Annual Flash Report (unaudited)
Fiscal Year ended March 31, 2017

ONO PHARMACEUTICAL CO., LTD.

May 11, 2017

Ono Pharmaceutical Co., Ltd. ("The Company") has announced its consolidated financial results ended March 31, 2017.
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, 2017 (unaudited) is summary information extracted from the financial statements announced, and the financial statements and the figures contained herein are prepared for reference only for the convenience of readers outside Japan with certain modifications and reclassifications made from the original financial statements presented in Japanese language.

The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan using the rate of 112 to $1, the approximate rate of exchange at March 31, 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$
	Year ended March 31, 2016	**Year ended March 31, 2017**	**Year ended March 31, 2017**
Revenue	¥ 160,284	**¥ 244,797**	**$ 2,185,690**
Profit (Owners of the parent company)	24,979	**55,793**	**498,152**
Total equity	476,255	**524,211**	**4,680,456**
Total assets	540,450	**617,461**	**5,513,043**
			US$
Basic earnings per share	¥ 47.13	**¥ 105.27**	**$ 0.94**
Diluted earnings per share	¥ 47.13	**¥ 105.26**	**$ 0.94**

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

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.

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, 2017, we expect to make a year-end dividend of 20 yen per share. With the payment of the second quarter dividend of 20 yen per share, the annual dividend is expected to be 40 yen per share.

Also, we marked the 300th anniversary of its founding in this year. To commemorate this anniversary and express our gratitude to shareholders for their constant support, we plan to add a commemorative dividend of 5 yen per share to the second quarter dividend. The forecast for the annual dividend for following fiscal year 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.

Annual Flash Report (unaudited)

Fiscal Year ended March 31, 2017

Consolidated Statement of Financial Position

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
ASSETS	As of March 31, 2016	**As of March 31, 2017**	**As of March 31, 2017**
Current assets			
Cash and cash equivalents	¥ 110,485	**¥ 146,323**	**$ 1,306,460**
Trade and other receivables	62,043	**73,255**	**654,062**
Marketable securities	21,583	**17,560**	**156,786**
Other financial assets	800	**819**	**7,311**
Inventories	23,232	**25,334**	**226,194**
Other current assets	5,430	**7,742**	**69,121**
Total current assets	223,573	**271,033**	**2,419,934**
Non-current assets			
Property, plant, and equipment	80,094	**83,659**	**746,952**
Intangible assets	38,324	**45,237**	**403,900**
Investment securities	182,396	**176,573**	**1,576,547**
Investments in associates	982	**114**	**1,019**
Other financial assets	6,753	**26,836**	**239,611**
Deferred tax assets	5,179	**10,739**	**95,880**
Other non-current assets	3,149	**3,271**	**29,201**
Total non-current assets	316,877	**346,428**	**3,093,110**
Total assets	¥ 540,450	**¥ 617,461**	**$ 5,513,043**

LIABILITIES AND EQUITY	Millions of yen		Thousands of US$
	As of March 31, 2016	**As of March 31, 2017**	**As of March 31, 2017**
Current liabilities			
Trade and other payables	¥ 31,250	¥ **30,905**	$ **275,936**
Borrowings	328	**423**	**3,778**
Other financial liabilities	3,068	**5,814**	**51,910**
Income taxes payable	6,585	**24,777**	**221,223**
Provisions	1,355	**6,086**	**54,342**
Other current liabilities	9,607	**14,928**	**133,287**
Total current liabilities	52,194	**82,933**	**740,477**
Non-current liabilities			
Borrowings	515	**542**	**4,841**
Other financial liabilities	19	**11**	**95**
Retirement benefit liabilities	4,093	**2,805**	**25,045**
Provisions	30	**30**	**268**
Deferred tax liabilities	885	**881**	**7,864**
Long-term advances received	5,814	**5,276**	**47,107**
Other non-current liabilities	643	**772**	**6,892**
Total non-current liabilities	12,000	**10,316**	**92,111**
Total liabilities	64,195	**93,250**	**832,587**
Equity			
Share capital	17,358	**17,358**	**154,985**
Capital reserves	17,103	**17,144**	**153,074**
Treasury shares	(59,358)	**(59,382)**	**(530,195)**
Other components of equity	43,307	**51,752**	**462,070**
Retained earnings	452,983	**492,237**	**4,394,976**
Equity attributable to owners of the parent company	471,393	**519,110**	**4,634,909**
Non-controlling interests	4,862	**5,101**	**45,546**
Total equity	476,255	**524,211**	**4,680,456**
Total liabilities and equity	¥ 540,450	¥ **617,461**	$ **5,513,043**

Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	Year ended March 31, 2016	**Year ended March 31, 2017**	**Year ended March 31, 2017**
Revenue	¥ 160,284	¥ **244,797**	$ **2,185,690**
Cost of sales	(41,524)	**(65,524)**	**(585,038)**
Gross profit	118,760	**179,273**	**1,600,651**
Selling, general, and administrative expenses	(43,979)	**(62,049)**	**(554,008)**
Research and development costs	(43,369)	**(57,506)**	**(513,448)**
Other income	708	**18,133**	**161,900**
Other expenses	(1,612)	**(5,567)**	**(49,706)**
Operating profit	30,507	**72,284**	**645,389**
Finance income	3,088	**3,057**	**27,291**
Finance costs	(291)	**(260)**	**(2,318)**
Share of profit (loss) from investments in associates and others	(32)	**(541)**	**(4,827)**
Profit before tax	33,272	**74,540**	**665,536**
Income tax expense	(8,080)	**(18,504)**	**(165,215)**
Profit for the period	25,192	**56,036**	**500,320**
Profit for the period attributable to:			
Owners of the parent company	24,979	**55,793**	**498,152**
Non-controlling interests	213	**243**	**2,168**
Profit for the period	25,192	**56,036**	**500,320**
Earnings per share:	Yen		US$
Basic earnings per share	47.13	**105.27**	**0.94**
Diluted earnings per share	47.13	**105.26**	**0.94**

Consolidated Statement of Comprehensive Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	Year ended March 31, 2016	**Year ended March 31, 2017**	**Year ended March 31, 2017**
Profit for the period	¥ 25,192	**¥ 56,036**	**$ 500,320**
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	(1,411)	**10,979**	**98,023**
Remeasurement of defined benefit plans	(3,261)	**1,165**	**10,403**
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(7)	**0**	**0**
	(4,679)	**12,144**	**108,426**
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	(360)	**(96)**	**(859)**
	(360)	**(96)**	**(859)**
Total other comprehensive income (loss)	(5,039)	**12,048**	**107,567**
Total comprehensive income for the period	20,153	**68,083**	**607,888**
Comprehensive income for the period attributable to:			
Owners of the parent company	19,926	**67,841**	**605,727**
Non-controlling interests	227	**242**	**2,160**
Total comprehensive income for the period	20,153	**68,083**	**607,888**

Consolidated Statement of Changes in Equity

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen							
	Equity attributable to owners of the parent company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non-controlling interests	Total equity
Balance at April 1, 2015	¥17,358	¥17,080	(¥59,308)	¥45,756	¥449,690	¥470,575	¥4,638	¥475,213
Profit for the period					24,979	24,979	213	25,192
Other comprehensive income				(5,054)		(5,054)	14	(5,039)
Total comprehensive income for the period	–	–	–	(5,054)	24,979	19,926	227	20,153
Purchase of treasury shares			(50)			(50)		(50)
Cash dividends					(19,081)	(19,081)	(3)	(19,084)
Share-based payments		23				23		23
Transfer from other components of equity to retained earnings				2,605	(2,605)	–		–
Total transactions with the owners	–	23	(50)	2,605	(21,686)	(19,108)	(3)	(19,111)
Balance at March 31, 2016	¥17,358	¥17,103	(¥59,358)	¥43,307	¥452,983	¥471,393	¥4,862	¥476,255

