Annual Flash Report (unaudited)

Fiscal Year ended March 31, 2018

ONO PHARMACEUTICAL CO., LTD.

May 10, 2018

Ono Pharmaceutical Co., Ltd. ("The Company") has announced its consolidated financial results ended March 31, 2018.
The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRSs”).

This Annual Flash Report for the year ended March 31, 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 ¥106 to $1, the approximate rate of exchange at March 30, 2018.

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$
	Year ended March 31, 2017	**Year ended March 31, 2018**	**Year ended March 31, 2018**
Revenue	¥ 244,797	¥ **261,836**	$ **2,470,150**
Profit (Owners of the parent company)	55,793	**50,284**	**474,375**
Total equity	524,211	**529,619**	**4,996,403**
Total assets	617,461	**609,226**	**5,747,411**
			US$
Basic earnings per share	¥ 105.27	¥ **97.00**	$ **0.92**
Diluted earnings per share	¥ 105.26	¥ **96.99**	$ **0.92**

Future Outlook

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Six months ending September 30, 2018		Year ending March 31, 2019	
	Millions of yen	Thousands of US$	Millions of yen	Thousands of US$
Revenue	¥ 134,500	$ 1,268,868	¥ 277,000	$ 2,613,208
Operating profit	28,500	268,868	61,500	580,189
Profit before tax	30,000	283,019	65,000	613,208
Profit (Owners of the parent company)	23,000	216,981	50,500	476,415
	Yen	US$	Yen	US$
Basic earnings per share	¥ 44.74	$ 0.42	¥ 98.23	$ 0.93

[Revenue]
In the fiscal year ending March 31, 2019, despite the National Health Insurance (NHI) drug price reduction and policies to promote the use of generics, it is expected that the use of Opdivo increases for the treatment of renal cell cancer and head and neck cancer approved two fiscal years ago, gastric cancer approved a fiscal year ago, and etc. Also, royalty revenue for Opdivo from Bristol-Myers Squibb and Merck is expected to increase.
In addition, sales of main products, Forxiga, Orencia, and Parsabiv, are expected to increase. Therefore, sales revenue is expected to be 277,000 millions of yen, an increase of 152 hundreds of millions of yen (5.8%) from the fiscal year ended March 31, 2018.

[Profit]
Research and development costs are expected to be 700 hundreds of millions of yen, an increase of 12 hundreds of millions of yen (1.7%) from the fiscal year ended March 31, 2018, due to active investment to achieve sustainable growth.
Selling, general, and administrative expenses (except for research and development costs) are expected to be 690 hundreds of millions of yen, an increase of 9 hundreds of millions of yen (1.4%) from the fiscal year ended March 31, 2018, due to an increase of operating activity costs for Opdivo and etc.
Therefore, operating profit is expected to be 61,500 millions of yen, an increase of 8 hundreds of millions of yen (1.3%) from the fiscal year ended March 31, 2018. Profit attributable to owners of parent company is expected to be 50,500 millions of yen, an increase of 2 hundreds of millions of yen (0.4%) from the fiscal year ended March 31, 2018.

Note: IFRS 15 "Revenue from Contracts with Customers" is applied from the fiscal year ending March 31, 2019.
With the application of this standard, upfront payment received, which was formerly recognized over time as deferred income, will be recognized as onetime income on out-licensing. Therefore, deferred revenue as of March 31, 2018 will not be recognized in revenue in the future. Also, certain items which were formerly deducted from revenue are treated as cost of sales. Calculating revenue and operating profit for the fiscal year ended March 31, 2018 using the same standards, growth rates in the forecast of consolidated business results would be an increase of 2.3% for revenue and an increase of 1.2% for operating profit, respectively.

(*)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.

Basic policy for profit distribution and dividends for the fiscal year under review and the following fiscal year

Distribution of profits to all our shareholders is one of our key management policies. We place great importance on the maintenance of stable dividends and profit sharing according to our business performance for the corresponding fiscal year.

