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

January 31, 2020

| | |
|---|---|
| Company name | : **ONO PHARMACEUTICAL CO., LTD.** |
| Stock exchange listing | : Tokyo Stock Exchange |
| Code number | : 4528 |
| URL | : https://www.ono.co.jp/ |
| Representative | : Gyo Sagara<br>President, Representative Director, and Chief Executive Officer |
| Contact | : Yukio Tani<br>Corporate Executive Officer / Head of Corporate Communications |
| Phone | : +81-(0)6-6263-5670 |
| Scheduled date of quarterly securities report submission | : February 7, 2020 |
| 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 Third Quarter of FY 2019 (April 1, 2019 to December 31, 2019)*

(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 | | Total comprehensive income for the period | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Million yen | % | Million yen | % | Million yen | % | Million yen | % | Million yen | % | Million yen | % |
| FY 2019 Q3 | 225,299 | 0.9 | 66,045 | 26.7 | 68,687 | 24.4 | 51,982 | 20.3 | 51,827 | 20.2 | 62,652 | 67.4 |
| FY 2018 Q3 | 223,197 | 11.3 | 52,146 | (0.1) | 55,234 | (0.2) | 43,212 | 4.0 | 43,133 | 4.1 | 37,419 | (43.1) |

| | Basic earnings per share | Diluted earnings per share |
|---|---|---|
| | Yen | Yen |
| FY 2019 Q3 | 102.54 | 102.53 |
| FY 2018 Q3 | 83.90 | 83.89 |

(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 December 31, 2019 | 659,217 | 573,022 | 567,495 | 86.1 |
| 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 | — | 22.50 | — | | |
| FY 2019 (Forecast) | | | | 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 | 71,000 | 14.5 | 73,000 | 12.1 | 55,100 | 6.6 | 55,000 | 6.7 | 108.82 |

(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 December 31, 2019 | 528,341,400 | shares |
| As of March 31, 2019 | 543,341,400 | shares |

2) Number of treasury shares as of the end of the period:

| | | |
|---|---|---|
| As of December 31, 2019 | 29,221,845 | shares |
| As of March 31, 2019 | 29,220,860 | shares |

3) Average number of shares outstanding during the period:

| | | |
|---|---|---|
| Nine months ended December 31, 2019 | 505,432,005 | shares |
| Nine months ended December 31, 2018 | 514,121,174 | 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) Future outlook” on page 4 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 3rd Quarter of FY 2019

(Millions of yen)

| | Nine months ended December 31, 2018 | Nine months ended December 31, 2019 | Change | Change (%) |
|---|---|---|---|---|
| Revenue | 223,197 | 225,299 | 2,102 | 0.9% |
| Operating profit | 52,146 | 66,045 | 13,899 | 26.7% |
| Profit before tax | 55,234 | 68,687 | 13,453 | 24.4% |
| Profit for the period (attributable to owners of the Company) | 43,133 | 51,827 | 8,694 | 20.2% |

**[Revenue]**

Revenue totaled ¥225.3 billion, which was an increase of ¥2.1 billion (0.9%) 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 etc., its sales were affected by the revision of the National Health Insurance (NHI) drug price reduction in November 2018 and intensifying competition with competitors' products, resulting in sales of ¥68.0 billion, a decrease of ¥3.4 billion (4.7%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥20.5 billion (3.0% decrease year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥15.2 billion (13.1% increase year-on-year), sales of Forxiga Tablets for diabetes were ¥13.8 billion (24.5% increase year-on-year), sales of both Emend Capsules and Proemend for Intravenous Injection for chemotherapy-induced nausea and vomiting were ¥8.9 billion (7.9% increase year-on-year), sales of Rivastach Patch for Alzheimer's disease were ¥6.7 billion (4.0% decrease year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥5.5 billion (23.7% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥4.6 billion (18.0% 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 ¥6.7 billion (19.0% decrease year-on-year), and sales of Recalbon Tablets for osteoporosis were ¥3.9 billion (36.7% decrease year-on-year), respectively.
- Royalty and others increased by ¥4.8 billion (8.1%) year-on-year to ¥64.2 billion, mainly due to the rise in royalty revenue from Bristol-Myers Squibb Company and Merck & Co., Inc.

