Second Quarter (April 1 – September 30, 2014) Flash Report (unaudited)
Six months ended September 30, 2014

ONO PHARMACEUTICAL CO., LTD.

November 5, 2014

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for six months ended September 30, 2014.
The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS").

This Second Quarter Flash Report 2015 (unaudited) is summary information extracted from the financial statements announced, and the financial statements contained herein are prepared for reference only for the convenience of readers outside Japan with certain modifications and reclassifications made from the original financial statements presented in Japanese language.

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 109 to $1, the approximate rate of exchange at September 30, 2014.

Financial Highlights

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen			Thousands of US$
	Six months ended Sep. 30, 2013	Year ended Mar. 31, 2014	**Six months ended Sep. 30, 2014**	**Six months ended Sep. 30, 2014**
Revenue	¥ 70,740	¥ 143,247	**¥ 62,381**	**$ 572,300**
Profit (Owners of the parent company)	11,530	20,344	**3,281**	**30,103**
Total equity	448,596	451,724	**456,324**	**4,186,461**
Total assets	480,457	486,141	**487,573**	**4,473,146**
	Yen			US$
Basic earnings per share	¥ 108.75	¥ 191.90	**¥ 30.95**	**$ 0.28**

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Consolidated Financial Forecast for the Year Ending March 31, 2015

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Year ending March 31, 2015			
	Millions of yen		Thousands of US$	
Revenue	¥	**129,400**	$	**1,187,156**
Operating profit		**13,100**		**120,183**
Profit before tax		**15,700**		**144,037**
Profit		**10,900**		**100,000**
(Owners of the parent company)				
	Yen		US$	
Basic earnings per share	¥	**102.82**	$	**0.94**

(*)The forecasts for the year ending March 31, 2015 are changed from May 13, 2014.

(*)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.

Second Quarter (April 1 – September 30, 2014) Flash Report (unaudited)
Six months ended September 30, 2014

Consolidated Statement of Financial Position

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

ASSETS	Millions of yen		Thousands of US$
	As of March 31, 2014	**As of September 30, 2014**	**As of September 30, 2014**
Current assets			
Cash and cash equivalents	¥ 104,898	**¥ 93,775**	**$ 860,324**
Trade and other receivables	42,240	**39,025**	**358,031**
Marketable securities	22,295	**21,294**	**195,360**
Other financial assets	905	**805**	**7,384**
Inventories	24,261	**27,742**	**254,511**
Other current assets	958	**1,438**	**13,189**
Total current assets	195,557	**184,079**	**1,688,798**
Noncurrent assets			
Property, plant and equipment	59,147	**61,160**	**561,101**
Intangible assets	22,690	**34,376**	**315,376**
Investment securities	188,360	**193,638**	**1,776,499**
Investments in associates	1,008	**1,019**	**9,346**
Other financial assets	5,913	**6,014**	**55,174**
Deferred tax assets	10,003	**3,986**	**36,568**
Retirement benefit assets	905	**744**	**6,830**
Other noncurrent assets	2,559	**2,556**	**23,453**
Total noncurrent assets	290,585	**303,494**	**2,784,348**
Total assets	¥ 486,141	**¥ 487,573**	**$ 4,473,146**

