

## Consolidated Financial Results for the First Quarter of the Fiscal Year Ending March 31, 2023 (IFRS)

August 1, 2022

Company name	: <b>ONO PHARMACEUTICAL CO., LTD.</b>
Stock exchange listing	: Tokyo Stock Exchange
Code number	: 4528
URL	: <a href="https://www.ono-pharma.com/">https://www.ono-pharma.com/</a>
Representative	: Gyo Sagara President, Representative Director, and Chief Executive Officer
Contact	: Yukio Tani Corporate Executive Officer / Head of Corporate Communications
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Scheduled date of quarterly securities report submission	: August 5, 2022
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 2022 (April 1, 2022 to June 30, 2022)

#### (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 2022 Q1	106,722	22.2	38,162	28.1	39,041	26.7	29,528	22.5	29,477	22.4	29,697	30.8
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)

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY 2022 Q1	60.37	60.36
FY 2021 Q1	48.23	48.22

#### (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, 2022	764,187	677,702	671,894	87.9
As of March 31, 2022	739,203	661,674	655,906	88.7

### 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 2021	—	28.00	—	28.00	56.00
FY 2022	—				
FY 2022 (Forecast)		33.00	—	33.00	66.00

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

### 3. Consolidated Financial Forecast for FY 2022 (April 1, 2022 to March 31, 2023)

(% 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 2022	425,000	17.6	145,000	40.5	146,000	39.0	110,100	36.5	110,000	36.6	225.30

(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, 2022	517,425,200	shares
As of March 31, 2022	528,341,400	shares
  - 2) Number of treasury shares as of the end of the period:

As of June 30, 2022	29,180,909	shares
As of March 31, 2022	40,096,713	shares
  - 3) Average number of shares outstanding during the period:

Three months ended June 30, 2022	488,244,535	shares
Three months ended June 30, 2021	499,146,863	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 consolidated financial forecast.

## Index of the Attachment

<b>1. Overview of Operating Results and Other Information .....</b>	<b>2</b>
(1) Overview of Operating Results for the 1st Quarter of FY 2022 .....	2
(2) Overview of Financial Position for the 1st Quarter of FY 2022 .....	3
(3) Overview of Cash Flows for the 1st Quarter of FY 2022 .....	3
(4) Future Outlook.....	4
<b>2. Basic Approach to the Selection of Accounting Standards.....</b>	<b>4</b>
<b>3. Condensed Interim Consolidated Financial Statements and Major Notes.....</b>	<b>5</b>
(1) Condensed Interim Consolidated Statements of Financial Position.....	5
(2) Condensed Interim Consolidated Statements of Income and Condensed Interim Consolidated Statements of Comprehensive Income.....	7
(3) Condensed Interim Consolidated Statements of Changes in Equity .....	9
(4) Condensed Interim Consolidated Statements of Cash Flows.....	10
(5) Notes to Condensed Interim Consolidated Financial Statements.....	11
(Note Regarding Assumption of Going Concern) .....	11
(Segment Information) .....	11
(Significant Subsequent Events) .....	11
<b>4. Supplementary Information .....</b>	<b>12</b>
(1) Sales Revenue and Forecasts of Major Products .....	12
(2) Details of Sales Revenue .....	12
(3) Revenue by Geographic Area .....	12
(4) Main Status of Development Pipelines (Oncology).....	13
(5) Main Status of Development Pipelines (Areas other than Oncology) .....	16

## 1. Overview of Operating Results and Other Information

### (1) Overview of Operating Results for the 1st Quarter of FY 2022

(Millions of yen)

	Three months ended June 30, 2021	Three months ended June 30, 2022	Change	Change (%)
Revenue	87,363	<b>106,722</b>	19,359	22.2%
Operating profit	29,792	<b>38,162</b>	8,370	28.1%
Profit before tax	30,804	<b>39,041</b>	8,237	26.7%
Profit for the period (attributable to owners of the Company)	24,074	<b>29,477</b>	5,403	22.4%