**[Operating Profit]**

Operating profit was ¥66.0 billion, an increase of ¥13.9 billion (26.7%) year-on-year.

- Cost of sales decreased by ¥5.0 billion (7.6%) year-on-year to ¥61.6 billion. This was mainly due to the absence of the one-time cost burden during the period under review, which was incurred in the same period of the previous fiscal year, as it was necessary to receive a stable supply of ingredients for Opdivo.
- Research and development costs decreased by ¥5.8 billion (11.3%) year-on-year to ¥45.4 billion mainly due to decreases in clinical trial costs and license fees associated with drug discovery alliance.
- Selling, general, and administrative expenses (except for research and development costs) decreased by ¥1.2 billion (2.4%) year-on-year to ¥50.9 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 ¥8.7 billion (20.2%) year-on-year to ¥51.8 billion in association with the increase of the profit before tax.

### (2) Overview of Financial Position for the 3rd Quarter of FY 2019

(Millions of yen)

| | As of March 31, 2019 | As of December 31, 2019 | Change |
|---|---|---|---|
| Total Assets | 655,056 | 659,217 | 4,161 |
| Equity attributable to owners of the Company | 557,350 | 567,495 | 10,145 |
| Ratio of equity attributable owners of the Company to total assets | 85.1% | 86.1% | |
| Equity attributable to owners of the Company per share | 1,084.08 yen | 1,136.99 yen | |

Total assets increased to ¥659.2 billion by ¥4.2 billion from the end of the previous fiscal year.
Current assets increased by ¥30.8 billion to ¥225.4 billion mainly due to increases in other financial assets and cash and cash equivalents.
Non-current assets decreased by ¥26.7 billion to ¥433.8 billion mainly due to a decrease in other financial assets, despite an increase in property, plant, and equipment resulting from right-of-use assets recorded as a result of the application of IFRS 16.
Liabilities decreased by ¥6.1 billion to ¥86.2 billion mainly due to decreases in trade and other payables and income taxes payable, despite increases in lease liabilities as a result of the application of IFRS 16 and provisions etc.
Equity attributable to owners of the Company increased by ¥10.1 billion to ¥567.5 billion mainly due to increases in retained earnings and other components of equity etc., despite the purchase of treasury shares.

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

(Millions of yen)

| | Nine months ended December 31, 2018 | Nine months ended December 31, 2019 | Change |
|---|---|---|---|
| Cash and cash equivalents at the beginning of the period | 65,273 | 59,981 | |
| Cash flows from operating activities | 43,005 | 50,178 | 7,173 |
| Cash flows from investing activities | (7,106) | 10,349 | 17,454 |
| Cash flows from financing activities | (21,418) | (53,391) | (31,973) |
| Net increase (decrease) in cash and cash equivalents | 14,481 | 7,136 | |
| Effects of exchange rate changes on cash and cash equivalents | (34) | (2) | |
| Cash and cash equivalents at the end of the period | 79,720 | 67,116 | |

Net increase/decrease in cash and cash equivalents was an increase of ¥7.1 billion.
Net cash provided by operating activities was ¥50.2 billion, as a result of profit before tax of ¥68.7 billion and depreciation and amortization of ¥10.4 billion etc., while income taxes paid amounted to ¥28.4 billion etc.
Net cash provided by investing activities was ¥10.3 billion, as a result of proceeds from withdrawal of time deposits of ¥25.6 billion and proceeds from sales and redemption of investments of ¥13.8 billion etc., while payments into time deposits of ¥10.6 billion, purchases of intangible assets of ¥12.7 billion, and purchases of property, plant, and equipment of ¥6.2 billion etc.
Net cash used in financing activities was ¥53.4 billion, as a result of purchases of treasury shares of ¥29.6 billion and dividends paid of ¥22.1 billion etc.

