

**Consolidated Financial Results**  
**for the First Quarter of the Fiscal Year Ending March 31, 2022 (IFRS)**

July 30, 2021

Company name : **ONO PHARMACEUTICAL CO., LTD.**  
 Stock exchange listing : Tokyo Stock Exchange  
 Code number : 4528  
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 Scheduled date of quarterly securities report submission : August 6, 2021  
 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 2021 (April 1, 2021 to June 30, 2021)**

(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 2021 Q1	87,363	16.6	29,792	10.2	30,804	8.8	24,108	12.0	24,074	12.0	22,696	(29.4)
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

	Basic earnings per share		Diluted earnings per share	
	Yen		Yen	
FY 2021 Q1	48.23		48.22	
FY 2020 Q1	43.07		43.06	

(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, 2021	742,873	650,133	644,493	86.8
As of March 31, 2021	746,842	641,157	635,547	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 2020	—	22.50	—	27.50	50.00
FY 2021	—				
FY 2021 (Forecast)		28.00	—	28.00	56.00

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

**3. Consolidated Financial Forecast for FY 2021 (April 1, 2021 to March 31, 2022)**

(% 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 2021	345,000	11.5	103,000	4.7	105,000	4.1	81,600	8.1	81,500	8.1	163.28

(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, 2021	528,341,400	shares
As of March 31, 2021	528,341,400	shares
  - 2) Number of treasury shares as of the end of the period:

As of June 30, 2021	29,179,701	shares
As of March 31, 2021	29,199,416	shares
  - 3) Average number of shares outstanding during the period:

Three months ended June 30, 2021	499,146,863	shares
Three months ended June 30, 2020	499,125,129	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 2021

(Millions of yen)

	Three months ended June 30, 2020	Three months ended June 30, 2021	Change	Change (%)
Revenue	74,913	<b>87,363</b>	12,450	16.6%
Operating profit	27,043	<b>29,792</b>	2,749	10.2%
Profit before tax	28,307	<b>30,804</b>	2,498	8.8%
Profit for the period (attributable to owners of the Company)	21,496	<b>24,074</b>	2,578	12.0%

#### [Revenue]

Revenue totaled ¥87.4 billion, which was an increase of ¥12.4 billion (16.6%) from the corresponding period of the previous fiscal year (year-on-year).

- While the competition with competitors' products intensified, use of Opdivo Intravenous Infusion for malignant tumors was expanded to first-line treatment for lung cancer and second-line treatment for esophageal cancer, resulting in sales of ¥29.0 billion, an increase of ¥4.6 billion (18.7%) year-on-year.
- With respect to other main products, sales of Forxiga Tablets for diabetes and chronic heart failure were ¥7.5 billion (43.3% increase year-on-year), sales of Glactiv Tablets for type-2 diabetes were ¥6.5 billion (1.1% decrease year-on-year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥5.7 billion (4.5% increase year-on-year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥2.2 billion (15.3% increase year-on-year), and sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥2.0 billion (18.9% increase year-on-year), respectively. Adlumiz Tablets for treatment of cancer cachexia were newly launched in April 2021 and Joyclu Intra-articular Injection for improvement of joint function was launched in May 2021.
- 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 ¥1.2 billion (17.5% decrease year-on-year), sales of Rivastach Patches for Alzheimer's disease were ¥0.8 billion (60.7% decrease year-on-year), respectively.
- Royalty and others increased by ¥5.5 billion (25.7%) year-on-year to ¥26.8 billion.

#### [Operating profit]

Operating profit was ¥29.8 billion, an increase of ¥2.7 billion (10.2%) year-on-year.

- Cost of sales increased by ¥2.2 billion (10.9%) year-on-year to ¥22.8 billion mainly due to an increase in sales of goods and products.
- Research and development costs increased by ¥2.9 billion (23.5%) year-on-year to ¥15.2 billion. The increase is largely attributable to higher costs associated with development amid a situation where development activities including the registrations of subjects mounted a gradual recovery, as well as higher costs associated with research.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥4.8 billion (33.5%) year-on-year to ¥19.0 billion, despite MRs refraining from visiting medical institutions and other restrictions on activities due to the impact of COVID-19. The increase is partly attributable to an increase in operating expenses largely associated with actively implementing online lectures, an increase in expenses pertaining to the launch of new products, and an increase in co-promotion fees associated with expanding sales of Forxiga Tablets.