#### [Revenue]

Revenue totaled ¥106.7 billion, which was an increase of ¥19.4 billion (22.2%) 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 gastric cancer, adjuvant therapy for esophageal cancer, and first-line treatment for non-small cell lung cancer, etc., resulting in sales of ¥34.1 billion, an increase of ¥5.1 billion (17.4%) year on year.
- With respect to other main products, sales of Forxiga Tablets for diabetes, chronic heart failure and chronic kidney disease were ¥13.1 billion (75.3% increase year on year), sales of Orencia Subcutaneous Injection for rheumatoid arthritis were ¥6.2 billion (9.4% increase year on year), sales of Glactiv Tablets for type-2 diabetes were ¥6.0 billion (6.7% decrease year on year), sales of Kyprolis for Intravenous Infusion for multiple myeloma were ¥2.2 billion (12.6% increase year on year), sales of Parsabiv Intravenous Injection for Dialysis for secondary hyperparathyroidism on hemodialysis were ¥2.1 billion (3.1% decrease year on year), sales of Velebru Tablets for malignant tumors were ¥2.1 billion (45.1% increase year on year), and sales of Ongentys Tablets for Parkinson's disease were ¥1.2 billion.
- Sales of long-term listed products were affected by the revision of the National Health Insurance (NHI) drug price reduction, etc., resulting in sales of Opalmon Tablets for peripheral circulatory disorder of ¥1.1 billion (6.5% decrease year on year) and sales of Onon Capsules for bronchial asthma and allergic rhinitis of ¥0.7 billion (36.3% decrease year on year).
- Royalty and others increased by ¥7.7 billion (28.8%) year on year to ¥34.6 billion.

#### [Operating profit]

Operating profit was ¥38.2 billion, an increase of ¥8.4 billion (28.1%) year on year.

- Cost of sales increased by ¥4.1 billion (18.1%) year on year to ¥26.9 billion mainly due to an increase in revenue of goods and products.
- Research and development costs increased by ¥4.2 billion (27.3%) year on year to ¥19.4 billion mainly due to increases in research costs and development costs for early clinical trials.
- Selling, general, and administrative expenses (except for research and development costs) increased by ¥2.8 billion (14.6%) year on year to ¥21.7 billion, mainly due to increases in co-promotion fees associated with expanding sales of Forxiga Tablets and investments in information infrastructure related to IT and digital technologies.

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

Profit attributable to owners of the Company increased by ¥5.4 billion (22.4%) year on year to ¥29.5 billion in association with the increase of the profit before tax.

**(2) Overview of Financial Position for the 1st Quarter of FY 2022**

(Millions of yen)

	As of March 31, 2022	As of June 30, 2022	Change
Total assets	739,203	<b>764,187</b>	24,983
Equity attributable to owners of the Company	655,906	<b>671,894</b>	15,988
Ratio of equity attributable to owners of the Company to total assets	88.7%	<b>87.9%</b>	
Equity attributable to owners of the Company per share	1,343.40 yen	<b>1,376.14 yen</b>	

Total assets increased by ¥25.0 billion to ¥764.2 billion from the end of the previous fiscal year.

Current assets increased by ¥30.7 billion to ¥312.0 billion mainly due to increases in cash and cash equivalents, and trade and other receivables.

Non-current assets decreased by ¥5.8 billion to ¥452.2 billion mainly due to decreases in investment securities and intangible assets.

Liabilities increased by ¥9.0 billion to ¥86.5 billion mainly due to an increase in income taxes payable.

Equity attributable to owners of the Company increased by ¥16.0 billion to ¥671.9 billion mainly due to the recording of the profit for the period despite there being cash dividends.

**(3) Overview of Cash Flows for the 1st Quarter of FY 2022**

(Millions of yen)

	Three months ended June 30, 2021	Three months ended June 30, 2022	Change
Cash and cash equivalents at the beginning of the period	61,045	<b>69,112</b>	
Cash flows from operating activities	6,756	<b>33,078</b>	26,322
Cash flows from investing activities	(5,121)	<b>(1,320)</b>	3,800
Cash flows from financing activities	(13,276)	<b>(13,355)</b>	(78)
Net increase (decrease) in cash and cash equivalents	(11,641)	<b>18,403</b>	
Effects of exchange rate changes on cash and cash equivalents	57	<b>424</b>	
Cash and cash equivalents at the end of the period	49,462	<b>87,940</b>	

Net increase/decrease in cash and cash equivalents for the first quarter (three months) of the fiscal year 2022 was an increase of ¥18.4 billion.

Net cash provided by operating activities was ¥33.1 billion, as a result of profit before tax of ¥39.0 billion, etc., while an increase in trade and other receivables of ¥10.1 billion and a decrease in trade and other payables of ¥5.9 billion, etc.

Net cash used in investing activities was ¥1.3 billion, as a result of purchases of property, plant, and equipment of ¥2.2 billion and purchases of intangible assets of ¥1.6 billion, while proceeds from sales and redemption of investments of ¥2.9 billion, etc.

