

## Consolidated Financial Results for the First Quarter of the Fiscal Year Ending March 31, 2020 (IFRS)

August 1, 2019

Company name	: <b>Ono Pharmaceutical Co., Ltd.</b>
Stock exchange listing	: Tokyo Stock Exchange
Code number	: 4528
URL	: <a href="https://www.ono.co.jp/">https://www.ono.co.jp/</a>
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Scheduled date of quarterly securities report submission	: August 7, 2019
Scheduled date of dividend payment commencement	: —
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 First Quarter of FY 2019 (April 1, 2019 to June 30, 2019)

#### (1) Consolidated Operating Results

(% 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		Total comprehensive income for the period	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%
FY 2019 Q1	73,982	3.8	19,980	11.1	21,196	9.1	16,381	7.4	16,330	7.2	13,536	(41.9)
FY 2018 Q1	71,242	17.0	17,980	26.0	19,428	23.0	15,251	29.2	15,236	29.4	23,285	21.9

	Basic earnings per share		Diluted earnings per share	
	Yen		Yen	
FY 2019 Q1	31.84		31.84	
FY 2018 Q1	29.64		29.63	

#### (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 June 30, 2019	641,060	554,704	549,283	85.7
As of March 31, 2019	655,056	562,736	557,350	85.1

### 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 2018	—	22.50	—	22.50	45.00
FY 2019	—				
FY 2019 (Forecast)		22.50	—	22.50	45.00

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

### 3. Consolidated Financial Forecasts for FY 2019 (April 1, 2019 to March 31, 2020)

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

	Revenue		Operating profit		Profit before tax		Profit for the year		Profit attributable to owners of the Company		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
FY 2019	290,000	0.5	67,000	8.0	70,000	7.5	53,100	2.8	53,000	2.8	103.09

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

## 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 reasons: 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 June 30, 2019	543,341,400	shares
As of March 31, 2019	543,341,400	shares
  - 2) Number of treasury shares as of the end of the period:

As of June 30, 2019	34,353,576	shares
As of March 31, 2019	29,220,860	shares
  - 3) Average number of shares outstanding during the period:

Three months ended June 30, 2019	512,837,304	shares
Three months ended June 30, 2018	514,121,453	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 2019” on page 3 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 1st Quarter of FY 2019

(Millions of yen)

	Three months ended June 30, 2018	Three months ended June 30, 2019	Change	Change (%)
Revenue	71,242	73,982	2,741	3.8%
Operating profit	17,980	19,980	2,000	11.1%
Profit before tax	19,428	21,196	1,768	9.1%
Profit for the period (attributable to owners of the Company)	15,236	16,330	1,094	7.2%

#### [Revenue]

Revenue totaled ¥74.0 billion, which was an increase of ¥2.7 billion (3.8%) from the corresponding period of the previous fiscal year (year-on-year).

- Despite the expanded use of Opdivo Intravenous Infusion for malignant tumors for the treatment of renal cell carcinoma, its sales were affected by the revision of the National Health Insurance (NHI) drug price reduction in November 2018 and intensified competition with competitive products, resulting in sales of ¥22.3 billion, a decrease of ¥0.5 billion (2.0%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥6.9 billion (2.1% decrease year-on-year), sales of Orenzia Subcutaneous Injection for rheumatoid arthritis were ¥4.9 billion (13.6% increase year-on-year), sales of Forxiga Tablets for diabetes were ¥4.4 billion (22.5% increase year-on-year), sales of both Emend Capsules and Proemend for Intravenous Injection for chemotherapy-induced nausea and vomiting were ¥2.9 billion (8.8% increase year-on-year), sales of Rivastach Patch for Alzheimer's disease were ¥2.3 billion (2.0% decrease year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥1.7 billion (33.2% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥1.4 billion (3.1% increase year-on-year).
- Sales of long-term listed products were affected by the impact of generic drug use promotion policies. Sales of Opalmon Tablets for peripheral circulatory disorder were ¥2.3 billion (20.2% decrease year-on-year), and sales of Recalbon Tablets for osteoporosis were ¥1.4 billion (49.3% decrease year-on-year), respectively.
- Royalty and others increased by ¥3.5 billion (20.0%) year-on-year to ¥20.8 billion, mainly due to the rise in Opdivo Intravenous Infusion royalty from Bristol-Myers Squibb Company.

