	(115)	**(235)**	**(1,927)**
Share of profit (loss) from investments in associates	13	**(9)**	**(73)**
Profit before tax	3,958	**13,208**	**108,263**
Income tax expense	(1,002)	**(3,727)**	**(30,552)**
Profit for the period	2,956	**9,481**	**77,710**
Profit for the period attributable to:			
Owners of the parent company	2,908	**9,453**	**77,485**
Non-controlling interests	48	**28**	**226**
Profit for the period	2,956	**9,481**	**77,710**
Earnings per share:	Yen		US$
Basic earnings per share	27.43	**89.17**	**0.73**

Consolidated Statement of Comprehensive 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, 2015**	**1st Quarter 3 months ended June 30, 2015**
Profit for the period	¥ 2,956	**¥ 9,481**	**$ 77,710**
Other comprehensive income:			
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	**4,300**	**35,246**
Remeasurement of defined benefit plans	(28)	**(1,559)**	**(12,781)**
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(11)	**(1)**	**(10)**
	5,639	**2,740**	**22,455**
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	(27)	**143**	**1,170**
Net fair value gain (loss) on cash flow hedges	(13)	**19**	**155**
	(40)	**162**	**1,325**
Total other comprehensive income	5,599	**2,901**	**23,781**
Total comprehensive income for the period	8,555	**12,382**	**101,491**
Comprehensive income for the period attributable to:			
Owners of the parent company	8,514	**12,332**	**101,081**
Non-controlling interests	41	**50**	**410**
Total comprehensive income for the period	8,555	**12,382**	**101,491**

Consolidated Statement of Changes in Equity

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen							
	Equity attributable to owners of the parent company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non-controlling interests	Total equity
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

	Millions of yen							
	Equity attributable to owners of the parent company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non-controlling interests	Total equity
Balance at April 1, 2015	¥17,358	¥17,080	(¥59,308)	¥45,756	¥449,690	¥470,575	¥4,638	¥475,213
Profit for the period					9,453	9,453	28	9,481
Other comprehensive income				2,879		2,879	22	2,901
Total comprehensive income for the period	–	–	–	2,879	9,453	12,332	50	12,382
Purchase of treasury shares			(7)			(7)		(7)
Cash dividends					(9,541)	(9,541)	(3)	(9,544)
Transfer from other components of equity to retained earnings				868	(868)	–		–
Total transactions with the owners	–	–	(7)	868	(10,409)	(9,547)	(3)	(9,550)
Balance at June 30, 2015	¥17,358	¥17,080	(¥59,315)	¥49,503	¥448,734	¥473,360	¥4,685	¥478,045

	Thousands of US $							
	Equity attributable to owners of the parent company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non-controlling interests	Total equity
Balance at April 1, 2015	**$142,281**	**$139,999**	**($486,133)**	**$375,049**	**$3,685,980**	**$3,857,176**	**$38,015**	**$3,895,191**
Profit for the period					**77,485**	**77,485**	**226**	**77,710**
Other comprehensive income				**23,597**		**23,597**	**184**	**23,781**
Total comprehensive income for the period	–	–	–	**23,597**	**77,485**	**101,081**	**410**	**101,491**
Purchase of treasury shares			**(55)**			**(55)**		**(55)**
Cash dividends					**(78,202)**	**(78,202)**	**(23)**	**(78,226)**
Transfer from other components of equity to retained earnings				**7,118**	**(7,118)**	–		–
Total transactions with the owners	–	–	**(55)**	**7,118**	**(85,321)**	**(78,258)**	**(23)**	**(78,281)**
Balance at June 30, 2015	**$142,281**	**$139,999**	**($486,188)**	**$405,764**	**$3,678,144**	**$3,880,000**	**$38,402**	**$3,918,401**

