First Quarter (April 1 – June 30, 2016) Flash Report (unaudited)

Three months ended June 30, 2016

ONO PHARMACEUTICAL CO., LTD.

August 2, 2016

Ono Pharmaceutical Co., Ltd. ("The Company") has announced its consolidated financial results for three months ended June 30, 2016.
The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRSs”).

This First Quarter Flash Report 2017 (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 102 to $1, the approximate rate of exchange at June 30, 2016.

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, 2015	Annual 12 months ended Mar. 31, 2016	**1st Quarter 3 months ended Jun. 30, 2016**	**1st Quarter 3 months ended Jun. 30, 2016**
Revenue	¥ 35,696	¥ 160,284	**¥ 58,757**	**$ 576,047**
Profit (Owners of the parent company)	9,453	24,979	**13,680**	**134,115**
Total equity	478,045	476,255	**477,791**	**4,684,225**
Total assets	527,832	540,450	**540,405**	**5,298,084**
		Yen		US$
Basic earnings per share	¥ 17.83	¥ 47.13	**¥ 25.81**	**$ 0.25**
Diluted earnings per share	¥ -	¥ 47.13	**¥ 25.81**	**$ 0.25**

(Note) The company conducted a stock split of common stocks at a ratio of 1:5 with an effective date of April 1, 2016. As for “Basic earnings per share” and “Diluted earnings per share”, it is calculated assuming that the stock split was conducted at April 1, 2015.

Consolidated Financial Forecast for the Six Months Ending September 30, 2016 and for the Year Ending March 31, 2017

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Six months ending September 30, 2016		Year ending March 31, 2017	
	Millions of yen	Thousands of US$	Millions of yen	Thousands of US$
Revenue	¥ 116,500	$ 1,142,157	¥ 259,000	$ 2,539,216
Operating profit	27,500	269,608	72,500	710,784
Profit before tax	29,000	284,314	75,000	735,294
Profit	21,500	210,784	55,800	547,059
(Owners of the parent company)				
	Yen	US$	Yen	US$
Basic earnings per share	¥ 40.56	$ 0.40	¥ 105.28	$ 1.03

(*)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.

(*) The company conducted a stock split of common stocks at a ratio of 1:5 with an effective date of April 1, 2016. As for “Basic earnings per share”, it is calculated based on the number of shares after the stock split.

Consolidated Statement of Financial Position

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
ASSETS	As of March 31, 2016	**As of June 30, 2016**	**As of June 30, 2016**
Current assets			
Cash and cash equivalents	¥ 110,485	¥ **100,091**	$ **981,286**
Trade and other receivables	62,043	**78,528**	**769,882**
Marketable securities	21,583	**19,530**	**191,470**
Other financial assets	800	**957**	**9,381**
Inventories	23,232	**24,344**	**238,666**
Other current assets	5,430	**4,721**	**46,289**
Total current assets	223,573	**228,171**	**2,236,973**
Non-current assets			
Property, plant, and equipment	80,094	**81,311**	**797,165**
Intangible assets	38,324	**38,486**	**377,310**
Investment securities	182,396	**175,420**	**1,719,805**
Investments in associates	982	**991**	**9,713**
Other financial assets	6,753	**6,782**	**66,490**
Deferred tax assets	5,179	**6,189**	**60,680**
Other non-current assets	3,149	**3,055**	**29,947**
Total non-current assets	316,877	**312,233**	**3,061,110**
Total assets	¥ 540,450	¥ **540,405**	$ **5,298,084**