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

Profit attributable to owners of the Company increased by ¥2.6 billion (12.0%) year-on-year to ¥24.1 billion in association with the increase of the profit before tax.

**(2) Overview of Financial Position for the 1st Quarter of FY 2021**

(Millions of yen)

	As of March 31, 2021	As of June 30, 2021	Change
Total Assets	746,842	<b>742,873</b>	(3,969)
Equity attributable to owners of the Company	635,547	<b>644,493</b>	8,946
Ratio of equity attributable to owners of the Company to total assets	85.1%	<b>86.8%</b>	
Equity attributable to owners of the Company per share	1,273.28 yen	<b>1,291.15 yen</b>	

Total assets decreased to ¥742.9 billion by ¥4.0 billion from the end of the previous fiscal year.

Current assets decreased by ¥4.0 billion to ¥243.7 billion mainly due to a decrease in cash and cash equivalents, despite factors such as an increase in trade and other receivables.

Non-current assets were ¥499.2 billion, mostly unchanged from the end of the previous fiscal year mainly due to a decrease in investment securities, despite factors such as an increase in intangible assets.

Liabilities decreased by ¥12.9 billion to ¥92.7 billion mainly due to a decrease in income taxes payable.

Equity attributable to owners of the Company increased by ¥8.9 billion to ¥644.5 billion mainly due to an increase in retained earnings.

**(3) Overview of Cash Flows for the 1st Quarter of FY 2021**

(Millions of yen)

	Three months ended June 30, 2020	Three months ended June 30, 2021	Change
Cash and cash equivalents at the beginning of the period	69,005	<b>61,045</b>	
Cash flows from operating activities	10,412	<b>6,756</b>	(3,656)
Cash flows from investing activities	(3,776)	<b>(5,121)</b>	(1,345)
Cash flows from financing activities	(10,803)	<b>(13,276)</b>	(2,474)
Net increase (decrease) in cash and cash equivalents	(4,166)	<b>(11,641)</b>	
Effects of exchange rate changes on cash and cash equivalents	12	<b>57</b>	
Cash and cash equivalents at the end of the period	64,851	<b>49,462</b>	

Net increase/decrease in cash and cash equivalents was a decrease of ¥11.6 billion.

Net cash provided by operating activities was ¥6.8 billion, as a result of profit before tax of ¥30.8 billion, etc., while income taxes paid amounted to ¥18.2 billion and an increase in trade and other receivables of ¥7.9 billion, etc.

Net cash used in investing activities was ¥5.1 billion, as a result of purchases of intangible assets of ¥5.1 billion, etc.

Net cash used in financing activities was ¥13.3 billion, as a result of dividends paid of ¥12.6 billion, etc.

**(4) Future outlook**

There are no changes from the forecasts of consolidated financial results for the year ending March 31, 2022 announced on May 13, 2021. For the sales forecast of each major product, please refer to “4. Supplementary Information, (1) Sales Revenue and Forecasts of Major Products” on page 12. As for the impact of COVID-19 on business and financial results, we assume that restrictions on certain activities will continue, but we expect that the impact on operating profit will remain immaterial.

**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, 2021	As of June 30, 2021
Assets		
Current assets:		
Cash and cash equivalents	61,045	49,462
Trade and other receivables	84,269	92,142
Marketable securities	2,978	1,716
Other financial assets	40,952	40,966
Inventories	39,151	39,450
Other current assets	19,246	19,936
Total current assets	247,642	243,671
Non-current assets:		
Property, plant, and equipment	113,866	113,190
Intangible assets	70,322	73,188
Investment securities	146,796	144,143
Investments in associates	112	114
Other financial assets	131,888	131,980
Deferred tax assets	33,619	33,637
Retirement benefit assets	7	287
Other non-current assets	2,590	2,663
Total non-current assets	499,200	499,202
Total assets	746,842	742,873

(Millions of yen)

