First Quarter (April 1 – June 30, 2017) Flash Report (unaudited)

Three months ended June 30, 2017

ONO PHARMACEUTICAL CO., LTD.

August 2, 2017

Ono Pharmaceutical Co., Ltd. ("The Company") has announced its consolidated financial results for three months ended June 30, 2017.
The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRSs”).

This First Quarter Flash Report 2018 (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 112 to $1, the approximate rate of exchange at June 30, 2017.

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, 2016	Annual 12 months ended Mar. 31, 2017	**1st Quarter 3 months ended Jun. 30, 2017**	**1st Quarter 3 months ended Jun. 30, 2017**
Revenue	¥ 58,757	¥ 244,797	**¥ 60,913**	**$ 543,865**
Profit (Owners of the parent company)	13,680	55,793	**11,774**	**105,129**
Total equity	477,791	524,211	**510,218**	**4,555,517**
Total assets	540,405	617,461	**577,330**	**5,154,731**
				US$
Basic earnings per share	¥ 25.81	¥ 105.27	**¥ 22.31**	**$ 0.20**
Diluted earnings per share	¥ 25.81	¥ 105.26	**¥ 22.31**	**$ 0.20**

Future Outlook

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Six months ending September 30, 2017		Year ending March 31, 2018	
	Millions of yen	Thousands of US$	Millions of yen	Thousands of US$
Revenue	¥ 112,500	$ 1,004,464	¥ 236,000	$ 2,107,143
Operating profit	13,200	117,857	36,500	325,893
Profit before tax	14,500	129,464	39,000	348,214
Profit	10,700	95,536	29,000	258,929
(Owners of the parent company)				
	Yen	US$	Yen	US$
Basic earnings per share	¥ 20.19	$ 0.18	¥ 54.72	$ 0.49

(*)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, 2017	**As of June 30, 2017**	**As of June 30, 2017**
Current assets			
Cash and cash equivalents	¥ 146,323	¥ **92,491**	$ **825,810**
Trade and other receivables	73,255	**74,435**	**664,597**
Marketable securities	17,560	**15,620**	**139,467**
Other financial assets	819	**810**	**7,228**
Inventories	25,334	**26,733**	**238,684**
Other current assets	7,742	**9,990**	**89,192**
Total current assets	271,033	**220,078**	**1,964,979**
Non-current assets			
Property, plant, and equipment	83,659	**85,169**	**760,441**
Intangible assets	45,237	**49,005**	**437,549**
Investment securities	176,573	**184,785**	**1,649,864**
Investments in associates	114	**119**	**1,063**
Other financial assets	26,836	**26,708**	**238,462**
Deferred tax assets	10,739	**7,685**	**68,619**
Other non-current assets	3,271	**3,781**	**33,755**
Total non-current assets	346,428	**357,252**	**3,189,752**
Total assets	¥ 617,461	¥ **577,330**	$ **5,154,731**

LIABILITIES AND EQUITY	Millions of yen		Thousands of US$
	As of March 31, 2017	**As of June 30, 2017**	**As of June 30, 2017**
Current liabilities			
Trade and other payables	¥ 30,905	¥ **27,736**	$ **247,645**
Borrowings	423	**436**	**3,891**
Other financial liabilities	5,814	**5,320**	**47,497**
Income taxes payable	24,777	**3,746**	**33,446**
Provisions	6,086	**7,134**	**63,700**
Other current liabilities	14,928	**12,743**	**113,781**
Total current liabilities	82,933	**57,115**	**509,959**
Non-current liabilities			
Borrowings	542	**468**	**4,180**
Other financial liabilities	11	**12**	**106**
Retirement benefit liabilities	2,805	**2,658**	**23,734**
Provisions	30	**30**	**268**
Deferred tax liabilities	881	**893**	**7,972**
Long-term advances received	5,276	**5,170**	**46,158**
Other non-current liabilities	772	**766**	**6,837**
Total non-current liabilities	10,316	**9,997**	**89,255**
Total liabilities	93,250	**67,112**	**599,214**
Equity			
Share capital	17,358	**17,358**	**154,985**
Capital reserves	17,144	**17,155**	**153,173**
Treasury shares	(59,382)	**(81,881)**	**(731,078)**
Other components of equity	51,752	**58,844**	**525,393**
Retained earnings	492,237	**493,596**	**4,407,110**
Equity attributable to owners of the parent company	519,110	**505,073**	**4,509,582**
Non-controlling interests	5,101	**5,145**	**45,935**
Total equity	524,211	**510,218**	**4,555,517**
Total liabilities and equity	¥ 617,461	¥ **577,330**	$ **5,154,731**

Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	1st Quarter 3 months ended June 30, 2016	**1st Quarter 3 months ended June 30, 2017**	**1st Quarter 3 months ended June 30, 2017**
Revenue	¥ 58,757	¥ **60,913**	$ **543,865**
Cost of sales	(16,202)	**(15,140)**	**(135,176)**
Gross profit	42,555	**45,773**	**408,689**
Selling, general, and administrative expenses	(14,054)	**(16,240)**	**(144,999)**
Research and development costs	(11,119)	**(14,938)**	**(133,376)**
Other income	21	**62**	**555**
Other expenses	(159)	**(382)**	**(3,410)**
Operating profit	17,244	**14,275**	**127,459**
Finance income	1,531	**1,523**	**13,594**
Finance costs	(540)	**(8)**	**(69)**
Share of profit (loss) from investments in associates	10	**6**	**50**
Profit before tax	18,245	**15,796**	**141,035**
Income tax expense	(4,541)	**(3,992)**	**(35,644)**
Profit for the period	13,704	**11,804**	**105,391**
Profit for the period attributable to:			
Owners of the parent company	13,680	**11,774**	**105,129**
Non-controlling interests	24	**29**	**261**
Profit for the period	13,704	**11,804**	**105,391**
Earnings per share:	Yen		US$
Basic earnings per share	25.81	**22.31**	**0.20**
Diluted earnings per share	25.81	**22.31**	**0.20**

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, 2016	**1st Quarter 3 months ended June 30, 2017**	**1st Quarter 3 months ended June 30, 2017**
Profit for the period	¥ 13,704	**¥ 11,804**	**$ 105,391**
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	(1,910)	**7,084**	**63,250**
Remeasurement of defined benefit plans	(206)	**185**	**1,651**
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(0)	**(0)**	**(1)**
Total of items that will not be reclassified to profit or loss	(2,117)	**7,269**	**64,900**
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	(470)	**19**	**171**
Net fair value gain (loss) on derivatives under hedge accounting	(25)	**6**	**57**
Total of items that may be reclassified subsequently to profit or loss	(495)	**26**	**228**
Total other comprehensive income (loss)	(2,612)	**7,294**	**65,129**
Total comprehensive income for the period	11,092	**19,098**	**170,519**
Comprehensive income for the period attributable to:			
Owners of the parent company	11,073	**19,052**	**170,103**
Non-controlling interests	19	**47**	**416**
Total comprehensive income for the period	11,092	**19,098**	**170,519**

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, 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

	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, 2017	¥17,358	¥17,144	(¥59,382)	¥51,752	¥492,237	¥519,110	¥5,101	¥524,211
Profit for the period					11,774	11,774	29	11,804
Other comprehensive income				7,277		7,277	17	7,294
Total comprehensive income for the period	–	–	–	7,277	11,774	19,052	47	19,098
Purchase of treasury shares			(22,499)			(22,499)		(22,499)
Cash dividends					(10,600)	(10,600)	(3)	(10,604)
Share-based payments		11				11		11
Transfer from other components of equity to retained earnings				(185)	185	–		–
Total transactions with the owners	–	11	(22,499)	(185)	(10,415)	(33,088)	(3)	(33,091)
Balance at June 30, 2017	¥17,358	¥17,155	(¥81,881)	¥58,844	¥493,596	¥505,073	¥5,145	¥510,218