### (4) Future outlook

The forecasts of consolidated financial results for the fiscal year ending March 31, 2020, as announced on May 9, 2019, has been revised as follows:

Revisions to the forecasts of consolidated financial results for the fiscal year ending March 31, 2020
(April 1, 2019 to March 31, 2020)

(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) | 290,000 | 67,000 | 70,000 | 53,100 | 53,000 | 103.09 yen |
| Revised forecast (B) | 290,000 | 71,000 | 73,000 | 55,100 | 55,000 | 108.82 yen |
| Amount of change (B-A) | — | 4,000 | 3,000 | 2,000 | 2,000 | |
| Change (%) | — | 6.0 | 4.3 | 3.8 | 3.8 | |
| (Reference) Consolidated results of FY2018 | 288,634 | 62,010 | 65,141 | 51,679 | 51,539 | 100.25 yen |

The forecast for revenue has not changed since the previously announced forecast.
In terms of expenses, although no changes have been made to the forecast for cost of sales since the previously announced forecast, the Company has downwardly revised the forecasts for research and development costs by ¥2.0 billion to ¥70.0 billion and similarly for selling, general and administrative expenses by ¥2.0 billion to ¥70.0 billion.
As a result, operating profit is forecasted to be ¥71.0 billion (up ¥4.0 billion from the previously announced forecast), profit before tax is forecasted to be ¥73.0 billion (up ¥3.0 billion), profit for the year is forecasted to be ¥55.1 billion (up ¥2.0 billion) and profit attributable to owners of the Company is forecasted to be ¥55.0 billion (up ¥2.0 billion) for the fiscal year ending March 31, 2020.

Note: The financial forecasts and statements contained in this announcement are made based on information that is available as of the date the announcement is made. Actual results may differ 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, 2019 | As of December 31, 2019 |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | 59,981 | 67,116 |
| Trade and other receivables | 76,285 | 82,116 |
| Marketable securities | 687 | 631 |
| Other financial assets | 10,800 | 30,828 |
| Inventories | 32,821 | 31,972 |
| Other current assets | 14,042 | 12,769 |
| Total current assets | 194,617 | 225,431 |
| Non-current assets: | | |
| Property, plant, and equipment | 108,870 | 114,786 |
| Intangible assets | 63,059 | 67,691 |
| Investment securities | 171,476 | 172,539 |
| Investments in associates | 113 | 121 |
| Other financial assets | 91,672 | 56,682 |
| Deferred tax assets | 21,079 | 18,622 |
| Other non-current assets | 4,171 | 3,346 |
| Total non-current assets | 460,439 | 433,787 |
| Total assets | 655,056 | 659,217 |

(Millions of yen)

| | As of March 31, 2019 | As of December 31, 2019 |
|---|---|---|
| Liabilities and Equity | | |
| Current liabilities: | | |
| Trade and other payables | 36,833 | 29,907 |
| Borrowings | 435 | – |
| Lease liabilities | – | 2,279 |
| Other financial liabilities | 515 | 2,993 |
| Income taxes payable | 15,980 | 6,441 |
| Provisions | 17,206 | 20,721 |
| Other current liabilities | 12,181 | 10,112 |
| Total current liabilities | 83,150 | 72,452 |
| Non-current liabilities: | | |
| Borrowings | 1,765 | – |
| Lease liabilities | – | 6,616 |
| Other financial liabilities | 5 | 6 |
| Retirement benefit liabilities | 5,515 | 5,232 |
| Deferred tax liabilities | 1,053 | 1,064 |
| Other non-current liabilities | 832 | 824 |
| Total non-current liabilities | 9,171 | 13,743 |
| Total liabilities | 92,321 | 86,195 |
| Equity: | | |
| Share capital | 17,358 | 17,358 |
| Capital reserves | 17,202 | 17,222 |
| Treasury shares | (38,151) | (44,736) |
| Other components of equity | 61,852 | 66,636 |
| Retained earnings | 499,088 | 511,015 |
| Equity attributable to owners of the Company | 557,350 | 567,495 |
| Non-controlling interests | 5,386 | 5,527 |
| Total equity | 562,736 | 573,022 |
| Total liabilities and equity | 655,056 | 659,217 |

