Second Quarter (April 1 – September 30, 2017) Flash Report (unaudited)
Six months ended September 30, 2017

ONO PHARMACEUTICAL CO., LTD.

November 6, 2017

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

This Second Quarter Flash Report 2018 (unaudited) is summary information extracted from the financial statements announced, and the financial statements and the figures contained herein are prepared for reference only for the convenience of readers outside Japan with certain modifications and reclassifications made from the original financial statements presented in Japanese language.

The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan using the rate of 112 to $1, the approximate rate of exchange at September 30, 2017.

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

Financial Highlights

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen			Thousands of US$
	2nd Quarter 6 months ended Sep. 30, 2016	Annual 12 months ended Mar. 31, 2017	**2nd Quarter 6 months ended Sep. 30, 2017**	**2nd Quarter 6 months ended Sep. 30, 2017**
Revenue	¥ 117,726	¥ 244,797	**¥ 121,446**	**$ 1,084,339**
Profit (Owners of the parent company)	23,119	55,793	**21,210**	**189,375**
Total equity	490,548	524,211	**507,272**	**4,529,215**
Total assets	557,753	617,461	**576,599**	**5,148,210**
		Yen		US$
Basic earnings per share	¥ 43.62	¥ 105.27	**¥ 40.63**	**$ 0.36**
Diluted earnings per share	¥ 43.62	¥ 105.26	**¥ 40.63**	**$ 0.36**

Revisions of Consolidated Financial Forecasts

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(1) Revisions to the full-year Consolidated Financial Forecasts Ending March 31, 2018 (April 1, 2017 ~ March 31, 2018)

(Unit: Millions of yen, except basic earnings per share)

	Revenue	Operating Profit	Profit before Tax	Profit	Profit (Owners of the Parent Company)	Basic earnings per share (Owners of the Parent Company)
Previous Forecast (A) *	236,000	36,500	39,000	29,200	29,000	54.72
Revised Forecast (B)	254,000	50,000	53,000	39,700	39,500	75.66
Change (B – A)	18,000	13,500	14,000	10,500	10,500	—
Change (%)	7.6	37.0	35.9	36.0	36.2	—
(Reference) Results of the previous fiscal year ended March 31, 2017	244,797	72,284	74,540	56,036	55,793	105.27

* The previous forecast was announced on May 11, 2017

(2) Reasons for the revisions

Regarding revenue, royalty revenue for Opdivo from Bristol-Myers Squibb is expected to exceed the previous forecast. Also, sales of our key product Opdivo in the previous forecast was ¥74.0 billion, a significant decrease of ¥29.9 billion (28.8%) from the previous fiscal year ended March 31, 2017 due to the effect of the reduction of the NHI drug price in Februrary 2017. However, sales forecast of Opdivo was revised to be ¥84.0 billion, a decrease of ¥19.9 billion (19.2%) from the previous fiscal year ended March 31, 2017 by factoring in sales of unresectable advanced or recurrent gastric cancer which has progressed after chemotherapy approved in September 2017. As the result, revenue forecast was upwardly revised to be ¥254.0 billion, an increase of ¥18.0 billion from the previous forecast ¥236.0 billion.

With regards to expenses, although cost of sales is increased due to an increase in sales, research and development costs and selling, general, and administrative expenses have been no changes from the previous forecast.

Consequently, operating profit is forecasted to be ¥50.0 billion (an increase by ¥13.5 billion from the previous forecast), profit before tax to be ¥53.0 billion (an increase by ¥14.0 billion from the previous forecast), profit for the year attributable to owners of the parent company to be ¥39.5 billion (an increase by ¥10.5 billion from the previous forecast).

(Note) The financial forecasts and statements contained in this announcement are made based on information that are available as of the date the announcement is made. Actual results may differ materially from those set forth in the announcements due to various uncertain factors.