	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, 2017	**$154,985**	**$153,074**	**($530,195)**	**$462,070**	**$4,394,976**	**$4,634,909**	**$45,546**	**$4,680,456**
Profit for the period					**105,129**	**105,129**	**261**	**105,391**
Other comprehensive income				**64,974**		**64,974**	**155**	**65,129**
Total comprehensive income for the period	–	–	–	**64,974**	**105,129**	**170,103**	**416**	**170,519**
Purchase of treasury shares			**(200,883)**			**(200,883)**		**(200,883)**
Cash dividends					**(94,646)**	**(94,646)**	**(28)**	**(94,674)**
Share-based payments		**99**				**99**		**99**
Transfer from other components of equity to retained earnings				**(1,651)**	**1,651**	–		–
Total transactions with the owners	–	**99**	**(200,883)**	**(1,651)**	**(92,995)**	**(295,430)**	**(28)**	**(295,458)**
Balance at June 30, 2017	**$154,985**	**$153,173**	**($731,078)**	**$525,393**	**$4,407,110**	**$4,509,582**	**$45,935**	**$4,555,517**

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, 2016	**1st Quarter 3 months ended June 30, 2017**	**1st Quarter 3 months ended June 30, 2017**
Cash flows from operating activities			
Profit before tax	¥ 18,245	**¥ 15,796**	**$ 141,035**
Depreciation and amortization	1,680	**2,217**	**19,794**
Impairment losses	9	**–**	**–**
Interest and dividend income	(1,526)	**(1,488)**	**(13,282)**
Interest expense	3	**4**	**33**
(Increase) Decrease in inventories	(1,143)	**(1,420)**	**(12,683)**
(Increase) Decrease in trade and other receivables	(16,415)	**(1,186)**	**(10,585)**
Increase (Decrease) in trade and other payables	(268)	**(3,243)**	**(28,958)**
Increase (Decrease) in provisions	(103)	**1,048**	**9,358**
Increase (Decrease) in retirement benefit liabilities	100	**120**	**1,074**
Increase (Decrease) in long-term advances received	(198)	**(106)**	**(949)**
Other	6,752	**(7,259)**	**(64,812)**
Subtotal	7,137	**4,483**	**40,026**
Interest received	39	**22**	**194**
Dividends received	1,487	**1,464**	**13,071**
Interest paid	(3)	**(4)**	**(33)**
Income taxes paid	(6,588)	**(24,693)**	**(220,475)**
Net cash provided by (used in) operating activities	2,072	**(18,728)**	**(167,218)**
Cash flows from investing activities			
Purchases of property, plant, and equipment	(8,751)	**(2,844)**	**(25,392)**
Purchases of intangible assets	(606)	**(4,478)**	**(39,985)**
Purchases of investments	–	**(40)**	**(357)**
Proceeds from sales and redemption of investments	6,000	**4,000**	**35,714**
Other	(74)	**133**	**1,187**
Net cash provided by (used in) investing activities	(3,432)	**(3,229)**	**(28,833)**
Cash flows from financing activities			
Dividends paid to owners of the parent company	(8,700)	**(9,310)**	**(83,125)**
Dividends paid to non-controlling interests	(3)	**(3)**	**(30)**
Repayments of long-term borrowings	(94)	**(104)**	**(926)**
Net increase (decrease) in short-term borrowings	(12)	**18**	**165**
Purchases of treasury shares	(20)	**(22,499)**	**(200,883)**
Net cash provided by (used in) financing activities	(8,830)	**(31,898)**	**(284,800)**
Net increase (decrease) in cash and cash equivalents	(10,190)	**(53,855)**	**(480,851)**
Cash and cash equivalents at the beginning of the period	110,485	**146,323**	**1,306,460**
Effects of exchange rate changes on cash and cash equivalents	(204)	**23**	**201**
Cash and cash equivalents at the end of the period	¥ 100,091	**¥ 92,491**	**$ 825,810**

First Quarter (April 1 – June 30, 2017) Flash Report (unaudited)