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

### Condensed Interim Consolidated Statement of Income

(Millions of yen)

| | Nine months ended December 31, 2018 | Nine months ended December 31, 2019 |
|---|---|---|
| Revenue | 223,197 | 225,299 |
| Cost of sales | (66,592) | (61,555) |
| Gross profit | 156,605 | 163,745 |
| Selling, general, and administrative expenses | (52,167) | (50,938) |
| Research and development costs | (51,172) | (45,371) |
| Other income | 583 | 584 |
| Other expenses | (1,703) | (1,976) |
| Operating profit | 52,146 | 66,045 |
| Finance income | 3,225 | 2,999 |
| Finance costs | (141) | (362) |
| Share of profit (loss) from investments in associates | 5 | 5 |
| Profit before tax | 55,234 | 68,687 |
| Income tax expense | (12,022) | (16,705) |
| Profit for the period | 43,212 | 51,982 |
| Profit for the period attributable to: | | |
| Owners of the Company | 43,133 | 51,827 |
| Non-controlling interests | 79 | 155 |
| Profit for the period | 43,212 | 51,982 |
| Earnings per share: | | |
| Basic earnings per share (Yen) | 83.90 | 102.54 |
| Diluted earnings per share (Yen) | 83.89 | 102.53 |

## Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

| | Nine months ended December 31, 2018 | Nine months ended December 31, 2019 |
|---|---|---|
| Profit for the period | 43,212 | 51,982 |
| 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 | (5,618) | 10,288 |
| Remeasurements of defined benefit plans | (208) | 396 |
| Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates | (8) | 3 |
| Total of items that will not be reclassified to profit or loss | (5,835) | 10,687 |
| Items that may be reclassified subsequently to profit or loss: | | |
| Exchange differences on translation of foreign operations | 51 | (36) |
| Net fair value gain (loss) on cash flow hedges | (10) | 19 |
| Total of items that may be reclassified subsequently to profit or loss | 42 | (17) |
| Total other comprehensive income (loss) | (5,793) | 10,670 |
| Total comprehensive income (loss) for the period | 37,419 | 62,652 |
| Comprehensive income (loss) for the period attributable to: | | |
| Owners of the Company | 37,330 | 62,508 |
| Non-controlling interests | 89 | 145 |
| Total comprehensive income (loss) for the period | 37,419 | 62,652 |

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

Nine months ended December 31, 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 | | | | | 43,133 | 43,133 | 79 | 43,212 |
| Other comprehensive income (loss) | | | | (5,803) | | (5,803) | 10 | (5,793) |
| Total comprehensive income (loss) for the period | – | – | – | (5,803) | 43,133 | 37,330 | 89 | 37,419 |
| Purchase of treasury shares | | | (2) | | | (2) | | (2) |
| Cash dividends | | | | | (21,850) | (21,850) | (5) | (21,856) |
| Share-based payments | | 20 | | | | 20 | | 20 |
| Transfer from other components of equity to retained earnings | | | | (863) | 863 | – | | – |
| Total transactions with the owners | – | 20 | (2) | (863) | (20,988) | (21,832) | (5) | (21,838) |
| Balance as of December 31, 2018 | 17,358 | 17,195 | (38,150) | 61,355 | 486,257 | 544,015 | 5,312 | 549,327 |