Net cash used in financing activities was ¥13.4 billion as a result of dividends paid of ¥12.7 billion, etc.

#### **(4) Future Outlook**

There are no changes from the consolidated financial forecast for the year ending March 31, 2023 announced on May 11, 2022. As for the impact of the novel coronavirus disease (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 Statements of Financial Position

	(Millions of yen)	
	As of March 31, 2022	As of June 30, 2022
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	69,112	87,940
Trade and other receivables	99,788	110,138
Marketable securities	60	20
Other financial assets	47,797	48,224
Inventories	41,817	42,641
Other current assets	22,692	23,043
<b>Total current assets</b>	<b>281,266</b>	<b>312,007</b>
<b>Non-current assets</b>		
Property, plant, and equipment	112,131	110,718
Intangible assets	64,734	63,124
Investment securities	125,046	121,210
Investments in associates	108	113
Other financial assets	127,302	127,237
Deferred tax assets	25,074	26,061
Retirement benefit assets	377	362
Other non-current assets	3,165	3,354
<b>Total non-current assets</b>	<b>457,937</b>	<b>452,180</b>
<b>Total assets</b>	<b>739,203</b>	<b>764,187</b>

(Millions of yen)

	As of March 31, 2022	As of June 30, 2022
<b>Liabilities and Equity</b>		
<b>Current liabilities</b>		
Trade and other payables	49,689	41,657
Lease liabilities	2,301	2,272
Other financial liabilities	716	2,805
Income taxes payable	1,526	10,349
Other current liabilities	11,694	17,928
<b>Total current liabilities</b>	<b>65,926</b>	<b>75,011</b>
<b>Non-current liabilities</b>		
Lease liabilities	6,501	6,377
Other financial liabilities	0	0
Retirement benefit liabilities	3,322	3,359
Deferred tax liabilities	1,009	995
Other non-current liabilities	771	743
<b>Total non-current liabilities</b>	<b>11,603</b>	<b>11,473</b>
<b>Total liabilities</b>	<b>77,529</b>	<b>86,484</b>
<b>Equity</b>		
Share capital	17,358	17,358
Capital reserves	17,241	17,080
Treasury shares	(74,683)	(54,328)
Other components of equity	51,236	50,282
Retained earnings	644,754	641,501
<b>Equity attributable to owners of the Company</b>	<b>655,906</b>	<b>671,894</b>
Non-controlling interests	5,768	5,808
<b>Total equity</b>	<b>661,674</b>	<b>677,702</b>
<b>Total liabilities and equity</b>	<b>739,203</b>	<b>764,187</b>



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

**Condensed Interim Consolidated Statements of Income**

	(Millions of yen)	
	Three months ended June 30, 2021	Three months ended June 30, 2022
Revenue	87,363	106,722
Cost of sales	(22,799)	(26,937)
Gross profit	64,564	79,785
Selling, general, and administrative expenses	(18,955)	(21,726)
Research and development costs	(15,245)	(19,413)
Other income	188	106
Other expenses	(760)	(590)
Operating profit	29,792	38,162
Finance income	1,316	1,159
Finance costs	(303)	(279)
Share of profit (loss) from investments in associates	(1)	0
Profit before tax	30,804	39,041
Income tax expense	(6,697)	(9,513)
Profit for the period	24,108	29,528
Profit for the period attributable to:		
Owners of the Company	24,074	29,477
Non-controlling interests	34	51
Profit for the period	24,108	29,528
Earnings per share:		
Basic earnings per share (Yen)	48.23	60.37
Diluted earnings per share (Yen)	48.22	60.36

**Condensed Interim Consolidated Statements of Comprehensive Income**

	(Millions of yen)	
	Three months ended June 30, 2021	Three months ended June 30, 2022
Profit for the period	24,108	29,528
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	(1,684)	(845)
Remeasurements of defined benefit plans	210	(10)
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	3	4
Total of items that will not be reclassified to profit or loss	(1,471)	(850)
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	51	875
Net fair value gain (loss) on cash flow hedges	9	144
Total of items that may be reclassified subsequently to profit or loss	60	1,019
Total other comprehensive income (loss)	(1,411)	169
Total comprehensive income (loss) for the period	22,696	29,697
Comprehensive income (loss) for the period attributable to:		
Owners of the Company	22,662	29,650
Non-controlling interests	34	47
Total comprehensive income (loss) for the period	22,696	29,697