LIABILITIES AND EQUITY	Millions of yen		Thousands of US$
	As of March 31, 2016	**As of June 30, 2016**	**As of June 30, 2016**
Current liabilities			
Trade and other payables	¥ 31,250	¥ **24,449**	$ **239,692**
Borrowings	328	**342**	**3,355**
Other financial liabilities	3,068	**5,370**	**52,651**
Income taxes payable	6,585	**4,634**	**45,434**
Provisions	1,355	**1,253**	**12,280**
Other current liabilities	9,607	**14,365**	**140,832**
Total current liabilities	52,194	**50,413**	**494,244**
Non-current liabilities			
Borrowings	515	**546**	**5,353**
Other financial liabilities	19	**18**	**173**
Retirement benefit liabilities	4,093	**4,489**	**44,014**
Provisions	30	**30**	**294**
Deferred tax liabilities	885	**881**	**8,634**
Long-term advances received	5,814	**5,617**	**55,065**
Other non-current liabilities	643	**620**	**6,081**
Total non-current liabilities	12,000	**12,201**	**119,614**
Total liabilities	64,195	**62,614**	**613,858**
Equity			
Share capital	17,358	**17,358**	**170,179**
Capital reserves	17,103	**17,111**	**167,756**
Treasury shares	(59,358)	**(59,379)**	**(582,149)**
Other components of equity	43,307	**40,906**	**401,044**
Retained earnings	452,983	**456,916**	**4,479,566**
Equity attributable to owners of the parent company	471,393	**472,912**	**4,636,396**
Non-controlling interests	4,862	**4,879**	**47,829**
Total equity	476,255	**477,791**	**4,684,225**
Total liabilities and equity	¥ 540,450	¥ **540,405**	$ **5,298,084**

Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	1st Quarter 3 months ended June 30, 2015	**1st Quarter 3 months ended June 30, 2016**	**1st Quarter 3 months ended June 30, 2016**
Revenue	¥ 35,696	¥ **58,757**	$ **576,047**
Cost of sales	(9,227)	**(16,202)**	**(158,845)**
Gross profit	26,468	**42,555**	**417,202**
Selling, general, and administrative expenses	(6,832)	**(14,054)**	**(137,781)**
Research and development costs	(7,835)	**(11,119)**	**(109,014)**
Other income	36	**21**	**204**
Other expenses	(164)	**(159)**	**(1,556)**
Operating profit	11,674	**17,244**	**169,056**
Finance income	1,779	**1,531**	**15,010**
Finance costs	(235)	**(540)**	**(5,297)**
Share of profit (loss) from investments in associates	(9)	**10**	**100**
Profit before tax	13,208	**18,245**	**178,868**
Income tax expense	(3,727)	**(4,541)**	**(44,517)**
Profit for the period	9,481	**13,704**	**134,352**
Profit for the period attributable to:			
Owners of the parent company	9,453	**13,680**	**134,115**
Non-controlling interests	28	**24**	**236**
Profit for the period	9,481	**13,704**	**134,352**
Earnings per share:	Yen		US$
Basic earnings per share	17.83	**25.81**	**0.25**
Diluted earnings per share	**-**	**25.81**	**0.25**

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, 2015	**1st Quarter 3 months ended June 30, 2016**	**1st Quarter 3 months ended June 30, 2016**
Profit for the period	¥ 9,481	**¥ 13,704**	**$ 134,352**
Other comprehensive income:			
Items that will not be reclassified to profit or loss:			
Net gain (loss) on financial assets measured at fair value through other comprehensive income	4,300	**(1,910)**	**(18,727)**
Remeasurement of defined benefit plans	(1,559)	**(206)**	**(2,024)**
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(1)	**(0)**	**(2)**
	2,740	**(2,117)**	**(20,753)**
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	143	**(470)**	**(4,605)**
Net fair value gain (loss) on derivatives under hedge accounting	19	**(25)**	**(246)**
	162	**(495)**	**(4,851)**
Total other comprehensive income (loss)	2,901	**(2,612)**	**(25,604)**
Total comprehensive income for the period	12,382	**11,092**	**108,747**
Comprehensive income for the period attributable to:			
Owners of the parent company	12,332	**11,073**	**108,558**
Non-controlling interests	50	**19**	**189**
Total comprehensive income for the period	12,382	**11,092**	**108,747**

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, 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