#### [Operating Profit]

Operating profit was ¥20.0 billion, an increase of ¥2.0 billion (11.1%) year-on-year.

- Cost of sales was ¥20.7 billion, an increase of ¥0.6 billion (2.9%) year-on-year.
- Research and development costs increased by ¥0.3 billion (1.6%) year-on-year to ¥16.0 billion mainly due to an increase of Opdivo Intravenous Infusion-related expenses.
- Selling, general, and administrative expenses (except for research and development costs) decreased by ¥0.5 billion (2.7%) year-on-year to ¥16.6 billion mainly due to a reduction in operating costs.

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

Profit attributable to owners of the Company increased by ¥1.1 billion (7.2%) year-on-year to ¥16.3 billion in association with the increase of the profit before tax.

## (2) Overview of Financial Position for the 1st Quarter of FY 2019

(Millions of yen)

	As of March 31, 2019	As of June 30, 2019	Change
Total Assets	655,056	641,060	(13,996)
Equity attributable to owners of the Company	557,350	549,283	(8,067)
Ratio of equity attributable owners of the Company to total assets	85.1%	85.7%	
Equity attributable to owners of the Company per share	1,084.08 yen	1,079.17 yen	

Total assets decreased to ¥641.1 billion by ¥14.0 billion from the end of the previous fiscal year.

Current assets decreased by ¥16.5 billion to ¥178.1 billion due to a decrease of cash and cash equivalents etc., despite an increase in trade and other receivables etc.

Non-current assets increased by ¥2.5 billion to ¥462.9 billion mainly due to an increase in property, plant, and equipment resulting from right-of-use assets recorded as a result of the application of IFRS 16, despite a decrease in investment securities etc.

Liabilities decreased by ¥6.0 billion to ¥86.4 billion due to a decrease in income taxes payable etc., despite an increase in lease liabilities as a result of the application of IFRS 16.

Equity attributable to owners of the Company decreased by ¥8.1 billion to ¥549.3 billion due to an increase in treasury shares etc.

## (3) Overview of Cash Flows for the 1st Quarter of FY 2019

(Millions of yen)

	Three months ended June 30, 2018	Three months ended June 30, 2019	Change
Cash and cash equivalents at the beginning of the period	65,273	59,981	
Cash flows from operating activities	14,261	6,337	(7,924)
Cash flows from investing activities	(6,887)	(5,531)	1,357
Cash flows from financing activities	(9,409)	(20,980)	(11,571)
Net increase (decrease) in cash and cash equivalents	(2,035)	(20,174)	
Effects of exchange rate changes on cash and cash equivalents	(8)	(188)	
Cash and cash equivalents at the end of the period	63,229	39,620	

Net increase/decrease in cash and cash equivalents was a decrease of ¥20.2 billion.

Net cash from operating activities was ¥6.3 billion, as a result of profit before tax of ¥21.2 billion etc., while income taxes paid amounted to ¥15.9 billion etc.

Net cash used in investing activities was ¥5.5 billion, as a result of purchases of intangible assets of ¥5.0 billion etc.

Net cash used in financing activities was ¥21.0 billion, as a result of dividends paid of ¥10.5 billion and purchases of treasury shares of ¥10.0 billion etc.

## (4) Outlook for FY 2019

There are no changes from the forecasts of consolidated financial results for the year ending March 31, 2020 announced on May 9, 2019.

