Consolidated Financial Results
for the Second Quarter of the Fiscal Year Ending March 31, 2019 (IFRS)

November 1, 2018

Company name : **Ono Pharmaceutical Co., Ltd.**
Stock exchange listing : Tokyo Stock Exchange
Code number : 4528
URL : http://www.ono.co.jp/
Representative : Gyo Sagara
President, Representative Director, and Chief Executive Officer
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Scheduled date of quarterly securities report submission : November 9, 2018
Scheduled date of dividend payment commencement : December 3, 2018
Supplementary materials for quarterly financial results : Yes
Earnings announcement for quarterly financial results : Yes (for institutional investors and securities analysts)

(Note: Amounts of less than one million yen are rounded.)

1. Consolidated Financial Results for the Second Quarter of FY 2018 (April 1, 2018 to September 30, 2018)

(1) Consolidated Operating Results (cumulative)

(% change from the same period of the previous fiscal year)

	Revenue		Operating profit		Profit before tax		Profit for the period		Profit attributable to owners of the Company	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%
FY 2018 Q2	144,395	18.9	35,151	31.2	36,917	30.0	28,883	35.7	28,845	36.0
FY 2017 Q2	121,446	3.2	26,789	(11.1)	28,393	(8.8)	21,287	(8.2)	21,210	(8.3)

	Total comprehensive income for the period		Basic earnings per share	Diluted earnings per share
	Million yen	%	Yen	Yen
FY 2018 Q2	46,571	43.7	56.11	56.10
FY 2017 Q2	32,418	36.0	40.63	40.63

(2) Consolidated Financial Position

	Total assets	Total equity	Equity attributable to owners of the Company	Ratio of equity attributable to owners of the Company to total assets
	Million yen	Million yen	Million yen	%
As of September 30, 2018	640,193	570,040	564,769	88.2
As of March 31, 2018	609,226	529,619	524,390	86.1

2. Dividends

	Annual dividends per share				
	End of first quarter	End of second quarter	End of third quarter	End of fiscal year	Total
	Yen	Yen	Yen	Yen	Yen
FY 2017	—	25.00	—	20.00	45.00
FY 2018	—	22.50			
FY 2018 (Forecast)			—	22.50	45.00

(Note) Revisions to dividends forecast most recently announced: None

3. Forecasts of Consolidated Financial Results for FY 2018 (April 1, 2018 to March 31, 2019)

(% change from the same period of the previous fiscal year)

	Revenue		Operating profit		Profit before tax		Profit for the period		Profit attributable to owners of the Company		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
FY 2018	280,000	6.9	63,500	4.6	67,000	4.8	52,100	3.4	52,000	3.4	101.14

(Note) Revisions to financial forecast most recently announced: Yes

Notes

(1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in a change in scope of consolidation): None

(2) Changes in accounting policies and changes in accounting estimates
1) Changes in accounting policies required by IFRS: Yes
2) Changes in accounting policies due to other than (2) – 1) above: None
3) Changes in accounting estimates: None

(3) Number of shares issued and outstanding (common stock)
1) Number of shares issued and outstanding as of the end of the period (including treasury shares):
As of September 30, 2018 543,341,400 shares
As of March 31, 2018 543,341,400 shares
2) Number of treasury shares as of the end of the period:
As of September 30, 2018 29,220,397 shares
As of March 31, 2018 29,219,787 shares
3) Average number of shares outstanding during the period:
Six months ended September 30, 2018 514,121,317 shares
Six months ended September 30, 2017 522,049,985 shares

* This financial results report is not subject to quarterly review procedures by certified public accountants or an auditing firm.

* Note to ensure appropriate use of forecasts, and other comments in particular
Forecasts and other forward-looking statements included in this report are based on information currently available and certain assumptions that the Company deems reasonable. Actual performance and other results may differ significantly due to various factors. Please refer to "(4) Outlook for FY 2018" on page 6 for information regarding the forecast of consolidated financial results.

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1. Overview of Operating Results and Other Information

(1) Overview of Operating Results for the 2nd Quarter of FY 2018

The financial results for the second quarter (April–September 2018) were as follows.

(Millions of yen)

	Six months ended September 30, 2017	Six months ended September 30, 2018	Change	Change (%)
Revenue	121,446	144,395	22,950	18.9%
Operating profit	26,789	35,151	8,362	31.2%
Profit before tax	28,393	36,917	8,524	30.0%
Profit for the period (attributable to owners of the Company)	21,210	28,845	7,635	36.0%

[Revenue]

Revenue totaled ¥144.4 billion, which was an increase of ¥23.0 billion (18.9%) from the corresponding period of the previous fiscal year (year-on-year).

- Although Opdivo Intravenous Infusion for malignant tumors was affected by the revision of the National Health Insurance (NHI) drug price reduction according to the drastic reform of NHI drug pricing system, its use was expanded for the treatment of renal cell carcinoma, and head and neck cancer approved in the fiscal year before last as well as gastric cancer etc. in the previous fiscal year, resulting in sales of ¥45.4 billion, an increase of ¥4.8 billion (11.9%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥13.7 billion (0.1% increase year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥8.6 billion (26.8% increase year-on-year), sales of Forxiga Tablets for type-2 diabetes were ¥7.0 billion (33.1% increase year-on-year), sales of both Emend Capsules and Proemend for Intravenous Injection for chemotherapy-induced nausea and vomiting were ¥5.3 billion (6.6% increase year-on-year), sales of Rivastach Patch for Alzheimer's disease were ¥4.5 billion (1.4% increase year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥2.7 billion (98.8% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥2.6 billion (4.6% decrease year-on-year).
- Sales of long-term listed products were affected by the impact of NHI drug price reduction and generic drug use promotion policies. Sales of Opalmon Tablets for peripheral circulatory disorder were ¥5.5 billion (26.8% decrease year-on-year), and sales of Recalbon Tablets for osteoporosis were ¥4.4 billion (19.0% decrease year-on-year), respectively.
- Royalty and Other Revenue increased by ¥15.3 billion (63.3%) year-on-year to ¥39.4 billion, mainly due to the rise in Opdivo Intravenous Infusion-related royalty from Bristol-Myers Squibb Company and recognition of the revenue associated with sales of long-term listed products (11 products for 5 brands of injections) to Maruishi Pharmaceutical Co., Ltd.

[Operating Profit]

Operating profit was ¥35.2 billion, an increase of ¥8.4 billion (31.2%) year-on-year.

- Cost of sales was ¥41.6 billion, an increase of ¥11.1 billion (36.5%) year-on-year.
- Research and development costs increased by ¥1.6 billion (5.2%) year-on-year to ¥33.0 billion mainly due to an increase of Opdivo Intravenous Infusion-related expenses and license fees associated with drug discovery alliance.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥1.6 billion (5.0%) year-on-year to ¥34.2 billion due to the rise in operating costs related to main new products such as Opdivo Intravenous Infusion and Forxiga Tablets.

[Profit for the period] (attributable to owners of the Company)

Profit attributable to owners of the Company increased by ¥7.6 billion (36.0%) year-on-year to ¥28.8 billion in association with the increase of the profit before tax.

Note: Our group has applied IFRS 15 "Revenue from Contracts with Customers" from the first quarter of the fiscal year ending March 31, 2019. For the condensed interim consolidated statement of income of the second quarter (six months) ended September 30, 2018, compared with the case calculated using the previous accounting standards, revenue increased by ¥5,145 million, cost of sales increased by ¥5,183 million, operating profit decreased by ¥38 million, and profit before tax decreased by ¥38 million.

(Research & Development Activities)

Upholding the corporate philosophy “Dedicated to Man’s Fight against Disease and Pain,” our group takes on the challenge against diseases that have not been overcome so far, and the disease area which has a low level of patient satisfaction with treatment and high medical needs. We are endeavoring to make creative and innovative drugs.