Nine months ended December 31, 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 | | | | | 51,827 | 51,827 | 155 | 51,982 |
| Other comprehensive income (loss) | | | | 10,680 | | 10,680 | (10) | 10,670 |
| Total comprehensive income (loss) for the period | – | – | – | 10,680 | 51,827 | 62,508 | 145 | 62,652 |
| Purchase of treasury shares | | | (29,585) | | | (29,585) | | (29,585) |
| Retirement of treasury shares | | | 22,999 | | (22,999) | – | | – |
| Cash dividends | | | | | (22,798) | (22,798) | (3) | (22,801) |
| Share-based payments | | 20 | | | | 20 | | 20 |
| Transfer from other components of equity to retained earnings | | | | (5,896) | 5,896 | – | | – |
| Total transactions with the owners | – | 20 | (6,586) | (5,896) | (39,901) | (52,363) | (3) | (52,366) |
| Balance as of December 31, 2019 | 17,358 | 17,222 | (44,736) | 66,636 | 511,015 | 567,495 | 5,527 | 573,022 |

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

(Millions of yen)

| | Nine months ended December 31, 2018 | Nine months ended December 31, 2019 |
|---|---|---|
| Cash flows from operating activities | | |
| Profit before tax | 55,234 | 68,687 |
| Depreciation and amortization | 7,773 | 10,426 |
| Impairment losses | 24 | 85 |
| Interest and dividend income | (3,054) | (2,881) |
| Interest expense | 14 | 57 |
| (Increase) decrease in inventories | (2,486) | 799 |
| (Increase) decrease in trade and other receivables | (8,746) | (5,944) |
| Increase (decrease) in trade and other payables | 3,126 | (588) |
| Increase (decrease) in provisions | 4,678 | 3,515 |
| Increase (decrease) in retirement benefit liabilities | 276 | 289 |
| Other | 1,584 | 1,294 |
| Subtotal | 58,424 | 75,739 |
| Interest received | 51 | 54 |
| Dividends received | 3,002 | 2,819 |
| Interest paid | (14) | (57) |
| Income taxes paid | (18,458) | (28,377) |
| Net cash provided by (used in) operating activities | 43,005 | 50,178 |
| Cash flows from investing activities | | |
| Purchases of property, plant, and equipment | (15,372) | (6,248) |
| Purchases of intangible assets | (2,410) | (12,677) |
| Proceeds from sales and redemption of investments | 10,844 | 13,838 |
| Payments into time deposits | (10,600) | (10,600) |
| Proceeds from withdrawal of time deposits | 10,600 | 25,600 |
| Other | (168) | 437 |
| Net cash provided by (used in) investing activities | (7,106) | 10,349 |
| Cash flows from financing activities | | |
| Dividends paid | (21,092) | (22,066) |
| Dividends paid to non-controlling interests | (5) | (3) |
| Repayments of long-term borrowings | (236) | – |
| Repayments of lease liabilities | – | (1,739) |
| Net increase (decrease) in short-term borrowings | (84) | – |
| Purchases of treasury shares | (1) | (29,584) |
| Net cash provided by (used in) financing activities | (21,418) | (53,391) |
| Net increase (decrease) in cash and cash equivalents | 14,481 | 7,136 |
| Cash and cash equivalents at the beginning of the period | 65,273 | 59,981 |
| Effects of exchange rate changes on cash and cash equivalents | (34) | (2) |
| Cash and cash equivalents at the end of the period | 79,720 | 67,116 |

## (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 of the fiscal year ending March 31, 2020.

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 third quarter (nine months) ended December 31, 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 third quarter (nine months) ended December 31, 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 third quarter (nine months) ended December 31, 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.