**(3) Condensed Interim Consolidated Statements of Changes in Equity**

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	581,950	634,133	5,610	639,743
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	592,507	643,079	5,641	648,720

Three months ended June 30, 2022

(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, 2022	17,358	17,241	(74,683)	51,236	644,754	655,906	5,768	661,674
Profit for the period					29,477	29,477	51	29,528
Other comprehensive income (loss)				173		173	(4)	169
Total comprehensive income (loss) for the period	—	—	—	173	29,477	29,650	47	29,697
Purchase of treasury shares			(1)			(1)		(1)
Retirement of treasury shares		(171)	20,356		(20,185)	—		—
Cash dividends					(13,671)	(13,671)	(6)	(13,677)
Share-based payments		10				10		10
Transfer from other components of equity to retained earnings				(1,127)	1,127	—		—
Total transactions with the owners	—	(161)	20,355	(1,127)	(32,729)	(13,662)	(6)	(13,669)
Balance as of June 30, 2022	17,358	17,080	(54,328)	50,282	641,501	671,894	5,808	677,702

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

	(Millions of yen)	
	Three months ended June 30, 2021	Three months ended June 30, 2022
Cash flows from operating activities		
Profit before tax	30,804	39,041
Depreciation and amortization	4,289	4,303
Interest and dividend income	(1,116)	(1,158)
Interest expense	17	22
(Increase) decrease in inventories	(271)	(674)
(Increase) decrease in trade and other receivables	(7,858)	(10,124)
Increase (decrease) in trade and other payables	(6,436)	(5,937)
Increase (decrease) in retirement benefit liabilities	79	24
(Increase) decrease in retirement benefit assets	—	12
Other	4,305	7,485
Subtotal	23,815	32,995
Interest received	4	8
Dividends received	1,109	1,157
Interest paid	(17)	(22)
Income taxes paid	(18,155)	(1,060)
Net cash provided by (used in) operating activities	6,756	33,078
Cash flows from investing activities		
Purchases of property, plant, and equipment	(1,196)	(2,166)
Purchases of intangible assets	(5,099)	(1,608)
Purchases of investments	(50)	(88)
Proceeds from sales and redemption of investments	1,752	2,880
Other	(529)	(339)
Net cash provided by (used in) investing activities	(5,121)	(1,320)
Cash flows from financing activities		
Dividends paid	(12,650)	(12,652)
Dividends paid to non-controlling interests	(4)	(6)
Repayments of lease liabilities	(622)	(696)
Purchases of treasury shares	(0)	(1)
Net cash provided by (used in) financing activities	(13,276)	(13,355)
Net increase (decrease) in cash and cash equivalents	(11,641)	18,403
Cash and cash equivalents at the beginning of the period	61,045	69,112
Effects of exchange rate changes on cash and cash equivalents	57	424
Cash and cash equivalents at the end of the period	49,462	87,940

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

**(Note Regarding Assumption of 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, 2022 (April 1, 2022 to June 30, 2022)			FY 2022 Forecast (April 1, 2022 to March 31, 2023)		
	Result	YoY		Forecast	YoY	
		Change	Change (%)		Change	Change (%)
Opdivo Intravenous Infusion	34.1	5.1	17.4%	155.0	42.6	37.8%
Forxiga Tablets	13.1	5.6	75.3%	47.0	10.3	28.2%
Orencia for Subcutaneous Injection	6.2	0.5	9.4%	23.0	0.1	0.5%
Glactiv Tablets	6.0	(0.4)	(6.7%)	23.0	(1.5)	(6.3%)
Kyprolis for Intravenous Infusion	2.2	0.3	12.6%	9.0	0.6	7.6%
Parsabiv Intravenous Injection	2.1	(0.1)	(3.1%)	8.0	(0.9)	(9.9%)
Velexbru Tablets	2.1	0.6	45.1%	7.0	0.7	11.7%
Ongentys Tablets	1.2	1.0	399.8%	5.0	2.1	73.6%
Onoact for Intravenous Infusion	1.1	(0.1)	(8.7%)	4.5	(0.4)	(7.6%)
Opalmon Tablets	1.1	(0.1)	(6.5%)	3.5	(1.2)	(26.0%)
Braftovi Capsules	0.9	0.2	30.6%	3.5	0.8	27.4%
Mektovi Tablets	0.7	0.2	29.5%	2.5	0.3	11.7%
Onon Capsules	0.7	(0.4)	(36.3%)	2.5	(1.1)	(29.7%)