Currently, the development pipeline comprises anticancer drugs including antibody drugs such as Opdivo and new drug candidate compounds in the field of supportive care for such drugs, candidates for treatment of chronic heart failure and parkinson’s disease, and so on. We are promoting development for the early launch of the product. Among these, the area of cancer treatment and its supportive care is positioned as an important strategic field because unmet medical needs are high, and we aim to contribute to comprehensive drug therapy for cancer patients.

In drug discovery research, based on our “Compound-Orient” unique drug discovery approach, we focus our management resources on cancers with high medical needs, immunological diseases, and central nervous diseases to be specified as priority research areas. In addition, we are aiming for the creation of drugs that bring innovation to the medical field by incorporating the world's most advanced technologies both in Japan and overseas through open innovation. We are also striving for the introduction of promising compounds through licensing activities and are working to further strengthen research and development activities.

The main results of research and development activities during the second quarter (six months) ended September 30, 2018 (including those up to October 29, 2018) are as follows.

[Main Progress of Research & Development Pipelines]
<Japan>

- In April 2018, a manufacturing and marketing approval application for Encorafenib (ONO-7702), a BRAF inhibitor, and Binimetinib (ONO-7703), a MEK inhibitor, were filed in Japan for the treatment of BRAF-mutant unresectable melanoma.
- In April 2018, a manufacturing and marketing approval application for Metyrosine (ONO-5371), a tyrosine hydroxylase inhibitor, was filed in Japan for the improvement of status of catecholamine excess secretion and its accompanying symptoms in patients with pheochromocytoma.
- In May 2018, approval for the partial change in approved items of the manufacturing and marketing approval for combination therapy with Opdivo and Yervoy was obtained for the treatment of unresectable melanoma.
- In June 2018, phase I of ONO-7705 (XPO1[1)] inhibitor) was initiated for the treatment of multiple myeloma and non-hodgkin lymphoma.
- In July 2018, phase II of Opdivo and ONO-4687 (BMS-986227) / Cabiralizumab (Anti-CSF-1R[2)] antibody) was initiated for the treatment of pancreatic cancer.
- In July 2018, a supplemental application for the partial change in approved items of the manufacturing and marketing approval for Onoact was filed in Japan for the treatment of ventricular arrhythmia.
- In July 2018, phase II of ONO-4059 (Btk[3)] inhibitor) was initiated for the treatment of primary macroglobulinemia and lymphoplasmacytic lymphoma.
- In August 2018, approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo was obtained for the treatment of unresectable advanced or recurrent malignant pleural mesothelioma which has progressed after chemotherapy and adjuvant treatment of melanoma. And approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo was obtained for the flat dose dosage and administration.
- In August 2018, approval for the partial change in approved items of the manufacturing and marketing approval for combination therapy with Opdivo and Yervoy was obtained for the treatment of unresectable or metastatic renal cell carcinoma.
- In August 2018, phase I of Opdivo and ONO-7475 (Axl/Mer inhibitor) was initiated for the treatment of advanced or metastatic solid tumor.
- In August 2018, phase III of combination therapy with Opdivo and cabozantinib (multi-kinase inhibitor) was initiated for the treatment of previously untreated advanced or metastatic renal cell carcinoma.
- In August 2018, phase I of combination therapy with Opdivo and Mogamulizumab (Anti-CCR4 antibody) for the treatment of solid tumor was discontinued due to the results being not indicative of anticipated efficacy.
- In September 2018, phase I of ONO-7269 (FXIa inhibitor) was initiated for Japanese healthy adult male subjects.
- In September 2018, a supplemental application for the formulation containing a new ingredient of Rivastach Patch was filed as the partial change in approved items of the manufacturing and marketing approval.
- In October 2018, phase I of combination therapy with Opdivo and NKTR-214 (BMS-986321), a PEGylated interleukin-2 formulation, was initiated for the treatment of solid tumor.

<Overseas>

- In April 2018, Bristol-Myers Squibb obtained approval for the partial change in approved items of the manufacturing and marketing approval for combination therapy with Opdivo and Yervoy in USA for the treatment of previously untreated intermediate and poor risk advanced renal cell carcinoma.
- In May 2018, Bristol-Myers Squibb announced that a supplemental application for the partial change in approved items of the manufacturing and marketing approval for combination therapy with Opdivo and Yervoy had been accepted in Europe for the treatment of first-line metastatic non-small cell lung cancer with tumor mutational burden of 10 mutations/megabase or more.
- In May 2018, phase I of ONO-5788 (growth hormone secretion inhibitor) was initiated for healthy adult subjects in USA.
- In May 2018, Bristol-Myers Squibb initiated phase III of Opdivo in Europe and USA for the treatment of ovarian cancer.
- In June 2018, Bristol-Myers Squibb obtained the importing and marketing approval for Opdivo for the treatment of locally advanced or metastatic non-small cell lung cancer after prior platinum-based chemotherapy in China.

- In June 2018, Bristol-Myers Squibb announced that a supplemental application for the partial change in approved items of the manufacturing and marketing approval for combination therapy with Opdivo and Yervoy had been accepted in USA for the treatment of first-line metastatic non-small cell lung cancer with tumor mutational burden of 10 mutations/megabase or more.
- In June 2018, Meiji Seika Pharma Co., Ltd. and Ono Pharmaceutical Co., Ltd. obtained the importing and marketing approval for OPALMON in Thailand for the treatment of lumbar spinal canal and thromboangiitis obliterans.
- In July 2018, Bristol-Myers Squibb initiated phase II of Opdivo in Europe and USA for the treatment of pancreatic cancer.
- In July 2018, Bristol-Myers Squibb obtained approval for the partial change in approved items of the manufacturing and marketing approval for combination therapy with Opdivo and Yervoy in USA for the treatment of microsatellite instability high or mismatch repair deficient metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin and irinotecan.
- In July 2018, Bristol-Myers Squibb obtained approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo in Europe for the adjuvant treatment of adult patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.
- In August 2018, Bristol-Myers Squibb obtained approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo in USA for the treatment of metastatic small cell lung cancer whose cancer has progressed after platinum-based chemotherapy and at least one other line of therapy.
- In August 2018, phase I/II of ONO-7579 (Trk[4)] inhibitor) for the treatment of solid tumor was discontinued due to the strategic reason.
- In August 2018, phase I of ONO-8055 (PG receptor (EP2 / EP3) agonist) for the treatment of underactive bladder was discontinued due to the strategic reason.
- In September 2018, Bristol-Myers Squibb initiated phase I/II of ONO-4578 (BMS-986310), a PG receptor (EP4) antagonist, in Europe and USA for the treatment of advanced solid tumor.
- In October 2018, approval for the partial change in approved items of the importing and marketing approval for combination therapy with Opdivo and Yervoy was obtained in South Korea for the treatment of previously untreated intermediate and high risk advanced renal cell carcinoma.

1) XPO1：Exportin1
2) CSF-1R：Colony stimulating factor 1 receptor
3) Btk：Bruton's tyrosine kinase
4) Tropomyosin receptor kinase

[Status of Drug Discovery / Research Alliance Activities]

- In May 2018, together with Keio University, Kochi University, the National Institutes of Biomedical Innovation, Health and Nutrition, Mitsubishi Tanabe Pharma Corporation, and Daiichi Sankyo Company, Limited, we established the Immune-mediated Inflammatory Diseases Consortium for Drug Development with the purpose of drug discovery research targeting immune-mediated inflammatory diseases.
- In September 2018, we entered into a collaboration agreement with Fate Therapeutics, Inc. in USA for the joint development and commercialization of off-the-shelf, iPSC-derived CAR-T cell product candidates for cancer.