Three months ended June 30, 2017

Sales of Major Products

Supplemental Data

For information purpose only

		Hundreds of Millions of yen								
		1st Quarter 3 months ended June 30, 2017				Year ending March 31, 2018				
		Results		Increase/Decrease		Forecast		Increase/Decrease		
Opdivo	Agent for treatment of unresectable melanoma, unresectable, advanced or recurrent non-small cell lung cancer, unresectable or metastatic renal cell carcinoma, relapsed or refractory classical hodgkin lymphoma, and recurrent or metastatic head and neck cancer	¥ **198**	¥	△ 54	△ 21.4 %	¥ **740**	¥	△ 299	△ 28.8 %
Glactiv	Agent for type II diabetes	**70**		△ 7	△ 8.6 %	**295**		+1	+0.4 %
Orencia SC	Agent for rheumatoid arthritis	**33**		+6	+23.1 %	**145**		+29	+25.2 %
Opalmon	Circulatory system agent	**38**		△ 9	△ 18.3 %	**140**		△ 30	△ 17.8 %
Recalbon	Agent for osteoporosis	**27**		△ 2	△ 6.0 %	**110**		△ 3	△ 2.6 %
Forxiga	Agent for type II diabetes	**26**		+8	+45.7 %	**100**		+22	+28.1 %
Rivastach	Agent for Alzheimer's disease	**22**		△ 0	△ 0.4 %	**100**		+11	+12.9 %
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	**25**		△ 1	△ 3.5 %	**100**		+1	+1.2 %
Kyprolis	Agent for relapsed or refractory multiple myeloma	**12**		+12	Launched in August 2016	**60**		+40	+206.1 %
Onoact	Agent for tachyarrhythmia during and post operation	**15**		+0	+0.5 %	**60**		+3	+4.8 %
Onon	Agent for bronchial asthma and allergic rhinitis	**13**		△ 4	△ 22.9 %	**55**		△ 13	△ 19.0 %
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	**11**		△ 2	△ 17.0 %	**45**		△ 3	△ 5.7 %
Parsabiv	Agent for secondary hyperparathyroidism	**6**		+6	Launched in February 2017	**30**		+28	+1439.8 %
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	**8**		△ 3	△ 26.0 %	**30**		△ 11	△ 26.9 %
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	**8**		△ 3	△ 24.9 %	**30**		△ 8	△ 21.7 %
Kinedak	Agent for diabetic peripheral neuropathy	**6**		△ 2	△ 27.7 %	**25**		△ 4	△ 13.2 %

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, 2016	1st Quarter 3 months ended June 30, 2017
Revenue of Goods and Products	536	485
Royalty and Other Revenue	51	124
Total	588	609

Note: In "Royalty and Other Revenue", royalty revenue of "Opdivo Intravenous Infusion" is included, which is 43 hundreds of millions of yen for the 1st quarter 3 months ended June 30, 2016 and 89 hundreds of millions of yen for the 1st quarter 3 months ended June 30, 2017.

Information about Revenue by Geographic Area

Supplemental Data

For information purpose only

(Hundreds of Millions of yen)

	1st Quarter 3 months ended June 30, 2016	1st Quarter 3 months ended June 30, 2017
Japan	537	484
Americas	43	115
Asia	6	11
Europe	1	0
Total	588	609

Note: Revenue by geographic area is attributable to countries or regions based on the customer location.

Supplemental Information

Status of Development Pipeline

as of July 28, 2017

I. Main Status of Development Pipelines (Oncology)

1. Development Status in Japan

< Approved >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
Kyprolis for Intravenous Infusion *1	Additional dosage and administration	Multiple myeloma / Proteasome inhibitor	Injection	In-license (Amgen Inc.)

Changes from Flash Report for the Fiscal Year ended March 2017

*1: Approval for the partial change in approved items of the manufacturing and marketing approval for Kyprolis for Intravenous Infusion was obtained in Japan for the treatment of patients with relapsed or refractory multiple myeloma.

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.

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Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Gastric cancer	Injection	In-house (Co-development with Bristol-Myers Squibb)

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.