	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

	Thousands of US $							
	Equity attributable to owners of the parent company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non-controlling interests	Total equity
Balance at April 1, 2016	**$154,985**	**$152,708**	**($529,986)**	**$386,669**	**$4,044,489**	**$4,208,865**	**$43,414**	**$4,252,279**
Profit for the period					**498,152**	**498,152**	**2,168**	**500,320**
Other comprehensive income				**107,575**		**107,575**	**(8)**	**107,567**
Total comprehensive income for the period	–	–	–	**107,575**	**498,152**	**605,727**	**2,160**	**607,888**
Purchase of treasury shares			**(209)**			**(209)**		**(209)**
Cash dividends					**(179,840)**	**(179,840)**	**(28)**	**(179,868)**
Share-based payments		**366**				**366**		**366**
Transfer from other components of equity to retained earnings				**(32,174)**	**32,174**	–		–
Total transactions with the owners	–	**366**	**(209)**	**(32,174)**	**(147,665)**	**(179,683)**	**(28)**	**(179,711)**
Balance at March 31, 2017	**$154,985**	**$153,074**	**($530,195)**	**$462,070**	**$4,394,976**	**$4,634,909**	**$45,546**	**$4,680,456**

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Fiscal Year ended March 31, 2017

Consolidated Statement of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	Year ended March 31, 2016	**Year ended March 31, 2017**	**Year ended March 31, 2017**
Cash flows from operating activities			
Profit before tax	¥ 33,272	**¥ 74,540**	**$ 665,536**
Depreciation and amortization	6,534	**7,821**	**69,829**
Impairment losses	1,188	**937**	**8,368**
Interest and dividend income	(2,782)	**(2,951)**	**(26,349)**
Interest expense	13	**15**	**132**
(Increase) Decrease in inventories	2,562	**(2,042)**	**(18,231)**
(Increase) Decrease in trade and other receivables	(20,099)	**(11,195)**	**(99,960)**
Increase (Decrease) in trade and other payables	9,312	**4,980**	**44,463**
Increase (Decrease) in provisions	613	**4,731**	**42,240**
Increase (Decrease) in retirement benefit liabilities	(6,031)	**389**	**3,477**
Increase (Decrease) in long-term advances received	(909)	**(538)**	**(4,806)**
Other	(3,722)	**6,292**	**56,176**
Subtotal	19,951	**82,978**	**740,876**
Interest received	314	**154**	**1,373**
Dividends received	2,522	**2,818**	**25,163**
Interest paid	(13)	**(15)**	**(132)**
Income taxes paid	(9,932)	**(11,485)**	**(102,548)**
Net cash provided by (used in) operating activities	12,842	**74,450**	**664,731**
Cash flows from investing activities			
Purchases of property, plant, and equipment	(7,021)	**(14,805)**	**(132,187)**
Proceeds from sales of property, plant and equipment	936	**274**	**2,449**
Purchases of intangible assets	(7,061)	**(9,274)**	**(82,805)**
Purchases of investments	(863)	**(3,240)**	**(28,933)**
Proceeds from sales and redemption of investments	27,693	**28,883**	**257,880**
Payments into time deposits	(800)	**(20,800)**	**(185,714)**
Other	153	**974**	**8,693**
Net cash provided by (used in) investing activities	13,037	**(17,989)**	**(160,616)**
Cash flows from financing activities			
Dividends paid to owners of the parent company	(19,059)	**(20,116)**	**(179,606)**
Dividends paid to non-controlling interests	(3)	**(3)**	**(31)**
Repayments of long-term borrowings	(366)	**(398)**	**(3,558)**
Net increase (decrease) in short-term borrowings	11	**(11)**	**(102)**
Purchases of treasury shares	(49)	**(22)**	**(199)**
Net cash provided by (used in) financing activities	(19,465)	**(20,552)**	**(183,496)**
Net increase (decrease) in cash and cash equivalents	6,414	**35,909**	**320,619**
Cash and cash equivalents at the beginning of the period	104,222	**110,485**	**986,471**
Effects of exchange rate changes on cash and cash equivalents	(152)	**(71)**	**(630)**
Cash and cash equivalents at the end of the period	¥ 110,485	**¥ 146,323**	**$ 1,306,460**

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Fiscal Year ended March 31, 2017