(2) Overview of Financial Position for the 2nd Quarter of FY 2018

(Millions of yen)

	As of March 31, 2018	As of September 30, 2018	Change
Total Assets	609,226	640,193	30,968
Equity attributable to owners of the Company	524,390	564,769	40,379
Ratio of equity attributable owners of the Company to total assets	86.1%	88.2%	
Equity attributable to owners of the Company per share	1,019.97 yen	1,098.51 yen	

Total assets increased to ¥640.2 billion by ¥31.0 billion from the end of the previous fiscal year.
Current assets increased by ¥8.2 billion to ¥217.6 billion due to an increase of cash and cash equivalents etc.
Non-current assets increased by ¥22.8 billion to ¥422.6 billion due to an increase of investment securities etc.
Liabilities decreased by ¥9.5 billion to ¥70.2 billion due to decreases of long-term advances received and trade and other payables etc.
Equity attributable to owners of the Company increased by ¥40.4 billion to ¥564.8 billion due to an increase in retained earnings and other components of equity etc.

(3) Overview of Cash Flows for the 2nd Quarter of FY 2018

(Millions of yen)

	Six months ended September 30, 2017	Six months ended September 30, 2018	Change
Cash and cash equivalents at the beginning of the period	146,323	65,273	
Cash flows from operating activities	(10,382)	35,591	45,973
Cash flows from investing activities	(36,147)	(11,952)	24,195
Cash flows from financing activities	(49,591)	(10,514)	39,077
Net increase (decrease) in cash and cash equivalents	(96,121)	13,125	
Effects of exchange rate changes on cash and cash equivalents	69	129	
Cash and cash equivalents at the end of the period	50,272	78,527	

Net increase/decrease in cash and cash equivalents was an increase of ¥13.1 billion.
Net cash from operating activities was ¥35.6 billion, as a result of profit before tax of ¥36.9 billion etc.
Net cash used in investing activities was ¥12.0 billion, as a result of purchase of property, plant, and equipment of ¥14.3 billion etc., while proceeds from sales and redemption of investments amounted to ¥4.1 billion.
Net cash used in financing activities was ¥10.5 billion, as a result of dividends paid of ¥10.3 billion etc.

(4) Outlook for FY 2018

The forecasts of consolidated financial results for the fiscal year ending March 31, 2019, as announced on May 10, 2018, has been revised as follows:

Revisions to the forecasts of consolidated financial results for the fiscal year ending March 31, 2019
(From April 1, 2018 to March 31, 2019)

(Millions of yen)

	Revenue	Operating profit	Profit before tax	Profit for the year	Profit attributable to owners of the Company	Basic earnings per share
Previous forecast (A)	277,000	61,500	65,000	50,600	50,500	98.23 yen
Revised forecast (B)	280,000	63,500	67,000	52,100	52,000	101.14 yen
Amount of change (B-A)	3,000	2,000	2,000	1,500	1,500	
Change (%)	1.1	3.3	3.1	3.0	3.0	
(Reference) Consolidated results of FY2017	261,836	60,684	63,922	50,397	50,284	97.00 yen

Revenue is revised from the initial forecast of ¥277.0 billion to ¥280.0 billion (an increase by ¥3.0 billion from the initial forecast), mainly due to the expected rise in royalty from Bristol-Myers Squibb Company and Merck & Co., Inc in addition to recognition of the revenue associated with sales of long-term listed products (11 products for 5 brands of injections) to Maruishi Pharmaceutical Co., Ltd.
With regards to expenses, although cost of sales is expected to increase, for research and development costs and selling, general, and administrative expenses, there have been no changes from the initial forecast.
Consequently, operating profit is forecasted to be ¥63.5 billion (an increase by ¥2.0 billion from the initial forecast), profit before tax to be ¥67.0 billion (an increase by ¥2.0 billion from the initial forecast), profit for the year to be ¥52.1 billion (an increase by ¥1.5 billion from the initial forecast), profit attributable to owners of the Company to be ¥52.0 billion (an increase by ¥1.5 billion from the initial 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.

2. Basic Approach to the Selection of Accounting Standards

Our group has applied International Financial Reporting Standards (IFRSs) from the fiscal year ended March 31, 2014, for the purpose of improving comparability by disclosing financial information based on international standards and enhancing the convenience of various stakeholders such as shareholders, investors, and business partners.

3. Condensed Interim Consolidated Financial Statements and Major Notes

(1) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of March 31, 2018	As of September 30, 2018
Assets		
Current assets:		
Cash and cash equivalents	65,273	78,527
Trade and other receivables	77,577	78,793
Marketable securities	9,670	5,749
Other financial assets	10,833	10,800
Inventories	31,290	32,322
Other current assets	14,821	11,450
Total current assets	209,464	217,641
Non-current assets:		
Property, plant, and equipment	94,321	102,461
Intangible assets	55,715	55,403
Investment securities	188,803	213,400
Investments in associates	116	121
Other financial assets	46,685	46,620
Deferred tax assets	10,192	1,080
Other non-current assets	3,929	3,467
Total non-current assets	399,761	422,552
Total assets	609,226	640,193

(Millions of yen)

	As of March 31, 2018	As of September 30, 2018
Liabilities and Equity		
Current liabilities:		
Trade and other payables	34,015	29,515
Borrowings	392	382
Other financial liabilities	3,756	520
Income taxes payable	8,742	8,760
Provisions	11,696	13,913
Other current liabilities	9,869	11,190
Total current liabilities	68,469	64,281
Non-current liabilities:		
Borrowings	320	470
Other financial liabilities	8	10
Retirement benefit liabilities	3,856	3,544
Provisions	30	30
Deferred tax liabilities	1,016	1,009
Long-term advances received	5,095	—
Other non-current liabilities	814	809
Total non-current liabilities	11,138	5,872
Total liabilities	79,607	70,153
Equity:		
Share capital	17,358	17,358
Capital reserves	17,175	17,188
Treasury shares	(38,148)	(38,149)
Other components of equity	68,021	85,318
Retained earnings	459,985	483,055
Equity attributable to owners of the Company	524,390	564,769
Non-controlling interests	5,228	5,271
Total equity	529,619	570,040
Total liabilities and equity	609,226	640,193

(2) Condensed Interim Consolidated Statement of Income and Condensed Interim Consolidated Statement of Comprehensive Income

Condensed Interim Consolidated Statement of Income

(Millions of yen)

	Six months ended September 30, 2017	Six months ended September 30, 2018
Revenue	121,446	144,395
Cost of sales	(30,491)	(41,628)
Gross profit	90,955	102,767
Selling, general, and administrative expenses	(32,592)	(34,206)
Research and development costs	(31,416)	(33,048)
Other income	340	543
Other expenses	(499)	(906)
Operating profit	26,789	35,151
Finance income	1,642	1,805
Finance costs	(46)	(40)
Share of profit (loss) from investments in associates	8	1
Profit before tax	28,393	36,917
Income tax expense	(7,106)	(8,034)
Profit for the period	21,287	28,883
Profit for the period attributable to:		
Owners of the Company	21,210	28,845
Non-controlling interests	77	37
Profit for the period	21,287	28,883
Earnings per share:	*Yen*	
Basic earnings per share	40.63	56.11
Diluted earnings per share	40.63	56.10

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Six months ended September 30, 2017	Six months ended September 30, 2018
Profit for the period	21,287	28,883
Other comprehensive income (loss):		
Items that will not be reclassified to profit or loss:		
Net gain (loss) on financial assets measured at fair value through other comprehensive income	10,630	17,076
Remeasurements of defined benefit plans	410	380
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	2	5
Total of items that will not be reclassified to profit or loss	11,042	17,461
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	86	227
Net fair value gain (loss) on cash flow hedges	3	—
Total of items that may be reclassified subsequently to profit or loss	89	227
Total other comprehensive income (loss)	11,131	17,688
Total comprehensive income (loss) for the period	32,418	46,571
Comprehensive income (loss) for the period attributable to:		
Owners of the Company	32,330	46,523
Non-controlling interests	88	48
Total comprehensive income (loss) for the period	32,418	46,571

(3) Condensed Interim Consolidated Statement of Changes in Equity

Six months ended September 30, 2017

(Millions of yen)

	Equity attributable to owners of the Company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
Balance as of 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 (loss)				11,120		11,120	11	11,131
Total comprehensive income (loss) 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 as of September 30, 2017	17,358	17,162	(98,153)	62,462	503,257	502,086	5,186	507,272