As for the dividend for the fiscal year ended March 31, 2018, we expect to make a year-end dividend of 20 yen per share. With the payment of the second quarter dividend of 25 yen per share including the 300th anniversary commemorative dividend of 5 yen per share, the annual dividend is expected to be 45 yen per share. Also, the annual dividend for the following fiscal year ending March 31, 2019 is expected to be 45 yen per share.

We actively utilize retained earnings for the future business development including research and development of new innovative drugs in Japan and abroad, alliance with bio-venture companies, and in-license of new drug candidate compounds for development risk reduction.

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 March 31, 2018**	**As of March 31, 2018**
Current assets			
Cash and cash equivalents	¥ 146,323	¥ **65,273**	$ **615,781**
Trade and other receivables	73,255	**77,577**	**731,862**
Marketable securities	17,560	**9,670**	**91,230**
Other financial assets	819	**10,833**	**102,198**
Inventories	25,334	**31,290**	**295,189**
Other current assets	7,742	**14,821**	**139,817**
Total current assets	271,033	**209,464**	**1,976,077**
Non-current assets			
Property, plant, and equipment	83,659	**94,321**	**889,822**
Intangible assets	45,237	**55,715**	**525,611**
Investment securities	176,573	**188,803**	**1,781,158**
Investments in associates	114	**116**	**1,096**
Other financial assets	26,836	**46,685**	**440,428**
Deferred tax assets	10,739	**10,192**	**96,153**
Other non-current assets	3,271	**3,929**	**37,067**
Total non-current assets	346,428	**399,761**	**3,771,334**
Total assets	¥ 617,461	¥ **609,226**	$ **5,747,411**

LIABILITIES AND EQUITY	Millions of yen		Thousands of US$
	As of March 31, 2017	**As of March 31, 2018**	**As of March 31, 2018**
Current liabilities			
Trade and other payables	¥ 30,905	¥ **34,015**	$ **320,894**
Borrowings	423	**392**	**3,694**
Other financial liabilities	5,814	**3,756**	**35,430**
Income taxes payable	24,777	**8,742**	**82,472**
Provisions	6,086	**11,696**	**110,340**
Other current liabilities	14,928	**9,869**	**93,099**
Total current liabilities	82,933	**68,469**	**645,930**
Non-current liabilities			
Borrowings	542	**320**	**3,015**
Other financial liabilities	11	**8**	**74**
Retirement benefit liabilities	2,805	**3,856**	**36,378**
Provisions	30	**30**	**283**
Deferred tax liabilities	881	**1,016**	**9,583**
Long-term advances received	5,276	**5,095**	**48,065**
Other non-current liabilities	772	**814**	**7,681**
Total non-current liabilities	10,316	**11,138**	**105,078**
Total liabilities	93,250	**79,607**	**751,008**
Equity			
Share capital	17,358	**17,358**	**163,757**
Capital reserves	17,144	**17,175**	**162,024**
Treasury shares	(59,382)	**(38,148)**	**(359,884)**
Other components of equity	51,752	**68,021**	**641,703**
Retained earnings	492,237	**459,985**	**4,339,480**
Equity attributable to owners of the parent company	519,110	**524,390**	**4,947,080**
Non-controlling interests	5,101	**5,228**	**49,323**
Total equity	524,211	**529,619**	**4,996,403**
Total liabilities and equity	¥ 617,461	¥ **609,226**	$ **5,747,411**

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Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	Year ended March 31, 2017	**Year ended March 31, 2018**	**Year ended March 31, 2018**
Revenue	¥ 244,797	¥ **261,836**	**$ 2,470,150**
Cost of sales	(65,524)	**(65,391)**	**(616,897)**
Gross profit	179,273	**196,445**	**1,853,252**
Selling, general, and administrative expenses	(62,049)	**(68,055)**	**(642,032)**
Research and development costs	(57,506)	**(68,821)**	**(649,251)**
Other income	18,133	**3,255**	**30,705**
Other expenses	(5,567)	**(2,139)**	**(20,181)**
Operating profit	72,284	**60,684**	**572,493**
Finance income	3,057	**3,277**	**30,918**
Finance costs	(260)	**(36)**	**(339)**
Share of profit (loss) from investments in associates	(541)	**(4)**	**(35)**
Profit before tax	74,540	**63,922**	**603,037**
Income tax expense	(18,504)	**(13,525)**	**(127,592)**
Profit for the period	56,036	**50,397**	**475,445**
Profit for the period attributable to:			
Owners of the parent company	55,793	**50,284**	**474,375**
Non-controlling interests	243	**113**	**1,070**
Profit for the period	56,036	**50,397**	**475,445**
Earnings per share:	Yen		US$
Basic earnings per share	105.27	**97.00**	**0.92**
Diluted earnings per share	105.26	**96.99**	**0.92**

