

Consolidated Financial Results for the First Quarter of the Fiscal Year Ending March 31, 2021 (IFRS)

July 31, 2020

Company name	: ONO PHARMACEUTICAL CO., LTD.
Stock exchange listing	: Tokyo Stock Exchange
Code number	: 4528
URL	: https://www.ono.co.jp/
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Scheduled date of quarterly securities report submission	: August 6, 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 First Quarter of FY 2020 (April 1, 2020 to June 30, 2020)

(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 2020 Q1	74,913	1.3	27,043	35.3	28,307	33.5	21,533	31.4	21,496	31.6	32,144	137.5
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)

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2020 Q1	43.07	43.06
FY 2019 Q1	31.84	31.84

(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, 2020	678,509	588,936	583,364	86.0
As of March 31, 2020	673,444	568,022	562,484	83.5

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 2019	—	22.50	—	22.50	45.00
FY 2020	—	—	—	—	—
FY 2020 (Forecast)	—	22.50	—	22.50	45.00

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

3. Consolidated Financial Forecasts for FY 2020 (April 1, 2020 to March 31, 2021)

(% change from 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 2020	303,000	3.6	80,000	3.2	82,000	2.9	61,100	2.0	61,000	2.2	121.04

(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: None
 - 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 June 30, 2020	528,341,400	shares
As of March 31, 2020	528,341,400	shares
 - 2) Number of treasury shares as of the end of the period:

As of June 30, 2020	29,198,091	shares
As of March 31, 2020	29,222,272	shares
 - 3) Average number of shares outstanding during the period:

Three months ended June 30, 2020	499,125,129	shares
Three months ended June 30, 2019	512,837,304	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 1st Quarter of FY 2020

(Millions of yen)

	Three months ended June 30, 2019	Three months ended June 30, 2020	Change	Change (%)
Revenue	73,982	74,913	931	1.3%
Operating profit	19,980	27,043	7,063	35.3%
Profit before tax	21,196	28,307	7,111	33.5%
Profit for the period (attributable to owners of the Company)	16,330	21,496	5,167	31.6%

[Revenue]

Revenue totaled ¥74.9 billion, which was an increase of ¥0.9 billion (1.3%) from the corresponding period of the previous fiscal year (year-on-year).

- While competition with competitors' products intensified, use of Opdivo Intravenous Infusion for malignant tumors expanded for the treatment of esophageal cancer while its use for the treatment of renal cell carcinoma and gastric cancer remained firm, resulting in sales of ¥24.4 billion, an increase of ¥2.1 billion (9.5%) year-on-year.
- With respect to other main products, sales of Glactiv Tablets for type-2 diabetes were ¥6.5 billion (5.9% decrease year-on-year), sales of Orenia Subcutaneous Injection for rheumatoid arthritis were ¥5.4 billion (10.6% increase year-on-year), sales of Forxiga Tablets for diabetes were ¥5.2 billion (17.8% increase year-on-year), sales of Rivastach Patch for Alzheimer's disease were ¥2.0 billion (10.0% decrease year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥1.9 billion (11.1% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for relapsed or refractory multiple myeloma were ¥1.7 billion (21.3% 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 ¥1.5 billion (36.8% decrease year-on-year), sales of Recalbon Tablets for osteoporosis were ¥0.8 billion (42.5% decrease year-on-year), and sales of Emend Capsules for chemotherapy-induced nausea and vomiting were ¥0.8 billion (64.1% decrease year-on-year), respectively.
- Royalty and others increased by ¥0.5 billion (2.5%) year-on-year to ¥21.3 billion.

[Operating Profit]

Operating profit was ¥27.0 billion, an increase of ¥7.1 billion (35.3%) year-on-year.

- Cost of sales decreased by ¥0.2 billion (0.8%) year-on-year to ¥20.6 billion.
- Research and development costs decreased by ¥3.6 billion (22.7%) year-on-year to ¥12.3 billion mainly due to the decrease in clinical trial costs caused by the delay of registrations of subjects for new clinical trials and the suspension of registrations of subjects for continuing clinical trials as a result of the impact of the novel coronavirus disease (COVID-19).
- Selling, general, and administrative expenses (except for research and development costs) decreased by ¥2.4 billion (14.3%) year-on-year to ¥14.2 billion mainly due to the decrease in operating expenses caused by cancellation or postponement of academic lectures and refraining from visiting medical institutions by MRs due to COVID-19.