	As of March 31, 2021	As of June 30, 2021
<b>Liabilities and Equity</b>		
<b>Current liabilities:</b>		
Trade and other payables	39,163	32,536
Lease liabilities	2,023	1,931
Other financial liabilities	616	2,437
Income taxes payable	19,047	7,130
Provisions	20,721	20,721
Other current liabilities	12,163	16,115
<b>Total current liabilities</b>	<b>93,733</b>	<b>80,870</b>
<b>Non-current liabilities:</b>		
Lease liabilities	7,030	6,919
Other financial liabilities	0	0
Retirement benefit liabilities	3,056	3,112
Deferred tax liabilities	1,052	1,046
Other non-current liabilities	813	792
<b>Total non-current liabilities</b>	<b>11,952</b>	<b>11,870</b>
<b>Total liabilities</b>	<b>105,685</b>	<b>92,740</b>
<b>Equity:</b>		
Share capital	17,358	17,358
Capital reserves	17,231	17,211
Treasury shares	(44,705)	(44,675)
Other components of equity	62,299	60,677
Retained earnings	583,363	593,921
<b>Equity attributable to owners of the Company</b>	<b>635,547</b>	<b>644,493</b>
Non-controlling interests	5,610	5,641
<b>Total equity</b>	<b>641,157</b>	<b>650,133</b>
<b>Total liabilities and equity</b>	<b>746,842</b>	<b>742,873</b>



**(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, 2020	Three months ended June 30, 2021
Revenue	74,913	87,363
Cost of sales	(20,563)	(22,799)
Gross profit	54,350	64,564
Selling, general, and administrative expenses	(14,199)	(18,955)
Research and development costs	(12,343)	(15,245)
Other income	91	188
Other expenses	(856)	(760)
Operating profit	27,043	29,792
Finance income	1,289	1,316
Finance costs	(27)	(303)
Share of profit (loss) from investments in associates	2	(1)
Profit before tax	28,307	30,804
Income tax expense	(6,774)	(6,697)
Profit for the period	21,533	24,108
Profit for the period attributable to:		
Owners of the Company	21,496	24,074
Non-controlling interests	36	34
Profit for the period	21,533	24,108
Earnings per share:		
Basic earnings per share (Yen)	43.07	48.23
Diluted earnings per share (Yen)	43.06	48.22

**Condensed Interim Consolidated Statement of Comprehensive Income**

	(Millions of yen)	
	Three months ended June 30, 2020	Three months ended June 30, 2021
Profit for the period	21,533	24,108
Other comprehensive income (loss):		
Items that will not be reclassified to profit or loss:		
Net gain (loss) on financial assets measured at fair value through other comprehensive income	10,279	(1,684)
Remeasurements of defined benefit plans	334	210
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	4	3
Total of items that will not be reclassified to profit or loss	10,616	(1,471)
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	(9)	51
Net fair value gain (loss) on cash flow hedges	4	9
Total of items that may be reclassified subsequently to profit or loss	(5)	60
Total other comprehensive income (loss)	10,611	(1,411)
Total comprehensive income (loss) for the period	32,144	22,696
Comprehensive income (loss) for the period attributable to:		
Owners of the Company	32,104	22,662
Non-controlling interests	40	34
Total comprehensive income (loss) for the period	32,144	22,696

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

Three months ended June 30, 2020

(Millions of yen)

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

Three months ended June 30, 2021

(Millions of yen)

	Equity attributable to owners of the Company							Total equity
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	
Balance as of April 1, 2021	17,358	17,231	(44,705)	62,299	583,363	635,547	5,610	641,157
Profit for the period					24,074	24,074	34	24,108
Other comprehensive income (loss)				(1,412)		(1,412)	1	(1,411)
Total comprehensive income (loss) for the period	—	—	—	(1,412)	24,074	22,662	34	22,696
Purchase of treasury shares			(1)			(1)		(1)
Disposition of treasury shares		(31)	31			0		0
Cash dividends					(13,726)	(13,726)	(4)	(13,730)
Share-based payments		11				11		11
Transfer from other components of equity to retained earnings				(210)	210	—		—
Total transactions with the owners	—	(20)	30	(210)	(13,516)	(13,716)	(4)	(13,720)
Balance as of June 30, 2021	17,358	17,211	(44,675)	60,677	593,921	644,493	5,641	650,133