	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, 2016	¥17,358	¥17,103	(¥59,358)	¥43,307	¥452,983	¥471,393	¥4,862	¥476,255
Profit for the period					13,680	13,680	24	13,704
Other comprehensive income				(2,607)		(2,607)	(5)	(2,612)
Total comprehensive income for the period	–	–	–	(2,607)	13,680	11,073	19	11,092
Purchase of treasury shares			(21)			(21)		(21)
Cash dividends					(9,540)	(9,540)	(3)	(9,544)
Share-based payments		8				8		8
Transfer from other components of equity to retained earnings				206	(206)	–		–
Total transactions with the owners	–	8	(21)	206	(9,747)	(9,553)	(3)	(9,556)
Balance at June 30, 2016	¥17,358	¥17,111	(¥59,379)	¥40,906	¥456,916	¥472,912	¥4,879	¥477,791

	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, 2016	**$170,179**	**$167,679**	**($581,945)**	**$424,578**	**$4,441,008**	**$4,621,499**	**$47,670**	**$4,669,169**
Profit for the period					**134,115**	**134,115**	**236**	**134,352**
Other comprehensive income				**(25,558)**		**(25,558)**	**(47)**	**(25,604)**
Total comprehensive income for the period	–	–	–	**(25,558)**	**134,115**	**108,558**	**189**	**108,747**
Purchase of treasury shares			**(203)**			**(203)**		**(203)**
Cash dividends					**(93,534)**	**(93,534)**	**(31)**	**(93,564)**
Share-based payments		**77**				**77**		**77**
Transfer from other components of equity to retained earnings				**2,024**	**(2,024)**	–		–
Total transactions with the owners	–	**77**	**(203)**	**2,024**	**(95,557)**	**(93,660)**	**(31)**	**(93,691)**
Balance at June 30, 2016	**$170,179**	**$167,756**	**($582,149)**	**$401,044**	**$4,479,566**	**$4,636,396**	**$47,829**	**$4,684,225**

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, 2015	**1st Quarter 3 months ended June 30, 2016**	**1st Quarter 3 months ended June 30, 2016**
Cash flows from operating activities			
Profit before tax	¥ 13,208	**¥ 18,245**	**$ 178,868**
Depreciation and amortization	1,610	**1,680**	**16,466**
Impairment losses	–	**9**	**91**
Interest and dividend income	(1,448)	**(1,526)**	**(14,958)**
Interest expense	3	**3**	**33**
(Increase) Decrease in inventories	8	**(1,143)**	**(11,201)**
(Increase) Decrease in trade and other receivables	(4,918)	**(16,415)**	**(160,934)**
Increase (Decrease) in trade and other payables	(162)	**(268)**	**(2,630)**
Increase (Decrease) in retirement benefit liabilities	(6,205)	**100**	**983**
(Increase) Decrease in retirement benefit assets	(34)	–	–
Increase (Decrease) in long-term advances received	(175)	**(198)**	**(1,937)**
Other	1,482	**6,650**	**65,192**
Subtotal	3,369	**7,137**	**69,975**
Interest received	87	**39**	**383**
Dividends received	1,367	**1,487**	**14,579**
Interest paid	(3)	**(3)**	**(33)**
Income taxes paid	(6,711)	**(6,588)**	**(64,591)**
Net cash provided by (used in) operating activities	(1,891)	**2,072**	**20,313**
Cash flows from investing activities			
Purchases of property, plant, and equipment	(566)	**(8,751)**	**(85,795)**
Purchases of intangible assets	(228)	**(606)**	**(5,945)**
Proceeds from sales and redemption of investments	10,179	**6,000**	**58,824**
Other	(27)	**(74)**	**(730)**
Net cash provided by (used in) investing activities	9,358	**(3,432)**	**(33,647)**
Cash flows from financing activities			
Dividends paid to owners of the parent company	(8,506)	**(8,700)**	**(85,297)**
Dividends paid to non-controlling interests	(3)	**(3)**	**(33)**
Repayments of long-term borrowings	(107)	**(94)**	**(922)**
Net increase (decrease) in short-term borrowings	43	**(12)**	**(114)**
Purchases of treasury shares	(6)	**(20)**	**(200)**
Net cash provided by (used in) financing activities	(8,579)	**(8,830)**	**(86,567)**
Net increase (decrease) in cash and cash equivalents	(1,113)	**(10,190)**	**(99,901)**
Cash and cash equivalents at the beginning of the period	104,222	**110,485**	**1,083,184**
Effects of exchange rate changes on cash and cash equivalents	69	**(204)**	**(1,998)**
Cash and cash equivalents at the end of the period	¥ 103,178	**¥ 100,091**	**$ 981,286**