Sales of Major Products

Supplemental Data

For information purpose only

		Hundreds of Millions of yen				
		Year ended March 31, 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	**¥ 1,039**	**¥** +828	+391.3 %	**¥ 740**	**¥** △ 299	△ 28.8 %
Glactiv	Agent for type II diabetes	**294**	△ 20	△ 6.5 %	**295**	+1	+0.4 %
Orencia SC	Agent for rheumatoid arthritis	**116**	+36	+44.5 %	**145**	+29	+25.2 %
Opalmon	Circulatory system agent	**170**	△ 57	△ 25.0 %	**140**	△ 30	△ 17.8 %
Recalbon	Agent for osteoporosis	**113**	△ 0	△ 0.0 %	**110**	△ 3	△ 2.6 %
Forxiga	Agent for type II diabetes	**78**	+35	+82.6 %	**100**	+22	+28.1 %
Rivastach	Agent for Alzheimer's disease	**89**	+10	+13.1 %	**100**	+11	+12.9 %
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	**99**	+4	+4.3 %	**100**	+1	+1.2 %
Kyprolis	Agent for relapsed or refractory multiple myeloma	**20**	Launched in August 2016		**60**	+40	+206.1 %
Onoact	Agent for tachyarrhythmia during and post operation	**57**	0	+0.3 %	**60**	+3	+4.8 %
Onon	Agent for bronchial asthma and allergic rhinitis	**68**	△ 22	△ 24.2 %	**55**	△ 13	△ 19.0 %
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	**48**	△ 4	△ 7.6 %	**45**	△ 3	△ 5.7 %
Parsabiv	Agent for secondary hyperparathyroidism	**2**	Launched in February 2017		**30**	+28	+1439.8 %
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	**41**	△ 15	△ 26.7 %	**30**	△ 11	△ 26.9 %
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	**38**	△ 13	△ 25.7 %	**30**	△ 8	△ 21.7 %
Kinedak	Agent for diabetic peripheral neuropathy	**29**	△ 12	△ 29.5 %	**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)

	Year ended March 31, 2016	Year ended March 31, 2017	Year ending March 31, 2018
Revenue of Goods and Products	1,446	2,143	1,920
Royalty and Other Revenue	157	305	440
Total	1,603	2,448	2,360

Note: In "Royalty and Other Revenue", royalty revenue of "Opdivo Intravenous Infusion" is included, which is 82 hundreds of millions of yen for the year ended March 31, 2016 and 267 hundreds of millions of yen for the year ended March 31, 2017.

Information about Revenue by Geographic Area

Supplemental Data

For information purpose only

(Hundreds of Millions of yen)

	Year ended March 31, 2016	Year ended March 31, 2017
Japan	1,471	2,140
Americas	109	273
Asia	20	31
Europe	3	4
Total	1,603	2,448

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

Comparison to business results of the previous fiscal year excluding the impact of retirement benefits plan revision

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Supplemental Data

For information purpose only

The Retirement Benefits Plan Revision was agreed between labor and management in April 2015. For previous 1st quarter ended June 30, 2015, the company computed actuarial calculations based on the revised retirement benefits plan and past service costs of retirement benefits obligations. As a result, for previous 1st quarter ended June 30, 2015, cost of sales decreased by 4 hundreds of millions of yen, research and development costs decreased by 22 hundreds of millions of yen, and selling, general, and administrative expenses decreased by 37 hundreds of millions of yen respectively, due to the effect of past service costs by the retirement benefits plan revision. Operating profit increased by 63 hundreds of millions of yen. The consolidated statement of income for the year ended March 31, 2016 excluding this impact and the year ended March 31, 2017 are as follows.

(Hundreds of Millions of yen)

	Year ended March 31, 2016		Year ended March 31, 2017		
	Actual	Actual excluding the Impact of Retirement Benefits Plan Revision	Actual	Changes	Changes excluding the Impact of Retirement Benefits Plan Revision in previous year
Revenue	¥ 1,603	¥ 1,603	¥ 2,448	52.7 %	52.7 %
Cost of sales	(415)	(420)	(655)	57.8 %	56.2 %
Gross profit	1,188	1,183	1,793	51.0 %	51.5 %
Selling, general, and administrative expenses	(440)	(476)	(620)	41.1 %	30.3 %
Research and development costs	(434)	(456)	(575)	32.6 %	26.1 %
Operating profit	305	242	723	136.9 %	198.6 %
Profit before tax	333	270	745	124.0 %	176.3 %
Income tax expense	(81)	(62)	(185)	129.0 %	200.7 %
Profit for the period	252	208	560	122.4 %	169.1 %
Profit for the period attributable to:					
Owners of the parent company	250	206	558	123.4 %	170.7 %

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Supplemental Information

Status of Development Pipeline

as of May 8, 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
Opdivo Intravenous Infusion	Additional indication	Head and neck cancer *1	Injection	In-house (Co-development with Bristol-Myers Squibb)

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2017

*1: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo Intravenous Infusion was obtained in Japan for the treatment of recurrent or metastatic head and neck 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.