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 September 30, 2017**	**As of September 30, 2017**
Current assets			
Cash and cash equivalents	¥ 146,323	¥ **50,272**	$ **448,855**
Trade and other receivables	73,255	**76,338**	**681,588**
Marketable securities	17,560	**13,624**	**121,641**
Other financial assets	819	**10,805**	**96,469**
Inventories	25,334	**28,390**	**253,479**
Other current assets	7,742	**11,319**	**101,060**
Total current assets	271,033	**190,746**	**1,703,091**
Non-current assets			
Property, plant, and equipment	83,659	**90,370**	**806,878**
Intangible assets	45,237	**50,876**	**454,250**
Investment securities	176,573	**187,936**	**1,677,999**
Investments in associates	114	**124**	**1,105**
Other financial assets	26,836	**46,581**	**415,904**
Deferred tax assets	10,739	**6,021**	**53,762**
Retirement benefit assets	–	**218**	**1,946**
Other non-current assets	3,271	**3,727**	**33,273**
Total non-current assets	346,428	**385,853**	**3,445,118**
Total assets	¥ 617,461	¥ **576,599**	$ **5,148,210**

LIABILITIES AND EQUITY	Millions of yen		Thousands of US$
	As of March 31, 2017	**As of September 30, 2017**	**As of September 30, 2017**
Current liabilities			
Trade and other payables	¥ 30,905	¥ **29,897**	$ **266,933**
Borrowings	423	**379**	**3,386**
Other financial liabilities	5,814	**4,099**	**36,595**
Income taxes payable	24,777	**7,240**	**64,647**
Provisions	6,086	**8,398**	**74,983**
Other current liabilities	14,928	**9,498**	**84,807**
Total current liabilities	82,933	**59,511**	**531,351**
Non-current liabilities			
Borrowings	542	**416**	**3,716**
Other financial liabilities	11	**13**	**117**
Retirement benefit liabilities	2,805	**2,612**	**23,322**
Provisions	30	**30**	**268**
Deferred tax liabilities	881	**896**	**8,001**
Long-term advances received	5,276	**5,069**	**45,262**
Other non-current liabilities	772	**779**	**6,956**
Total non-current liabilities	10,316	**9,816**	**87,643**
Total liabilities	93,250	**69,327**	**618,995**
Equity			
Share capital	17,358	**17,358**	**154,985**
Capital reserves	17,144	**17,162**	**153,230**
Treasury shares	(59,382)	**(98,153)**	**(876,366)**
Other components of equity	51,752	**62,462**	**557,695**
Retained earnings	492,237	**503,257**	**4,493,366**
Equity attributable to owners of the parent company	519,110	**502,086**	**4,482,909**
Non-controlling interests	5,101	**5,186**	**46,306**
Total equity	524,211	**507,272**	**4,529,215**
Total liabilities and equity	¥ 617,461	¥ **576,599**	$ **5,148,210**

Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	2nd Quarter 6 months ended Sep. 30, 2016	**2nd Quarter 6 months ended Sep. 30, 2017**	**2nd Quarter 6 months ended Sep. 30, 2017**
Revenue	¥ 117,726	**¥ 121,446**	**$ 1,084,339**
Cost of sales	(32,227)	**(30,491)**	**(272,239)**
Gross profit	85,499	**90,955**	**812,100**
Selling, general, and administrative expenses	(29,286)	**(32,592)**	**(290,996)**
Research and development costs	(25,323)	**(31,416)**	**(280,503)**
Other income	226	**340**	**3,034**
Other expenses	(980)	**(499)**	**(4,452)**
Operating profit	30,135	**26,789**	**239,184**
Finance income	1,623	**1,642**	**14,660**
Finance costs	(648)	**(46)**	**(407)**
Share of profit (loss) from investments in associates	17	**8**	**74**
Profit before tax	31,127	**28,393**	**253,511**
Income tax expense	(7,938)	**(7,106)**	**(63,448)**
Profit for the period	23,189	**21,287**	**190,064**
Profit for the period attributable to:			
Owners of the parent company	23,119	**21,210**	**189,375**
Non-controlling interests	70	**77**	**689**
Profit for the period	23,189	**21,287**	**190,064**
Earnings per share:	Yen		US$
Basic earnings per share	43.62	**40.63**	**0.36**
Diluted earnings per share	43.62	**40.63**	**0.36**