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Esophageal cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Glioblastoma	Injection	III	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Urothelial cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
Kyprolis for Intravenous Infusion	Change of dosage and administration	Multiple myeloma / Proteasome inhibitor	Injection	III	In-license (Amgen Inc.)
ONO-7643 / Anamorelin	New chemical entities	Cancer anorexia / cachexia / Ghrelin mimetic	Tablet	III	In-license (Helsinn Healthcare, S.A.)
ONO-7702 / Encorafenib	New chemical entities	Melanoma *2 / BRAF inhibitor	Capsule	III	In-license (Array Biopharma Inc.)
ONO-7703 / Binimetinib	New chemical Entities	Melanoma *3 / MEK inhibitor	Tablet	III	In-license (Array Biopharma Inc.)
Opdivo Intravenous Infusion	Additional indication	Solid tumor (Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma)	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central nervous system lymphoma, Primary testicular lymphoma	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Multiple myeloma *4	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-house (Co-development with Bristol-Myers Squibb)
ONO-5371 / Metyrosine	New chemical entities	Pheochromocytoma / Tyrosine hydroxylase inhibitor	Capsule	I / II	In-license (Valeant Pharmaceuticals North America LLC.)
ONO-4686 (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Central nervous system lymphoma *5 / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I / II	In-house
Opdivo Intravenous Infusion	Additional indication	Biliary tract cancer	Injection	I	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
ONO-4481 (BMS-663513) / Urelumab	New chemical entities	Solid tumor / Anti-CD137 antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4482 (BMS-986016)	New chemical entities	Solid tumor / Anti-LAG-3 antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4687 (BMS-986227) / Cabiralizumab	New chemical entities	Solid tumor and hematologic cancer / Anti-CSF-1R antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-7701 (BMS-986205)	New chemical entities	Solid tumor and hematologic cancer / IDO1 Inhibitor	Capsule	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483 (BMS-986015) / Lirilumab	New chemical entities	Solid tumor / Anti-KIR antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4578	New chemical entities	Solid tumor / PG receptor (EP4) antagonist	Tablet	I	In-house

Changes from Flash Report for the Fiscal Year ended March 2017

*2: BRAF inhibitor (ONO-7702) is under Phase III for the treatment of melanoma.

*3: MEK inhibitor (ONO-7703) is under Phase III for the treatment of melanoma.

*4: Phase II of Opdivo was initiated for the treatment of multiple myeloma.

*5: Phase I/II of Btk inhibitor (ONO-4059) was initiated for the treatment of central nervous system lymphoma.

* Phase I of ONO-7268MX1 and ONO-7268MX2 for the treatment of hepatocellular carcinoma were discontinued due to the strategic reason.

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.

2. Development Status in S. Korea and Taiwan

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Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Non-small cell lung cancer (Non- Squamous)	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hodgkin lymphoma *6	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer *7	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer *8	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)

Changes from Flash Report for the Fiscal Year ended March 2017

*6: A supplemental application for a partial change in the approved items of the importing and marketing approval for Opdivo was submitted in Taiwan for the treatment of hodgkin lymphoma.

*7: A supplemental application for a partial change in the approved items of the importing and marketing approval for Opdivo was submitted in Taiwan for the treatment of urothelial cancer.

*8: A supplemental application for a partial change in the approved items of the importing and marketing approval for Opdivo was submitted in Taiwan for the treatment of gastric 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.

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Head and neck cancer	Injection	III	South Korea	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	South Korea	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Hepatocellular carcinoma	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	South Korea	In-house (Co-development with Bristol-Myers Squibb)
ONO-7702 / Encorafenib	New chemical entities	Colon cancer *9 / BRAF inhibitor	Capsule	III	South Korea	In-license (Array Biopharma Inc.)
	New chemical entities	Melanoma *10 / BRAF inhibitor	Capsule	III	South Korea	In-license (Array Biopharma Inc.)
ONO-7703 / Binimetinib	New chemical entities	Colon cancer *11 / MEK inhibitor	Tablet	III	South Korea	In-license (Array Biopharma Inc.)
	New chemical entities	Melanoma *12 / MEK inhibitor	Tablet	III	South Korea	In-license (Array Biopharma Inc.)
Opdivo Intravenous Infusion	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)

Changes from Flash Report for the Fiscal Year ended March 2017

*9: BRAF inhibitor (ONO-7702) is under Phase III for the treatment of colon cancer in South Korea.

*10: BRAF inhibitor (ONO-7702) is under Phase III for the treatment of melanoma in South Korea.

*11: MEK inhibitor (ONO-7703) is under Phase III for the treatment of colon cancer in South Korea.

*12: MEK inhibitor (ONO-7703) is under Phase III for the treatment of melanoma in South Korea.

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.