## 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, 2019	As of June 30, 2019
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	59,981	39,620
Trade and other receivables	76,285	81,994
Marketable securities	687	671
Other financial assets	10,800	10,844
Inventories	32,821	31,347
Other current assets	14,042	13,634
<b>Total current assets</b>	<b>194,617</b>	<b>178,110</b>
Non-current assets:		
Property, plant, and equipment	108,870	114,922
Intangible assets	63,059	63,713
Investment securities	171,476	166,183
Investments in associates	113	109
Other financial assets	91,672	91,674
Deferred tax assets	21,079	22,201
Other non-current assets	4,171	4,149
<b>Total non-current assets</b>	<b>460,439</b>	<b>462,950</b>
<b>Total assets</b>	<b>655,056</b>	<b>641,060</b>

(Millions of yen)

	As of March 31, 2019	As of June 30, 2019
<b>Liabilities and Equity</b>		
Current liabilities:		
Trade and other payables	36,833	30,182
Lease liabilities	435	1,901
Other financial liabilities	515	2,237
Income taxes payable	15,980	5,059
Provisions	17,206	18,944
Other current liabilities	12,181	14,076
Total current liabilities	83,150	72,399
Non-current liabilities:		
Lease liabilities	1,765	6,471
Other financial liabilities	5	4
Retirement benefit liabilities	5,515	5,634
Deferred tax liabilities	1,053	1,039
Other non-current liabilities	832	807
Total non-current liabilities	9,171	13,956
Total liabilities	92,321	86,356
Equity:		
Share capital	17,358	17,358
Capital reserves	17,202	17,209
Treasury shares	(38,151)	(48,153)
Other components of equity	61,852	58,721
Retained earnings	499,088	504,148
Equity attributable to owners of the Company	557,350	549,283
Non-controlling interests	5,386	5,422
Total equity	562,736	554,704
Total liabilities and equity	655,056	641,060

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

**Condensed Interim Consolidated Statement of Income**

(Millions of yen)

	Three months ended June 30, 2018	Three months ended June 30, 2019
Revenue	71,242	73,982
Cost of sales	(20,145)	(20,730)
Gross profit	51,096	53,252
Selling, general, and administrative expenses	(17,025)	(16,573)
Research and development costs	(15,710)	(15,966)
Other income	219	122
Other expenses	(601)	(855)
Operating profit	17,980	19,980
Finance income	1,580	1,490
Finance costs	(132)	(276)
Share of profit (loss) from investments in associates	0	1
Profit before tax	19,428	21,196
Income tax expense	(4,177)	(4,814)
Profit for the period	15,251	16,381
Profit for the period attributable to:		
Owners of the Company	15,236	16,330
Non-controlling interests	15	51
Profit for the period	15,251	16,381
Earnings per share:		
Basic earnings per share (Yen)	29.64	31.84
Diluted earnings per share (Yen)	29.63	31.84



### Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Three months ended June 30, 2018	Three months ended June 30, 2019
Profit for the period	15,251	16,381
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	7,815	(2,630)
Remeasurements of defined benefit plans	148	38
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(0)	(4)
Total of items that will not be reclassified to profit or loss	7,963	(2,596)
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	67	(223)
Net fair value gain (loss) on cash flow hedges	5	(26)
Total of items that may be reclassified subsequently to profit or loss	71	(249)
Total other comprehensive income (loss)	8,034	(2,846)
Total comprehensive income (loss) for the period	23,285	13,536
Comprehensive income (loss) for the period attributable to:		
Owners of the Company	23,267	13,496
Non-controlling interests	18	39
Total comprehensive income (loss) for the period	23,285	13,536

### (3) Condensed Interim Consolidated Statement of Changes in Equity

Three months ended June 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					15,236	15,236	15	15,251
Other comprehensive income (loss)				8,031		8,031	3	8,034
Total comprehensive income (loss) for the period	–	–	–	8,031	15,236	23,267	18	23,285
Purchase of treasury shares			(1)			(1)		(1)
Cash dividends					(10,282)	(10,282)	(5)	(10,288)
Share-based payments		6				6		6
Transfer from other components of equity to retained earnings				(148)	148	–		–
Total transactions with the owners	–	6	(1)	(148)	(10,134)	(10,277)	(5)	(10,282)
Balance as of June 30, 2018	17,358	17,181	(38,149)	75,903	469,214	541,508	5,241	546,749