Consolidated Statement of Comprehensive Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	2nd Quarter 6 months ended Sep. 30, 2016	**2nd Quarter 6 months ended Sep. 30, 2017**	**2nd Quarter 6 months ended Sep. 30, 2017**
Profit for the period	¥ 23,189	**¥ 21,287**	**$ 190,064**
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	1,237	**10,630**	**94,907**
Remeasurement of defined benefit plans	(46)	**410**	**3,661**
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	1,191	**11,042**	**98,591**
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	(541)	**86**	**768**
Net fair value gain (loss) on derivatives under hedge accounting	–	**3**	**25**
Total of items that may be reclassified subsequently to profit or loss	(541)	**89**	**794**
Total other comprehensive income (loss)	650	**11,131**	**99,385**
Total comprehensive income for the period	23,839	**32,418**	**289,448**
Comprehensive income for the period attributable to:			
Owners of the parent company	23,770	**32,330**	**288,661**
Non-controlling interests	69	**88**	**787**
Total comprehensive income for the period	23,839	**32,418**	**289,448**

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					23,119	23,119	70	23,189
Other comprehensive income				652		652	(1)	650
Total comprehensive income for the period	–	–	–	652	23,119	23,770	69	23,839
Purchase of treasury shares			(22)			(22)		(22)
Cash dividends					(9,540)	(9,540)	(3)	(9,544)
Share-based payments		19				19		19
Transfer from other components of equity to retained earnings				(79)	79	–		–
Total transactions with the owners	–	19	(22)	(79)	(9,461)	(9,543)	(3)	(9,546)
Balance at September 30, 2016	¥17,358	¥17,122	(¥59,380)	¥43,879	¥466,640	¥485,620	¥4,928	¥490,548

	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					21,210	21,210	77	21,287
Other comprehensive income				11,120		11,120	11	11,131
Total comprehensive income for the period	–	–	–	11,120	21,210	32,330	88	32,418
Purchase of treasury shares			(38,771)			(38,771)		(38,771)
Cash dividends					(10,600)	(10,600)	(3)	(10,604)
Share-based payments		17				17		17
Transfer from other components of equity to retained earnings				(410)	410	–		–
Total transactions with the owners	–	17	(38,771)	(410)	(10,190)	(49,354)	(3)	(49,357)
Balance at September 30, 2017	¥17,358	¥17,162	(¥98,153)	¥62,462	¥503,257	¥502,086	¥5,186	¥507,272

	Thousands of US $							
	Equity attributable to owners of the parent company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non-controlling interests	Total equity
Balance at April 1, 2017	**$154,985**	**$153,074**	**($530,195)**	**$462,070**	**$4,394,976**	**$4,634,909**	**$45,546**	**$4,680,456**
Profit for the period					**189,375**	**189,375**	**689**	**190,064**
Other comprehensive income				**99,287**		**99,287**	**98**	**99,385**
Total comprehensive income for the period	–	–	–	**99,287**	**189,375**	**288,661**	**787**	**289,448**
Purchase of treasury shares			**(346,171)**			**(346,171)**		**(346,171)**
Cash dividends					**(94,646)**	**(94,646)**	**(28)**	**(94,674)**
Share-based payments		**156**				**156**		**156**
Transfer from other components of equity to retained earnings				**(3,661)**	**3,661**	–		–
Total transactions with the owners	–	**156**	**(346,171)**	**(3,661)**	**(90,985)**	**(440,661)**	**(28)**	**(440,689)**
Balance at September 30, 2017	**$154,985**	**$153,230**	**($876,366)**	**$557,695**	**$4,493,366**	**$4,482,909**	**$46,306**	**$4,529,215**