LIABILITIES AND EQUITY	Millions of yen		Thousands of US$
	As of March 31, 2014	**As of September 30, 2014**	**As of September 30, 2014**
Current liabilities			
Trade and other payables	¥ 11,288	**¥ 12,315**	**$ 112,986**
Borrowings	508	**439**	**4,026**
Other financial liabilities	846	**2,517**	**23,089**
Income taxes payable	4,303	**1,007**	**9,238**
Provisions	1,063	**673**	**6,175**
Other current liabilities	10,264	**8,013**	**73,511**
Total current liabilities	28,272	**24,964**	**229,025**
Noncurrent liabilities			
Borrowings	468	**366**	**3,356**
Other financial liabilities	17	**19**	**173**
Retirement benefit liabilities	3,945	**4,240**	**38,896**
Provisions	87	**88**	**806**
Deferred tax liabilities	1,002	**964**	**8,844**
Other noncurrent liabilities	626	**609**	**5,585**
Total noncurrent liabilities	6,146	**6,285**	**57,660**
Total liabilities	34,418	**31,249**	**286,685**
Equity			
Share capital	17,358	**17,358**	**159,250**
Capital reserves	17,080	**17,080**	**156,696**
Treasury shares	(59,274)	**(59,283)**	**(543,884)**
Other components of equity	15,626	**26,306**	**241,335**
Retained earnings	456,537	**450,398**	**4,132,089**
Equity attributable to owners of the parent company	447,327	**451,858**	**4,145,486**
Non-controlling interests	4,397	**4,466**	**40,974**
Total equity	451,724	**456,324**	**4,186,461**
Total liabilities and equity	¥ 486,141	**¥ 487,573**	**$ 4,473,146**

Second Quarter (April 1 – September 30, 2014) Flash Report (unaudited)
Six months ended September 30, 2014

Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	Six months ended Sep. 30, 2013	**Six months ended Sep. 30, 2014**	**Six months ended Sep. 30, 2014**
Revenue	¥ 70,740	**¥ 62,381**	**$ 572,300**
Cost of sales	(15,452)	**(16,694)**	**(153,156)**
Gross profit	55,289	**45,687**	**419,144**
Selling, general and administrative expenses	(18,574)	**(21,923)**	**(201,132)**
Research and development costs	(21,474)	**(19,653)**	**(180,300)**
Other income	264	**297**	**2,727**
Other expenses	(464)	**(1,382)**	**(12,677)**
Operating profit	15,041	**3,026**	**27,762**
Finance income	1,642	**1,696**	**15,556**
Finance costs	(31)	**(42)**	**(389)**
Share of profit from investments in associates	(3)	**17**	**160**
Profit before tax	16,649	**4,697**	**43,089**
Income tax expense	(5,026)	**(1,331)**	**(12,213)**
Profit for the period	11,624	**3,365**	**30,876**
Profit for the period attributable to :			
Owners of the parent company	11,530	**3,281**	**30,103**
Non-controlling interests	94	**84**	**773**
Profit for the period	11,624	**3,365**	**30,876**

Earnings per share:	Yen		US$
Basic earnings per share	108.75	**30.95**	**0.28**

Consolidated Statement of Comprehensive Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	Six months ended Sep. 30, 2013	**Six months ended Sep. 30, 2014**	**Six months ended Sep. 30, 2014**
Profit for the period	¥ 11,624	**¥ 3,365**	**$ 30,876**
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	3,926	**10,351**	**94,963**
Remeasurement of defined benefit plans	168	**222**	**2,038**
Share of net loss on financial assets measured at fair value through other comprehensive income of investments in associates	(4)	**(5)**	**(49)**
	4,090	**10,568**	**96,952**
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	146	**224**	**2,059**
Net fair value gain (loss) on cash flow hedges	14	**(4)**	**(33)**
	161	**221**	**2,026**
Total other comprehensive income	4,251	**10,789**	**98,978**
Total comprehensive income for the period	15,875	**14,154**	**129,854**
Comprehensive income for the period attributable to:			
Owners of the parent company	15,786	**14,081**	**129,185**
Non-controlling interests	89	**73**	**669**
Total comprehensive income for the period	15,875	**14,154**	**129,854**

Second Quarter (April 1 – September 30, 2014) Flash Report (unaudited)

