Second Quarter (April 1 – September 30, 2015) Flash Report (unaudited)
Six months ended September 30, 2015

ONO PHARMACEUTICAL CO., LTD.

November 4, 2015

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

This Second 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 119 to $1, the approximate rate of exchange at September 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$
	2nd Quarter 6 months ended Sep. 30, 2014	Annual 12 months ended Mar. 31, 2015	**2nd Quarter 6 months ended Sep. 30, 2015**	**2nd Quarter 6 months ended Sep. 30, 2015**
Revenue	¥ 62,381	¥ 135,775	**¥ 70,303**	**$ 590,783**
Profit (Owners of the parent company)	3,281	12,976	**11,873**	**99,776**
Total equity	456,324	475,213	**469,973**	**3,949,351**
Total assets	487,573	524,588	**516,637**	**4,341,487**
		Yen		US$
Basic earnings per share	¥ 30.95	¥ 122.40	**¥ 112.01**	**$ 0.94**
Diluted earnings per share	¥ -	¥ -	**¥ 112.00**	**$ 0.94**

Consolidated Financial Forecast for the Year Ending March 31, 2016

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Year ending March 31, 2016	
	Millions of yen	Thousands of US$
Revenue	¥ 144,500	$ 1,214,286
Operating profit	15,200	127,731
Profit before tax	17,800	149,580
Profit (Owners of the parent company)	13,100	110,084
	Yen	US$
Basic earnings per share	123.58	1.04

(*) The forecasts for the year ending March 31, 2016 are revised from May 12, 2015 for the following reasons.
The sales of its new products such as the anti-cancer drug launched last year “OPDIVO® Intravenous Infusion” and the rheumatoid arthritis drug “ORENCIA® Subcutaneous Injection”, and license revenues are expected to exceed the previous forecast.
Also, profits are expected to exceed the previous forecast because a certain portion of selling, general, and administrative expenses which were originally scheduled in the first half is postponed until the 3rd quarter or later.
For the above reasons, the Company has upwardly revised its consolidated financial forecasts.

(*)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.

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 September 30, 2015**	**As of September 30, 2015**
Current assets			
Cash and cash equivalents	¥ 104,222	¥ **108,775**	$ **914,072**
Trade and other receivables	41,960	**43,539**	**365,871**
Marketable securities	22,746	**20,629**	**173,354**
Other financial assets	820	**826**	**6,938**
Inventories	25,805	**25,545**	**214,661**
Other current assets	2,311	**3,608**	**30,316**
Total current assets	197,865	**202,920**	**1,705,212**
Non-current assets			
Property, plant, and equipment	70,754	**74,263**	**624,057**
Intangible assets	33,913	**37,533**	**315,407**
Investment securities	212,162	**187,920**	**1,579,161**
Investments in associates	1,023	**961**	**8,076**
Other financial assets	6,314	**6,483**	**54,481**
Deferred tax assets	45	**4,103**	**34,479**
Other non-current assets	2,512	**2,453**	**20,613**
Total non-current assets	326,723	**313,717**	**2,636,275**
Total assets	¥ 524,588	¥ **516,637**	$ **4,341,487**

LIABILITIES AND EQUITY	Millions of yen		Thousands of US$
	As of March 31, 2015	**As of September 30, 2015**	**As of September 30, 2015**
Current liabilities			
Trade and other payables	¥ 13,745	¥ **18,386**	**$ 154,505**
Borrowings	287	**305**	**2,566**
Other financial liabilities	2,585	**2,975**	**24,997**
Income taxes payable	6,587	**4,594**	**38,604**
Provisions	684	**748**	**6,284**
Other current liabilities	11,109	**9,108**	**76,541**
Total current liabilities	34,997	**36,116**	**303,498**
Non-current liabilities			
Borrowings	317	**451**	**3,789**
Other financial liabilities	21	**21**	**173**
Retirement benefit liabilities	5,426	**2,070**	**17,397**
Provisions	89	**94**	**793**
Deferred tax liabilities	1,156	**925**	**7,770**
Long-term advances received	6,724	**6,373**	**53,556**
Other non-current liabilities	645	**614**	**5,160**
Total non-current liabilities	14,378	**10,548**	**88,638**
Total liabilities	49,375	**46,664**	**392,136**
Equity			
Share capital	17,358	**17,358**	**145,868**
Capital reserves	17,080	**17,088**	**143,594**
Treasury shares	(59,308)	**(59,323)**	**(498,515)**
Other components of equity	45,756	**39,316**	**330,388**
Retained earnings	449,690	**450,816**	**3,788,366**
Equity attributable to owners of the parent company	470,575	**465,254**	**3,909,700**
Non-controlling interests	4,638	**4,718**	**39,650**
Total equity	475,213	**469,973**	**3,949,351**
Total liabilities and equity	¥ 524,588	¥ **516,637**	**$ 4,341,487**

Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	2nd Quarter 6 months ended Sep. 30, 2014	**2nd Quarter 6 months ended Sep. 30, 2015**	**2nd Quarter 6 months ended Sep. 30, 2015**
Revenue	¥ 62,381	¥ **70,303**	$ **590,783**
Cost of sales	(16,694)	**(18,555)**	**(155,921)**
Gross profit	45,687	**51,749**	**434,862**
Selling, general, and administrative expenses	(21,923)	**(18,212)**	**(153,044)**
Research and development costs	(19,653)	**(19,097)**	**(160,475)**
Other income	297	**294**	**2,475**
Other expenses	(1,382)	**(331)**	**(2,778)**
Operating profit	3,026	**14,404**	**121,039**
Finance income	1,696	**1,833**	**15,404**
Finance costs	(42)	**(280)**	**(2,355)**
Share of profit (loss) from investments in associates	17	**(52)**	**(440)**
Profit before tax	4,697	**15,904**	**133,648**
Income tax expense	(1,331)	**(3,964)**	**(33,315)**
Profit for the period	3,365	**11,940**	**100,333**
Profit for the period attributable to:			
Owners of the parent company	3,281	**11,873**	**99,776**
Non-controlling interests	84	**66**	**557**
Profit for the period	3,365	**11,940**	**100,333**
Earnings per share:	Yen		US$
Basic earnings per share	30.95	**112.01**	**0.94**
Diluted earnings per share	**-**	**112.00**	**0.94**

Consolidated Statement of Comprehensive Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	2nd Quarter 6 months ended Sep. 30, 2014	**2nd Quarter 6 months ended Sep. 30, 2015**	**2nd Quarter 6 months ended Sep. 30, 2015**
Profit for the period	¥ 3,365	**¥ 11,940**	**$ 100,333**
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	10,351	**(5,666)**	**(47,614)**
Remeasurement of defined benefit plans	222	**(1,912)**	**(16,064)**
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(5)	**(7)**	**(62)**
	10,568	**(7,585)**	**(63,739)**
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	224	**(44)**	**(374)**
Net fair value gain (loss) on cash flow hedges	(4)	**-**	**-**
	221	**(44)**	**(374)**
Total other comprehensive income (loss)	10,789	**(7,629)**	**(64,113)**
Total comprehensive income for the period	14,154	**4,310**	**36,220**
Comprehensive income for the period attributable to:			
Owners of the parent company	14,081	**4,227**	**35,520**
Non-controlling interests	73	**83**	**700**
Total comprehensive income for the period	14,154	**4,310**	**36,220**

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					3,281	3,281	84	3,365
Other comprehensive income				10,800		10,800	(11)	10,789
Total comprehensive income for the period	–	–	–	10,800	3,281	14,081	73	14,154
Purchase of treasury shares			(9)			(9)		(9)
Cash dividends					(9,541)	(9,541)	(4)	(9,545)
Transfer from other components of equity to retained earnings				(120)	120	–		–
Total transactions with the owners	–	–	(9)	(120)	(9,421)	(9,550)	(4)	(9,554)
Balance at September 30, 2014	¥17,358	¥17,080	(¥59,283)	¥26,306	¥450,398	¥451,858	¥4,466	¥456,324

	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					11,873	11,873	66	11,940
Other comprehensive income				(7,647)		(7,647)	17	(7,629)
Total comprehensive income for the period	–	–	–	(7,647)	11,873	4,227	83	4,310
Purchase of treasury shares			(15)			(15)		(15)
Cash dividends					(9,541)	(9,541)	(3)	(9,544)
Share-based payments		8				8		8
Transfer from other components of equity to retained earnings				1,207	(1,207)	–		–
Total transactions with the owners	–	8	(15)	1,207	(10,747)	(9,548)	(3)	(9,551)
Balance at September 30, 2015	¥17,358	¥17,088	(¥59,323)	¥39,316	¥450,816	¥465,254	¥4,718	¥469,973