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

Profit attributable to owners of the Company increased by ¥5.2 billion (31.6%) year-on-year to ¥21.5 billion in association with the increase of the profit before tax.

(2) Overview of Financial Position for the 1st Quarter of FY 2020

(Millions of yen)

	As of March 31, 2020	As of June 30, 2020	Change
Total Assets	673,444	678,509	5,064
Equity attributable to owners of the Company	562,484	583,364	20,880
Ratio of equity attributable to owners of the Company to total assets	83.5%	86.0%	
Equity attributable to owners of the Company per share	1,126.95 yen	1,168.73 yen	

Total assets increased to ¥678.5 billion by ¥5.1 billion from the end of the previous fiscal year.

Current assets decreased by ¥0.6 billion to ¥224.6 billion mainly due to a decrease in cash and cash equivalents etc., despite increases in inventories, marketable securities, and trade and other receivables etc.

Non-current assets increased by ¥5.6 billion to ¥453.9 billion mainly due to an increase in investment securities etc., despite a decrease in deferred tax assets etc.

Liabilities decreased by ¥15.8 billion to ¥89.6 billion mainly due to decreases in income taxes payable and trade and other payables etc.

Equity attributable to owners of the Company increased by ¥20.9 billion to ¥583.4 billion mainly due to increases in retained earnings and other components of equity etc.

(3) Overview of Cash Flows for the 1st Quarter of FY 2020

(Millions of yen)

	Three months ended June 30, 2019	Three months ended June 30, 2020	Change
Cash and cash equivalents at the beginning of the period	59,981	69,005	
Cash flows from operating activities	6,337	10,412	4,075
Cash flows from investing activities	(5,531)	(3,776)	1,755
Cash flows from financing activities	(20,980)	(10,803)	10,177
Net increase (decrease) in cash and cash equivalents	(20,174)	(4,166)	
Effects of exchange rate changes on cash and cash equivalents	(188)	12	
Cash and cash equivalents at the end of the period	39,620	64,851	

Net increase/decrease in cash and cash equivalents was a decrease of ¥4.2 billion.

Net cash provided by operating activities was ¥10.4 billion, as a result of profit before tax of ¥28.3 billion and depreciation and amortization of ¥3.8 billion etc., while income taxes paid amounted to ¥19.7 billion etc.

Net cash used in investing activities was ¥3.8 billion, as a result of purchases of property, plant, and equipment of ¥2.2 billion and purchases of intangible assets of ¥1.5 billion etc.

Net cash used in financing activities was ¥10.8 billion, as a result of dividends paid of ¥10.2 billion etc.

(4) Future outlook

There are no changes from the forecasts of consolidated financial results for the year ending March 31, 2021 announced on May 12, 2020.

<Impact of COVID-19 on Business and Financial Results>

Our group strives to ensure a stable supply of drugs as a life-related pharmaceutical company by collaborating with subsidiaries, affiliates, and business partners. For the time being, there are no problems with our drug production or system of supply to medical institutions. In addition, we refrained from visiting medical institutions to ensure the safety and protect the health of patients, medical providers, and employees, and to prevent the spread of infection. Since June, however, following the lifting of the state of emergency declaration, we have been gradually resuming development activities such as the registration of subjects which had been suspended. In our operating activities, as well as incrementally starting activities in less affected areas and medical institutions, we are engaged in information provision activities, which are a responsibility of MRs, by not just making traditional visits but also by employing new methods such as online meetings and planning of remote lectures.

Regarding the effects of COVID-19 on the financial results for the full fiscal year, the financial forecasts reflected the effects of continuing to refrain from visiting medical institutions and other activities until the end of June 2020. Although revenue is expected to decline slightly due to refraining from activities, restraints on consultations, etc. in July and thereafter, the impact on operating profit is estimated to be immaterial as expenditures will be controlled due to refraining from business activities. Going forward, if any revisions to the financial forecasts are necessary, the Company will promptly announce them.