Six months ended September 30, 2014

Consolidated Statement of Changes in Equity

Ono Pharmaceutical Co.. Ltd. and Consolidated Subsidiaries

	Millions of yen							
	Equity attributable to owners of the parent company							
	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, 2013	¥17,358	¥17,080	(¥59,231)	¥8,198	¥454,681	¥438,086	¥4,190	¥442,276
Profit for the period					11,530	11,530	94	11,624
Other comprehensive income				4,256		4,256	(5)	4,251
Total comprehensive income for the period	–	–	–	4,256	11,530	15,786	89	15,875
Purchase of treasury shares			(10)			(10)		(10)
Cash dividends					(9,541)	(9,541)	(3)	(9,545)
Transfer from other components of equity to retained earnings				(167)	167	–		–
Total transactions with the owners	–	–	(10)	(167)	(9,374)	(9,551)	(3)	(9,555)
Balance at September 30, 2013	¥17,358	¥17,080	(¥59,241)	¥12,287	¥456,836	¥444,321	¥4,276	¥448,596

	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

	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, 2014	**$159,250**	**$156,696**	**($543,802)**	**$143,356**	**$4,188,415**	**$4,103,915**	**$40,341**	**$4,144,256**
Profit for the period					**30,103**	**30,103**	**773**	**30,876**
Other comprehensive income				**99,082**		**99,082**	**(104)**	**98,978**
Total comprehensive income for the period	–	–	–	**99,082**	**30,103**	**129,185**	**669**	**129,854**
Purchase of treasury shares			**(81)**			**(81)**		**(81)**
Cash dividends					**(87,532)**	**(87,532)**	**(35)**	**(87,567)**
Transfer from other components of equity to retained earnings				**(1,103)**	**1,103**	–		–
Total transactions with the owners	–	–	**(81)**	**(1,103)**	**(86,429)**	**(87,613)**	**(35)**	**(87,648)**
Balance at September 30, 2014	**$159,250**	**$156,696**	**($543,884)**	**$241,335**	**$4,132,089**	**$4,145,486**	**$40,974**	**$4,186,461**

Second Quarter (April 1 – September 30, 2014) Flash Report (unaudited)

Six months ended September 30, 2014

Consolidated Statement of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	Six months ended Sep. 30, 2013	**Six months ended Sep. 30, 2014**	**Six months ended Sep. 30, 2014**
Cash flows from operating activities			
Profit before tax	¥ 16,649	**¥ 4,697**	**$ 43,089**
Depreciation and amortization	2,425	**2,950**	**27,067**
Impairment losses	1,898	**—**	**—**
Interest and dividend income	(1,492)	**(1,408)**	**(12,921)**
Interest expense	6	**7**	**65**
Increase in inventories	(1,684)	**(3,479)**	**(31,918)**
Decrease in trade and other receivables	3,481	**3,216**	**29,507**
Increase in trade and other payables	1,169	**1,866**	**17,116**
Increase in retirement benefit liabilities	260	**258**	**2,371**
Decrease in retirement benefit assets	505	**541**	**4,968**
Other	(2,889)	**(1,546)**	**(14,185)**
Subtotal	20,328	**7,102**	**65,158**
Interest received	371	**251**	**2,300**
Dividends received	1,200	**1,197**	**10,985**
Interest paid	(6)	**(7)**	**(65)**
Income taxes paid	(5,728)	**(4,400)**	**(40,370)**
Net cash provided by operating activities	16,165	**4,143**	**38,008**
Cash flows from investing activities			
Purchases of property, plant and equipment	(2,523)	**(4,996)**	**(45,835)**
Purchases of intangible assets	(3,283)	**(12,580)**	**(115,417)**
Purchases of investments	(14,963)	**(200)**	**(1,836)**
Proceeds from sales and redemption of investments	27,303	**12,412**	**113,871**
Other	(212)	**(165)**	**(1,512)**
Net cash provided by (used in) investing activities	6,323	**(5,529)**	**(50,729)**
Cash flows from financing activities			
Dividends paid to owners of the parent company	(9,539)	**(9,528)**	**(87,414)**
Dividends paid to non-controlling interests	(3)	**(4)**	**(35)**
Repayments of long-term borrowings	(247)	**(252)**	**(2,314)**
Net increase in short-term borrowings	10	**10**	**90**
Purchases of treasury shares	(9)	**(8)**	**(76)**
Net cash used in financing activities	(9,788)	**(9,783)**	**(89,749)**
Net increase (decrease) in cash and cash equivalents	12,700	**(11,169)**	**(102,469)**
Cash and cash equivalents at the beginning of the period	89,117	**104,898**	**962,365**
Effects of exchange rate changes on cash and cash equivalents	37	**47**	**428**
Cash and cash equivalents at the end of the period	¥ 101,853	**¥ 93,775**	**$ 860,324**