	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	**$145,868**	**$143,528**	**($498,388)**	**$384,504**	**$3,778,904**	**$3,954,416**	**$38,973**	**$3,993,389**
Profit for the period					**99,776**	**99,776**	**557**	**100,333**
Other comprehensive income				**(64,256)**		**(64,256)**	**143**	**(64,113)**
Total comprehensive income for the period	–	–	–	**(64,256)**	**99,776**	**35,520**	**700**	**36,220**
Purchase of treasury shares			**(127)**			**(127)**		**(127)**
Cash dividends					**(80,174)**	**(80,174)**	**(24)**	**(80,198)**
Share-based payments		**66**				**66**		**66**
Transfer from other components of equity to retained earnings				**10,140**	**(10,140)**	–		–
Total transactions with the owners	–	**66**	**(127)**	**10,140**	**(90,314)**	**(80,235)**	**(24)**	**(80,259)**
Balance at September 30, 2015	**$145,868**	**$143,594**	**($498,515)**	**$330,388**	**$3,788,366**	**$3,909,700**	**$39,650**	**$3,949,351**

Consolidated Statement of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	2nd Quarter 6 months ended Sep. 30, 2014	**2nd Quarter 6 months ended Sep. 30, 2015**	**2nd Quarter 6 months ended Sep. 30, 2015**
Cash flows from operating activities			
Profit before tax	¥ 4,697	**¥ 15,904**	**$ 133,648**
Depreciation and amortization	2,950	**3,226**	**27,108**
Impairment losses	–	**1,000**	**8,403**
Interest and dividend income	(1,408)	**(1,575)**	**(13,236)**
Interest expense	7	**6**	**51**
(Increase) Decrease in inventories	(3,479)	**255**	**2,144**
(Increase) Decrease in trade and other receivables	3,216	**(1,585)**	**(13,319)**
Increase (Decrease) in trade and other payables	1,866	**929**	**7,803**
Increase (Decrease) in retirement benefit liabilities	258	**(6,174)**	**(51,882)**
(Increase) Decrease in retirement benefit assets	541	**–**	**–**
Increase (Decrease) in long-term advances received	–	**(350)**	**(2,945)**
Other	(1,546)	**(2,776)**	**(23,324)**
Subtotal	7,102	**8,860**	**74,452**
Interest received	251	**185**	**1,551**
Dividends received	1,197	**1,423**	**11,958**
Interest paid	(7)	**(6)**	**(51)**
Income taxes paid	(4,400)	**(6,728)**	**(56,537)**
Net cash provided by (used in) operating activities	4,143	**3,733**	**31,373**
Cash flows from investing activities			
Purchases of property, plant, and equipment	(4,996)	**(1,725)**	**(14,494)**
Purchases of intangible assets	(12,580)	**(5,394)**	**(45,330)**
Purchases of investments	(200)	**(250)**	**(2,102)**
Proceeds from sales and redemption of investments	12,412	**18,079**	**151,924**
Other	(165)	**(134)**	**(1,130)**
Net cash provided by (used in) investing activities	(5,529)	**10,575**	**88,867**
Cash flows from financing activities			
Dividends paid to owners of the parent company	(9,528)	**(9,530)**	**(80,080)**
Dividends paid to non-controlling interests	(4)	**(3)**	**(24)**
Repayments of long-term borrowings	(252)	**(188)**	**(1,577)**
Net increase (decrease) in short-term borrowings	10	**15**	**129**
Purchases of treasury shares	(8)	**(15)**	**(122)**
Net cash provided by (used in) financing activities	(9,783)	**(9,719)**	**(81,674)**
Net increase (decrease) in cash and cash equivalents	(11,169)	**4,589**	**38,566**
Cash and cash equivalents at the beginning of the period	104,898	**104,222**	**875,819**
Effects of exchange rate changes on cash and cash equivalents	47	**(37)**	**(312)**
Cash and cash equivalents at the end of the period	¥ 93,775	**¥ 108,775**	**$ 914,072**

Second Quarter (April 1 – September 30, 2015) Flash Report (unaudited)