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, 2015**	**1st Quarter 3 months ended June 30, 2015**
Cash flows from operating activities			
Profit before tax	¥ 3,958	**¥ 13,208**	**$ 108,263**
Depreciation and amortization	1,487	**1,610**	**13,200**
Interest and dividend income	(1,282)	**(1,448)**	**(11,866)**
Interest expense	4	**3**	**25**
(Increase) Decrease in inventories	(3,022)	**8**	**67**
(Increase) Decrease in trade and other receivables	(4,733)	**(4,918)**	**(40,309)**
Increase (Decrease) in trade and other payables	3,156	**(162)**	**(1,326)**
Increase (Decrease) in retirement benefit liabilities	139	**(6,205)**	**(50,863)**
(Increase) Decrease in retirement benefit assets	271	**(34)**	**(281)**
Increase (Decrease) in long-term advances received	–	**(175)**	**(1,436)**
Other	2,375	**1,482**	**12,144**
Subtotal	2,353	**3,369**	**27,618**
Interest received	128	**87**	**712**
Dividends received	1,172	**1,367**	**11,203**
Interest paid	(4)	**(3)**	**(25)**
Income taxes paid	(4,450)	**(6,711)**	**(55,012)**
Net cash provided by (used in) operating activities	(800)	**(1,891)**	**(15,503)**
Cash flows from investing activities			
Purchases of property, plant, and equipment	(1,609)	**(566)**	**(4,641)**
Purchases of intangible assets	(8,777)	**(228)**	**(1,870)**
Proceeds from sales and redemption of investments	6,120	**10,179**	**83,438**
Other	(124)	**(27)**	**(225)**
Net cash provided by (used in) investing activities	(4,391)	**9,358**	**76,702**
Cash flows from financing activities			
Dividends paid to owners of the parent company	(8,490)	**(8,506)**	**(69,719)**
Dividends paid to non-controlling interests	(4)	**(3)**	**(23)**
Repayments of long-term borrowings	(128)	**(107)**	**(876)**
Net increase (decrease) in short-term borrowings	23	**43**	**349**
Purchases of treasury shares	(3)	**(6)**	**(53)**
Net cash provided by (used in) financing activities	(8,602)	**(8,579)**	**(70,322)**
Net increase (decrease) in cash and cash equivalents	(13,793)	**(1,113)**	**(9,123)**
Cash and cash equivalents at the beginning of the period	104,898	**104,222**	**854,282**
Effects of exchange rate changes on cash and cash equivalents	12	**69**	**563**
Cash and cash equivalents at the end of the period	¥ 91,117	**¥ 103,178**	**$ 845,722**

First Quarter (April 1 – June 30, 2015) Flash Report (unaudited)

Three months ended June 30, 2015

Sales of Major Products

Supplemental Data

For information purpose only

Hundreds of Millions of yen

		1st Quarter 3 months ended June 30, 2015			Year ending March 31,2016
		Results	Increase/Decrease		Forecast
Glactiv	Agent for type II diabetes	¥ 82	¥ +4	+4.8 %	¥ 320
Opalmon	Circulatory system agent	62	Δ 3	Δ 4.1 %	225
Recalbon	Agent for osteoporosis	29	+7	+32.3 %	110
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	24	+4	+21.9 %	95
Onon	Agent for bronchial asthma and allergic rhinitis	22	Δ 3	Δ 10.6 %	90
Rivastach	Agent for Alzheimer's disease	20	+5	+32.4 %	85
Orencia SC	Agent for rheumatoid arthritis	18	+13	+246.8 %	70
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	15	Δ 2	Δ 12.2 %	50
Opdivo	Agent for treatment of unresectable melanoma	14	—	—	35
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	14	+2	+14.5 %	45
Onoact	Agent for tachyarrhythmia during and post operation etc	14	+3	+31.7 %	50
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	13	Δ 1	Δ 4.6 %	55
Kinedak	Agent for diabetic peripheral neuropathy	12	Δ 2	Δ 16.3 %	45
Forxiga	Agent for type II diabetes	8	Δ 4	Δ 35.1 %	75
Elaspol	Agent for acute lung injury associated with SIRS	5	Δ 2	Δ 23.2 %	20

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

2 Opdivo was launched in Fiscal year ended March 31, 2015 and a year-on-year change in value and percentage is therefore not available.