Notes to Consolidated Financial Statements

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Note 1 This Second Quarter Flash Report 2015 (unaudited) is a summary information extracted from the financial statements announced by the Company on November 5, 2014.
The financial statements announced have been prepared and stated in accordance with International Financial Reporting Standards ("IFRS").
The financial statements and figures contained in this Second Quarter Flash Report 2015 (unaudited) are prepared for the reference only for the convenience of readers outside Japan with certain modifications and reclassifications made from the original financial statements presented in Japanese language.

Note 2 Amounts of less than one million yen and one thousand U.S. dollars have been rounded to the nearest million yen and one thousand U.S. dollars in the presentation of the accompanying consolidated financial statements.

Note 3 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 109 to $1, the approximate rate of exchange at September 30, 2014.

Second Quarter (April 1 – September 30, 2014) Flash Report (unaudited)

Six months ended September 30, 2014

Sales of Major Products

Supplemental Data

For information purpose only

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

Products	Indication	Six months ended September 30, 2014			Year ending March 31, 2015
		Results	Increase/Decrease		Forecast
Glactiv	Agent for type II diabetes	¥ 159	¥ Δ 23	Δ 12.7 %	¥ 320
Opalmon	Circulatory system agent	127	Δ 40	Δ 23.9 %	250
Recalbon	Agent for osteoporosis	49	Δ 3	Δ 5.0 %	115
Onon	Agent for bronchial asthma and allergic rhinitis	45	Δ 16	Δ 25.8 %	100
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	42	Δ 0	Δ 1.0 %	90
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	32	Δ 10	Δ 23.4 %	60
Rivastach	Agent for Alzheimer's disease	32	+3	+11.0 %	70
Kinedak	Agent for diabetic peripheral neuropathy	27	Δ 11	Δ 29.9 %	50
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	25	Δ 6	Δ 18.4 %	55
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	25	Δ 5	Δ 16.7 %	60
Onoact	Agent for tachyarrhythmia during and post operation, or tachyarrhythmia in left ventricular dysfunction.	22	+3	+13.5 %	50
Orencia SC	Agent for rheumatoid arthritis	15	+14	+2186.1 %	35
Elaspol	Agent for acute lung injury associated with SIRS	13	Δ 3	Δ 21.0 %	25
Forxiga	Agent for type II diabetes	13	—	—	30
Opdivo	Agent for treatment of unresectable melanoma	3	—	—	20

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

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

Second Quarter (April 1– September 30, 2014) Flash Report (unaudited)

Six months ended September 30, 2014

Supplemental Information

Status of Development Pipeline

as of November 5, 2014

I. Main Pipelines Other than ONO-4538

ⅰ. Developments Status in Japan

NDA approved

- **Opalmon® Tablets (OP-1206・α-CD) *1**
  - **New formulation**
  - Thromboangitis obliterans and lumbar spinal canal stenosis [Blood vessel dilation]
  - Tablet
  - ***In-house (Co-development with Sumitomo Dainippon Pharma Co., Ltd.)***

NDA filed

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

Ongoing clinical studies

- **Rivastach® Patch (ONO-2540 / ENA713D)**
  - **Additional Dosing Regimen**
  - Alzheimer's disease [dual inhibitor of AChE and BuChE] /Phase III
  - Transdermal patch
  - ***In-license (Novartis Pharma AG)***
- **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]/Phase III
  - Injection
  - ***In-license* (Merck & Co., Inc.)**
- **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** *2
  - **New chemical entities**
  - Secondary hyperparathyroidism [Calcium sensing receptor agonist] / Phase III
  - Injection
  - ***In-license (Amgen Inc.)***
- **ONO-7643 / RC-1291**
  - **New chemical entities**
  - Cancer anorexia/cachexia [Ghrelin mimetic]/Phase II
  - Tablet
  - ***In-license (Helsinn Healthcare, S.A.)***