Six months ended September 30, 2015

Sales of Major Products

Supplemental Data

For information purpose only

		Hundreds of Millions of yen			
		2nd Quarter 6 months ended September 30, 2015			Year ending March 31,2016
		Results	Increase/Decrease		Forecast
Glactiv	Agent for type II diabetes	¥ 160	¥ +1	+0.6 %	¥ 320
Opalmon	Circulatory system agent	119	Δ 8	Δ 6.3 %	225
Recalbon	Agent for osteoporosis	57	+8	+17.1 %	110
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	47	+5	+12.9 %	95
Onon	Agent for bronchial asthma and allergic rhinitis	41	Δ 4	Δ 9.6 %	90
Rivastach	Agent for Alzheimer's disease	39	+7	+20.5 %	85
Forxiga	Agent for type II diabetes	16	+4	+29.6 %	45
Orencia SC	Agent for rheumatoid arthritis	37	+22	+148.2 %	80
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	25	+0	+0.1 %	55
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	28	Δ 4	Δ 12.7 %	50
Onoact	Agent for tachyarrhythmia during and post operation etc	28	+6	+27.8 %	50
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	26	+1	+4.6 %	45
Kinedak	Agent for diabetic peripheral neuropathy	22	Δ 5	Δ 17.5 %	45
Opdivo	Agent for treatment of unresectable melanoma	30	+27	+942.0 %	55
Elaspol	Agent for acute lung injury associated with SIRS	9	Δ 4	Δ 29.2 %	20

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

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 the 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 the 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 six months ended September 30, 2015 excluding this impact is as follows.

	Hundreds of Millions of yen				Millions of US$
	2nd Quarter 6 months ended Sep. 30, 2014	2nd Quarter 6 months ended Sep. 30, 2015		2nd Quarter 6 months ended Sep. 30, 2015	2nd Quarter 6 months ended Sep. 30, 2015
	Actual	Actual	Change (%)	Excluding the Impact of Retirement Benefits Plan Revision	Excluding the Impact of Retirement Benefits Plan Revision
Revenue	¥ 624	¥ 703	12.7 %	¥ 703	$ 591
Cost of sales	(167)	(186)	11.1 %	(190)	(160)
Gross profit	457	517	13.3 %	513	431
Selling, general, and administrative expenses	(219)	(182)	Δ 16.9 %	(219)	(184)
Research and development costs	(197)	(191)	Δ 2.8 %	(213)	(179)
Operating profit	30	144	376.0 %	81	68
Profit before tax	47	159	238.6 %	96	81
Income tax expense	(13)	(40)	197.8 %	(24)	(20)
Profit for the period	34	119	254.8 %	72	61
Profit for the period attributable to:					
Owners of the parent company	33	119	261.9 %	72	60

Supplemental Information

Status of Development Pipeline

as of October 31, 2015

I. Main Pipelines Other than ONO-4538

ⅰ. Developments Status in Japan

Approved

- **Rivastach® Patch (ONO-2540 / ENA713D)*1**
  - **Additional Dosing Regimen**
  - Alzheimer's disease [dual inhibitor of AChE and BuChE]
  - Transdermal patch
  - ***In-license (Novartis Pharma AG)***

Filed

- **Proemend® for i.v. infusion (ONO-7847 / MK-0517)**
  - **Additional indication for pediatric use**
  - Chemotherapy-induced nausea and vomiting in pediatric patients [NK_1 receptor antagonist]
  - Injection
  - ***In-license (Merck & Co., Inc.)***
- **ONO-7057 / Carfilzomib*2**
  - **New chemical entities**
  - Multiple Myeloma [Proteasome inhibitor]
  - Injection
  - ***In-license (Onyx Pharmaceuticals, 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)*3**
  - **Additional indication**
  - Rheumatoid Arthritis [T-cell activation inhibitor] / Phase III
  - Injection
  - ***In-license (Bristol-Myers Squibb Company)***
- **ONO-7057 / Carfilzomib**
  - **Additional Dosing Regimen**
  - 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-1162 / Ivabradine*4**
  - **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***

Ongoing clinical studies

- **Onoact® Intravenous Infusion 50 mg / 150 mg (ONO-1101)**
  - **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-6950**
  - **New chemical entities**
  - Bronchial asthma [LT receptor antagonist] / Phase II
  - Tablet
  - ***In-house***
- **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-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 First Quarter Flash Report for the Fiscal Year ending March 2016 announced on August 4, 2015
*1: Approval was obtained for the 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: Manufacturing and Marketing Approval Application was filed for "Carfilzomib (ONO-7057)", which is a proteasome inhibitor, to seek an indication for relapsed or refractory multiple myeloma.
*3: Phase III of Orencia® SC (ONO-4164 / BMS-188667) (T-cell activation inhibitor) was initiated for anti-rheumatic drug previously untreated patients with rheumatoid arthritis.
*4: Phase III of ONO-1162 / Ivabradine (If channel inhibitor) was initiated for chronic heart failure.
*: Development of ONO-7056 / Salirasib (Ras signal inhibitor) 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***