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, 2020	As of June 30, 2020
Assets		
Current assets:		
Cash and cash equivalents	69,005	64,851
Trade and other receivables	76,834	77,391
Marketable securities	614	1,909
Other financial assets	30,800	30,938
Inventories	32,906	34,570
Other current assets	15,063	14,978
Total current assets	225,222	224,636
Non-current assets:		
Property, plant, and equipment	114,628	112,967
Intangible assets	66,436	65,292
Investment securities	137,670	151,178
Investments in associates	108	113
Other financial assets	91,694	91,734
Deferred tax assets	34,817	29,991
Other non-current assets	2,871	2,597
Total non-current assets	448,222	453,872
Total assets	673,444	678,509

(Millions of yen)

	As of March 31, 2020	As of June 30, 2020
Liabilities and Equity		
Current liabilities:		
Trade and other payables	34,439	29,163
Lease liabilities	2,188	2,083
Other financial liabilities	450	2,251
Income taxes payable	20,346	7,066
Provisions	20,721	20,721
Other current liabilities	13,185	14,947
Total current liabilities	<u>91,329</u>	<u>76,231</u>
Non-current liabilities:		
Lease liabilities	6,173	5,806
Other financial liabilities	0	0
Retirement benefit liabilities	6,048	5,697
Deferred tax liabilities	1,059	1,046
Other non-current liabilities	813	793
Total non-current liabilities	<u>14,093</u>	<u>13,342</u>
Total liabilities	<u>105,422</u>	<u>89,573</u>
Equity:		
Share capital	17,358	17,358
Capital reserves	17,229	17,198
Treasury shares	(44,737)	(44,701)
Other components of equity	48,030	58,355
Retained earnings	524,605	535,154
Equity attributable to owners of the Company	<u>562,484</u>	<u>583,364</u>
Non-controlling interests	5,538	5,572
Total equity	<u>568,022</u>	<u>588,936</u>
Total liabilities and equity	<u>673,444</u>	<u>678,509</u>

**(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, 2019	Three months ended June 30, 2020
Revenue	73,982	74,913
Cost of sales	(20,730)	(20,563)
Gross profit	53,252	54,350
Selling, general, and administrative expenses	(16,573)	(14,199)
Research and development costs	(15,966)	(12,343)
Other income	122	91
Other expenses	(855)	(856)
Operating profit	19,980	27,043
Finance income	1,490	1,289
Finance costs	(276)	(27)
Share of profit (loss) from investments in associates	1	2
Profit before tax	21,196	28,307
Income tax expense	(4,814)	(6,774)
Profit for the period	16,381	21,533
Profit for the period attributable to:		
Owners of the Company	16,330	21,496
Non-controlling interests	51	36
Profit for the period	16,381	21,533
Earnings per share:		
Basic earnings per share (Yen)	31.84	43.07
Diluted earnings per share (Yen)	31.84	43.06

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Three months ended June 30, 2019	Three months ended June 30, 2020
Profit for the period	16,381	21,533
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	(2,630)	10,279
Remeasurements of defined benefit plans	38	334
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	(4)	4
Total of items that will not be reclassified to profit or loss	<u>(2,596)</u>	<u>10,616</u>
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	(223)	(9)
Net fair value gain (loss) on cash flow hedges	(26)	4
Total of items that may be reclassified subsequently to profit or loss	<u>(249)</u>	<u>(5)</u>
Total other comprehensive income (loss)	<u>(2,846)</u>	<u>10,611</u>
Total comprehensive income (loss) for the period	<u>13,536</u>	<u>32,144</u>
Comprehensive income (loss) for the period attributable to:		
Owners of the Company	13,496	32,104
Non-controlling interests	39	40
Total comprehensive income (loss) for the period	<u>13,536</u>	<u>32,144</u>

(3) Condensed Interim Consolidated Statement of Changes in Equity

Three months ended June 30, 2019

(Millions of yen)

	Equity attributable to owners of the Company						Non-controlling interests	Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company		
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

Three months ended June 30, 2020

(Millions of yen)