Three months ended June 30, 2019

(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, 2019	17,358	17,202	(38,151)	61,852	499,088	557,350	5,386	562,736
Profit for the period					16,330	16,330	51	16,381
Other comprehensive income (loss)				(2,833)		(2,833)	(12)	(2,846)
Total comprehensive income (loss) for the period	–	–	–	(2,833)	16,330	13,496	39	13,536
Purchase of treasury shares			(10,003)			(10,003)		(10,003)
Cash dividends					(11,568)	(11,568)	(3)	(11,571)
Share-based payments		7				7		7
Transfer from other components of equity to retained earnings				(298)	298	–		–
Total transactions with the owners	–	7	(10,003)	(298)	(11,270)	(21,564)	(3)	(21,567)
Balance as of June 30, 2019	17,358	17,209	(48,153)	58,721	504,148	549,283	5,422	554,704

**(4) Condensed Interim Consolidated Statement of Cash Flows**

(Millions of yen)

	Three months ended June 30, 2018	Three months ended June 30, 2019
<b>Cash flows from operating activities</b>		
Profit before tax	19,428	21,196
Depreciation and amortization	2,559	3,363
Interest and dividend income	(1,580)	(1,490)
Interest expense	3	19
(Increase) decrease in inventories	(703)	1,387
(Increase) decrease in trade and other receivables	(3,994)	(5,886)
Increase (decrease) in trade and other payables	(414)	(2,989)
Increase (decrease) in provisions	1,481	1,738
Increase (decrease) in retirement benefit liabilities	104	177
Other	4,446	3,211
Subtotal	21,331	20,725
Interest received	13	6
Dividends received	1,565	1,476
Interest paid	(3)	(19)
Income taxes paid	(8,645)	(15,852)
Net cash provided by (used in) operating activities	14,261	6,337
<b>Cash flows from investing activities</b>		
Purchases of property, plant, and equipment	(8,762)	(1,733)
Purchases of intangible assets	(847)	(4,972)
Proceeds from sales and redemption of investments	2,060	1,452
Other	661	(278)
Net cash provided by (used in) investing activities	(6,887)	(5,531)
<b>Cash flows from financing activities</b>		
Dividends paid	(9,245)	(10,460)
Dividends paid to non-controlling interests	(5)	(3)
Repayments of lease liabilities	(101)	(514)
Net increase (decrease) in short-term borrowings	(57)	-
Purchases of treasury shares	(0)	(10,002)
Net cash provided by (used in) financing activities	(9,409)	(20,980)
Net increase (decrease) in cash and cash equivalents	(2,035)	(20,174)
Cash and cash equivalents at the beginning of the period	65,273	59,981
Effects of exchange rate changes on cash and cash equivalents	(8)	(188)
Cash and cash equivalents at the end of the period	63,229	39,620

## (5) Notes to Condensed Interim Consolidated Financial Statements

### (Changes in Accounting Policies)

Our group has applied IFRS 16 “Leases” (issued in January 2016) (“IFRS 16”) from the first quarter ended June 30, 2019.

On application of IFRS 16, right-of-use assets and lease liabilities were recognized on the date of initial application of IFRS 16 (April 1, 2019) for leases previously classified as operating leases under IAS 17 “Leases” (“IAS 17”).

In addition, operating lease payments that had been expensed as incurred under the previous accounting standard were recorded as depreciation charge for right-of-use assets and interest expense on lease liabilities in the condensed interim consolidated statement of income for the first quarter ended June 30, 2019, and reclassified from a reduction in cash flows from operating activities to a reduction in cash flows from financing activities in the condensed interim consolidated statement of cash flows for the same period.

For lease transactions as a lessee, our group measures right-of-use assets at cost and lease liabilities at the present value of future lease payments at the commencement date of the lease transactions in accordance with IFRS 16.

A right-of-use asset is depreciated by using the straight-line method from the commencement date to the earlier of the end of the useful life of the right-of-use asset or the end of the lease term.

Lease payments are allocated to finance costs and repayments of lease liabilities based on the effective interest method. The finance costs are recognized in the condensed interim consolidated statement of income.

However, our group has elected not to recognize right-of-use assets and lease liabilities for leases of intangible assets, leases for which the underlying asset is of low value (“low-value leases”), and short-term leases with a lease term of 12 months or less. Lease payments associated with low-value leases and short-term leases are recognized as expense on either a straight-line basis or another systematic basis over the lease term.