Six months ended September 30, 2018

(Millions of yen)

	Equity attributable to owners of the Company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
Balance as of April 1, 2018	17,358	17,175	(38,148)	68,021	459,985	524,390	5,228	529,619
Changes in Accounting Policies					4,127	4,127		4,127
Restated balance	17,358	17,175	(38,148)	68,021	464,112	528,517	5,228	533,746
Profit for the period					28,845	28,845	37	28,883
Other comprehensive income (loss)				17,678		17,678	11	17,688
Total comprehensive income (loss) for the period	–	–	–	17,678	28,845	46,523	48	46,571
Purchase of treasury shares			(2)			(2)		(2)
Cash dividends					(10,282)	(10,282)	(5)	(10,288)
Share-based payments		13				13		13
Transfer from other components of equity to retained earnings				(380)	380	–		–
Total transactions with the owners	–	13	(2)	(380)	(9,902)	(10,271)	(5)	(10,276)
Balance as of September 30, 2018	17,358	17,188	(38,149)	85,318	483,055	564,769	5,271	570,040

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Six months ended September 30, 2017	Six months ended September 30, 2018
Cash flows from operating activities		
Profit before tax	28,393	36,917
Depreciation and amortization	4,453	5,123
Impairment losses	—	24
Interest and dividend income	(1,586)	(1,687)
Interest expense	7	7
(Increase) decrease in inventories	(3,061)	(956)
(Increase) decrease in trade and other receivables	(3,084)	(1,145)
Increase (decrease) in trade and other payables	(3,308)	(1,387)
Increase (decrease) in provisions	2,311	3,040
Increase (decrease) in retirement benefit liabilities	180	235
Increase (decrease) in long-term advances received	(207)	–
Other	(11,523)	2,114
Subtotal	12,576	42,285
Interest received	51	41
Dividends received	1,538	1,650
Interest paid	(7)	(7)
Income taxes paid	(24,540)	(8,378)
Net cash provided by (used in) operating activities	(10,382)	35,591
Cash flows from investing activities		
Purchases of property, plant, and equipment	(8,504)	(14,347)
Purchases of intangible assets	(5,516)	(1,890)
Purchases of investments	(40)	–
Proceeds from sales and redemption of investments	8,000	4,060
Payments into time deposits	(30,200)	(10,200)
Proceeds from withdrawal of time deposits	200	10,200
Other	(88)	226
Net cash provided by (used in) investing activities	(36,147)	(11,952)
Cash flows from financing activities		
Dividends paid	(10,581)	(10,275)
Dividends paid to non-controlling interests	(3)	(5)
Repayments of long-term borrowings	(210)	(205)
Net increase (decrease) in short-term borrowings	(26)	(28)
Purchases of treasury shares	(38,772)	(1)
Net cash provided by (used in) financing activities	(49,591)	(10,514)
Net increase (decrease) in cash and cash equivalents	(96,121)	13,125
Cash and cash equivalents at the beginning of the period	146,323	65,273
Effects of exchange rate changes on cash and cash equivalents	69	129
Cash and cash equivalents at the end of the period	50,272	78,527

(5) Notes to Condensed Interim Consolidated Financial Statements

(Changes in Accounting Policies)

Our group has applied the following standards from the first quarter of the fiscal year ending March 31, 2019.

IFRS		Overview of establishment and amendments
IFRS 15	Revenue from Contracts with Customers	Issuance of a single and comprehensive model for accounting treatment for revenue from contracts with customers
IFRS 9 (amended in July 2014)	Financial Instruments	Impairment of financial assets and revision of hedge accounting
IFRIC 22	Foreign Currency Transactions and Advance Consideration	Clarification of the accounting for transactions that include the receipt or payment of advance consideration in a foreign currency

1) IFRS 15 “Revenue from Contracts with Customers”

Our group has applied IFRS 15 “Revenue from Contracts with Customers” (published in May 2014) and “Clarifications to IFRS 15” (published in April 2016) (hereinafter collectively referred to as “IFRS 15”) from the first quarter of the fiscal year ending March 31, 2019.
Along with application of IFRS 15, excluding the interest and dividend income etc. based on IFRS 9 “Financial Instruments”, revenue is recognized by applying the following five steps.

Step 1: Identify the contract with a customer
Step 2: Identify the performance obligations in the contract
Step 3: Determine the transaction price
Step 4: Allocate the transaction price to the performance obligations in the contract
Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation

(i) Sale of merchandise

For the sale of merchandise, revenue is recognized at the point where it is delivered, since material risks and economic value associated with ownership of said merchandise is transferred to customers at the time of its delivery, and customers acquire control over it, and thereby our group’s performance obligations are considered to be satisfied.
The revenue arising from sale of merchandise is calculated by deducting the amount of rebates and discounts based on the number and amount of sales from the consideration in the sales contract, and the consideration to be refunded to customers and the amounts to be collected on behalf of third-parties is recognized as a refund liability. The most likely amount method based on contractual conditions and past results is used to estimate rebates etc. Revenue is recognized only to the extent that it is highly probable that there will not be a significant reversal of revenue previously recognized.
Consideration related to sale of merchandise is mainly received within one year from the delivery of merchandise to customers. This does not include significant financing components.

(ii) Royalty revenue etc.

Royalty revenue is consideration for license contracts etc. calculated on the basis of revenue etc. of the other party in the contract, and it is recognized as revenue taking the time of occurrence into consideration.
The license revenue is upfront payment and milestone revenue received under license contracts etc. related to development or rights to develop or sell products etc. executed between our group and third-parties. For license contracts etc., when performance obligations are satisfied at a specific point in time, performance obligations under the contract are considered to be satisfied at the time of granting development or selling rights etc. for upfront payment and milestone revenue, and at this point the upfront payment and milestone revenue is recognized as revenue. When performance obligations are satisfied over a certain period of time, the consideration is recognized as contract liabilities, and upfront payment and milestone revenue is recognized as revenue over a certain period of time such as the estimated development period according to the method of measuring the degree of progress regarding satisfaction of the performance obligations determined for each individual contract.
For milestone revenue, considering the probability that there will be a significant reversal of revenue previously recognized, it is recognized as revenue from the time that milestones specified in the contract are achieved.
The royalty revenue etc. are mainly received within one year from the vesting under the contract. This does not include significant financing components.

Based on the five-step approach above, as a result of reviewing the revenue recognition period for license revenue such as upfront payment received under license contracts in light of satisfying performance obligations, upfront payment received from license contracts, which was recognized over time as deferred income under previous standard, is recognized as one-time income at the time of granting development or selling rights etc.. Also, as result of a review in light of the definition of customers, certain items which were formerly deducted from revenue are treated as cost of sales from the first quarter of the fiscal year ending March 31, 2019.
For the application of these standards, our group adopted a method to recognize the cumulative effect recognized as a transitional measure on the date of initial application.
Also, certain accounts payable formerly included and presented within trade and other payables, as well as certain provisions , are included and presented within trade and other payables as refund liabilities from the first quarter of the fiscal year ending March 31, 2019.

Consequently, compared with the case calculated using the previous accounting standards, at the beginning of the second quarter (six months) of the fiscal year ending March 31, 2019, mainly trade and other payables increased by ¥618 million, retained earnings increased by ¥4,127 million, deferred tax assets decreased by ¥1,820 million, provisions decreased by ¥823 million, other current liabilities decreased by ¥646 million, and long-term advances received decreased by ¥5,095 million.
For the condensed interim consolidated statement of income of the second quarter (six months) ended September 30, 2018, compared with the case calculated using the previous accounting standards, revenue increased by ¥5,145 million, cost of sales increased by ¥5,183 million, operating profit decreased by ¥38 million, and profit before tax decreased by ¥38 million.
Also, for the condensed interim consolidated statement of financial position as at the end of the second quarter of the fiscal year ending March 31, 2019, compared with the case calculated using the previous accounting standards, mainly trade and other payables increased by ¥947 million, retained earnings increased by ¥4,101 million, deferred tax assets decreased by ¥1,808 million, provisions decreased by ¥1,189 million, other current liabilities decreased by ¥69 million, and long-term advances received decreased by ¥5,598 million.