Consolidated Statement of Comprehensive Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	Year ended March 31, 2017	**Year ended March 31, 2018**	**Year ended March 31, 2018**
Profit for the period	¥ 56,036	**¥ 50,397**	**$ 475,445**
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	10,979	**17,797**	**167,901**
Remeasurement of defined benefit plans	1,165	**(478)**	**(4,514)**
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	0	**2**	**22**
Total of items that will not be reclassified to profit or loss	12,144	**17,321**	**163,408**
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	(96)	**(112)**	**(1,054)**
Total of items that may be reclassified subsequently to profit or loss	(96)	**(112)**	**(1,054)**
Total other comprehensive income (loss)	12,048	**17,210**	**162,355**
Total comprehensive income for the period	68,083	**67,607**	**637,800**
Comprehensive income for the period attributable to:			
Owners of the parent company	67,841	**67,477**	**636,571**
Non-controlling interests	242	**130**	**1,228**
Total comprehensive income for the period	68,083	**67,607**	**637,800**

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					55,793	55,793	243	56,036
Other comprehensive income				12,048		12,048	(1)	12,048
Total comprehensive income for the period	–	–	–	12,048	55,793	67,841	242	68,083
Purchase of treasury shares			(23)			(23)		(23)
Cash dividends					(20,142)	(20,142)	(3)	(20,145)
Share-based payments		41				41		41
Transfer from other components of equity to retained earnings				(3,604)	3,604	–		–
Total transactions with the owners	–	41	(23)	(3,604)	(16,539)	(20,125)	(3)	(20,128)
Balance at March 31, 2017	¥17,358	¥17,144	(¥59,382)	¥51,752	¥492,237	¥519,110	¥5,101	¥524,211

	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					50,284	50,284	113	50,397
Other comprehensive income				17,193		17,193	17	17,210
Total comprehensive income for the period	–	–	–	17,193	50,284	67,477	130	67,607
Purchase of treasury shares			(38,773)			(38,773)		(38,773)
Retirement of treasury shares			60,007		(60,007)	–		–
Cash dividends					(23,453)	(23,453)	(3)	(23,457)
Share-based payments		30				30		30
Transfer from other components of equity to retained earnings				(924)	924	–		–
Total transactions with the owners	–	30	21,234	(924)	(82,536)	(62,196)	(3)	(62,199)
Balance at March 31, 2018	¥17,358	¥17,175	(¥38,148)	¥68,021	¥459,985	¥524,390	¥5,228	¥529,619

	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	**$163,757**	**$161,739**	**($560,206)**	**$488,225**	**$4,643,748**	**$4,897,263**	**$48,125**	**$4,945,387**
Profit for the period					**474,375**	**474,375**	**1,070**	**475,445**
Other comprehensive income				**162,197**		**162,197**	**158**	**162,355**
Total comprehensive income for the period	–	–	–	**162,197**	**474,375**	**636,571**	**1,228**	**637,800**
Purchase of treasury shares			**(365,781)**			**(365,781)**		**(365,781)**
Retirement of treasury shares			**566,103**		**(566,103)**	–		–
Cash dividends					**(221,259)**	**(221,259)**	**(29)**	**(221,288)**
Share-based payments		**286**				**286**		**286**
Transfer from other components of equity to retained earnings				**(8,719)**	**8,719**	–		–
Total transactions with the owners	–	**286**	**200,322**	**(8,719)**	**(778,643)**	**(586,754)**	**(29)**	**(586,784)**
Balance at March 31, 2018	**$163,757**	**$162,024**	**($359,884)**	**$641,703**	**$4,339,480**	**$4,947,080**	**$49,323**	**$4,996,403**