In accordance with the transition under IFRS 16, our group has retrospectively adopted IFRS 16 and recognized the cumulative effect of initially applying IFRS 16 as an adjustment to the opening balance of retained earnings for the first quarter ended June 30, 2019. In transitioning to IFRS 16, our group has elected the practical expedient provided in paragraph C3 of IFRS 16 and carried forward the assessment of whether a contract contains a lease in accordance with IAS 17 and IFRIC 4 “Determining whether an Arrangement contains a Lease.”

Our group measures the lease liability at the present value of the lease payments that are not paid at the date of initial application by discounting them at the lessee’s incremental borrowing rate as of the date of initial application. The weighted average lessee’s incremental borrowing rate applied to lease liabilities recognized in the condensed interim consolidated statement of financial position at the date of initial application is 0.9%. Our group initially measures the right-of-use assets at the initial measurement amount of the lease liability adjusted by the amount of any prepaid or accrued lease payments.

For leases that were classified as finance leases applying IAS 17, the right-of-use asset and the lease liability are measured at the carrying amount of the leased asset and lease liability at the end of the previous fiscal year.

As a result, as of the beginning of the first quarter ended June 30, 2019, property, plant, and equipment and lease liabilities each increased by ¥6,245 million, compared with the amounts under the previous accounting standard. There is no impact for the opening balance of retained earnings at the date of initial application, because our group measures right-of-use assets at the date of initial application at the amount of lease liabilities measured after adjusting the amount of any prepaid and accrued lease payments.

The following is the reconciliation of operating lease contracts disclosed under IAS 17 as of March 31, 2019 and lease liabilities at the date of initial application recognized in the condensed interim consolidated statement of financial position.

	(Millions of yen)
	Amount
Operating lease contracts disclosed as of March 31, 2019	499
Operating lease contracts discounted at the incremental borrowing rate as of April 1, 2019	499
Finance lease contracts disclosed as of March 31, 2019	2,200
Cancelable operating lease contracts	5,757
Other	(11)
Lease liabilities as of April 1, 2019	8,445

When applying IFRS 16, our group used the following practical expedients provided in paragraph C10 of IFRS 16:

- A single discount rate is applied to a portfolio of leases with reasonably similar characteristics.
- Leases for which the lease term ends within 12 months of the date of initial application are accounted for in the same way as short-term leases.
- Initial direct costs are excluded from the measurement of the right-of-use asset at the date of initial application.
- Hindsight is used, such as in determining the lease term if the contract contains options to extend or terminate the lease.

**(Changes in Method of Presentation)**

**Condensed Interim Consolidated Statement of Financial Position**

Along with the application of IFRS 16, lease liabilities presented as “Borrowings” under current and non-current liabilities for the fiscal year ended March 31, 2019 is presented as “Lease liabilities” from the first quarter of the fiscal year ending March 31, 2020.

In order to reflect this change in the method of presentation, ¥435 million and ¥1,765 million for “Borrowings” presented under current liabilities and non-current liabilities, respectively, in the Condensed Interim Consolidated Statement of Financial Position for the fiscal year ended March 31, 2019 are presented as ¥435 million and ¥1,765 million for “Lease liabilities.”

**Condensed Interim Consolidated Statement of Cash Flows**

Along with the application of IFRS 16, repayments of lease liabilities presented as “Repayments of long-term borrowings” in cash flows from financing activities for the first quarter ended June 30, 2018 is presented as “Repayments of lease liabilities” from the first quarter ended June 30, 2019.

In order to reflect this change in the method of presentation, (¥101) million for “Repayments of long-term borrowings” presented in cash flows from financing activities in the Condensed Interim Consolidated Statement of Cash Flows for the first quarter ended June 30, 2018, is presented as (¥101) million for “Repayments of lease liabilities.”

**(Segment Information)**

Segment information is omitted herein, because our group’s business is a single segment of the pharmaceutical business.