Ongoing clinical studies

- **ONO-1162 / Ivabradine**
  - **New chemical entities**
  - Chronic heart failure [If channel inhibitor] /Phase II
  - Tablet
  - ***In-license (Les Laboratoires Servier)***
- **ONO-6950**
  - **New chemical entities**
  - Bronchial asthma [LT receptor antagonist]/ Phase I
  - Tablet
  - ***In-house***
- **ONO-7056 / Salirasib**
  - **New chemical entities**
  - Solid tumor [Ras signal inhibitor] / Phase I
  - Tablet
  - ***In-license (Kadmon Corporation LLC)***
- **ONO-7268 MX1**
  - **New chemical entities**
  - Hepatocellular carcinoma [Therapeutic cancer peptide vaccines] /Phase I
  - Injection
  - ***In-license (OncoTherapy Science, Inc.)***
- **ONO-7268 MX2**
  - **New chemical entities**
  - Hepatocellular carcinoma [Therapeutic cancer peptide vaccines]/ Phase I
  - Injection
  - ***In-license (OncoTherapy Science, Inc.)***
- **ONO-2160/CD**
  - **New chemical entities**
  - Parkinson's disease [levodopa pro-drug]/ Phase I
  - Tablet
  - ***In-house***
- **ONO-4053**
  - **New chemical entities**
  - Allergic rhinitis [PGD2 receptor antagonist] /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 *3**
  - **New chemical entities**
  - B cell lymphoma [Bruton's tyrosine kinase (Btk) inhibitor] /Phase I
  - Capsule
  - ***In-house***

Changes from Fist Quarter Flash Report for the Fiscal Year ending March 2015 announced on August 4, 2014

*1: Approval of new formulation of Opalmon (Improved stability) was obtained.

*2: Phase III of ONO-5163 (Calcium sensing receptor agonist) was initiated for the treatment of Secondary hyperparathyroidism.

*3: Phase I of ONO-4059 (Btk inhibitor) was initiated for the treatment of B cell lymphoma.

* Development of ONO-2745 (short acting $GABA_A$ receptor modulator) was decided to discontinue on strategic reasons considering issues in pharmacokinetic features, while no adverse events of concern were observed during clinical trials.

* Development of ONO-7165 (therapeutic cancer peptide vaccine targeting the tumor antigen MUC-1) 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-4053**
  - **New chemical entities**
  - Allergic rhinitis [PGD2 receptor antagonist]/Phase II
  - Tablet
  - Europe
  - ***In-house***
- **ONO-2952**
  - **New chemical entities**
  - Irritable bowel syndrome [TSPO antagonist]/Phase II
  - Tablet
  - USA
  - ***In-house***
- **ONO-9054**
  - **New chemical entities**
  - Glaucoma, ocular hypertension [PG receptor (FP / EP3) agonist] /Phase II
  - Eye drop
  - USA
  - ***In-house***
- **ONO-4059**
  - **New chemical entities**
  - B cell lymphoma [Bruton's tyrosine kinase (Btk) inhibitor] /Phase I
  - Capsule
  - Europe
  - ***In-house***
- **ONO-8055**
  - **New chemical entities**
  - Underactive bladder [PG receptor (EP2 / EP3) agonist]/Phase I
  - Tablet
  - Europe
  - ***In-house***
- **ONO-8539**
  - **New chemical entities**
  - Gastroesophageal reflux disease (GERD) [PG receptor (EP1) antagonist]/Phase I
  - Tablet
  - Europe
  - ***In-house***
- **ONO-1266**
  - **New chemical entities**
  - Portal hypertension [S1P receptor antagonist]/Phase I
  - Capsule
  - USA
  - ***In-house***
- **ONO-4232**
  - **New chemical entities**
  - Acute heart failure [PG receptor (EP4) agonist] /Phase I
  - Injection
  - USA
  - ***In-house***