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	Melanoma	Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Non-small cell lung cancer	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)

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)
	Esophageal cancer *1	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Small cell lung cancer *2	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Urothelial cancer	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Ovarian cancer *3	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Glioblastoma *4	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)
	Virus-positive/negative solid tumor *5	Phase I/II	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Biliary tract cancer *6	Phase I	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.)
	Solid tumor (combination with Urelumab) *7	Phase I	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Solid tumor (combination with LAG3 immune Checkpoint inhibitor) *8	Phase I	Japan	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from First Quarter Flash Report for the Fiscal Year ending March 2016 announced on August 4, 2015
*1: Phase III of Opdivo® Intravenous Infusion was initiated for the treatment of Esophageal cancer.
*2: Phase III of Opdivo® Intravenous Infusion was initiated for the treatment of Small cell lung cancer.
*3: Phase II of Opdivo® Intravenous Infusion was initiated for the treatment of Ovarian cancer.
*4: Phase II of Opdivo® Intravenous Infusion was initiated for the treatment of Glioblastoma.
*5: Phase I/II of Opdivo® Intravenous Infusion was initiated for the treatment of Virus-positive/negative solid tumor.
*6: Phase I of Opdivo® Intravenous Infusion was initiated for the treatment of Biliary tract cancer.
*7: Phase I of Opdivo® Intravenous Infusion was initiated for the treatment of Solid tumor (combination with Urelumab).
*8: Phase I of Opdivo® Intravenous Infusion was initiated for the treatment of Solid tumor (combination with LAG3 immune Checkpoint inhibitor).

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 (combination) *1	USA	In-house (Co-development with Bristol-Myers Squibb Company)
	Non-small cell lung cancer *2	USA	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from First Quarter Flash Report for the Fiscal Year ending March 2016 announced on August 4, 2015
*1: Manufacturing and Marketing authorization of Opdivo® Intravenous Infusion was obtained in USA for the Opdivo + Yervoy regimen for the treatment of melanoma.
*2: Manufacturing and Marketing authorization of Opdivo® Intravenous Infusion was obtained in USA for the treatment of non-squamous non-small cell lung cancer, following the approval for the treatment of squamous non-small cell lung cancer.

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	Non-small cell lung cancer (Non-squamous Non-small cell lung cancer)	Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Melanoma (combination) *3	Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from First Quarter Flash Report for the Fiscal Year ending March 2016 announced on August 4, 2015
*3: Manufacturing and Marketing Approval Application of Opdivo® Intravenous Infusion was filed in Europe for the Opdivo + Yervoy regimen for the treatment of melanoma.

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	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, bladder cancer, ovarian cancer)	Phase I/II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Virus-positive/negative solid tumor *4	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 First Quarter Flash Report for the Fiscal Year ending March 2016 announced on August 4, 2015
*4: Phase I/II of Opdivo® Intravenous Infusion was initiated for the treatment of Virus-positive/negative solid tumor.

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.

Supplemental Information

New Drugs in Development

as of October 31, 2015

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

Rivastach® Patch(ONO-2540 / ENA713D)

Japan: J-NDA approved / Alzheimer's disease (additional dosing regimen) (co-development with Novartis Pharma AG)

Proemend® Intravenous Infusion (ONO-7847 / MK-0517)

Japan: J-NDA filed / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication)
USA & Other Countries: Phase III / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication) (Merck & Co., Inc.)

ONO-7057 / Carfilzomib (injection)

ONO-7057 is a proteasome inhibitor being developed for multiple myeloma, which is a cancer of plasma cells (one of blood cells). ONO-7057 is highly expected to be a new treatment option for multiple myeloma of which prognosis is considered poor.

Japan: J-NDA filed / multiple myeloma, Phase III / multiple myeloma (Additional Dosing Regimen)
Overseas: Approved in the United States / multiple myeloma (launched in August 2012), Filed in Europe / multiple myeloma (Onyx Pharmaceuticals, Inc.).