	Equity attributable to owners of the Company						Non-controlling interests	Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company		
Balance as of April 1, 2020	17,358	17,229	(44,737)	48,030	524,605	562,484	5,538	568,022
Profit for the period					21,496	21,496	36	21,533
Other comprehensive income (loss)				10,608		10,608	4	10,611
Total comprehensive income (loss) for the period	–	–	–	10,608	21,496	32,104	40	32,144
Purchase of treasury shares			(1)			(1)		(1)
Disposition of treasury shares		(38)	38			0		0
Cash dividends					(11,230)	(11,230)	(6)	(11,236)
Share-based payments		7				7		7
Transfer from other components of equity to retained earnings				(283)	283	–		–
Total transactions with the owners	–	(31)	37	(283)	(10,947)	(11,224)	(6)	(11,230)
Balance as of June 30, 2020	17,358	17,198	(44,701)	58,355	535,154	583,364	5,572	588,936

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Three months ended June 30, 2019	Three months ended June 30, 2020
Cash flows from operating activities		
Profit before tax	21,196	28,307
Depreciation and amortization	3,363	3,823
Interest and dividend income	(1,490)	(1,237)
Interest expense	19	17
(Increase) decrease in inventories	1,387	(1,648)
(Increase) decrease in trade and other receivables	(5,886)	(527)
Increase (decrease) in trade and other payables	(2,989)	(2,833)
Increase (decrease) in provisions	1,738	–
Increase (decrease) in retirement benefit liabilities	177	129
Other	3,211	2,844
Subtotal	20,725	28,875
Interest received	6	4
Dividends received	1,476	1,227
Interest paid	(19)	(17)
Income taxes paid	(15,852)	(19,677)
Net cash provided by (used in) operating activities	6,337	10,412
Cash flows from investing activities		
Purchases of property, plant, and equipment	(1,733)	(2,155)
Purchases of intangible assets	(4,972)	(1,513)
Proceeds from sales and redemption of investments	1,452	40
Payments into time deposits	–	(134)
Other	(278)	(14)
Net cash provided by (used in) investing activities	(5,531)	(3,776)
Cash flows from financing activities		
Dividends paid	(10,460)	(10,180)
Dividends paid to non-controlling interests	(3)	(6)
Repayments of lease liabilities	(514)	(617)
Purchases of treasury shares	(10,002)	(0)
Net cash provided by (used in) financing activities	(20,980)	(10,803)
Net increase (decrease) in cash and cash equivalents	(20,174)	(4,166)
Cash and cash equivalents at the beginning of the period	59,981	69,005
Effects of exchange rate changes on cash and cash equivalents	(188)	12
Cash and cash equivalents at the end of the period	39,620	64,851

(5) Notes to Condensed Interim Consolidated Financial Statements

(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 Name	Three months ended June 30, 2020 (April 1, 2020 to June 30, 2020)			FY 2020 Forecasts (April 1, 2020 to March 31, 2021)		
	Results	YoY		Forecasts	YoY	
		Change	Change (%)		Change	Change (%)
Opdivo Intravenous Infusion	24.4	2.1	9.5%	90.0	2.7	3.1%
Glactive Tablets	6.5	(0.4)	(5.9%)	25.0	(1.1)	(4.1%)
Forxiga Tablets	5.2	0.8	17.8%	22.5	4.4	24.6%
Orencia for Subcutaneous Injection	5.4	0.5	10.6%	21.5	1.7	8.4%
Rivastach Patch	2.0	(0.2)	(10.0%)	8.5	(0.0)	(0.3%)
Parsabiv Intravenous Infusion	1.9	0.2	11.1%	7.5	0.4	6.1%
Kyprolis for Intravenous Injection	1.7	0.3	21.3%	6.5	0.5	8.4%
Onoact for Intravenous Infusion	1.0	(0.2)	(19.1%)	6.0	1.1	23.4%
Opalmon Tablets	1.5	(0.9)	(36.8%)	5.0	(3.3)	(40.0%)
Proemend for Intravenous Injection	0.7	(0.0)	(3.1%)	3.5	0.9	33.3%
Emend Capsules	0.8	(1.4)	(64.1%)	3.5	(4.6)	(56.7%)
Onon Capsules	0.7	(0.3)	(28.4%)	3.0	(0.5)	(13.1%)
Recalbon Tablets	0.8	(0.6)	(42.5%)	2.0	(2.7)	(57.8%)
Newly launched products during FY 2020	0.1	–	–	5.0	5.0	–

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

2. Regarding sales revenue forecasts for the FY 2020, only currently approved indications are covered.

3. Newly launched products during FY 2020 include ¥0.1 billion in sales of Velexbu Tablets for recurrent or refractory primary central nervous system lymphoma launched in May 2020.