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Consolidated Statement of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	Year ended March 31, 2017	**Year ended March 31, 2018**	**Year ended March 31, 2018**
Cash flows from operating activities			
Profit before tax	¥ 74,540	**¥ 63,922**	**$ 603,037**
Depreciation and amortization	7,821	**9,213**	**86,912**
Impairment losses	937	**306**	**2,883**
Interest and dividend income	(2,951)	**(2,990)**	**(28,207)**
Interest expense	15	**14**	**134**
(Increase) Decrease in inventories	(2,042)	**(5,971)**	**(56,332)**
(Increase) Decrease in trade and other receivables	(11,195)	**(4,333)**	**(40,873)**
Increase (Decrease) in trade and other payables	4,980	**300**	**2,827**
Increase (Decrease) in provisions	4,731	**5,611**	**52,931**
Increase (Decrease) in retirement benefit liabilities	389	**362**	**3,412**
Increase (Decrease) in long-term advances received	(538)	**(181)**	**(1,709)**
Other	6,292	**(17,138)**	**(161,679)**
Subtotal	82,978	**49,114**	**463,337**
Interest received	154	**95**	**896**
Dividends received	2,818	**2,902**	**27,379**
Interest paid	(15)	**(14)**	**(134)**
Income taxes paid	(11,485)	**(36,370)**	**(343,113)**
Net cash provided by (used in) operating activities	74,450	**15,727**	**148,365**
Cash flows from investing activities			
Purchases of property, plant, and equipment	(14,805)	**(15,620)**	**(147,358)**
Proceeds from sales of property, plant and equipment	274	**4,663**	**43,995**
Purchases of intangible assets	(9,274)	**(14,218)**	**(134,136)**
Purchases of investments	(3,240)	**(60)**	**(566)**
Proceeds from sales and redemption of investments	28,883	**21,315**	**201,083**
Payments into time deposits	(20,800)	**(30,800)**	**(290,566)**
Other	974	**531**	**5,012**
Net cash provided by (used in) investing activities	(17,989)	**(34,189)**	**(322,534)**
Cash flows from financing activities			
Dividends paid to owners of the parent company	(20,116)	**(23,414)**	**(220,890)**
Dividends paid to non-controlling interests	(3)	**(3)**	**(29)**
Repayments of long-term borrowings	(398)	**(417)**	**(3,932)**
Net increase (decrease) in short-term borrowings	(11)	**58**	**548**
Purchases of treasury shares	(22)	**(38,773)**	**(365,779)**
Net cash provided by (used in) financing activities	(20,552)	**(62,549)**	**(590,082)**
Net increase (decrease) in cash and cash equivalents	35,909	**(81,011)**	**(764,251)**
Cash and cash equivalents at the beginning of the period	110,485	**146,323**	**1,380,410**
Effects of exchange rate changes on cash and cash equivalents	(71)	**(40)**	**(379)**
Cash and cash equivalents at the end of the period	¥ 146,323	**¥ 65,273**	**$ 615,781**

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Fiscal Year ended March 31, 2018