3. Development Status in Europe and the United States

< Approved >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Urothelial cancer *13	Injection	Europe	In-house (Co-development with Bristol-Myers Squibb)

Changes from Flash Report for the Fiscal Year ended March 2017

*13: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo was obtained in Europe for the treatment of patients with locally advanced or metastatic urothelial carcinoma (mUC).

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 / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Colon cancer	Injection	USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma *14	Injection	USA	In-house (Co-development with Bristol-Myers Squibb)

Changes from Flash Report for the Fiscal Year ended March 2017

*14: A supplemental application for the partial change in approved items of the manufacturing and marketing approval for Opdivo was submitted in USA for the treatment of previously treated hepatocellular carcinoma.

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.

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Glioblastoma	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	Europe	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Multiple myeloma	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Diffuse large B cell lymphoma	Injection	II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Follicular lymphoma	Injection	II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central Nervous System Lymphoma, Primary Testicular Lymphoma	Injection	II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	B cell lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	Europe	In-house (Out-license to Gilead Sciences, Inc.)
ONO-7579	New chemical entities	Solid tumor / Tropomyosin receptor kinase (Trk) inhibitor	Tablet	I / II	Europe USA	In-house
Opdivo Intravenous Infusion	Additional indication	Colon cancer	Injection	I / II	Europe	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Solid tumors (Triple negative breast cancer, Gastric cancer, Pancreatic cancer, Small cell lung cancer, Urothelial cancer, Ovarian cancer)	Injection	I / II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive/negative solid carcinoma	Injection	I / II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hematologic cancer (T-cell lymphoma, Multiple myeloma, Chronic leukemia, etc.)	Injection	I	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Chronic myeloid leukemia	Injection	I	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	B cell lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I	USA	In-house (Out-license to Gilead Sciences, Inc.)
ONO-7475	New chemical entities	Acute leukemia / Axl / Mer inhibitor	Tablet	I	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 Status of Development Pipelines (Non-Oncology)

1. Development Status in Japan

< Filed >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
Orencia IV	Additional indication	Juvenile Idiopathic Arthritis / T-cell activation inhibitor	Injection	In-license (Bristol-Myers Squibb)

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

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Orencia IV	Additional indication	Lupus nephritis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
Orencia SC	Additional indication	Untreated rheumatoid arthritis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
	Additional indication	Primary sjögren syndrome / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
	Additional indication	Polymyositis / Dermatomyositis *15 / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
ONO-1162 / Ivabradine	New chemical entities	Chronic heart failure / If channel inhibitor	Tablet	III	In-license (Les Laboratoires Servier)
Onoact for Intravenous Infusion 50 mg / 150 mg (ONO-1101)	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / Short acting beta 1 blocker	Injection	II / III	In-house
	Additional indication	Ventricular arrhythmia / Short acting beta 1 blocker	Injection	II / III	In-house
ONO-2370 / Opicapone	New chemical entities	Parkinson's disease / Long acting COMT inhibitor	Tablet	II	In-license (Bial)
ONO-8577	New chemical entities	Overactive bladder / Bladder smooth muscle relaxant	Tablet	II	In-house
Opdivo Intravenous Infusion	Additional indication	Sepsis *16	Injection	I / II	In-house (Co-development with Bristol-Myers Squibb)

Changes from Flash Report for the Fiscal Year ended March 2017

*15: Phase III of Orencia SC was initiated for the treatment of polymyositis/dermatomyositis.

*16: Phase I/II of Opdivo was initiated for the treatment of sepsis.

* Phase I of ONO-2160/CD (levodopa pro-drug) for the treatment of parkinson's disease was discontinued due to no expected treatment effect.

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

2. Development Status in Overseas

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
ONO-4474	New chemical entities	Osteoarthritis / Tropomyosin receptor kinase (Trk) inhibitor	Capsule	II	Europe	In-house
ONO-4059 / Tirabrutinib	New chemical entities	Sjögren syndrome / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	USA	In-house (Out-license to Gilead Sciences, Inc.)
Opdivo Intravenous Infusion	Additional indication	Hepatitis C	Injection	I	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Sepsis	Injection	I	USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-8055	New chemical entities	Underactive bladder / PG receptor (EP2 / EP3) agonist	Tablet	I	Europe	In-house

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