Consolidated Statement of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	2nd Quarter 6 months ended Sep. 30, 2016	**2nd Quarter 6 months ended Sep. 30, 2017**	**2nd Quarter 6 months ended Sep. 30, 2017**
Cash flows from operating activities			
Profit before tax	¥ 31,127	**¥ 28,393**	**$ 253,511**
Depreciation and amortization	3,598	**4,453**	**39,761**
Impairment losses	674	**–**	**–**
Interest and dividend income	(1,622)	**(1,586)**	**(14,159)**
Interest expense	7	**7**	**65**
(Increase) Decrease in inventories	(2,563)	**(3,061)**	**(27,334)**
(Increase) Decrease in trade and other receivables	(11,035)	**(3,084)**	**(27,534)**
Increase (Decrease) in trade and other payables	4,362	**(3,308)**	**(29,540)**
Increase (Decrease) in provisions	(111)	**2,311**	**20,632**
Increase (Decrease) in retirement benefit liabilities	207	**180**	**1,610**
Increase (Decrease) in long-term advances received	(349)	**(207)**	**(1,844)**
Other	4,495	**(11,523)**	**(102,885)**
Subtotal	28,792	**12,576**	**112,283**
Interest received	87	**51**	**457**
Dividends received	1,547	**1,538**	**13,735**
Interest paid	(7)	**(7)**	**(65)**
Income taxes paid	(6,557)	**(24,540)**	**(219,110)**
Net cash provided by (used in) operating activities	23,863	**(10,382)**	**(92,700)**
Cash flows from investing activities			
Purchases of property, plant, and equipment	(11,174)	**(8,504)**	**(75,925)**
Purchases of intangible assets	(6,016)	**(5,516)**	**(49,248)**
Purchases of investments	(2,437)	**(40)**	**(357)**
Proceeds from sales and redemption of investments	11,406	**8,000**	**71,429**
Payments into time deposits	(20,200)	**(30,200)**	**(269,643)**
Other	80	**112**	**1,004**
Net cash provided by (used in) investing activities	(28,341)	**(36,147)**	**(322,740)**
Cash flows from financing activities			
Dividends paid to owners of the parent company	(9,534)	**(10,581)**	**(94,475)**
Dividends paid to non-controlling interests	(3)	**(3)**	**(28)**
Repayments of long-term borrowings	(192)	**(210)**	**(1,873)**
Net increase (decrease) in short-term borrowings	4	**(26)**	**(229)**
Purchases of treasury shares	(21)	**(38,772)**	**(346,177)**
Net cash provided by (used in) financing activities	(9,746)	**(49,591)**	**(442,781)**
Net increase (decrease) in cash and cash equivalents	(14,224)	**(96,121)**	**(858,222)**
Cash and cash equivalents at the beginning of the period	110,485	**146,323**	**1,306,460**
Effects of exchange rate changes on cash and cash equivalents	(677)	**69**	**617**
Cash and cash equivalents at the end of the period	¥ 95,584	**¥ 50,272**	**$ 448,855**

Sales of Major Products

Supplemental Data

		Hundreds of Millions of yen					
		2nd Quarter 6 months ended September 30, 2017			Year ending March 31, 2018		
		Results	Increase/Decrease		Forecasts	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, recurrent or metastatic head and neck cancer, and unresectable advanced or recurrent gastric cancer which has progressed after chemotherapy	¥ **406**	¥ △ 127	△ 23.8 %	¥ **840**	¥ △ 199	△ 19.2 %
Glactiv	Agent for type II diabetes	**137**	△ 11	△ 7.5 %	**295**	1	0.4 %
Orencia SC	Agent for rheumatoid arthritis	**68**	13	24.7 %	**145**	29	25.2 %
Opalmon	Circulatory system agent	**75**	△ 13	△ 14.9 %	**140**	△ 30	△ 17.8 %
Recalbon	Agent for osteoporosis	**54**	△ 2	△ 3.5 %	**110**	△ 3	△ 2.6 %
Forxiga	Agent for type II diabetes	**53**	17	47.6 %	**110**	32	40.9 %
Rivastach	Agent for Alzheimer's disease	**45**	1	1.8 %	**100**	11	12.9 %
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	**50**	0	0.3 %	**100**	1	1.2 %
Kyprolis	Agent for relapsed or refractory multiple myeloma	**27**	25	1440.0 %	**60**	40	206.1 %
Onoact	Agent for tachyarrhythmia during and post operation	**27**	0	△ 0.1 %	**60**	3	4.8 %
Onon	Agent for bronchial asthma and allergic rhinitis	**24**	△ 6	△ 20.3 %	**55**	△ 13	△ 19.0 %
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	**21**	△ 3	△ 13.8 %	**45**	△ 3	△ 5.7 %
Parsabiv	Agent for secondary hyperparathyroidism	**14**		Launched in February 2017	**30**	28	1439.8 %
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	**15**	△ 4	△ 20.8 %	**30**	△ 11	△ 26.9 %
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	**16**	△ 4	△ 21.2 %	**30**	△ 8	△ 21.7 %
Kinedak	Agent for diabetic peripheral neuropathy	**12**	△ 4	△ 24.9 %	**25**	△ 4	△ 13.2 %

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

Breakdown of Revenue

Supplemental Data

(Hundreds of Millions of yen)

	2nd Quarter 6 months ended September 30, 2016	2nd Quarter 6 months ended September 30, 2017	Year ending March 31, 2018
Revenue of Goods and Products	1,073	974	2,030
Royalty and Other Revenue	104	241	510
Total	1,177	1,214	2,540

Note: In "Royalty and Other Revenue", royalty revenue of "Opdivo Intravenous Infusion" is included, which is 87 hundreds of millions of yen for the 2nd quarter 6 months ended September 30, 2016 and 180 hundreds of millions of yen for the 2nd quarter 6 months ended September 30, 2017.