ONO-4164IV / BMS-188667IV (injection)

ONO-4164IV is an intravenous preparation of Orencia® and is marketed in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed and overseas where it is indicated for use in patients with juvenile idiopathic arthritis.

Japan: Phase III / juvenile idiopathic arthritis (additional indication) (co-development with Bristol-Myers Squibb Company), Phase III / lupus nephritis (additional indication) (co-development with Bristol-Myers Squibb Company, being conducted as global clinical trial)
Overseas: Phase III / lupus nephritis (additional indication) (Bristol-Myers Squibb Company, being conducted as global clinical trial)

ONO-4164SC / BMS-188667SC (injection)

ONO-4164SC is a subcutaneous formulation of Orencia® and is marketed in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed.

Japan: Phase III / rheumatoid arthritis (additional indication) (co-development with Bristol-Myers Squibb Company, being conducted as global clinical trial)
Overseas: Phase III / rheumatoid arthritis (additional indication) (Bristol-Myers Squibb Company, being conducted as global clinical trial)

ONO-5163 / AMG-416 (injection)

ONO-5163 is a calcium sensing receptor agonist currently being developed for the treatment of secondary hyperparathyroidism.

Japan: Phase III / secondary hyperparathyroidism
Overseas (USA & Europe): Filed / secondary hyperparathyroidism (Amgen Inc.)

ONO-1162 (tablet)

ONO-1162 is an If channel blocker and is approved for the indication of chronic heart failure in addition to stable angina in Europe. It is under development in Japan for the indication of chronic heart failure.

Japan: Phase III / chronic heart failure
Overseas: Marketed / stable angina, chronic heart failure (Les Laboratoires Servier)

Onoact® Intravenous Infusion 50mg/150 mg (ONO-1101)

Japan: Phase II/III / tachyarrhythmia in low cardiac function in pediatric patients (additional indication), Phase II/III / ventricular arrhythmia (additional indication)

ONO-7643 / RC-1291 (tablet)

ONO-7643 is a small-molecule ghrelin mimetic being developed for cancer anorexia / cachexia. ONO-7643 has similar pharmacological actions to ghrelin, a circulating peptide hormone with multiple physiological actions, including appetite stimulation and muscle-building, and is therefore expected to be a breakthrough drug that improves quality of life (QOL) for patients impaired by a systemic wasting condition characterized by anorexia, lipolysis and muscle loss associated with the progression of cancer.

Japan: Phase II / cancer anorexia / cachexia
USA & Other Countries: Phase III / cancer anorexia / cachexia (Helsinn Healthcare, S.A.)

ONO-6950 (tablet)

ONO-6950 is a leukotriene receptor antagonist, and is under clinical development for bronchial asthma. It is expected to improve symptoms associated with the disease by inhibiting airway inflammation.

Japan: Phase II / bronchial asthma
USA: Phase II / bronchial asthma

ONO-5371/ Metyrosine (capsule)

ONO-5371 is a tyrosine hydroxylase inhibitor against catecholamine biosynthesis, and is under clinical development for pheochromocytoma. ONO-5371 was approved and launched in the United States in 1979. In Japan, the Review Committee on Unapproved and Off-Label Drugs with High Medical Needs, set up by the Ministry of Health, Labour and Welfare (MHLW) regarded metyrosine as a drug with high medical needs and MHLW publicly sought pharmaceutical companies to develop metyrosine.

Japan: Phase I/II / pheochromocytoma
USA: Marketed / pheochromocytoma (Valeant Pharmaceuticals North America LLC)

ONO-7268MX1 / ONO-7268MX2 (injection)

ONO-7268MX1 and ONO-7268MX2 are peptide vaccines and are expected to have effects on cancers such as hepatocellular carcinoma.

Japan: Phase I / hepatocellular carcinoma

ONO-2160/CD (tablet)

ONO-2160 is a combination product with levodopa pro-drug and carbidopa which is currently developed for Parkinson's disease.

Japan: Phase I / Parkinson's disease

ONO-2370/Opicapone (tablet)

ONO-2370 is a long acting COMT inhibitor being developed for the treatment of Parkinson's disease. ONO-2370 is filed in Europe and the compound has shown a long-lasting effect on COMT inhibition from once daily dosing in clinical studies so far and is expected to improve a dosing convenience.

Japan: Phase I / Parkinson's disease
Europe: Filed / Parkinson's disease (Bial)

ONO-4059 (capsule)

ONO-4059 is a Btk inhibitor being developed for the treatment of B cell lymphoma.