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

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

ⅰ. Developments Status in Japan

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

Additional indication

[human anti-human PD-1 monoclonal antibody]

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

Ongoing clinical studies

Development Indication	Clinical Stage
Renal cell cancer	Phase III
Non-small cell lung cancer *1	Phase III
Head and neck cancer *2	Phase III
Gastric cancer *3	Phase III
Esophageal cancer	Phase II

ⅱ. Developments Status outside Japan

ONO-4538 / BMS-936558

New chemical entities / Injection

[human anti-human PD-1 monoclonal antibody]

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

NDA filed

Development Indication	Area
Non-small cell lung cancer *4	USA, Europe
Melanoma *5	USA, Europe
Melanoma *6	South Korea

Ongoing clinical studies

Development Indication	Clinical Stage	Area
Renal cell cancer	Phase III	USA, Europe
Non-small cell lung cancer	Phase III	USA, Europe
	Phase III	Taiwan
	Phase II	South Korea
Melanoma	Phase III	USA, Europe
Head and neck cancer	Phase III	USA, Europe
	Phase III	Taiwan
Glioblastoma	Phase III	USA, Europe
Diffuse large B cell lymphoma	Phase II	USA, Europe
Follicular lymphoma	Phase II	USA, Europe
Hodgkin's lymphoma *7	Phase II	USA, Europe
Solid tumors (triple negative breast cancer, stomach cancer, pancreatic cancer, small cell lung cancer, bladder cancer)	Phase I/II	USA, Europe
Colon cancer	Phase I/II	USA, Europe
Hepatocellular carcinoma	Phase I	USA, Europe
Chronic myeloid leukemia	Phase I	USA, Europe
Hepatitis C	Phase I	USA, Europe

Changes from Fist Quarter Flash Report for the Fiscal Year ending March 2015 announced on August 4, 2014
*1: Phase III of ONO-4538 was initiated in Japan for the treatment of non-small cell lung cancer.
*2: Phase III ofONO-4538 was initiated in Japan for the treatment of head and neck cancer.
*3: Phase III ofONO-4538 was initiated in Japan for the treatment of gastric cancer.
*4: BLA for the indication of NSCLC was filed in USA and Europe.
*5: BLA for the indication of melanoma was filed in USA and Europe.
*6: BLA for the indication of melanoma was filed in South Korea.
*7: Phase II of ONO-4538/BMS-936558 was initiated in USA and Europe for the treatment of Hodgkin's 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

Supplemental Information

New Drugs in Development

as of November 5, 2014

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:

Opalmon® Tablets (OP-1206・α-CD)

Japan: J-NDA approved / thromboangitis obliterans, lumbar spinal canal stenosis (new formulation, co-development with Sumitomo Dainippon Pharma Co., Ltd.)

Onoact® Intravenous Infusion 150 mg (ONO-1101)

Japan: J-NDA filed / post operative tachyarrhythmia under monitoring hemodynamics, tachyarrhythmia in low cardiac function (additional formulation)

Rivastach® Patch(ONO-2540 / ENA713D) (In-licensed from Novartis Pharma AG)

Japan: Phase III / Alzheimer's disease (additional dosing regimen) (co-development with Novartis Pharma AG)

Proemend® Intravenous Infusion (ONO-7847 / MK-0517) (In-licensed from Merck & Co., Inc.)

Japan: Phase III / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication)
USA & Other Countries: Phase II / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication)

ONO-4164 / BMS-188667 (injection)(In-licensed from Bristol-Myers Squibb Company)

ONO-4164 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-7057 / Carfilzomib (injection) (In-licensed from Onyx Pharmaceuticals, Inc.)

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: Phase III / multiple myeloma
Overseas: Approved under Accelerated Drug Approval Program in US / multiple myeloma (launched in August 2012), Phase III in Europe / multiple myeloma (Onyx Pharmaceuticals, Inc.).