**(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 Forecasts of Major Products

(Billions of yen)

| Product | Nine months ended December 31, 2019 (April 1, 2019 to December 31, 2019) | | | | | | FY 2019 Forecasts (April 1, 2019 to March 31, 2020) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Cumulative | | | | YoY | | Forecasts | YoY | |
| | Apr ~ Jun | Jul ~ Sep | Oct ~ Dec | | Change | Change (%) | | Change | Change (%) |
| Opdivo | 22.3 | 24.5 | 21.2 | 68.0 | (3.4) | (4.7%) | 85.0 | (5.6) | (6.2%) |
| Glactive | 6.9 | 6.3 | 7.3 | 20.5 | (0.6) | (3.0%) | 26.5 | (0.4) | (1.5%) |
| Orencia | 4.9 | 5.1 | 5.2 | 15.2 | 1.8 | 13.1% | 19.0 | 1.6 | 9.0% |
| Forxiga | 4.4 | 4.3 | 5.1 | 13.8 | 2.7 | 24.5% | 16.5 | 2.0 | 13.8% |
| Emend / Proemend | 2.9 | 3.0 | 3.0 | 8.9 | 0.6 | 7.9% | 11.5 | 0.9 | 8.4% |
| Rivastach Patch | 2.3 | 2.1 | 2.4 | 6.7 | (0.3) | (4.0%) | 9.5 | 0.6 | 6.8% |
| Opalmon | 2.3 | 2.1 | 2.3 | 6.7 | (1.6) | (19.0%) | 9.0 | (1.4) | (13.1%) |
| Parsabiv | 1.7 | 1.8 | 2.0 | 5.5 | 1.0 | 23.7% | 7.0 | 1.3 | 22.4% |
| Kyprolis | 1.4 | 1.5 | 1.7 | 4.6 | 0.7 | 18.0% | 5.5 | 0.6 | 11.8% |
| Recalbon | 1.4 | 1.2 | 1.3 | 3.9 | (2.2) | (36.7%) | 5.0 | (2.3) | (31.9%) |
| Onoact | 1.3 | 1.1 | 1.6 | 4.0 | 0.4 | 10.2% | 4.5 | (0.1) | (1.8%) |
| Onon Capsules | 0.9 | 0.7 | 0.9 | 2.5 | (0.6) | (18.6%) | 3.5 | (0.9) | (19.9%) |
| Staybla | 0.9 | 0.7 | 0.8 | 2.5 | (0.5) | (16.0%) | 3.5 | (0.2) | (5.3%) |
| Onon Dry Syrup | 0.6 | 0.4 | 0.7 | 1.7 | (0.3) | (17.0%) | 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 Sales Revenue

(Billions of yen)

| | Nine months ended December 31, 2018 | Nine months ended December 31, 2019 |
|---|---|---|
| Revenue of goods and products | 163.8 | 161.1 |
| Royalty and others | 59.4 | 64.2 |
| Total | 223.2 | 225.3 |

Notes: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥43.3 billion for the third quarter (nine months) ended December 31, 2018 and ¥46.0 billion for the third quarter (nine months) ended December 31, 2019. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥9.0 billion for the third quarter (nine months) ended December 31, 2018 and ¥13.8 billion for the third quarter (nine months) ended December 31, 2019.

### (3) Revenue by Geographic Area

(Billions of yen)

| | Nine months ended December 31, 2018 | Nine months ended December 31, 2019 |
|---|---|---|
| Japan | 163.0 | 158.6 |
| Americas | 53.1 | 60.2 |
| Asia | 5.6 | 6.2 |
| Europe | 1.4 | 0.3 |
| Total | 223.2 | 225.3 |

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

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

As of January 24, 2020

### 1. Development Status in Japan

**<Approved>**

| Product Name / Development Code / Generic Name | Classification | Target indication / Pharmacological Action | Dosage form | In-house*) / In-license |
|---|---|---|---|---|
| Kyprolis for Intravenous Infusion *1 / Carfilzomib | Change in dosage and administration | Multiple myeloma / Proteasome inhibitor | Injection | In-license (Amgen Inc.) |

Changes from the announcement of financial results for the second quarter of the fiscal year ending March 2020

*1: An application was approved for the addition of once-weekly dosage and administration of multiple myeloma treatment Kyprolis for the treatment of relapsed or refractory multiple myeloma.