Sales of Major Products

Supplemental Data

		Hundreds of Millions of yen				
		Year ended March 31, 2018			Year ending March 31, 2019	
		Results	Increase/Decrease		Forecasts	Increase/Decrease	
Opdivo	Agent for cancer	¥ 901	¥ △ 138	△ 13.3 %	¥ 900	¥ △ 1	△ 0.1 %
Glactiv	Agent for type II diabetes	274	△ 20	△ 6.7 %	260	△ 14	△ 5.1 %
Orencia SC	Agent for rheumatoid arthritis	141	26	22.0 %	165	24	16.8 %
Forxiga	Agent for type II diabetes	111	33	41.8 %	130	19	17.4 %
Opalmon	Circulatory system agent	144	△ 27	△ 15.6 %	105	△ 39	△ 26.9 %
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	99	1	0.7 %	105	6	5.5 %
Recalbon	Agent for osteoporosis	109	△ 4	△ 3.3 %	95	△ 14	△ 13.0 %
Rivastach	Agent for Alzheimer's disease	89	0	0.3 %	90	1	1.3 %
Kyprolis	Agent for multiple myeloma	55	36	182.4 %	65	10	17.4 %
Parsabiv	Agent for secondary hyperparathyroidism	34	32	1660.3 %	55	21	60.4 %
Onon	Agent for bronchial asthma and allergic rhinitis	55	△ 13	△ 19.5 %	45	△ 10	△ 17.6 %
Onoact	Agent for tachyarrhythmia during and post operation	56	△ 1	△ 1.8 %	40	△ 16	△ 28.8 %
Staybla	Agent for overactive bladder	41	△ 6	△ 13.4 %	35	△ 6	△ 15.3 %
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	33	△ 8	△ 18.8 %	25	△ 8	△ 25.0 %

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

Breakdown of Revenue

Supplemental Data

(Hundreds of Millions of yen)

	Year ended March 31, 2017	Year ended March 31, 2018	Year ending March 31, 2019
Revenue of Goods and Products	2,143	2,059	2,060
Royalty and Other Revenue	305	559	710
Total	2,448	2,618	2,770

Note: In "Royalty and Other Revenue", royalty revenue of "Opdivo Intravenous Infusion" is included, which is 267 hundreds of millions of yen for the year ended March 31, 2017 and 398 hundreds of millions of yen for the year ended March 31, 2018, respectively.

Information about Revenue by Geographic Area

Supplemental Data

(Hundreds of Millions of yen)

	Year ended March 31, 2017	Year ended March 31, 2018
Japan	2,140	2,040
Americas	273	525
Asia	31	51
Europe	4	2
Total	2,448	2,618

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

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Supplemental Information

Status of Development Pipeline

as of April 26, 2018

I. Main Status of Development Pipelines (Oncology)

1. Development Status in Japan

< Filed>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Malignant pleural mesothelioma	Injection	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection	Additional indication	Renal cell carcinoma	Injection	In-license (Co-development with Bristol-Myers Squibb)
ONO-7702 *1 / Encorafenib	New chemical entities	Melanoma / BRAF inhibitor	Capsule	In-license (Array Biopharma Inc.)
ONO-7703 *1 / Binimetinib	New chemical entities	Melanoma / MEK inhibitor	Tablet	In-license (Array Biopharma Inc.)
ONO-5371 *2 / Metyrosine	New chemical entities	Pheochromocytoma / Tyrosine hydroxylase inhibitor	Capsule	In-license (Valeant Pharmaceuticals North America LLC.)

Changes from Third Quarter Flash Report for the Fiscal Year ended March 2018

*1: A manufacturing and marketing approval application for Encorafenib (ONO-7702), a BRAF inhibitor, and Binimetinib (ONO-7703), a MEK inhibitor, were filed in Japan for the treatment of BRAF-mutant unresectable melanoma.
*2: A manufacturing and marketing approval application for Metyrosine (ONO-5371), a tyrosine hydroxylase inhibitor, was filed in Japan for the improvement of excess secretion of pheochromocytoma catecholamines and its accompanying symptoms.

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)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Opdivo Intravenous Infusion	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)
	Additional indication	Urothelial cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection	Additional indication	Non-small cell lung cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
Kyprolis for Intravenous Infusion	Change in 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	Colon cancer *3 / BRAF inhibitor	Capsule	III	In-license (Array Biopharma Inc.)
ONO-7703 / Binimetinib	New chemical entities	Colon cancer *3 / MEK inhibitor	Tablet	III	In-license (Array Biopharma Inc.)
ONO-7701 (BMS-986205)	New chemical entities	Melanoma / IDO1 inhibitor	Capsule	III	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Colon cancer *4	Injection	II / 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	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	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)
Yervoy Injection	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
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 / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I / II	In-house
ONO-4482 (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7807 *5 (BMS-986258)	New chemical entities	Solid tumor / Anti-TIM-3 antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Biliary tract cancer	Injection	I	In-house (Co-development with Bristol-Myers Squibb)
ONO-4481 (BMS-663513) / Urelumab	New chemical entities	Solid tumor / Anti-CD137 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-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 Third Quarter Flash Report for the Fiscal Year ended March 2018