Consolidated Statement of Income excluding the Impact of Retirement Benefits Plan Revision

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Supplemental Data

For information purpose only

The Retirement Benefits Plan Revision was agreed between labor and management in April 2015. For this 1st quarter ended June 30, 2015, the company computed actuarial calculations based on the revised retirement benefits plan and past service costs of retirement benefits obligations. As a result, for this 1st quarter ended June 30, 2015, operating profit increased by 63 hundreds of millions of yen, for the reason of decrease of personnel expenses due to the effect of past service costs by the retirement benefits plan revision. The consolidated statement of income for the quarter ended June 30, 2015 excluding this impact is as follows.

	Hundreds of Millions of yen				Millions of US$
	1st Quarter 3 months ended June 30, 2014	1st Quarter 3 months ended June 30, 2015		1st Quarter 3 months ended June 30, 2015	1st Quarter 3 months ended June 30, 2015
	Actual	Actual	Change (%)	Excluding the Impact of Retirement Benefits Plan Revision	Excluding the Impact of Retirement Benefits Plan Revision
Revenue	¥ 318	¥ 357	12.2 %	¥ 357	$ 293
Cost of sales	(83)	(92)	11.2 %	(97)	(79)
Gross profit	235	265	12.6 %	260	213
Selling, general, and administrative expenses	(114)	(68)	Δ 40.1 %	(105)	(86)
Research and development costs	(92)	(78)	Δ 14.9 %	(101)	(82)
Operating profit	28	117	320.4 %	54	44
Profit before tax	40	132	233.7 %	69	57
Income tax expense	(10)	(37)	271.9 %	(19)	(16)
Profit for the period	30	95	220.7 %	50	41
Profit for the period attributable to:					
Owners of the parent company	29	95	225.0 %	50	41

Supplemental Information

Status of Development Pipeline

as of August 4, 2015

I. Main Pipelines Other than ONO-4538

ⅰ. Developments Status in Japan

Filed

- **Rivastach® Patch (ONO-2540 / ENA713D)**
  - **Additional Dosing Regimen**
  - Alzheimer's disease [dual inhibitor of AChE and BuChE]
  - Transdermal patch
  - ***In-license (Novartis Pharma AG)***

- **Proemend® for i.v. infusion (ONO-7847 / MK-0517)*1**
  - **Additional indication for pediatric use**
  - Chemotherapy-induced nausea and vomiting in pediatric patients [NK_1 receptor antagonist]
  - Injection
  - ***In-license (Merck & Co., Inc.)***

Ongoing clinical studies

- **Orencia® IV (ONO-4164 / BMS-188667)**
  - **Additional indication**
  - Juvenile Rheumatoid Arthritis [T-cell activation inhibitor] / Phase III
  - Injection
  - ***In-license (Bristol-Myers Squibb Company)***
- **Orencia® 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.)***
- **Onoact® Intravenous Infusion 50 mg / 150 mg (ONO-1101)**
  - **Additional indication for pediatric use**
  - Tachyarrhythmia in low cardiac function [Short acting beta 1 blocker] / Phase II/III
  - Injection
  - ***In-house***
- **Onoact® Intravenous Infusion 50 mg / 150 mg (ONO-1101)*2**
  - **Additional indication**
  - Ventricular arrhythmia [Short acting beta 1 blocker] / Phase II/III
  - Injection
  - ***In-house***
- **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**
  - **New chemical entities**
  - Bronchial asthma [LT receptor antagonist] / Phase II
  - Tablet
  - ***In-house***

- **ONO-5371 / Metyrosine *3**
  - **New chemical entities**
  - Pheochromocytoma [Tyrosine hydroxylase inhibitor] / Phase I/II
  - Capsule
  - ***In-license (Valeant Pharmaceuticals North America LLC.)***

- **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***

Changes from Flash Report for the Fiscal Year ending March 2015 announced on May 12, 2015
*1: Application was filed for the approval of additional indication of Proemend® for i.v. infusion (NK1 receptor antagonist) for Chemotherapy-induced nausea and vomiting in pediatric patients.
*2: Phase II/III of Onoact® Intravenous Infusion 50 mg/150 mg (Short acting beta 1 blocker) was initiated for ventricular arrhythmia.
*3: Phase I/II of ONO-5371 / Metyrosine (Tyrosine hydroxylase inhibitor) was initiated for pheochromocytoma.
*: Development of ONO-4053 (PGD2 receptor antagonist) was discontinued due to no expected treatment effect.