2) IFRS 9 “Financial Instruments”

Our group has applied IFRS 9 “Financial Instruments” (amended in July 2014) from the first quarter of the fiscal year ending March 31, 2019. The application of this standard does not have a significant effect on our group’s financial results and financial position.

3) IFRIC 22 “Foreign Currency Transactions and Advance Consideration”

Our group has applied IFRIC 22 “Foreign Currency Transactions and Advance Consideration” from the first quarter of the fiscal year ending March 31, 2019. The application of this standard does not have a significant effect on our group’s financial results and financial position.

(Changes in Method of Presentation)

Condensed Interim Consolidated Statement of Cash Flows

“Proceeds from withdrawal of time deposits” included in “Other” in cash flows from investing activities for the second quarter (six months) ended September 30, 2017 is separately listed from the second quarter (six months) ended September 30, 2018 due to the increased quantitative materiality. In order to reflect this change in the presentation method, the Condensed Interim Consolidated Financial Statements are classified for the second quarter (six months) ended September 30, 2017.

As a result, ¥112 million for “Other,” which was shown in cash flows from investing activities in the Condensed Interim Consolidated Statement of Cash Flows for the second quarter (six months) ended September 30, 2017, is classified into ¥200 million in “Proceeds from withdrawal of time deposits” and (¥88) million in “Other.”

(Significant Subsequent Events)

Not Applicable

(Notes Regarding Assumption of a Going Concern)

Not Applicable

2nd Quarter of Fiscal Year 2018 (Ending March 31, 2019)
(from April 1, 2018 to September 30, 2018)

Supplementary Materials
(Consolidated IFRS)

ONO PHARMACEUTICAL CO., LTD.

Contents

【2nd Quarter of Fiscal Year 2018 Ending March 31, 2019 (from April 1, 2018 to September 30, 2018)】

Note: “(Billions of yen)” are rounded.

Summary of Financial Results for the 2nd Quarter of FY 2018 Ending March 31, 2019

(Billions of yen)

	Six months ended September 30, 2017	Six months ended September 30, 2018	YoY	Full year ended March 31, 2018
Revenue	121.4	144.4	18.9%	261.8
Operating profit	26.8	35.2	31.2%	60.7
Profit before tax	28.4	36.9	30.0%	63.9
Profit for the period (attributable to owners of the Company)	21.2	28.8	36.0%	50.3

Note: The business of the Company and its affiliates consists of a single segment, the Pharmaceutical business.

1. Revenue ¥144.4 billion YoY an increase of 18.9% (FY2017 2Q YTD ¥121.4 billion)

- Although Opdivo Intravenous Infusion for malignant tumors was affected by the revision of the National Health Insurance (NHI) drug price reduction according to the drastic reform of NHI drug pricing system, its use was expanded for the treatment of renal cell carcinoma, and head and neck cancer approved in the fiscal year before last as well as gastric cancer etc. in the previous fiscal year, resulting in sales of ¥45.4 billion, an increase of ¥4.8 billion (11.9%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥13.7 billion (0.1% increase year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥8.6 billion (26.8% increase year-on-year), sales of Forxiga Tablets for type-2 diabetes were ¥7.0 billion (33.1% increase year-on-year), sales of both Emend Capsules and Proemend for Intravenous Injection for chemotherapy-induced nausea and vomiting were ¥5.3 billion (6.6% increase year-on-year), sales of Rivastach Patch for Alzheimer's disease were ¥4.5 billion (1.4% increase year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥2.7 billion (98.8% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥2.6 billion (4.6% decrease year-on-year).
- Sales of long-term listed products were affected by the impact of NHI drug price reduction and generic drug use promotion policies. Sales of Opalmon Tablets for peripheral circulatory disorder were ¥5.5 billion (26.8% decrease year-on-year), and sales of Recalbon Tablets for osteoporosis were ¥4.4 billion (19.0% decrease year-on-year), respectively.
- Royalty and Other Revenue increased by ¥15.3 billion (63.3%) year-on-year to ¥39.4 billion, mainly due to the rise in Opdivo Intravenous Infusion-related royalty from Bristol-Myers Squibb Company and recognition of the revenue associated with sales of long-term listed products (11 products for 5 brands of injections) to Maruishi Pharmaceutical Co., Ltd.

2. Operating profit ¥35.2 billion YoY an increase of 31.2% (FY2017 2Q YTD ¥26.8 billion)

- Cost of sales was ¥41.6 billion, an increase of ¥11.1 billion (36.5%) year-on-year.
- Research and development costs increased by ¥1.6 billion (5.2%) year-on-year to ¥33.0 billion mainly due to an increase of Opdivo Intravenous Infusion-related expenses and license fees associated with drug discovery alliance.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥1.6 billion (5.0%) year-on-year to ¥34.2 billion due to the rise in operating costs related to main new products such as Opdivo Intravenous Infusion and Forxiga Tablets.

3. Profit before tax ¥36.9 billion YoY an increase of 30.0% (FY2017 2Q YTD ¥28.4 billion)

- Net financial income was ¥1.8 billion, an increase of ¥0.2 billion (10.0%) year-on-year.

4. Profit for the period ¥28.8 billion YoY an increase of 36.0% (FY2017 2Q YTD ¥21.2 billion) (attributable to owners of the Company)

- Profit attributable to owners of the Company increased by ¥7.6 billion (36.0%) year-on-year to ¥28.8 billion in association with the increase of the profit before tax.

Note: Our group has applied IFRS 15 "Revenue from Contracts with Customers" from the first quarter of the fiscal year ending March 31, 2019. For the condensed interim consolidated statement of income of the second quarter (six months) ended September 30, 2018, compared with the case calculated using the previous accounting standards, revenue increased by ¥5,145 million, cost of sales increased by ¥5,183 million, operating profit decreased by ¥38 million, and profit before tax decreased by ¥38 million.

Sales revenue and forecast of Major Products

(Billions of yen)

Product	Six months ended September 30, 2018 (From April 1, 2018 to September 30, 2018)					FY 2018 Forecasts (From April 1, 2018 to March 31, 2019)				
	Actual			YoY		Previous Forecasts	Change from Previous Forecasts	Revised Forecasts	YoY	
	Apr ~ Jun	Jul ~ Sep		Change	Change (%)				Change	Change (%)
Opdivo	22.8	22.6	45.4	4.8	11.9%	90.0		90.0	(0.1)	(0.1%)
Glactive	7.1	6.6	13.7	0.0	0.1%	26.0		26.0	(1.4)	(5.1%)
Orencia	4.3	4.3	8.6	1.8	26.8%	16.5	0.5	17.0	2.9	20.3%
Forxiga	3.6	3.4	7.0	1.7	33.1%	13.0	1.5	14.5	3.4	31.0%
Opalmon	2.9	2.6	5.5	(2.0)	(26.8%)	10.5		10.5	(3.9)	(26.9%)
Emend / Proemend	2.7	2.6	5.3	0.3	6.6%	10.5		10.5	0.6	5.5%
Recalbon	2.7	1.7	4.4	(1.0)	(19.0%)	9.5	(2.0)	7.5	(3.4)	(31.3%)
Rivastach Patch	2.3	2.2	4.5	0.1	1.4%	9.0		9.0	0.1	1.3%
Kyprolis	1.3	1.2	2.6	(0.1)	(4.6%)	6.5		6.5	1.0	17.4%
Parsabiv	1.3	1.4	2.7	1.3	98.8%	5.5		5.5	2.1	60.4%
Onon Capsules	1.1	0.8	1.9	(0.5)	(19.7%)	4.5		4.5	(1.0)	(17.6%)
Onoact	1.1	1.0	2.2	(0.5)	(19.6%)	4.0		4.0	(1.6)	(28.8%)
Staybla	1.0	0.9	1.9	(0.2)	(9.0%)	3.5		3.5	(0.6)	(15.3%)
Onon Dry Syrup	0.7	0.5	1.2	(0.3)	(19.2%)	2.5		2.5	(0.8)	(25.0%)

Notes: 1. Sales revenue is shown in a gross sales basis (shipment price).
2. Regarding sales revenue forecast for the FY 2018, only currently approved indications are covered.