First Quarter (April 1 – June 30, 2016) Flash Report (unaudited)

Three months ended June 30, 2016

Sales of Major Products

Supplemental Data

For information purpose only

		Hundreds of Millions of yen					
		1st Quarter 3 months ended June 30, 2016			Year ending March 31, 2017		
		Results	Increase/Decrease		Forecast	Increase/Decrease	
Opdivo	Agent for treatment of unresectable melanoma and unresectable, advanced or recurrent non-small cell lung cancer	¥ 252	¥ +238	+1,640.7 %	¥ 1,260	¥ +1,048	+495.7 %
Glactiv	Agent for type II diabetes	77	Δ 5	Δ 6.0 %	295	Δ 19	Δ 6.1 %
Opalmon	Circulatory system agent	47	Δ 15	Δ 24.8 %	175	Δ 52	Δ 22.9 %
Recalbon	Agent for osteoporosis	29	Δ 0	Δ 0.7 %	115	+2	+1.8 %
Forxiga	Agent for type II diabetes	18	+10	+124.7 %	100	+57	+134.0 %
Orencia SC	Agent for rheumatoid arthritis	26	+9	+48.4 %	100	+20	+24.8 %
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	25	+2	+6.4 %	100	+5	+5.6 %
Rivastach	Agent for Alzheimer's disease	22	+3	+13.9 %	90	+12	+14.9 %
Onon	Agent for bronchial asthma and allergic rhinitis	17	Δ 5	Δ 23.3 %	65	Δ 25	Δ 27.4 %
Onoact	Agent for tachyarrhythmia during and post operation	14	+0	+2.9 %	65	+8	+13.9 %
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	13	Δ 1	Δ 6.9 %	50	Δ 2	Δ 3.2 %
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	11	Δ 3	Δ 20.0 %	45	Δ 11	Δ 19.7 %
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	11	Δ 4	Δ 25.6 %	40	Δ 12	Δ 22.4 %
Kinedak	Agent for diabetic peripheral neuropathy	8	Δ 3	Δ 28.2 %	30	Δ 11	Δ 26.6 %
Elaspol	Agent for acute lung injury associated with SIRS	3	Δ 2	Δ 47.7 %	10	Δ 7	Δ 42.8 %

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

Breakdown of Revenue

Supplemental Data

For information purpose only

(Hundreds of Millions of yen)

	1st Quarter 3 months ended June 30, 2015	1st Quarter 3 months ended June 30, 2016
Revenue of Goods and Products	337	536
Royalty and Other Revenue	20	51
Total	357	588

Note: In "Royalty and Other Revenue", royalty revenue of "Opdivo Intravenous Infusion" is included, which is 6 hundreds of millions of yen for April-June 2015 and 43 hundreds of millions of yen for April-June 2016.

Information about Revenue by Geographic Area

Supplemental Data

For information purpose only

(Hundreds of Millions of yen)

	1st Quarter 3 months ended June 30, 2015	1st Quarter 3 months ended June 30, 2016
Japan	338	537
Americas	14	43
Asia	5	6
Europe	1	1
Total	357	588

Consolidated Statement of Income excluding the Impact of Retirement Benefits Plan Revision in previous first quarter ended June 30, 2015

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 previous 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 previous 1st quarter ended June 30, 2015, cost of sales decreased by 4 hundreds of millions of yen, research and development costs decreased by 22 hundreds of millions of yen, and selling, general, and administrative expenses decreased by 37 hundreds of millions of yen respectively, due to the effect of past service costs by the retirement benefits plan revision. Operating profit increased by 63 hundreds of millions of yen. The consolidated statement of income for the quarter ended June 30, 2015 excluding this impact and the quarter ended June 30, 2016 are as follows.