Information about Revenue by Geographic Area

Supplemental Data

(Hundreds of Millions of yen)

	2nd Quarter 6 months ended September 30, 2016	2nd Quarter 6 months ended September 30, 2017
Japan	1,073	972
Americas	90	222
Asia	13	19
Europe	2	1
Total	1,177	1,214

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

Supplemental Information

Status of Development Pipeline

as of October 27, 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	Gastric cancer *1	Injection	In-house (Co-development with Bristol-Myers Squibb)

Changes from First Quarter Flash Report for the Fiscal Year ending March 2018

*1: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo was obtained in Japan for the treatment of unresectable advanced or recurrent gastric cancer which has progressed after chemotherapy.

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

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

< Clinical Trial Stage >

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Kyprolis for Intravenous Infusion	Change of dosage and administration	Multiple myeloma / Proteasome inhibitor	Injection	III	In-license (Amgen Inc.)
ONO-7643 / Anamorelin	New chemical entities	Cancer anorexia / cachexia / Ghrelin mimetic	Tablet	III	In-license (Helsinn Healthcare, S.A.)
ONO-7702 / Encorafenib	New chemical entities	Melanoma / BRAF inhibitor	Capsule	III	In-license (Array Biopharma Inc.)
ONO-7703 / Binimetinib	New chemical Entities	Melanoma / MEK inhibitor	Tablet	III	In-license (Array Biopharma Inc.)
Opdivo Intravenous Infusion	Additional indication	Solid tumor (Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma)	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central nervous system lymphoma, Primary testicular lymphoma	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Multiple myeloma	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-house (Co-development with Bristol-Myers Squibb)
ONO-5371 / Metyrosine	New chemical entities	Pheochromocytoma / Tyrosine hydroxylase inhibitor	Capsule	I / II	In-license (Valeant Pharmaceuticals North America LLC.)
ONO-4686 (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Central nervous system lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I / II	In-house
Opdivo Intravenous Infusion	Additional indication	Biliary tract cancer	Injection	I	In-house (Co-development with Bristol-Myers Squibb)
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) / Relatlimab	New chemical entities	Solid tumor / Anti-LAG-3 antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4687 (BMS-986227) / Cabiralizumab	New chemical entities	Solid tumor and hematologic cancer / Anti-CSF-1R antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-7701 (BMS-986205)	New chemical entities	Solid tumor and hematologic cancer / IDO1 Inhibitor	Capsule	I	In-license (Co-development with Bristol-Myers Squibb)

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

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	Renal cell cancer *2	Injection	South Korea	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hodgkin lymphoma *2	Injection	South Korea	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer *2	Injection	South Korea	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer *2	Injection	South Korea	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer *3	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Non-small cell lung cancer (Non- Squamous) *3	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hodgkin lymphoma *3	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer *3	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)

Changes from First Quarter Flash Report for the Fiscal Year ending March 2018

*2: 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 patients with advanced renal cell carcinoma who have been previously treated, those with classical hodgkin lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation and post-transplantation brentuximab vedotin, those with recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after platinum-based therapy, those with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy, and those with unresectable or metastatic melanoma in combination with ipilimumab.