Details of Revenue

(Billions of yen)

	Six months ended September 30, 2017	Six months ended September 30, 2018
Revenue of goods and products	97.4	105.0
Royalty and other revenue	24.1	39.4
Total	121.4	144.4

Notes: 1. In "Royalty and Other Revenue", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥18.0 billion for the second quarter (six months) ended September 30, 2017 and ¥28.1 billion for the second quarter (six months) ended September 30, 2018. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥2.6 billion for the second quarter (six months) ended September 30, 2017 and ¥5.6 billion for the second quarter (six months) ended September 30, 2018.
2. Our group has applied IFRS 15 from the first quarter of the fiscal year ending March 31, 2019. Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the first quarter of the fiscal year ending March 31, 2019 according to the transitional option, the amount for the second quarter (six months) ended September 30, 2017 is not restated.

Revenue by geographic area

(Billions of yen)

	Six months ended September 30, 2017	Six months ended September 30, 2018
Japan	97.2	105.3
Americas	22.2	34.3
Asia	1.9	3.5
Europe	0.1	1.3
Total	121.4	144.4

Notes: 1. Revenue of goods and products is presented on the basis of the place of customers.

2. Our group has applied IFRS 15 from the first quarter of the fiscal year ending March 31, 2019. Since the cumulative effect of the initial application is recognized as adjustment of the retained earnings at the beginning of the first quarter of the fiscal year ending March 31, 2019 according to the transitional option, the amount for the second quarter (six months) ended September 30, 2017 is not restated.

Forecasts of Consolidated Financial Results for FY 2018 Ending March 31, 2019 (IFRS)

(Billions of yen)

	FY 2017 (From April 1, 2017 to March 31, 2018)	FY 2018 Forecasts (From April 1, 2018 to March 31, 2019)	YoY
Revenue	261.8	280.0	6.9%
Operating profit	60.7	63.5	4.6%
Profit before tax	63.9	67.0	4.8%
Profit for the period (attributable to owners of the Company)	50.3	52.0	3.4%

Details of Revenue (Forecasts)

(Billions of yen)

	FY 2017 (From April 1, 2017 to March 31, 2018)	FY 2018 Forecasts (From April 1, 2018 to March 31, 2019)
Revenue of goods and products	205.9	206.0
Royalty and other revenue	55.9	74.0
Total	261.8	280.0

1. Revenue ¥280.0 billion YoY an increase of ¥18.2 billion (6.9%) (FY 2017 ¥261.8 billion)

- Regarding the period under review, despite being affected by the revision of the NHI drug price reduction and generic drug use promotion policies, in the case of Opdivo Intravenous Infusion, its use is expected to expand for the treatment of renal cell carcinoma, and head and neck cancer, approved in the fiscal year before last, as well as for gastric cancer etc., approved in the previous fiscal year. Increase is also expected in royalty revenue from Bristol-Myers Squibb Company and Merck & Co., Inc. In addition, sales of main new products, Forxiga Tablets, Orencia SC, and Parsabiv Intravenous Injection for Dialysis, are expected to increase. Sales revenue is expected to be ¥280.0 billion, an increase of ¥18.2 billion (6.9%) year-on-year.

2. Operating profit ¥63.5 billion YoY an increase of ¥2.8 billion (4.6%) (FY 2017 ¥60.7 billion)

- Research and development costs are expected to be ¥70.0 billion, an increase of ¥1.2 billion (1.7%) year-on-year, providing for active investments to achieve sustainable growth.
- Selling, general, and administrative expenses (except for research and development costs) are expected to be ¥69.0 billion, an increase of ¥0.9 billion (1.4%) year-on-year, mainly due to an increase of operating activity costs for Opdivo.

Therefore, operating profit is expected to be ¥63.5 billion, an increase of ¥2.8 billion (4.6%) year-on-year.

3. Profit before tax ¥67.0 billion YoY an increase of ¥3.1 billion (4.8%) (FY 2017 ¥63.9 billion)

4. Profit for the period (attributable to owners of the Company) ¥52.0 billion YoY an increase of ¥1.7 billion (3.4%) (FY 2017 ¥50.3 billion)

Note: Our group has applied IFRS 15 “Revenue from Contracts with Customers” from the first quarter of the fiscal year ending March 31, 2019. For the fiscal year ending March 31, 2019, compared with the case calculated using the previous accounting standards, sales revenue is expected to increase by ¥8.0 billion, cost of sales is expected to increase by ¥8.7 billion, and operating profit is expected to decrease by ¥0.7 million.

Depreciation and Amortization, and Capital Expenditure

Depreciation and Amortization

(Billions of yen)

	FY 2017 (From April 1, 2017 to March 31, 2018)	FY2018 Q2 YTD (From April 1, 2018 to September 30, 2018)	FY 2018 Forecasts (From April 1, 2018 to March 31, 2019)
Property, plant, and equipment	5.6	3.2	6.8
Intangible assets	3.6	1.9	4.0
Total	9.2	5.1	10.8
Ratio to sales revenue (%)	3.5%	3.5%	3.8%

Capital Expenditure

(Billions of yen)

	FY 2017 (From April 1, 2017 to March 31, 2018)	FY2018 Q2 YTD (From April 1, 2018 to September 30, 2018)	FY 2018 Forecasts (From April 1, 2018 to March 31, 2019)
Property, plant, and equipment	18.6	11.2	23.2
Intangible assets	14.2	1.5	10.4
Total	32.8	12.7	33.6

Number of Employees (Consolidated)

	FY2017 Q2 (as of September 30, 2017)	FY2017 (as of March 31, 2018)	FY2018 Q2 (as of September 30, 2018)
Number of employees	3,420	3,480	3,576

Status of Shares (as of September 30, 2018)

Number of Shares

	As of September 30, 2018
Total number of authorized shares	1,500,000,000
Number of shares issued and outstanding	543,341,400

Number of Shareholders

	As of September 30, 2018
Number of shareholders	82,998

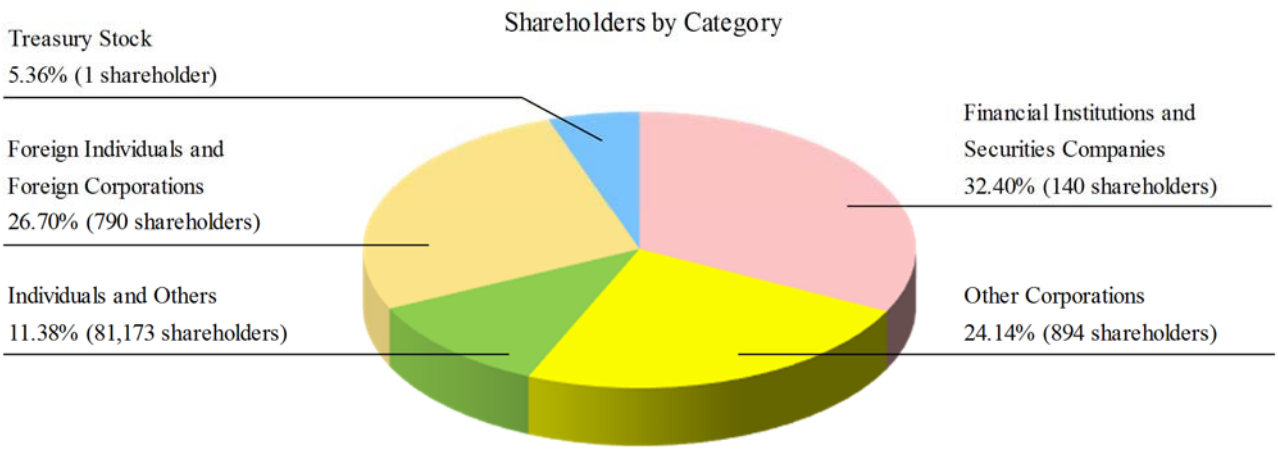
Principal Shareholders

(As of September 30, 2018)

Name of shareholders	Number of shares held (Thousands of shares)	Shareholding percentage
The Master Trust Bank of Japan, Ltd. (Trust account)	33,305	6.12%
Japan Trustee Services Bank, Ltd. (Trust account)	29,684	5.46%
STATE STREET BANK AND TRUST COMPANY 505001	21,930	4.03%
Meiji Yasuda Life Insurance Company	18,594	3.42%
Ono Scholarship Foundation	16,428	3.02%
KAKUMEISOU Co., LTD	16,161	2.97%
Japan Trustee Services Bank, Ltd. (Trust account5)	9,205	1.69%
MUFG Bank, Ltd.	8,640	1.59%
Aioi Nissay Dowa Insurance Co., Ltd.	8,606	1.58%
STATE STREET BANK WEST CLIENT - TREATY 505234	6,920	1.27%

Note: The Company is excluded from the principal shareholders listed in the table above, although the Company holds 29,157 thousand shares of treasury stock.