ONO-5163 / AMG-416 (injection) (In-licensed from Amgen Inc.)

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

Japan: Phase III / secondary hyperparathyroidism
USA & Other Countries: Phase III / secondary hyperparathyroidism (Amgen Inc.)

ONO-7643 / RC-1291 (tablet)(In-licensed from Helsinn Therapeutics (US), Inc.)

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
US & Other Countries: Phase III / cancer anorexia / cachexia (Helsinn Therapeutics (U.S.), Inc.)

ONO-1162 (tablet) (In-licensed from Servier)

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 II / chronic heart failure
Overseas: Marketed / stable angina, chronic heart failure (Servier)

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 I / bronchial asthma
US: Phase II / bronchial asthma

ONO-7056 / Salirasib (tablet) (In-licensed from Kadmon Pharmaceuticals, Inc.)
ONO-7056 is a Ras signal inhibitor which is expected to be effective in the cancers, such as pancreatic cancer, in which high RAS genetic mutation is found.

Japan: Phase I / solid tumor
US: Phase II / pancreatic cancer (Kadmon Pharmaceuticals, Inc.), Phase II / non-small cell lung cancer (Kadmon Pharmaceuticals, Inc.)

ONO-7268MX1 / ONO-7268MX2 (injection) (In-licensed from OncoTherapy Science, Inc.)
ONO-7268MX1 and ONO-7268MX2 are peptide vaccines and are expected to have effects on cancers such as hepatocarcinoma.

Japan: Phase I / hepatocarcinoma

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-4053 (tablet)
ONO-4053 is a PGD2 receptor antagonist and is under clinical development for allergic rhinitis. It is expected to improve particularly nasal congestion, one of the three major symptoms of allergic rhinitis such as nasal congestion, sneezing and nasal discharge.

Japan: Phase I / allergic rhinitis
Europe: Phase II / allergic rhinitis

ONO-2370/Opicapone (tablet) (In-licensed from Bial)
ONO-2370 is a long acting COMT inhibitor being developed for the treatment of Parkinson's disease. Bial is currently conducting the Phase III trials overseas 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: Phase III / 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
Europe: Phase I / B cell lymphoma

ONO-5371 (capsule) (In-licensed from Valeant Pharmaceuticals North America LLC)
ONO-5371 is a tyrosine hydroxylase inhibitor against catecholamine biosynthesis, and is under clinical development for pheochromocytoma. ONO-5371 (generic name: metyrosine) 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 preparation / pheochromocytoma
US: Marketed / pheochromocytoma

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.

US: Phase II / IBS

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

US: 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-8539 (tablet)
ONO-8539 is a prostaglandin receptor (EP1) antagonist being developed for the treatment of gastroesophageal reflux disease (GERD).

Europe: Phase I /GERD

ONO-1266 (capsule)

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

US: Phase I /portal hypertension

ONO-4232 (injection)

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

US: Phase I /acute heart failure

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. Further,

Japan:
Launched in September 2014 / melanoma,
Phase III / renal cell cancer (global clinical trial),
Phase III / non-small cell lung cancer (global clinical trial),
Phase III / head and neck cancer (global clinical trial),
Phase III / gastric cancer,
Phase II / esophageal cancer

US and Europe:
NDA filed / non-small cell lung cancer,
Phase III / renal cell cancer,
Phase III / melanoma,
Phase III / glioblastoma,
Phase II / diffuse large B cell lymphoma,
Phase II / follicular lymphoma,
Phase II / Hodgkin's lymphoma,
Phase I/II / solid tumors (triple negative breast cancer, stomach cancer, pancreatic cancer, small cell lung cancer, bladder cancer),
Phase I/II / colon cancer,
Phase I / hepatocellular carcinoma,
Phase I / chronic myelocytic leukemia,
Phase I / hepatitis C

US, Europe & South Korea:
NDA filed / melanoma

US, Europe & Taiwan:
Phase III / non-small cell lung cancer,
Phase III / head and neck cancer

South Korea:
Phase II / non-small cell lung cancer