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-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
  - USA & Europe
  - ***In-house***
- **ONO-8055**
  - **New chemical entities**
  - Underactive bladder [PG receptor (EP2 / EP3) agonist] / 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***
- **ONO-4474**
  - **New chemical entities**
  - Osteoarthritis [Tropomyosin receptor kinase (Trk) inhibitor] / Phase I
  - Capsule
  - Europe
  - ***In-house***

Changes from Flash Report for the Fiscal Year ending March 2015 announced on May 12, 2015
*: Development of ONO-4053 (PGD2 receptor antagonist) was discontinued due to no expected treatment effect

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 etc

ⅰ. Developments Status in Japan, South Korea, and Taiwan

Approved

Product Name / Development Code	Development Indications	Area	In-house / In-license
Yervoy® Intravenous Infusion	Melanoma *1	Japan	In-license (Co-development with Bristol-Myers Squibb Company)

Changes from Flash Report for the Fiscal Year ending March 2015 announced on May 12, 2015
*1: Marketing authorization of Yervoy® Intravenous Infusion was obtained in Japan for the treatment of unresectable or metastatic melanoma with disease progression.

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

Filed

Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) /BMS-936558	Melanoma	Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Non-small cell lung cancer *2	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Flash Report for the Fiscal Year ending March 2015 announced on May 12, 2015
*2: Opdivo® Intravenous Infusion was filed in Japan and South Korea for the treatment of non-small cell lung cancer.

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

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558	Renal cell cancer	Phase III	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Head and neck cancer	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Gastric cancer	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Urothelial cancer *3	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Esophageal cancer	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Hodgkin's lymphoma	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatocellular carcinoma	Phase I	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Solid tumor (combination with Mogamulizumab)	Phase I	Japan	In-house (Co-development with Bristol-Myers Squibb Company and Kyowa Hakko Kirin Co., Ltd.)

Changes from Flash Report for the Fiscal Year ending March 2015 announced on May 12, 2015
*3: Phase II of Opdivo® Intravenous Infusion was initiated for the treatment of urothelial cancer.

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 in Europe and the United States

Approved

Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558	Melanoma *1	Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Non-small cell lung cancer *2	Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Flash Report for the Fiscal Year ending March 2015 announced on May 12, 2015
*1: Marketing authorization of Opdivo® Intravenous Infusion was obtained in Europe for the treatment of melanoma.
*2: Marketing authorization of Opdivo® Intravenous Infusion was obtained in Europe for the treatment of squamous non-small cell lung cancer.

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

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Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) /BMS-936558	Non-small cell lung cancer *3	Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Flash Report for the Fiscal Year ending March 2015 announced on May 12, 2015
*3: Opdivo® Intravenous Infusion was filed in Europe for the treatment of non-squamous non-small cell lung cancer.

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

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558	Renal cell cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Head and neck cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Glioblastoma	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Small cell lung cancer *4	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Diffuse large B cell lymphoma	Phase II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Follicular lymphoma	Phase II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hodgkin's lymphoma	Phase II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Urothelial cancer	Phase II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Colon cancer	Phase I/II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Solid tumors (triple negative breast cancer, gastric cancer, pancreatic cancer, small cell lung cancer, urothelial cancer)	Phase I/II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatocellular carcinoma	Phase I	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hematologic cancer (T-cell lymphoma, multiple myeloma, chronic leukemia, etc.)	Phase I	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Chronic myeloid leukemia	Phase I	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatitis C	Phase I	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Flash Report for the Fiscal Year ending March 2015 announced on May 12, 2015
*4: Phase III was initiated for the treatment of small cell lung cancer by Bristol-Myers Squibb Company.

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.