Ownership and Distribution of Shares



Note: The ratio by shareholders listed above is rounded down to two decimal places. Therefore, their total do not amount to 100%.

I. Main Status of Development Pipelines (Oncology)

As of October 29, 2018

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	Malignant pleural mesothelioma*2	Injection	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection*1	Additional indication	Renal cell carcinoma*3	Injection	In-license (Co-development with Bristol-Myers Squibb)

*1: Combination with Opdivo.

Changes from First Quarter Flash Report for the Fiscal Year ending March 2019

*2: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo was obtained for the treatment of unresectable advanced or recurrent malignant pleural mesothelioma which has progressed after chemotherapy.

*3: Approval for the partial change in approved items of the manufacturing and marketing approval for combination therapy with Opdivo and Yervoy was obtained for the treatment of unresectable or metastatic renal cell carcinoma.

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

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

<Filed>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
ONO-7702 / Encorafenib	New chemical entities	Melanoma / BRAF inhibitor	Capsule	In-license (Array BioPharma Inc.)
ONO-7703 / Binimetinib	New chemical entities	Melanoma / MEK inhibitor	Tablet	In-license (Array BioPharma Inc.)
ONO-5371 / Metyrosine	New chemical entities	Pheochromocytoma / Tyrosine hydroxylase inhibitor	Capsule	In-license (Valeant Pharmaceuticals North America LLC)

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	Ovarian cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection*1	Additional indication	Non-small cell lung cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
Kyprolis for Intravenous Infusion	Change in dosage and administration	Multiple myeloma / Proteasome inhibitor	Injection	III	In-license (Amgen Inc.)
ONO-7643 / Anamorelin	New chemical entities	Cancer anorexia / cachexia / Ghrelin mimetic	Tablet	III	In-license (Helsinn Healthcare, S.A.)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
ONO-7702 / Encorafenib	New chemical entities	Colon cancer / BRAF inhibitor	Capsule	III	In-license (Array BioPharma Inc.)
ONO-7703 / Binimetinib	New chemical entities	Colon cancer / MEK inhibitor	Tablet	III	In-license (Array BioPharma Inc.)
ONO-7701*1 (BMS-986205)	New chemical entities	Melanoma / IDO1 inhibitor	Capsule	III	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Colon cancer	Injection	II / III	In-house (Co-development with Bristol-Myers Squibb)
ONO-4687*1 (BMS-986227) / Cabiralizumab	New chemical entities	Pancreatic cancer / Anti-CSF-1R antibody	Injection	II	In-license (Co-development with Bristol-Myers Squibb)
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	Pancreatic cancer	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Primary macroglobulinemia, Lymphoplasmacytic lymphoma*4 / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	In-house
Opdivo Intravenous Infusion	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection*1	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4686*1 (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Central nervous system lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I / II	In-house
ONO-4482*1 (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7807*1 (BMS-986258)	New chemical entities	Solid tumor / Anti-TIM-3 antibody	Injection	I / II	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
Opdivo Intravenous Infusion	Additional indication	Biliary tract cancer	Injection	I	In-house (Co-development with Bristol-Myers Squibb)
ONO-4481*1 (BMS-663513) / Urelumab	New chemical entities	Solid tumor / Anti-CD137 antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483*1 (BMS-986015) / Lirilumab	New chemical entities	Solid tumor / Anti-KIR antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4578*1	New chemical entities	Solid tumor / PG receptor (EP4) antagonist	Tablet	I	In-house
ONO-7705	New chemical entities	Multiple myeloma and non-hodgkin lymphoma / XPO1 inhibitor	Tablet	I	In-license (Karyopharm Therapeutics Inc.)
ONO-7475*1*5	New chemical entities	Solid tumor / Axl/Mer inhibitor	Tablet	I	In-house

*1: Combination with Opdivo.

Changes from First Quarter Flash Report for the Fiscal Year ending March 2019

*4: Phase II of ONO-4059 (Btk inhibitor) was initiated for the treatment of primary macroglobulinemia and lymphoplasmacytic lymphoma.

*5: Phase I of ONO-7475 (Axl/Mer inhibitor) was initiated for the treatment of advanced or metastatic 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 South Korea and Taiwan

<Approved>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Yervoy Injection*1*6	Additional indication	Renal cell carcinoma	Injection	South Korea	In-license (Co-development with Bristol-Myers Squibb)

Changes from First Quarter Flash Report for the Fiscal Year ending March 2019

*6: Approval for the partial change in approved items of the importing and marketing approval for combination therapy with Opdivo and Yervoy was obtained in South Korea for the treatment of previously untreated intermediate and high risk advanced renal cell carcinoma.

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

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

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Esophageal cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	South Korea	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection*1	Additional indication	Renal cell carcinoma	Injection	III	Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Non-small cell lung cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
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.)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
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	Pancreatic cancer	Injection	II	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
ONO-4687*1 (BMS-986227) / Cabiralizumab	New chemical entities	Pancreatic cancer / Anti-CSF-1R antibody	Injection	II	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection*1	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)

*1: Combination with Opdivo.

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	Small cell lung cancer *7	Injection	USA	In-house (Co-development with Bristol-Myers Squibb)

Changes from First Quarter Flash Report for the Fiscal Year ending March 2019

*7: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo was obtained in USA for the treatment of metastatic small cell lung cancer whose cancer has progressed after platinum-based chemotherapy and at least one other line of therapy.

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

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

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Glioblastoma	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	Europe	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	Europe	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Multiple myeloma	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Colon cancer	Injection	II / III	Europe	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Diffuse large B cell lymphoma	Injection	II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Follicular lymphoma	Injection	II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central nervous system lymphoma / Primary testicular lymphoma	Injection	II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Prostate cancer	Injection	II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Pancreatic cancer	Injection	II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	B cell lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	Europe	In-house (Out-license to Gilead Sciences, Inc.)
ONO-4578*1*8	New chemical entities	Solid tumor / PG receptor (EP4) antagonist	Tablet	I / II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Solid tumors (Triple negative breast cancer, Gastric cancer, Pancreatic cancer, Small cell lung cancer, Urothelial cancer, Ovarian cancer)	Injection	I / II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hematologic cancer (T-cell lymphoma, Multiple myeloma, Chronic leukemia, etc.)	Injection	I	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Chronic myeloid leukemia	Injection	I	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	B cell lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I	USA	In-house (Out-license to Gilead Sciences, Inc.)
ONO-7475	New chemical entities	Acute leukemia / Axl/Mer inhibitor	Tablet	I	USA	In-house

*1: Combination with Opdivo.

Changes from First Quarter Flash Report for the Fiscal Year ending March 2019
*8: Phase I / II of ONO-4578 prostaglandin receptor (EP4) antagonist was initiated for the treatment of advanced 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.