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

	(Millions of yen)	
	Three months ended June 30, 2020	Three months ended June 30, 2021
<b>Cash flows from operating activities</b>		
Profit before tax	28,307	30,804
Depreciation and amortization	3,823	4,289
Interest and dividend income	(1,237)	(1,116)
Interest expense	17	17
(Increase) decrease in inventories	(1,648)	(271)
(Increase) decrease in trade and other receivables	(527)	(7,858)
Increase (decrease) in trade and other payables	(2,833)	(6,436)
Increase (decrease) in retirement benefit liabilities	129	79
Other	2,844	4,305
Subtotal	28,875	23,815
Interest received	4	4
Dividends received	1,227	1,109
Interest paid	(17)	(17)
Income taxes paid	(19,677)	(18,155)
Net cash provided by (used in) operating activities	10,412	6,756
<b>Cash flows from investing activities</b>		
Purchases of property, plant, and equipment	(2,155)	(1,196)
Purchases of intangible assets	(1,513)	(5,099)
Purchases of investments	—	(50)
Proceeds from sales and redemption of investments	40	1,752
Payments into time deposits	(134)	—
Other	(14)	(529)
Net cash provided by (used in) investing activities	(3,776)	(5,121)
<b>Cash flows from financing activities</b>		
Dividends paid	(10,180)	(12,650)
Dividends paid to non-controlling interests	(6)	(4)
Repayments of lease liabilities	(617)	(622)
Purchases of treasury shares	(0)	(0)
Net cash provided by (used in) financing activities	(10,803)	(13,276)
Net increase (decrease) in cash and cash equivalents	(4,166)	(11,641)
Cash and cash equivalents at the beginning of the period	69,005	61,045
Effects of exchange rate changes on cash and cash equivalents	12	57
Cash and cash equivalents at the end of the period	64,851	49,462

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

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

Not Applicable

**(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

#### 4. Supplementary Information

##### (1) Sales Revenue and Forecasts of Major Products

(Billions of yen)

Product Name	Three months ended June 30, 2021 (April 1, 2021 to June 30, 2021)			FY 2021 Forecasts (April 1, 2021 to March 31, 2022)				
	Results	YoY		Previous Forecasts	Change from Previous Forecasts	Revised Forecasts	YoY	
		Change	Change (%)				Change	Change (%)
Opdivo Intravenous Infusion	29.0	4.6	18.7%	110.0		110.0	11.2	11.3%
Forxiga Tablets	7.5	2.3	43.3%	30.0	5.0	35.0	12.6	56.6%
Glactiv Tablets	6.5	(0.1)	(1.1%)	24.5		24.5	(1.0)	(3.9%)
Orencia for Subcutaneous Injection	5.7	0.2	4.5%	22.5		22.5	0.6	2.7%
Parsabiv Intravenous Injection	2.2	0.3	15.3%	8.0		8.0	(0.1)	(0.6%)
Kyprolis for Intravenous Infusion	2.0	0.3	18.9%	7.5		7.5	0.4	5.3%
Velexbru Tablets	1.4	1.4	1663.5%	3.5	1.5	5.0	2.9	142.6%
Onoact for Intravenous Infusion	1.2	0.2	15.3%	4.0		4.0	(0.7)	(14.1%)
Opalmon Tablets	1.2	(0.3)	(17.5%)	4.0		4.0	(1.5)	(26.7%)
Rivastach Patches	0.8	(1.2)	(60.7%)	3.0		3.0	(3.6)	(54.6%)
Braftovi Capsules	0.7	0.5	280.1%	3.0		3.0	1.9	180.6%
Ongentys Tablets	0.2	0.2	-	2.5		2.5	2.2	631.1%
Mektovi Tablets	0.5	0.4	236.3%	2.5		2.5	1.5	150.9%
Onon Capsules	1.1	0.4	67.6%	2.5		2.5	(0.4)	(14.2%)
Newly launched products during FY 2021	0.3	0.3	-	7.0	(4.5)	2.5	2.5	-

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

2. Regarding sales revenue forecasts for the FY 2021, only currently approved indications are covered.

3. Results for newly launched products during FY 2021 include sales of Adlumiz Tablets launched in April 2021 and Joyclu Intra-articular Injection launched in May 2021.

##### (2) Details of Sales Revenue

(Billions of yen)

	Three months ended June 30, 2020	Three months ended June 30, 2021
Revenue of goods and products	53.6	60.5
Royalty and others	21.3	26.8
Total	74.9	87.4

Notes: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥14.0 billion for the first quarter (three months) ended June 30, 2020 and ¥17.0 billion for the first quarter (three months) ended June 30, 2021. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥5.7 billion for the first quarter (three months) ended June 30, 2020 and ¥6.8 billion for the first quarter (three months) ended June 30, 2021.

##### (3) Revenue by Geographic Area

(Billions of yen)

	Three months ended June 30, 2020	Three months ended June 30, 2021
Japan	52.9	59.8
Americas	20.0	24.6
Asia	1.8	1.9
Europe	0.2	1.1
Total	74.9	87.4

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, 2021

**<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
Yervoy Injection ★ / Ipilimumab	Additional indication	Malignant pleural mesothelioma *1	Injection	Japan S. Korea	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

Changes from the announcement of financial results for the fiscal year ended March 2021

\*1: Applications were approved in Japan and South Korea for combination therapy of Opdivo and Yervoy for the treatment of unresectable advanced or recurrent malignant pleural mesothelioma.