(Hundreds of Millions of yen)

	1st Quarter 3 months ended June 30, 2015		1st Quarter 3 months ended June 30, 2016		
	Actual	Actual excluding the Impact of Retirement Benefits Plan Revision	Actual	Changes (%)	Changes excluding the Impact of Retirement Benefits Plan Revision in previous year (%)
Revenue	¥ 357	¥ 357	¥ 588	64.6 %	64.6 %
Cost of sales	(92)	(97)	(162)	75.6 %	67.8 %
Gross profit	265	260	426	60.8 %	63.4 %
Selling, general, and administrative expenses	(68)	(105)	(141)	105.7 %	34.1 %
Research and development costs	(78)	(101)	(111)	41.9 %	10.6 %
Operating profit	117	54	172	47.7 %	220.7 %
Profit before tax	132	69	182	38.1 %	164.0 %
Income tax expense	(37)	(19)	(45)	21.8 %	135.8 %
Profit for the period	95	50	137	44.5 %	174.9 %
Profit for the period attributable to:					
Owners of the parent company	95	50	137	44.7 %	175.9 %

Supplemental Information

Status of Development Pipeline

as of July 27, 2016

I. Main Pipelines Other than ONO-4538

ⅰ. Developments Status in Japan

Approved

- **KYPROLIS® / ONO-7057 / Carfilzomib *1**
  - **New chemical entities**
  - Multiple Myeloma [Proteasome inhibitor]
  - Injection
  - ***In-license (Onyx Pharmaceuticals, Inc.)***

Filed

- **ONO-5163 / AMG-416 / Etelcalcetide Hydrochloride**
  - **New chemical entities**
  - Secondary hyperparathyroidism [Calcium sensing receptor agonist]
  - Injection
  - ***In-license (Amgen 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)***

- **Orencia® SC (ONO-4164 / BMS-188667)**
  - **Additional indication**
  - Rheumatoid Arthritis [T-cell activation inhibitor] / Phase III
  - Injection
  - ***In-license (Bristol-Myers Squibb Company)***

- **ONO-7057 / Carfilzomib**
  - **Additional Dosing Regimen and additional indication**
  - Multiple Myeloma [Proteasome inhibitor] / Phase III
  - Injection
  - ***In-license (Onyx Pharmaceuticals, Inc.)***

- **ONO-1162 / Ivabradine**
  - **New chemical entities**
  - Chronic heart failure [If channel inhibitor] / Phase III
  - Tablet
  - ***In-license (Les Laboratoires Servier)***

- **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)**
  - **Additional indication**
  - Ventricular arrhythmia [Short acting beta 1 blocker] / Phase II/III
  - Injection
  - ***In-house***

Ongoing clinical studies

- **ONO-7643 / RC-1291**
  - **New chemical entities**
  - Cancer anorexia/cachexia [Ghrelin mimetic] / Phase II
  - Tablet
  - ***In-license (Helsinn Healthcare, S.A.)***

- **ONO-2370 / Opicapone**
  - **New chemical entities**
  - Parkinson's disease [Long acting COMT inhibitor] / Phase II
  - Tablet
  - ***In-license (Bial)***

- **ONO-5371 / Metyrosine**
  - **New chemical entities**
  - Pheochromocytoma [Tyrosine hydroxylase inhibitor] / Phase I/II
  - Capsule
  - ***In-license (Valeant Pharmaceuticals North America 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-4059**
  - **New chemical entities**
  - B cell lymphoma [Bruton's tyrosine kinase (Btk) inhibitor] / Phase I
  - Capsule
  - ***In-house***

- **ONO-8577**
  - **New chemical entities**
  - Overactive bladder [bladder smooth muscle relaxant] / Phase I
  - Tablet
  - ***In-house***