**<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.) |
| Opdivo Intravenous Infusion / Nivolumab | Additional indication | Colorectal cancer (MSI-H) | Injection | In-house (Co-development with Bristol-Myers Squibb) |
| | Additional indication | Esophageal cancer | Injection | In-house (Co-development with Bristol-Myers Squibb) |
| ONO-4059 / Tirabrutinib | New chemical entities | Central nervous system lymphoma / Bruton's tyrosine kinase (Btk) inhibitor | Tablet | In-house |
| | New chemical entities | Primary macroglobulinemia, Lymphoplasmacytic lymphoma *2 / Bruton's tyrosine kinase (Btk) inhibitor | Tablet | In-house |
| Yervoy Injection ★ / Ipilimumab | Additional indication | Colorectal cancer (MSI-H) *3 | Injection | In-license (Co-development with Bristol-Myers Squibb) |
| | Additional indication | Non-small cell lung cancer *4 | Injection | In-license (Co-development with Bristol-Myers Squibb) |

★: Combination with Opdivo

Changes from the announcement of financial results for the second quarter of the fiscal year ending March 2020

*2: An approval application for Bruton's tyrosine kinase inhibitor (ONO-4059 / Tirabrutinib) was filed for the treatment of primary macroglobulinemia and lymphoplasmacytic lymphoma.

*3: An approval application for combination therapy of Opdivo and Yervoy was filed for the treatment of microsatellite instability-high (MSI-H) unresectable advanced or recurrent colorectal cancer that has progressed following chemotherapy.

*4: An approval application for combination therapy of Opdivo and Yervoy was filed for the treatment of unresectable advanced or recurrent non-small cell lung 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 / Nivolumab | 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 ★ / Ipilimumab | 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) |
| | Additional indication | Hepatocellular carcinoma | Injection | III | In-license (Co-development with Bristol-Myers Squibb) |
| Braftovi Capsule / Encorafenib | New chemical entities | Colorectal cancer / BRAF inhibitor | Capsule | III | In-license (Pfizer Inc.) |
| Mektovi Tablet / Binimetinib | New chemical entities | Colorectal cancer / MEK inhibitor | Tablet | III | In-license (Pfizer Inc.) |
| ONO-7701 ★ (BMS-986205) / Linrodostat | New chemical entities | Bladder cancer / IDO1 inhibitor | Tablet | III | In-license (Co-development with Bristol-Myers Squibb) |

| Product Name / Development Code / Generic Name | Classification | Target indication / Pharmacological Action | Dosage form | Phase | In-house*) / In-license |
|---|---|---|---|---|---|
| ONO-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 / Nivolumab | 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) |
| | Additional indication | Biliary tract cancer *5 | Injection | II | In-house (Co-development with Bristol-Myers Squibb) |
| | Additional indication | Virus positive / negative solid carcinoma | Injection | I / II | In-house (Co-development with Bristol-Myers Squibb) |
| Yervoy Injection ★ / Ipilimumab | 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-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) |
| 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.) |
| ONO-7475 ★ | New chemical entities | Solid tumor / Axl/Mer inhibitor | Tablet | I | In-house |
| ONO-7911 ★ (BMS-986321) / Bempegaldesleukin | 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 second quarter of the fiscal year ending March 2020
*5: Phase II of Opdivo was initiated for the treatment of biliary tract 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.