(2) Details of Sales Revenue

(Billions of yen)

	Three months ended June 30, 2019	Three months ended June 30, 2020
Revenue of goods and products	53.2	53.6
Royalty and others	20.8	21.3
Total	74.0	74.9

Notes: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥15.4 billion for the first quarter (three months) ended June 30, 2019 and ¥14.0 billion for the first quarter (three months) ended June 30, 2020. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥4.0 billion for the first quarter (three months) ended June 30, 2019 and ¥5.7 billion for the first quarter (three months) ended June 30, 2020.

(3) Revenue by Geographic Area

(Billions of yen)

	Three months ended June 30, 2019	Three months ended June 30, 2020
Japan	52.3	52.9
Americas	19.6	20.0
Asia	2.0	1.8
Europe	0.1	0.2
Total	74.0	74.9

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 24, 2020

<Approved>

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Esophageal cancer *1	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)

Changes from the announcement of financial results for the fiscal year ended March 2020

*1: An application for Opdivo was approved in Taiwan for the treatment of unresectable advanced or recurrent squamous cell carcinoma of esophageal cancer progressing after fluoropyrimidine- and platinum-based chemotherapy.

<Filed>

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
ONO-7643 / Anamorelin	New chemical entities	Cancer cachexia / Ghrelin receptor agonist	Tablet	Japan	In-license (Helsinn Healthcare, S.A.)
ONO-4059 / Tirabrutinib	Additional indication	Waldenstrom macroglobulinemia, Lymphoplasmacytic lymphoma / Bruton’s tyrosine kinase (Btk) inhibitor	Tablet	Japan	In-house
Yervoy Injection * / Ipilimumab	Additional indication	Colorectal cancer (MSI-H)	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Non-small cell lung cancer	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)
Braftovi Capsule / Encorafenib	New chemical entities	Colorectal cancer / BRAF inhibitor	Capsule	Japan	In-license (Pfizer Inc.)
Mektovi Tablet / Binimetinib	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	Japan	In-license (Pfizer Inc.)

★: Combination with Opdivo.

<Clinical Trial Stage>

<Opdivo>						
*) : “In-house” compounds include a compound generated from collaborative research.						
Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	Japan S. Korea	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Glioblastoma	Injection	Japan	III	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Urothelial cancer	Injection	Japan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	Japan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Bladder cancer	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Prostate cancer *2	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Solid tumor (Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma)	Injection	Japan	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central nervous system lymphoma / Primary testicular lymphoma	Injection	Japan	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Pancreatic cancer	Injection	Japan S. Korea Taiwan	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Biliary tract cancer	Injection	Japan	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	Japan S. Korea Taiwan	I / II	In-house (Co-development with Bristol-Myers Squibb)
<Yervoy> *) : “In-house” compounds include a compound generated from collaborative research.						
Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
Yervoy Injection * / Ipilimumab	Additional indication	Non-small cell lung cancer	Injection	S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma	Injection	Japan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	Japan S. Korea Taiwan	I / II	In-license (Co-development with Bristol-Myers Squibb)