< Filed >

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)
Kyprolis for Intravenous Infusion	Additional dosage and administration	Multiple Myeloma / Proteasome inhibitor	Injection	In-license (Amgen Inc.)

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	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.)
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	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)
Opdivo Intravenous Infusion	Additional indication	Biliary tract cancer	Injection	I	In-house (Co-development with Bristol-Myers Squibb)
ONO-7268 MX1	New chemical entities	Hepatocellular carcinoma / Therapeutic cancer peptide vaccines	Injection	I	In-license (OncoTherapy Science, Inc.)
ONO-7268 MX2	New chemical entities	Hepatocellular carcinoma / Therapeutic cancer peptide vaccines	Injection	I	In-license (OncoTherapy Science, Inc.)

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 *2 / 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 *3 / IDO1 Inhibitor	Capsule	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483 (BMS-986015) / Lirilumab	New chemical entities	Solid tumor *4 / Anti-KIR antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	B cell lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Capsule	I	In-house
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 ending March 2017

*2: Phase I of Anti-CSF-1R antibody (ONO-4687 / BMS-986227) was initiated for the treatment of solid tumor and hematologic cancer.
*3: Phase I of IDO1 inhibitor (ONO-7701 / BMS-986205) was initiated for the treatment of solid tumor and hematologic cancer.
*4: Phase I of Anti-KIR antibody (ONO-4483 / BMS-986015) 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*) / Out-license
Opdivo Intravenous Infusion	Additional indication	Renal cell carcinoma *5	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2017

*5: Approval for the partial change in approved items of the importing and marketing approval for Opdivo Intravenous Infusion was obtained in Taiwan for the treatment of advanced renal cell carcinoma who have received prior anti-angiogenic 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.

< Filed >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / Out-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)

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*) / Out-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, Taiwan	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)
	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, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive/negative solid carcinoma	Injection	I / II	South Korea, Taiwan	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.

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*) / Out-license
Opdivo Intravenous Infusion	Additional indication	Urothelial cancer *6	Injection	USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer *7	Injection	Europe	In-house (Co-development with Bristol-Myers Squibb)

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2017

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

*7: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo Intravenous Infusion was obtained in Europe for the treatment of squamous cell cancer of the head and neck (SCCHN) in adults progressing on or after platinum-based therapy.

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

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

< Filed >

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

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2017

*8: A supplemental application for the partial change in approved items of the manufacturing and marketing approval for Opdivo Intravenous Infusion was submitted in USA for the treatment of previously treated dMMR or MSI-H metastatic colorectal 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*) / Out-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 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*) / Out-license
Opdivo Intravenous Infusion	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	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	Capsule	II	Europe USA	Out-license (Gilead Sciences, Inc.)
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-7475	New chemical entities	Acute leukemia / Axl / Mer inhibitor	Tablet	I	USA	In-house

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / Out-license
ONO-7579	New chemical entities	Solid tumor / Tropomyosin receptor kinase (Trk) inhibitor	Tablet	I	Europe 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.

I. Main Status of Development Pipelines (other than 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 *9	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 ending March 2017

*9: A supplemental application of Orencia intravenous infusion (rheumatoid arthritis treatment) was submitted for the treatment of active polyarticular juvenile idiopathic arthritis (JIA) for a partial change in approved items of manufacturing and marketing approval in Japan.

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)
Orencia SC	Additional indication	Primary sjögren syndrome / 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
Onoact for Intravenous Infusion 50 mg / 150 mg (ONO-1101)	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 *10	New chemical entities	Overactive bladder / Bladder smooth muscle relaxant	Tablet	II	In-house

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
ONO-2160 / CD	New chemical entities	Parkinson's disease / Levodopa pro-drug	Tablet	I	In-house

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2017

*10: Phase II of ONO-8577 (bladder smooth muscle relaxant) was initiated for overactive bladder.