**(Significant Subsequent Events)**

Not Applicable

**(Notes Regarding Assumption of a Going Concern)**

Not Applicable

#### 4. Supplementary Information

##### (1) Sales revenue and forecast of Major Products

(Billions of yen)

Product	Three months ended June 30, 2019 (From April 1, 2019 to June 30, 2019)			FY 2019 (From April 1, 2019 to March 31, 2020)		
	Actual	Change from FY 2018 Q1	Change from FY 2018 Q1 (%)	Forecasts	Change from FY 2018	Change from FY 2018 (%)
Opdivo	22.3	(0.5)	(2.0%)	85.0	(5.6)	(6.2%)
Glactive	6.9	(0.2)	(2.1%)	26.5	(0.4)	(1.5%)
Orencia	4.9	0.6	13.6%	19.0	1.6	9.0%
Forxiga	4.4	0.8	22.5%	16.5	2.0	13.8%
Emend / Proemend	2.9	0.2	8.8%	11.5	0.9	8.4%
Rivastach Patch	2.3	(0.0)	(2.0%)	9.5	0.6	6.8%
Opalmon	2.3	(0.6)	(20.2%)	9.0	(1.4)	(13.1%)
Parsabiv	1.7	0.4	33.2%	7.0	1.3	22.4%
Kyprolis	1.4	0.0	3.1%	5.5	0.6	11.8%
Recalbon	1.4	(1.3)	(49.3%)	5.0	(2.3)	(31.9%)
Onoact	1.3	0.2	13.1%	4.5	(0.1)	(1.8%)
Onon Capsules	0.9	(0.2)	(19.5%)	3.5	(0.9)	(19.9%)
Staybla	0.9	(0.2)	(15.6%)	3.5	(0.2)	(5.3%)
Onon Dry Syrup	0.6	(0.1)	(14.4%)	2.0	(0.7)	(25.9%)

Notes: 1. Sales revenue is shown in a gross sales basis (shipment price).

2. Regarding sales revenue forecast for the FY 2019, only currently approved indications are covered.

##### (2) Details of Revenue

(Billions of yen)

	Three months ended June 30, 2018	Three months ended June 30, 2019
Revenue of goods and products	53.9	53.2
Royalty and others	17.4	20.8
Total	71.2	74.0

Notes: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥13.4 billion for the first quarter (three months) ended June 30, 2018 and ¥15.4 billion for the first quarter (three months) ended June 30, 2019. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥2.6 billion for the first quarter (three months) ended June 30, 2018 and ¥4.0 billion for the first quarter (three months) ended June 30, 2019.

**(3) Revenue by geographic area**

(Billions of yen)

	Three months ended June 30, 2018	Three months ended June 30, 2019
Japan	53.1	52.3
Americas	16.5	19.6
Asia	1.6	2.0
Europe	0.1	0.1
Total	71.2	74.0

Notes: Revenue by geographic area is presented on the basis of the place of customers.

**(4) Main Status of Development Pipelines (Oncology)**

As of July 26, 2019

**1. Development Status in Japan**

<Filed>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
ONO-7643 / Anamorelin	New chemical entities	Cancer cachexia / Ghrelin receptor agonist	Tablet	In-license (Helsinn Healthcare, S.A.)
Kyprolis for Intravenous Infusion	Change in dosage and administration	Multiple myeloma / Proteasome inhibitor	Injection	In-license (Amgen Inc.)
Opdivo Intravenous Infusion	Additional indication	Colorectal cancer (MSI-H)	Injection	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer *1	Injection	In-house (Co-development with Bristol-Myers Squibb)

Changes from the announcement of financial results for the fiscal year ended March 2019

\*1: An approval application for Opdivo was filed in Japan for the treatment of unresectable advanced or recurrent esophageal cancer.

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

In the case of clinical development of the oncology drugs 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	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)
	Additional indication	Bladder cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection *	Additional indication	Non-small cell lung cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
Braftovi Capsule	New chemical entities	Colorectal cancer / BRAF inhibitor	Capsule	III	In-license (Array BioPharma Inc.)
Mektovi Tablet	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	III	In-license (Array BioPharma Inc.)



Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
ONO-7701 ★ (BMS-986205)	New chemical entities	Bladder cancer / IDO1 inhibitor	Tablet	III	In-license (Co-development with Bristol-Myers Squibb)
ONO-4687 ★ (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	Pancreatic cancer	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Primary macroglobulinemia, Lymphoplasmacytic lymphoma / 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 ★	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4686 ★ (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Central nervous system lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I / II	In-house
ONO-4482 ★ (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7807 ★ (BMS-986258)	New chemical entities	Solid tumor / Anti-TIM-3 antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Biliary tract cancer	Injection	I	In-house (Co-development with Bristol-Myers Squibb)
ONO-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
ONO-7705 / Selinexor	New chemical entities	Multiple myeloma and non-hodgkin lymphoma / XPO1 inhibitor	Tablet	I	In-license (Karyopharm Therapeutics Inc.)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
ONO-7475 ★	New chemical entities	Solid tumor / Axl/Mer inhibitor	Tablet	I	In-house
ONO-7911 ★ (BMS-986321)	New chemical entities	Solid tumor / PEGylated interleukin-2	Injection	I	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

Changes from the announcement of financial results for the fiscal year ended March 2019

\*The Phase III of combination therapy of IDO1 inhibitor (ONO-7701) and Opdivo for the treatment of melanoma was discontinued because the Company reviewed the development plan of the combination therapy based on the study results of the combination therapy of similar IDO1 inhibitor and anti-PD-1 antibody.

\*Phase I of combination therapy of anti-CD137 antibody (ONO-4481) and Opdivo for the treatment of solid tumor was discontinued due to strategic reasons.

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

In the case of clinical development of the oncology drugs 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
Opdivo Intravenous Infusion *2	Additional indication	Colorectal cancer (MSI-H)	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection **3	Additional indication	Colorectal cancer (MSI-H)	Injection	Taiwan	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

Changes from the announcement of financial results for the fiscal year ended March 2019

\*2: Opdivo was approved in Taiwan for the treatment of “microsatellite instability-high (MSI-H) or DNA mismatch repair deficiency (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.”

\*3: The combination therapy of Opdivo and Yervoy was approved in Taiwan for the treatment of “microsatellite instability-high (MSI-H) or DNA mismatch repair deficiency (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.”

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

In the case of clinical development of the oncology drugs 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)
	Additional indication	Bladder cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection *	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	Colorectal 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	Colorectal 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.)
ONO-7701 * (BMS-986205)	New chemical entities	Bladder cancer / IDO1 inhibitor	Tablet	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Pancreatic cancer	Injection	II	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
ONO-4687 * (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)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Yervoy Injection ★	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

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

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

### 3. Development Status in Europe and the United States

#### <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	Bladder cancer	Injection	III	Europe, USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Colorectal 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)
	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 *	New chemical entities	Solid tumor / PG receptor (EP4) antagonist	Tablet	I / 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	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

★: Combination with Opdivo.

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

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

**(5) Main Status of Development Pipelines (Non-Oncology)**

As of July 26, 2019

**1. Development Status in Japan**

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Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
ONO-1162 / Ivabradine	New chemical entities	Chronic heart failure / HCN channel inhibitor	Tablet	In-license (Les Laboratoires Servier)
ONO-2370 / Opicapone	New chemical entities	Parkinson's disease / Long acting COMT inhibitor	Tablet	In-license (Bial)
Orencia IV Orencia SC	Additional indication	Structural damage of the joints in rheumatoid 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 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-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 / $\beta_1$ blocker (short acting)	Injection	II / III	In-house
	Additional indication	Tachyarrhythmia upon sepsis / $\beta_1$ blocker (short acting)	Injection	II / III	In-house
ONO-5704 / SI-613	New chemical entities	Enthesopathy / Hyaluronic acid-NSAID	Injection	II	In-license (Seikagaku Corporation)
ONO-4059 / Tirabrutinib	New chemical entities	Pemphigus / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	In-house
ONO-7269	New chemical entities	Cerebral infarction / FXIa inhibitor	Injection	I	In-house
ONO-4685 *4	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	Injection	I	In-house

Changes from the announcement of financial results for the fiscal year ended March 2019

\*4: Phase I of PD-1 x CD3 bispecific antibody (ONO-4685) was initiated for the treatment of autoimmune disease.

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.)
ONO-5788	New chemical entities	Acromegaly / Growth hormone secretion inhibitor	Capsule	I	USA	In-house
ONO-7684	New chemical entities	Thrombosis / FXIa inhibitor	Tablet	I	Europe	In-house

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