*3: Phase III of ONO-7702 (BRAF inhibitor) and ONO-7703 (MEK inhibitor) was initiated for the treatment of colon cancer.
*4: Phase II / III of Opdivo was initiated for the treatment of colon cancer.
*5: Phase I / II of ONO-7807 / BMS-986258 (Anti-TIM-3 antibody) was initiated for the treatment of 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.

2. Development Status in S. Korea and Taiwan

< Approved>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Hepatocellular carcinoma *6	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Gastric cancer *7	Injection	South Korea	In-house (Co-development with Bristol-Myers Squibb)

Changes from Third Quarter Flash Report for the Fiscal Year ended March 2018

*6: Approval for the partial change in approved items of the importing and marketing approval for Opdivo was obtained in Taiwan for the treatment of patients with hepatocellular carcinoma who have been previously treated with sorafenib.
*7: Approval for the partial change in approved items of the importing and marketing approval for Opdivo was obtained in South Korea for the treatment of advanced or recurrent gastric or gastroesophageal junction adenocarcinoma after two or more prior chemotherapy regimens.

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	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)
	Additional indication	Hepatocellular carcinoma	Injection	III	South Korea	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection	Additional indication	Renal cell carcinoma	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Non-small cell lung cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	South Korea, Taiwan	In-license (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
ONO-7702 / Encorafenib	New chemical entities	Colon cancer / BRAF inhibitor	Capsule	III	South Korea	In-license (Array Biopharma Inc.)
	New chemical entities	Melanoma / BRAF inhibitor	Capsule	III	South Korea	In-license (Array Biopharma Inc.)
ONO-7703 / Binimetinib	New chemical entities	Colon cancer / MEK inhibitor	Tablet	III	South Korea	In-license (Array Biopharma Inc.)
	New chemical entities	Melanoma / 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)
Yervoy Injection	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	South Korea, Taiwan	In-license (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.

3. Development Status in Europe and the United States

< Filed>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Small cell lung cancer *8	Injection	USA	In-house (Co-development with Bristol-Myers Squibb)

Changes from Third Quarter Flash Report for the Fiscal Year ended March 2018

*8: Application for the partial change in approved items of the manufacturing and marketing approval for Opdivo was accepted for priority review in US for the treatment of patients with small cell lung cancer (SCLC) whose disease has progressed after two or more prior lines of therapy.

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

In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

< 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	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)
	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	Colon cancer *9	Injection	II / III	Europe	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)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Prostate cancer	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	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

Changes from Third Quarter Flash Report for the Fiscal Year ended March 2018

*9: Phase II / III of Opdivo was initiated in Europe for the treatment of colon cancer.

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

In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

II. Main Status of Development Pipelines (Non-Oncology)

1. Development Status in Japan

< Approved >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
Orencia IV *10	Additional indication	Juvenile Idiopathic Arthritis / T-cell activation inhibitor	Injection	In-license (Bristol-Myers Squibb)

Changes from Third Quarter Flash Report for the Fiscal Year ended March 2018

*10: Approval for the partial change in approved items of the manufacturing and marketing approval for Orencia IV was obtained in Japan for the treatment of active polyarticular juvenile idiopathic arthritis.

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 / 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)
ONO-5704 / SI-613	New chemical entities	Osteoarthritis / Hyaluronic acid-NSAID	Injection	III	In-license (Seikagaku Corporation)
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
	Additional indication	Tachyarrhythmia upon sepsis / 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-5704 / SI-613	New chemical entities	Enthesopathy / Hyaluronic acid-NSAID	Injection	II	In-license (Seikagaku Corporation)
Opdivo Intravenous Infusion	Additional indication	Sepsis	Injection	I / II	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Autoimmune disease / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I	In-house

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-4059 / Tirabrutinib	New chemical entities	Sjögren syndrome / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	Europe 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.