Japan: Phase I / B cell lymphoma
USA & Europe: Phase I / B cell lymphoma

ONO-2952 (tablet)

ONO-2952 is an antagonist of translocator protein (TSPO) that is involved in neurosteroid production mainly in central nervous system, and is under clinical development for irritable bowel syndrome. It is expected to improve various symptoms of the disease by blocking the mechanism eliciting abnormality of brain-gut interactions under stress.

USA: Phase II / IBS

ONO-9054 (eye drop)

ONO-9054 is a prostaglandin receptor (FP/EP3) agonist being developed for glaucoma and ocular hypertension.

USA: Phase II / glaucoma and ocular hypertension

ONO-8055 (tablet)

ONO-8055 is a prostaglandin receptor (EP2/EP3) agonist being developed for the treatment of underactive bladder.

Europe: Phase I / underactive bladder

ONO-1266 (capsule)

ONO-1266 is a sphingosine-1-phosphate receptor (S1P) antagonist being developed for the treatment of portal hypertension.

USA: Phase I /portal hypertension

ONO-4232 (injection)

ONO-4232 is a prostaglandin receptor (EP4) agonist being developed for the treatment of acute heart failure.

USA: Phase I /acute heart failure

ONO-4474 (capsule)

ONO-4474 is a tropomyosin receptor kinase (Trk) inhibitor being developed for the treatment of osteoarthritis.
Europe: Phase I /osteoarthritis

ONO-4538 / BMS-936558 (injection)

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

In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

Japan:

Launched in September 2014 / melanoma,
J-NDA filed / non-small cell lung cancer,
Phase III / renal cell cancer (global clinical trial),
Phase III / head and neck cancer (global clinical trial),
Phase III / gastric cancer (global clinical trial),
Phase III / esophageal cancer (global clinical trial),
Phase III / small cell lung cancer (global clinical trial),
Phase II / urothelial cancer (global clinical trial),
Phase II / ovarian cancer,
Phase II / glioblastoma,
Phase II / Hodgkin's lymphoma,
Phase I/II / virus-positive/negative solid tumor,
Phase I / biliary tract cancer,
Phase I / hepatocellular carcinoma,
Phase I / Solid tumor (combination with Mogamulizumab),
Phase I / Solid tumor (combination with Urelumab),
Phase I / Solid tumor (combination with LAG3 immune Checkpoint inhibitor)

Overseas:

USA / Launched in December 2014 / melanoma,
South Korea / Approved in March 2015 / melanoma,
USA / Approved in March 2015 / squamous non-small cell lung cancer,
Europe / Approved in June 2015 / melanoma,
Europe / Approved in July 2015 / squamous non-small cell lung cancer,
USA / Approved in September 2015 / melanoma (combination with Yervoy),
USA / Approved in October 2015 / non-squamous non-small cell lung cancer,
Europe / Filed / melanoma (combination with Yervoy),
Taiwan / Filed / melanoma,
Europe / Filed / non-squamous non-small cell lung cancer,
Taiwan / Filed / squamous non-small cell lung cancer,
South Korea / Filed / non-small cell lung cancer,
South Korea, Taiwan / Phase III / gastric cancer,
South Korea, Taiwan / Phase III / esophageal cancer,
USA, Europe / Phase III / renal cell cancer,
USA, Europe, South Korea, Taiwan / Phase III / head and neck cancer,
USA, Europe / Phase III / glioblastoma,
USA, Europe, South Korea, Taiwan / Phase III / small cell lung cancer,
USA, Europe / Phase II / diffuse large B cell lymphoma,
USA, Europe / Phase II / follicular lymphoma,
USA, Europe / Phase II / hodgkin's lymphoma,
USA, Europe / Phase II / urothelial cancer
USA, Europe / Phase I/II / colon cancer,
USA, Europe / Phase I/II / solid tumors (triple negative breast cancer, gastric cancer, pancreatic cancer, small cell lung cancer, bladder cancer, ovarian cancer),
USA, Europe, South Korea, Taiwan / Phase I/II / virus-positive/negative solid tumor,
USA, Europe / Phase I / hepatocellular carcinoma,
USA, Europe / Phase I / hematological cancer (T-cell lymphoma, multiple myeloma, chronic leukemia, etc),
USA, Europe / Phase I / chronic myelocytic leukemia,
USA, Europe / Phase I / hepatitis C