Changes from Flash Report for the Fiscal Year ended March 2016 announced on May 11, 2016
*1: A manufacturing and marketing approval for KYPROLIS® for Intravenous Injection 10 mg and 40 mg, which is a proteasome inhibitor, was obtained in Japan for the treatment of patients with relapsed or refractory multiple myeloma.
*: Development of ONO-6950 (LT 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-2952**
  - **New chemical entities**
  - Irritable bowel syndrome [TSPO antagonist] / Phase II
  - Tablet
  - USA
  - ***In-house***
- **ONO-4059**
  - **New chemical entities**
  - B cell lymphoma [Bruton's tyrosine kinase (Btk) inhibitor] / Phase I
  - Capsule
  - USA & Europe
  - ***Out-license (Gilead Sciences, Inc.)***
- **ONO-8055**
  - **New chemical entities**
  - Underactive bladder [PG receptor (EP2 / EP3) agonist] / Phase I
  - Tablet
  - Europe
  - ***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 ended March 2016 announced on May 11, 2016
*: Development of ONO-6950 (LT receptor antagonist) was discontinued due to no expected treatment effect.
*: Development of ONO-1266 (S1P receptor antagonist) was discontinued due to the strategic reason associated with the change of external environment.

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

Filed

Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) /BMS-936558	Non-small cell lung cancer (Non- Squamous)	Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Renal cell carcinoma	Japan Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Hodgkin's lymphoma	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Head and neck cancer	Japan*1 Taiwan*2	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Flash Report for the Fiscal Year ended March 2016 announced on May 11, 2016
*1: A manufacturing and marketing approval partial amendment application for Opdivo® Intravenous Infusion was filed in Japan for the treatment of recurrent or metastatic head and neck cancer.
*2: An importing and marketing approval partial amendment application for Opdivo® Intravenous Infusion was filed in Taiwan for the treatment of recurrent or metastatic squamous cell carcinoma of the head and neck after platinum based therapy.

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.

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo®Intravenous Infusion (ONO-4538) /BMS-936558	Head and neck cancer	Phase III	South Korea	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)
	Esophageal cancer	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Small cell lung cancer	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatocellular carcinoma	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Glioblastoma	Phase III	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Urothelial cancer	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Ovarian cancer	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo®Intravenous Infusion (ONO-4538) /BMS-936558	Solid tumor (Cervical cancer, Endometrial cancer, Soft tissue sarcoma)	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Malignant pleural mesothelioma	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Virus-positive/negative solid tumor	Phase I/II	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Biliary tract cancer	Phase I	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
Urelumab (ONO-4481) /BMS-663513	Solid tumor	Phase I	Japan	In-house (Co-development with 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.

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	Hodgkin's lymphoma*3	USA	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Flash Report for the Fiscal Year ended March 2016 announced on May 11, 2016
*3: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo® Intravenous Infusion was obtained in USA for the treatment of previously treated classical Hodgkin lymphoma.

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.

Filed

Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) /BMS-936558	Hodgkin's lymphoma	Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Head and neck cancer*4	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Flash Report for the Fiscal Year ended March 2016 announced on May 11, 2016
*4: A supplemental application for approval for the additional indication of Opdivo® Intravenous Infusion was filed in USA and Europe for the treatment of previously treated recurrent or metastatic squamous cell carcinoma of the head and neck.

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.

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo®Intravenous Infusion (ONO-4538) / BMS-936558	Glioblastoma	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Small cell lung cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Urothelial cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatocellular carcinoma	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Esophageal cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558	Multiple myeloma*5	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Esophagogastric junction cancer and Esophageal cancer*6	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)
	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, ovarian cancer)	Phase I/II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Virus-positive/negative solid tumor	Phase I/II	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 ended March 2016 announced on May 11, 2016
*5: Phase III of Opdivo® Intravenous Infusion was initiated for the treatment of Multiple myeloma.
*6: Phase III of Opdivo® Intravenous Infusion was initiated for the treatment of Esophagogastric junction cancer and Esophageal 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.