**<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
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Urothelial cancer	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Cancer of unknown primary *2	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication for pediatric use	Hodgkin lymphoma*3	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)

Changes from the announcement of financial results for the fiscal year ended March 2021

\*2: An approval application for Opdivo was filed in Japan for the treatment of cancer of unknown primary.

\*3: An approval application for Opdivo was filed in Japan for the treatment of pediatric patients with hodgkin lymphoma.

**<Clinical Trial Stage>**

<b>&lt;Opdivo&gt;</b>						
*) : “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	Esophageal cancer	Injection	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	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	Injection	Japan S. Korea Taiwan	III	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 S. Korea Taiwan	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)

<b>&lt;Yervoy&gt;</b> *) : “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	Gastric cancer	Injection	Japan S. Korea Taiwan	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)
<b>&lt;I-O Related&gt;</b> *) : “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-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-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)
ONO-4578 *	New chemical entities	Colorectal cancer / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Pancreatic cancer / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Non-small cell lung cancer / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Solid tumor · Gastric cancer / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
ONO-7913 * /Magrolimab	New chemical entities	Pancreatic cancer* <sup>4</sup> / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
	New chemical entities	Colorectal cancer* <sup>4</sup> / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)



<b>&lt;Others&gt;</b>						
*) : “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
Braftovi Capsules / 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.)
Mektovi Tablets / 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.)
Braftovi Capsules / Encorafenib	Additional indication	Thyroid cancer / BRAF inhibitor	Capsule	Japan	II	In-license (Pfizer Inc.)
Mektovi Tablets / Binimetinib	Additional indication	Thyroid cancer / MEK inhibitor	Tablet	Japan	II	In-license (Pfizer Inc.)
ONO-4059 / Tirabrutinib Hydrochloride	New chemical entities	Primary central nervous system lymphoma *5 / BTK inhibitor	Tablet	USA	II	In-house
ONO-7475	New chemical entities	Acute leukemia / Axl/Mer inhibitor	Tablet	USA	I / II	In-house
	New chemical entities	Non-small cell lung cancer*6 / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-7912 (CPI-613) / Devimistat	New chemical entities	Pancreatic cancer / Cancer metabolism inhibitor	Injection	Japan	I	In-license (Rafael Pharmaceuticals, Inc.)
ONO-7913 / Magrolimab	New chemical entities	Solid tumor / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
	New chemical entities	Myelodysplastic syndromes (MDS)*7 / 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 2021

\*4: Phase I of combination therapy of Opdivo and ONO-7913 was initiated in Japan for the treatment of pancreatic cancer and colorectal cancer.

\*5: Phase II of ONO-4059 was initiated in the USA for the treatment of primary central nervous system lymphoma.

\*6: Phase I of ONO-7475 was initiated in Japan for the treatment of non-small cell lung cancer.

\*7: Phase I of ONO-7913 was initiated in Japan for the treatment of myelodysplastic syndromes (MDS).

\* Development of ONO-4483 for the treatment of solid tumor was discontinued in Japan due to strategic reasons.

\* Development involving combination therapy of Opdivo and Yervoy for the treatment of head and neck cancer was discontinued because it did not meet primary endpoints.

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 26, 2021

<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 $\beta_1$ blocker	Injection	Japan	II / III	In-house
Joyclu Intra-articular Injection / ONO-5704 / SI-613	Additional indication	Enthesopathy / Hyaluronic acid-NSAID	Injection	Japan	II	In-license (Seikagaku Corporation)
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Pemphigus / BTK inhibitor	Tablet	Japan	II	In-house
ONO-2910	New chemical entities	Diabetic polyneuropathy / Schwann cell differentiation promoter	Tablet	Japan	II	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	Japan Europe	I	In-house
ONO-2909	New chemical entities	Narcolepsy / Prostaglandin receptor (DP1) antagonist	Tablet	Japan	I	In-house
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Systemic sclerosis / BTK inhibitor	Tablet	Japan	I	In-house

Changes from the announcement of financial results for the fiscal year ended March 2021

\* Phase III of protease enzyme inhibitor Foipan Tablets for the treatment of COVID-19 in Japan was discontinued because the clinical trial did not demonstrate efficacy.