Supplemental Information

Profile for Main Development

KYPROLIS® for Intravenous Infusion (ONO-7057) / Carfilzomib (injection)

Kyprolis (ONO-7057) is a proteasome inhibitor, being developed for change in dosage and administration after launched for multiple myeloma. It is highly expected to be a new treatment option for multiple myeloma, which is a cancer of plasma cells (one of blood cells) and prognosis is considered poor.

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

Orencia (ONO-4164) is marketed in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed, after that, additionally approved for the treatment of active polyarticular juvenile idiopathic arthritis (JIA). Also, in overseas, it is marketed for use in patients of rheumatoid arthritis for whom other therapies have failed and with juvenile idiopathic arthritis.

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

Orencia (ONO-4164) is marketed for use in patients of rheumatoid arthritis for whom other therapies have failed.

ONO-1162 / Ivabradine (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.

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

Onoact is being developed for ventricular arrhythmia, tachyarrhythmia upon sepsis, and tachyarrhythmia in low cardiac function in pediatric. It is designated as orphan drugs for rare diseases in August 2016.

ONO-7643 / Anamorelin (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.

ONO-2370 / Opicapone (tablet)

ONO-2370 is a long acting COMT inhibitor being developed for the treatment of parkinson's disease. ONO-2370 is approved for the treatment of parkinson's disease in overseas by Bial 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.

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.

ONO-4059 (tablet)

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

ONO-4059 (capsule)

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

ONO-4578 (tablet)

ONO-4578 is a prostaglandin receptor (EP4) antagonist being developed for the treatment of solid tumor.

ONO-8055 (tablet)

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

ONO-7475 (tablet)

ONO-7475 is a Axl/Mer inhibitor being developed for the treatment of acute leukemia.

ONO-7579 (tablet)

ONO-7579 is a tropomyosin receptor kinase (Trk) inhibitor being developed for the treatment of solid tumor.

Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558 (injection)

Opdivo (ONO-4538), a human anti-human PD-1 monoclonal antibody, is being developed for the treatment of 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.

Yervoy® Intravenous Infusion (ONO-4480) / Ipilimumab (injection)

Yervoy (ONO-4480), a human anti-human CTLA-4 monoclonal antibody, is being developed for the treatment of cancer.
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.

ONO-4481 / Urelumab / BMS-663513 (injection)

ONO-4481, a human anti-human CD137 monoclonal antibody, is being developed for the treatment of cancer.
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.

ONO-4482 / Relatimab / BMS-986016 (injection)

ONO-4482, a human anti-human LAG-3 monoclonal antibody, is being developed for the treatment of cancer.
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.

ONO-4686 / BMS-986207 (injection)

ONO-4686, a human anti-human TIGIT monoclonal antibody, is being developed for the treatment of cancer.
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.

ONO-4687 / Cabiralizumab / BMS-986227 (injection)

ONO-4687, a human anti-human CSF-1R monoclonal antibody, is being developed for the treatment of cancer.
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.

ONO-7701 / BMS-986205 (capsule)

ONO-7701, IDO1 inhibitor, is being developed for the treatment of cancer.
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.

ONO-4483 / Lirilumab / BMS-986015 (injection)

ONO-4483, a human anti-human KIR monoclonal antibody, is being developed for the treatment of cancer.
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.

ONO-7702 / Encorafenib (capsule)

ONO-7702, BRAF inhibitor, is being developed for the treatment of melanoma and colon cancer.

ONO-7703 / Binimetinib (tablet)

ONO-7703, MEK inhibitor, is being developed for the treatment of melanoma and colon cancer.

ONO-5704 / SI-613 (injection)

ONO-5704, hyaluronic acid-NSAID, is being developed for the treatment of osteoarthritis and enthesopathy.

ONO-7807 / BMS-986258 (injection)

ONO-7807, a human anti-human TIM-3 monoclonal antibody, is being developed for the treatment of cancer.
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.