*3: 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 recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after platinum-based therapy, those with advanced non-squamous non-small cell lung cancer which has been previously treated with platinum-based therapy, those with classical hodgkin lymphoma that has relapsed or progressed, those with locally advanced unresctable or metastatic urothelial carcinoma, and those with unresectable or metastatic melanoma

< Filed >

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

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

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

3. Development Status in Europe and the United States

< Approved >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Colon cancer *4	Injection	USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma *4	Injection	USA	In-house (Co-development with Bristol-Myers Squibb)

Changes from First Quarter Flash Report for the Fiscal Year ending March 2018

*4: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo was obtained in USA for the treatment of patients with microsatellite instabilityhigh (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan and those with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

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

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

< Clinical Trial Stage >

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

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

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

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

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

1. Development Status in Japan

< Filed >

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

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

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Orencia IV	Additional indication	Lupus nephritis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
Orencia SC	Additional indication	Untreated rheumatoid arthritis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
	Additional indication	Primary sjögren syndrome / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
	Additional indication	Polymyositis / Dermatomyositis / 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*5 / 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
ONO-2370 / Opicapone	New chemical entities	Parkinson's disease / Long acting COMT inhibitor	Tablet	II	In-license (Bial)
ONO-8577	New chemical entities	Overactive bladder / Bladder smooth muscle relaxant	Tablet	II	In-house
ONO-5704 / SI-613	New chemical entities	Enthesopathy *6 / 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)

Changes from First Quarter Flash Report for the Fiscal Year ending March 2018

*5: Phase III of ONO-5704 / SI-613 (hyaluronic acid-NSAID) was initiated for the treatment of osteoarthritis.

*6: Phase II of ONO-5704 / SI-613 (hyaluronic acid-NSAID) was initiated for the treatment of enthesopathy.

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

2. Development Status in Overseas

< Clinical Trial Stage >

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

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

Supplemental Information

New Drugs in Development

as of October 27, 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, Approved in May 2017 / 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), Phase III / polymyositis / dermatomyositis (additional indication) (co-development with Bristol-Myers Squibb Company, being conducted as global clinical trial)
Overseas: Approved in September 2016 / untreated rheumatoid arthritis

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 approved 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-4059 (tablet)

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

Japan: Phase I / B cell lymphoma, Phase I/II / central nervous system lymphoma
Europe: Phase II / B cell lymphoma (Gilead Sciences, Inc.)
USA: Phase II / Sjögren syndrome (Gilead Sciences, Inc.), Phase I / B cell lymphoma (Gilead Sciences, Inc.)

ONO-4059 (capsule)

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

Japan: Phase I / B cell lymphoma

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/II / 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 approved in September 2017 / gastric cancer,
J-NDA filed / melanoma (combination with Yervoy),
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 II / multiple myeloma
Phase I/II / sepsis
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,
Europe / Approved in June 2017 / urothelial cancer,
Taiwan / Approved in August 2017 / head and neck cancer,
South Korea / Approved in August 2017 / renal cell carcinoma,
South Korea / Approved in August 2017 / hodgkin's lymphoma,
South Korea / Approved in August 2017 / head and neck cancer,
South Korea / Approved in August 2017 / urothelial cancer,
South Korea / Approved in August 2017 / melanoma (combination with Yervoy),
USA / Approved in August 2017 / colon cancer,
USA / Approved in September 2017 / hepatocellular carcinoma,
Taiwan / Approved in September 2017 / non-squamous non-small cell lung cancer,
Taiwan / Approved in October 2017 / hodgkin's lymphoma,
Taiwan / Approved in October 2017 / urothelial cancer,
Taiwan / Approved in October 2017 / melanoma (combination with Yervoy),
Taiwan / Filed / gastric cancer,
USA, Europe / Phase III / multiple myeloma,
USA, Europe, South Korea / 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,
USA, Europe / Phase III / glioblastoma,
USA, Europe, South Korea, Taiwan / Phase III / small cell lung cancer,
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

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

ONO-4481, a human anti-human CD137 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 / Relatimab / 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 / Cabiralizumab / 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 / Lirilumab / 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

ONO-7702 / Encorafenib (capsule)

ONO-7702, BRAF inhibitor, is expected to be a potential treatment for melanoma etc.

Japan: Phase III / melanoma
South Korea: Phase III / melanoma, Phase III / colon cancer

ONO-7703 / Binimetinib (tablet)

ONO-7703, MEK inhibitor, is expected to be a potential treatment for cancer etc.

Japan: Phase III / melanoma
South Korea: Phase III / melanoma, Phase III / colon cancer

ONO-5704 / SI-613 (injection)

ONO-5704, hyaluronic acid-NSAID, is expected to be a potential treatment for osteoarthritis and enthesopathy.

Japan: Phase III / osteoarthritis
Japan: Phase II / enthesopathy