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

As of October 29, 2018

1. Development Status in Japan

<Filed>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house / In-license
Onoact for Intravenous Infusion 50mg / 150mg (ONO-1101)	Additional indication	Ventricular arrhythmia / β_1 blocker (short acting)	Injection	In-house
Rivastach Patch*9	Change of dosage form	Alzheimer's disease / Cholinesterase inhibitor	Patch	In-license (Novartis Pharma)

Changes from First Quarter Flash Report for the Fiscal Year ending March 2019

*9: Application for the partial change in approved items of the manufacturing and marketing approval was filed in Japan for Rivastach Patch for formulation with new ingredient.

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

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Orencia IV	Additional indication	Lupus nephritis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
Orencia SC	Additional indication	Untreated rheumatoid arthritis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
	Additional indication	Primary Sjögren syndrome / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
	Additional indication	Polymyositis / Dermatomyositis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
ONO-1162 / Ivabradine	New chemical entities	Chronic heart failure / If channel inhibitor	Tablet	III	In-license (Les Laboratoires Servier)
ONO-5704 / SI-613	New chemical entities	Osteoarthritis / Hyaluronic acid-NSAID	Injection	III	In-license (Seikagaku Corporation)
Onoact for Intravenous Infusion 50mg / 150mg (ONO-1101)	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / β_1 blocker (short acting)	Injection	II / III	In-house
	Additional indication	Tachyarrhythmia upon sepsis / β_1 blocker (short acting)	Injection	II / III	In-house
ONO-2370 / Opicapone	New chemical entities	Parkinson's disease / Long acting COMT inhibitor	Tablet	II	In-license (Bial)
ONO-5704 / SI-613	New chemical entities	Enthesopathy / Hyaluronic acid-NSAID	Injection	II	In-license (Seikagaku Corporation)
Opdivo Intravenous Infusion	Additional indication	Sepsis	Injection	I / II	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Autoimmune disease / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I	In-house
ONO-7269*10	New chemical entities	Cerebral infarction / FXIa inhibitor	Injection	I	In-house

Changes from First Quarter Flash Report for the Fiscal Year ending March 2019

*10: Phase I of ONO-7269 (FXIa inhibitor) was initiated for Japanese healthy adult male subjects.

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

2. Development Status in Overseas

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
ONO-4059 / Tirabrutinib	New chemical entities	Sjögren syndrome / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	Europe, USA	In-house (Out-license to Gilead Sciences, Inc.)
Opdivo Intravenous Infusion	Additional indication	Hepatitis C	Injection	I	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Sepsis	Injection	I	USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-5788	New chemical entities	Acromegaly / Growth hormone secretion inhibitor	Capsule	I	USA	In-house

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

Profile for Main Development

Kyprolis for Intravenous Infusion (ONO-7057) / Carfilzomib (injection)
Kyprolis (ONO-7057) is a proteasome inhibitor, being developed for change in dosage and administration after launched for multiple myeloma. It has become a new treatment option for multiple myeloma, which is a cancer of plasma cells (one of blood cells) and prognosis is considered poor.

Orencia IV (ONO-4164) / BMS-188667 (injection)
Orencia (ONO-4164) is marketed in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed, after that, additionally approved for the treatment of active polyarticular juvenile idiopathic arthritis (JIA). Also, in overseas, it is marketed for use in patients of rheumatoid arthritis and juvenile idiopathic arthritis.

Orencia SC (ONO-4164) / BMS-188667 (injection)
Orencia (ONO-4164) is marketed for use in patients of rheumatoid arthritis for whom other therapies have failed.

ONO-1162 / Ivabradine (tablet)
ONO-1162 is an If channel blocker and is marketed in Europe for use in patients of stable angina and chronic heart failure, and in US for use in patients of chronic heart failure, respectively. It is under development in Japan for the indication of chronic heart failure.

Onoact for Intravenous Infusion 50 mg/150 mg (ONO-1101) (injection)
Onoact is being developed for ventricular arrhythmia, tachyarrhythmia upon sepsis, and tachyarrhythmia in low cardiac function in pediatric. It is designated as orphan drugs for rare diseases in August 2016.
(Target indication or efficacy: refractory and urgent fatal arrhythmia; ventricular fibrillation and hemodynamically unstable ventricular tachycardia)

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 for the systemic wasting condition characterized by anorexia, lipolysis and muscle loss associated with the progression of cancer.

ONO-2370 / Opicapone (tablet)
ONO-2370 is a long acting COMT inhibitor being developed for the treatment of parkinson's disease. ONO-2370 is approved for the treatment of parkinson's disease in overseas by Bial and the compound has shown a long-lasting effect on COMT inhibition from once daily dosing in clinical studies so far and is expected to improve a dosing convenience.

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

ONO-4059 / Tirabrutinib (tablet)
ONO-4059 is a Btk inhibitor being developed for the treatment of B cell lymphoma, Sjögren syndrome, central nervous system lymphoma, primary macroglobulinemia, lymphoplasmacytic lymphoma and autoimmune disease.

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

ONO-7475 (tablet)
ONO-7475 is a Axl/Mer inhibitor being developed for the treatment of acute leukemia and solid tumor.

Opdivo Intravenous Infusion (ONO-4538) / BMS-936558 (injection)
Opdivo (ONO-4538), a human anti-human PD-1 monoclonal antibody, is being developed for the treatment of cancer etc. PD-1 is one of the receptors expressed on activated lymphocytes, and is involved in the negative regulatory system to suppress the activated lymphocytes. It has been reported that tumor cells utilize this system to escape from the host immune responses. It is anticipated that blockade of the negative regulatory signal mediated by PD-1 will promote the host's immune response, in which tumor cells and viruses are recognized as foreign and eliminated.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

Yervoy Intravenous Infusion (ONO-4480) / Ipilimumab (injection)
Yervoy (ONO-4480), a human anti-human CTLA-4 monoclonal antibody, is being developed for the treatment of cancer.
In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-4481 / Urelumab / BMS-663513 (injection)
ONO-4481, a human anti-human CD137 monoclonal antibody, is being developed for the treatment of cancer. In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-4482 / Relatlimab / BMS-986016 (injection)
ONO-4482, a human anti-human LAG-3 monoclonal antibody, is being developed for the treatment of cancer. In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-4686 / BMS-986207 (injection)
ONO-4686, a human anti-human TIGIT monoclonal antibody, is being developed for the treatment of cancer. In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-4687 / Cabiralizumab / BMS-986227 (injection)
ONO-4687, a human anti-human CSF-1R monoclonal antibody, is being developed for the treatment of cancer. In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-7701 / BMS-986205 (capsule)
ONO-7701, IDO1 inhibitor, is being developed for the treatment of cancer. In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-4483 / Lirilumab / BMS-986015 (injection)
ONO-4483, a human anti-human KIR monoclonal antibody, is being developed for the treatment of cancer. In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-7702 / Encorafenib (capsule)
ONO-7702, BRAF inhibitor, is being developed for the treatment of melanoma and colon cancer.

ONO-7703 / Binimetinib (tablet)
ONO-7703, MEK inhibitor, is being developed for the treatment of melanoma and colon cancer.

ONO-5704 / SI-613 (injection)
ONO-5704, hyaluronic acid-NSAID, is being developed for the treatment of osteoarthritis and enthesopathy.

ONO-7807 / BMS-986258 (injection)
ONO-7807, a human anti-human TIM-3 monoclonal antibody, is being developed for the treatment of cancer. In Japan, South Korea, and Taiwan, Ono is co-developing this with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing this.

ONO-7705 (tablet)
ONO-7705, XPO1 inhibitor, is being developed for the treatment of multiple myeloma and non-hodgkin lymphoma.

ONO-7269 (injection)
ONO-7269, FXIa inhibitor, is being developed for the treatment of cerebral infarction.

ONO-5788 (capsule)
ONO-5788, growth hormone secretion inhibitor, is being developed for the treatment of acromegaly.

Rivastach Patch (ONO-2540) / ENA713D (transdermal patch)
Formulation with new ingredient is being developed in collaboration with Novartis Pharma.