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

2. Regarding sales revenue forecasts for the FY 2022, only currently approved indications are covered.

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

(Billions of yen)

	Three months ended June 30, 2021	Three months ended June 30, 2022
Revenue of goods and products	60.5	72.2
Royalty and others	26.8	34.6
Total	87.4	106.7

Note: In "Royalty and others", royalty revenue of Opdivo Intravenous Infusion from Bristol-Myers Squibb Company is included, which is ¥17.0 billion for the first quarter (three months) ended June 30, 2021 and ¥20.8 billion for the first quarter (three months) ended June 30, 2022. And, royalty revenue of Keytruda® from Merck & Co., Inc. is included, which is ¥6.8 billion for the first quarter (three months) ended June 30, 2021 and ¥9.8 billion for the first quarter (three months) ended June 30, 2022.

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

(Billions of yen)

	Three months ended June 30, 2021	Three months ended June 30, 2022
Japan	59.8	70.8
Americas	24.6	31.9
Asia	1.9	2.7
Europe	1.1	1.3
Total	87.4	106.7

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

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

As of July 25, 2022

**<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	Esophageal cancer *1	Injection	Japan Taiwan	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo

The change from the announcement of financial results for the fiscal year ended March 2022 is as follows:

\*1: Applications for the combination therapy of Opdivo and Yervoy, and the combination therapy of Opdivo and chemotherapy were approved in Japan and Taiwan for the treatment of unresectable advanced or recurrent esophageal cancer.

**<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	Hepatocellular carcinoma	Injection	Japan S. Korea	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	Japan S. Korea Taiwan	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	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	S. Korea	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial carcinoma	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-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-7475 ★	New chemical entities	Solid tumor / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-4578 ★	New chemical entities	Colorectal cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Pancreatic cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Non-small cell lung cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Solid tumor • Gastric cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
ONO-7913 ★ / Magrolimab	New chemical entities	Pancreatic cancer / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
	New chemical entities	Colorectal cancer / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
ONO-7119 ★ / Atamparib	New chemical entities	Solid tumor / PARP7 inhibitor	Tablet	Japan	I	In-license (Ribon Therapeutics, Inc.)
ONO-7122 ★	New chemical entities	Solid tumor / TGF-β inhibitor	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-7914 ★	New chemical entities	Solid tumor / STING agonist	Injection	Japan	I	In-house



<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
ONO-7913 / Magrolimab	New chemical entities	TP53-mutant acute myeloid leukemia / Anti-CD47 antibody	Injection	Japan	III	In-license (Gilead Sciences, Inc.)
	New chemical entities	Acute myeloid leukemia / Anti-CD47 antibody	Injection	S. Korea Taiwan	III	In-license (Gilead Sciences, 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 / 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	EGFR-mutated non-small cell lung cancer / Axl/Mer inhibitor	Tablet	Japan	I	In-house
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) / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
ONO-4578	New chemical entities	Hormone receptor-positive, HER2-negative breast cancer / Prostaglandin receptor (EP4) antagonist	Tablet	Japan	I	In-house
ONO-4685	New chemical entities	T-cell lymphoma / PD-1 x CD3 bispecific antibody	Injection	USA	I	In-house

★: Combination with Opdivo

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 25, 2022

<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
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / Short-acting selective $\beta_1$ blocker	Injection	Japan	In-house

<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
ONO-2017 / Cenobamate	New chemical entities	Primary generalized tonic- clonic seizures / Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABA <sub>A</sub> ion channel	Tablet	Japan	III	In-license (SK Bipharmaceuticals)
	New chemical entities	Partial-onset seizures / Inhibition of voltage-gated sodium currents/positive allosteric modulator of GABA <sub>A</sub> ion channel	Tablet	Japan	III	In-license (SK Bipharmaceuticals)
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Pemphigus / BTK inhibitor	Tablet	Japan	III	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 Europe	I	In-house
ONO-7684	New chemical entities	Thrombosis / FXIa inhibitor	Tablet	Europe	I	In-house
ONO-2808	New chemical entities	Neurodegenerative disease / S1P5 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
ONO-2020 *2	New chemical entities	Neurodegenerative disease / Epigenetic Regulation	Tablet	USA	I	In-house

The change from the announcement of financial results for the fiscal year ended March 2022 is as follows:

\*2: Phase I of ONO-2020 (Epigenetic Regulation) was initiated in the U.S. for the treatment of neurodegenerative disease.