<I-O Related>						
*) : “In-house” compounds include a compound generated from collaborative research.						
Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
ONO-7701 * (BMS-986205) / Linrodostat	New chemical entities	Bladder cancer / IDO1 inhibitor	Tablet	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
ONO-4687 * (BMS-986227) / Cabiralizumab	New chemical entities	Pancreatic cancer / Anti-CSF-1R antibody	Injection	Japan S. Korea Taiwan	II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4686 * (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4482 * (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7807 * (BMS-986258)	New chemical entities	Solid tumor / Anti-TIM-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483 * (BMS-986015) / Lirilumab	New chemical entities	Solid tumor / Anti-KIR antibody	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4578 *	New chemical entities	Solid tumor / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
ONO-7475 *	New chemical entities	Solid tumor / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-7911 * (BMS-986321) / Bempegaldesleukin	New chemical entities	Solid tumor / PEGylated IL-2	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
<Others>						
*) : “In-house” compounds include a compound generated from collaborative research.						
Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
ONO-7702 / Encorafenib	New chemical entities	Colorectal cancer / BRAF inhibitor	Capsule	S. Korea	III	In-license (Pfizer Inc.)
	New chemical entities	Melanoma / BRAF inhibitor	Capsule	S. Korea	III	In-license (Pfizer Inc.)
ONO-7703 / Binimetinib	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	S. Korea	III	In-license (Pfizer Inc.)
	New chemical entities	Melanoma / MEK inhibitor	Tablet	S. Korea	III	In-license (Pfizer Inc.)
ONO-7912 (CPI-613) / Devimistat	New chemical entities	Pancreatic cancer / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, Inc.)
	New chemical entities	Acute myeloid leukemia / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, Inc.)
	New chemical entities	Pancreatic cancer *3 / Cancer metabolism inhibitor	Injection	Japan	I	In-license (Rafael Pharmaceuticals, Inc.)
ONO-7475	New chemical entities	Acute leukemia / Axl/Mer inhibitor	Tablet	USA	I	In-house

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
ONO-7913 / Magrolimab	New chemical entities	Solid tumor / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)

★: Combination with Opdivo.

Changes from the announcement of financial results for the fiscal year ended March 2020

*2: Phase III of Opdivo was initiated in Japan, South Korea, and Taiwan for the treatment of prostate cancer.

*3: Phase I of cancer metabolism inhibitor (ONO-7912) was initiated in Japan for the treatment of pancreatic cancer.

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 (Areas other than Oncology)

As of July 24, 2020

<Approved>

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
ONO-2370 *4 / Opicapone	New chemical entities	Parkinson’s disease / Long acting COMT inhibitor	Tablet	Japan	In-license (Bial)
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication	Tachyarrhythmia upon sepsis *5 / Short-acting selective β_1 blocker	Injection	Japan	In-house

Changes from the announcement of financial results for the fiscal year ended March 2020

*4: An application was approved for a catechol-*O*-methyltransferase (COMT) inhibitor (ONO-2370) for the improvement of the end-of-dose motor fluctuations (wearing-off phenomenon) in parkinson’s disease in combination with levodopa-carbidopa or levodopa-benserazide hydrochloride.

*5: An application was approved for a short-acting selective β_1 blocker (Onoact for Intravenous Infusion) for the treatment of tachyarrhythmia associated with sepsis (atrial fibrillation, atrial flutter and sinus tachycardia).

<Filed>

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
ONO-5704 / SI-613	New chemical entities	Osteoarthritis / Hyaluronic acid-NSAID	Injection	Japan	In-license (Seikagaku Corporation)

<Clinical Trial Stage>

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
Orencia SC / Abatacept	Additional indication	Polymyositis / Dermatomyositis / T-cell activation inhibitor	Injection	Japan	III	In-license (Co-development with Bristol-Myers Squibb)
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / Short-acting selective β_1 blocker	Injection	Japan	II / III	In-house
ONO-5704 / SI-613	New chemical entities	Enthesopathy / Hyaluronic acid-NSAID	Injection	Japan	II	In-license (Seikagaku Corporation)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
ONO-4059 / Tirabrutinib	Additional indication	Pemphigus / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	Japan	II	In-house
ONO-7269	New chemical entities	Cerebral infarction / FXIa inhibitor	Injection	Japan	I	In-house
ONO-4685	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	Injection	Japan	I	In-house
ONO-7684	New chemical entities	Thrombosis / FXIa inhibitor	Tablet	Europe	I	In-house
ONO-2808	New chemical entities	Neurodegenerative diseases / SIP5 receptor agonist	Tablet	Europe	I	In-house
ONO-2910 *6	New chemical entities	Peripheral neuropathy / Schwann cell differentiation promoter	Tablet	Japan	I	In-house
Foipan Tablets *7 / Camostat mesilate	Additional indication	Novel coronavirus infection (COVID-19) / Protease enzyme inhibitor	Tablet	Japan	I	In-house

Changes from the announcement of financial results for the fiscal year ended March 2020

*6: Phase I of Schwann cell differentiation promoter (ONO-2910) was initiated for healthy adult male subjects.

*7: Clinical trials were initiated on protease enzyme inhibitor Foipan Tablets as a treatment for COVID-19.