**2. Development Status in South Korea and Taiwan**

**<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 / Nivolumab | 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 ★ / Ipilimumab | 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) |
| | Additional indication | Hepatocellular carcinoma | 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 (Pfizer Inc.) |
| | New chemical entities | Melanoma / BRAF inhibitor | Capsule | III | South Korea | In-license (Pfizer Inc.) |
| ONO-7703 / Binimetinib | New chemical entities | Colorectal cancer / MEK inhibitor | Tablet | III | South Korea | In-license (Pfizer Inc.) |
| | New chemical entities | Melanoma / MEK inhibitor | Tablet | III | South Korea | In-license (Pfizer Inc.) |
| ONO-7701 ★ (BMS-986205) / Linrodostat | New chemical entities | Bladder cancer / IDO1 inhibitor | Tablet | III | South Korea, Taiwan | In-license (Co-development with Bristol-Myers Squibb) |
| ONO-7912 *6 (CPI-613) / Devimistat | New chemical entities | Pancreatic cancer / Cancer metabolism inhibitor | Injection | III | South Korea | In-license (Rafael Pharmaceuticals, Inc.) |
| | New chemical entities | Acute myeloid leukemia / Cancer metabolism inhibitor | Injection | III | South Korea | In-license (Rafael Pharmaceuticals, Inc.) |
| Opdivo Intravenous Infusion / Nivolumab | 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) |

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

★: Combination with Opdivo

Changes from the announcement of financial results for the second quarter of the fiscal year ending March 2020

*6: Phase III of cancer metabolism inhibitor (ONO-7912 (CPI-613) / Devimistat) was initiated in South Korea for the treatment of pancreatic cancer and acute myeloid leukemia.

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 / Nivolumab | 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) |

| 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 | 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) |
| Opdivo Intravenous Infusion / Nivolumab | 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 January 24, 2020

### 1. Development Status in Japan

**<Filed>**

| Product Name / Development Code / Generic Name | Classification | Target indication / Pharmacological Action | Dosage form | In-house*) / In-license |
|---|---|---|---|---|
| ONO-2370 / Opicapone | New chemical entities | Parkinson's disease / Long acting COMT inhibitor | Tablet | In-license (Bial) |
| Orencia IV<br>Orencia SC / Abatacept | Additional indication | Structural damage of the joints in rheumatoid arthritis / T-cell activation inhibitor | Injection | In-license (Bristol-Myers Squibb) |
| Onoact for Intravenous Infusion / Landiolol Hydrochloride | Additional indication | Tachyarrhythmia upon sepsis / $\beta_1$ blocker (short acting) | Injection | In-house |
| ONO-5704 *7 / SI-613 | New chemical entities | Osteoarthritis / Hyaluronic acid-NSAID | Injection | In-license (Seikagaku Corporation) |

Changes from the announcement of financial results for the second quarter of the fiscal year ending March 2020
*7: An approval application for hyaluronic acid-NSAID (ONO-5704 / SI-613) was filed for the treatment of osteoarthritis (knee joint, hip joint, ankle joint).

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 / Abatacept | 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) |
| Onoact for Intravenous Infusion / Landiolol Hydrochloride | Additional indication for pediatric use | Tachyarrhythmia in low cardiac function / $\beta_1$ 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 | New chemical entities | Autoimmune disease / PD-1 x CD3 bispecific antibody | Injection | I | In-house |

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

**2. Development Status in Overseas**

**<Clinical Trial Stage>**

| Product Name / Development Code / Generic Name | Classification | Target indication / Pharmacological Action | Dosage form | Phase | Area | In-house*) / In-license |
|---|---|---|---|---|---|---|
| ONO-4059 / Tirabrutinib | New chemical entities | Sjögren syndrome / Bruton's tyrosine kinase (Btk) inhibitor | Tablet | II | Europe, USA | In-house (Out-license to Gilead Sciences, Inc.) |
| ONO-7684 | New chemical entities | Thrombosis / FXIa inhibitor | Tablet | I | Europe | In-house |
| ONO-2808 *8 | New chemical entities | Neurodegenerative diseases / S1P5 receptor agonist | Tablet | I | Europe | In-house |

Changes from the announcement of financial results for the second quarter of the fiscal year ending March 2020
*8: Phase I of S1P5 receptor agonist (ONO-2808) was initiated for treatment in healthy adults.
*Phase I of growth hormone secretion inhibitor (ONO-5788) for the treatment of acromegaly was discontinued due to strategic reasons.

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