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*) / Out-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 *11 / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	USA	Out-license (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

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2017

*11: Phase II of ONO-4059 (Bruton's tyrosine kinase (Btk) inhibitor) was initiated for Sjögren syndrome.

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

Supplemental Information

New Drugs in Development

as of May 8, 2017

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:

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

Kyprolis (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: Launched in August 2016 / multiple myeloma, J-NDA filed / multiple myeloma (additional dosage and administration), Phase III / multiple myeloma (change of dosage and administration)
Overseas: Launched in August 2012 / United States / multiple myeloma, Launched in November 2015 / Europe / multiple myeloma (Amgen Inc.)

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 and overseas where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed and with juvenile idiopathic arthritis.

Japan: J-NDA filed / juvenile idiopathic arthritis (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)

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.

Japan: Launched in May 2016 / Orencia® SC 125 mg Auto-injector 1 mL, Phase III / untreated rheumatoid arthritis (additional indication) (co-development with Bristol-Myers Squibb Company, being conducted as global clinical trial), Phase III / primary sjögren syndrome (additional indication) (co-development with Bristol-Myers Squibb Company, being conducted as global clinical trial)
Overseas: Approved in September 2016 / untreated rheumatoid arthritis

PARSABIV® / ONO-5163 / AMG-416 / Etelcalcetide Hydrochloride (injection)

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

Japan: Launched in February 2017 / secondary hyperparathyroidism
Overseas: Approved in November 2016 / Europe / secondary hyperparathyroidism, Approved in February 2017 / United States / secondary hyperparathyroidism (Amgen Inc.)

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.

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

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

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

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.

Japan: Phase III / cancer anorexia / cachexia
USA: Phase III / cancer anorexia / cachexia (Helsinn Healthcare, S.A.)
Europe: Filed / cancer anorexia / cachexia (Helsinn Healthcare, S.A.)

ONO-2370 / Opicapone (tablet)

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

Japan: Phase II / Parkinson's disease
Europe: Approved in July 2016 / Parkinson's disease (Bial)

ONO-5371 / Metyrosine (capsule)

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

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

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

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

Japan: Phase I / hepatocellular carcinoma

ONO-2160/CD (tablet)

ONO-2160 / CD 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-4059 (capsule)

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

Japan: Phase I / B cell lymphoma
USA & Europe: Phase II / B cell lymphoma (Gilead Sciences, Inc.)

ONO-4059 (tablet)

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

USA: Phase II / Sjögren syndrome (Gilead Sciences, Inc.)

ONO-8577 (tablet)

ONO-8577 is a bladder smooth muscle relaxant being developed for the treatment of overactive bladder.

Japan: Phase II / overactive bladder

ONO-4578 (tablet)

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

Japan: Phase I / solid tumor

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-4474 (capsule)

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

Europe: Phase II /osteoarthritis

ONO-7475 (tablet)

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

USA: Phase I / acute leukemia

ONO-7579 (tablet)

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

USA & Europe: Phase I / solid tumor

Opdivo® Intravenous Infusion (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.

Japan:

Launched in September 2014 / melanoma,
J-NDA approved in December 2015 / non-small cell lung cancer,
J-NDA approved in August 2016 / renal cell carcinoma,
J-NDA approved in December 2016 / hodgkin's lymphoma,
J-NDA approved in March 2017 / head and neck cancer,
J-NDA filed / gastric cancer (global clinical trial),
Phase III / esophageal cancer (global clinical trial),
Phase III / gastro-esophageal junction cancer and esophageal cancer (global clinical trial),
Phase III / small cell lung cancer (global clinical trial),
Phase III / urothelial cancer (global clinical trial),
Phase III / hepatocellular carcinoma (global clinical trial),
Phase III / glioblastoma (global clinical trial),
Phase III / malignant pleural mesothelioma (global clinical trial),
Phase III / ovarian cancer,
Phase II / solid tumor (cervix carcinoma, uterine body cancer, soft tissue sarcoma),
Phase II / central nervous system lymphoma, primary testicular lymphoma (global clinical trial),
Phase I/II / virus positive/negative solid carcinoma (global clinical trial),
Phase I / biliary tract cancer

Overseas:

USA / Launched in December 2014 / melanoma,
South Korea / Approved in March 2015 / melanoma,
USA / Approved in March 2015 / squamous non-small cell lung cancer,
Europe / Approved in June 2015 / melanoma,
Europe / Approved in July 2015 / squamous non-small cell lung cancer,
USA / Approved in September 2015 / melanoma (combination with Yervoy),
USA / Approved in October 2015 / non-squamous non-small cell lung cancer,
USA / Approved in November 2015 / renal cell carcinoma,
Europe / Approved in April 2016 / non-squamous non-small cell lung cancer,
South Korea / Approved in April 2016 / non-small cell lung cancer,
Europe / Approved in April 2016 / renal cell carcinoma,
USA / Approved in May 2016 / hodgkin's lymphoma,
Europe / Approved in May 2016 / melanoma (combination with Yervoy),
Taiwan / Approved in May 2016 / melanoma,
Taiwan / Approved in May 2016 / squamous non-small cell lung cancer,
Europe / Approved in November 2016 / hodgkin's lymphoma,
USA / Approved in November 2016 / head and neck cancer,
USA / Approved in February 2017 / urothelial cancer,
Taiwan / Approved in April 2017 / renal cell carcinoma
Europe / Approved in April 2017 / head and neck cancer,
USA / Filed / colon cancer,
Europe / Filed / urothelial cancer,
Taiwan / Filed / non-squamous non-small cell lung cancer,
Taiwan / Filed / head and neck cancer,
USA, Europe / Phase III / multiple myeloma,
USA, Europe, South Korea, Taiwan / Phase III / gastric cancer,
USA, Europe, South Korea, Taiwan / Phase III / esophageal cancer,
USA, Europe, South Korea, Taiwan / Phase III / gastro-esophageal junction cancer and esophageal cancer,
South Korea / Phase III / head and neck cancer,
USA, Europe / Phase III / glioblastoma,
USA, Europe, South Korea, Taiwan / Phase III / small cell lung cancer,
South Korea, Taiwan / Phase III / urothelial cancer,
USA, Europe, South Korea, Taiwan / Phase III / hepatocellular carcinoma,
USA, Europe / Phase III / malignant pleural mesothelioma,
USA, Europe / Phase II / central nervous system lymphoma, primary testicular lymphoma,
USA, Europe / Phase II / diffuse large B cell lymphoma,
USA, Europe / Phase II / follicular lymphoma,
Europe / Phase I/II / colon cancer,
USA, Europe / Phase I/II / solid tumors (triple negative breast cancer, gastric cancer, pancreatic cancer, small cell lung cancer, urothelial cancer, ovarian cancer),
USA, Europe, South Korea, Taiwan / Phase I/II / virus positive/negative solid carcinoma,
USA, Europe / Phase I / hematologic cancer (T-cell lymphoma, multiple myeloma, chronic leukemia, etc),
USA, Europe / Phase I / chronic myeloid leukemia,
USA, Europe / Phase I / hepatitis C
USA / Phase I / Sepsis

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

ONO-4481, a human anti-human CD-137 monoclonal antibody, is expected to be a potential treatment for cancer etc.
In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

Japan: Phase I / solid tumor

ONO-4482 / BMS-986016 (injection)

ONO-4482, a human anti-human LAG-3 monoclonal antibody, is expected to be a potential treatment for cancer etc.
In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

Japan: Phase I / solid tumor

ONO-4686 / BMS-986207 (injection)

ONO-4686, a human anti-human TIGIT monoclonal antibody, is expected to be a potential treatment for cancer etc.
In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

Japan: Phase I/II / solid tumor

ONO-4687 / BMS-986227 (injection)

ONO-4687, a human anti-human CSF-1R monoclonal antibody, is expected to be a potential treatment for cancer etc.
In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

Japan: Phase I / solid tumor and hematologic cancer

ONO-7701 / BMS-986205 (capsule)

ONO-7701, IDO1 inhibitor, is expected to be a potential treatment for cancer etc.
In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

Japan: Phase I / solid tumor and hematologic cancer

ONO-4483 / BMS-986015 (injection)

ONO-4483, a human anti-human KIR monoclonal antibody, is expected to be a potential treatment for cancer etc.
In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

Japan: Phase I / solid tumor