Revenue

Revenue	YoY
¥ 225.3 billion	+ 0.9 %

Breakdown of Revenue

(Billion yen)

	FY 2018 Q3	FY 2019 Q3	YoY
Revenue of Goods and Products	163.8	161.1	− 1.7 %
Royalty & Other Revenue	59.4	64.2	+ 8.1 %
(Opdivo)	(43.3)	(46.0)	(+ 6.1 %)
Total	223.2	225.3	+ 0.9 %

In Q3, revenue increased by JPY2.1 billion, 0.9% YoY, to JPY225.3 billion. The breakdown of revenues was as follows. Product sales of Orencia SC, Forxiga, Parsabiv, etc. were firm, but sales of Opdivo and long-term listed products decreased. As a result, product revenue decreased by JPY2.7 billion, -1.7% YoY, to JPY161.1 billion.

Royalties and other revenues increased by JPY4.8 billion, 8.1% YoY, to JPY64.2 billion. Royalty income for Opdivo, primarily from Bristol-Myers Squibb, rose by JPY2.7 billion, 6.1%, to JPY46.0 billion. Royalty income from Merck increased by JPY4.8 billion, 53.0% YoY, to JPY13.8 billion.

Revenue

Sales of Major Products

(Billion yen)

	FY 2018 Q3	FY 2019 Q3	YoY
Opdivo	71.3	**68.0**	- 4.7 %
Glactiv	21.2	**20.5**	- 3.0 %
Orencia SC	13.4	**15.2**	+ 13.1 %
Forxiga	11.1	**13.8**	+ 24.5 %
Emend/Proemend	8.2	**8.9**	+ 7.9 %
Rivastach	7.0	**6.7**	- 4.0 %
Parsabiv	4.4	**5.5**	+ 23.7 %
Kyprolis	3.9	**4.6**	+ 18.0 %
Onoact	3.6	**4.0**	+ 10.2 %
Staybla	2.9	**2.5**	- 16.0 %

By product, sales of Opdivo, an anticancer drug, decreased by JPY3.4 billion, -4.7% YoY, to JPY68.0 billion. This was due to the impact of the NHI price revision in November 2018 and intensified competition with competitors' products, despite an increase in the use for the treatment of renal cell cancer and other cancers.

As for other major products, sales of Orencia, for a rheumatoid arthritis, rose by JPY1.8 billion, 13.1%, to JPY15.2 billion. Forxiga, for diabetes, rose by JPY2.7 billion, 24.5%, to JPY13.8 billion. Sales of Emend and Proemend, for nausea and vomiting associated with anticancer drugs, totaled JPY8.9 billion, an increase of JPY0.6 billion, 7.9%.

Sales of Parsabiv, for a secondary hyperparathyroidism under hemodialysis, increased by JPY1 billion, or 23.7%, to JPY5.5 billion. Sales of Kyprolis, for multiple myeloma, increased by JPY0.7 billion, 18%, to JPY4.6 billion.

Meanwhile, sales of Glactiv, for type 2 diabetes, decreased by JPY0.6 billion, -3% YoY, to JPY20.5 billion. Sales of Rivastach, for Alzheimer's dementia, declined by JPY0.3 billion, -4%, to JPY6.7 billion.

Revenue

Sales of Long-term Listed Products

(Billion yen)

	FY 2018 Q3	FY 2019 Q3	YoY
Opalmon	8.3	**6.7**	- 19.0 %
Recalbon	6.1	**3.9**	- 36.7 %
Onon Capsule	3.0	**2.5**	- 18.6 %
Onon Dry Syrup	2.0	**1.7**	- 17.0 %

Sales of long-term listed products declined sharply for both Opalmon and Recalbon due to the impact of measures to promote the use of generics.

Operating Profit

Operating Profit	YoY
¥ 66.0 billion	+ 26.7 %

Costs, etc.

(Billion yen)

	FY 2019 Q3	YoY	
・Cost of Sales	61.6	(- 7.6%)	
・R&D Expenses	45.4	(- 11.3%)	①
・SG&A Expenses	50.9	(- 2.4%)	②
①+② Total	96.3	(- 6.8%)	
・Other Income	0.6	(+ 0.2%)	
・Other Expenses	2.0	(+ 16.0%)	

Operating profit rose by JPY13.9 billion, 26.7% YoY, to JPY66.0 billion. In terms of expenses, cost of sales decreased by JPY5.0 billion, -7.6%, to JPY61.6 billion, mainly due to the absence of one-time contribution incurred in the same period of the previous fiscal year to secure stable supplies of the active pharmaceutical ingredients for Opdivo.

R&D expenses declined by JPY5.8 billion, -11.3% YoY, to JPY45.4 billion, mainly due to a decrease in clinical trial expenses and licensing fees for drug discovery partnerships. Selling, general, and administrative (SG&A) expenses, excluding R&D expenses, decreased by JPY1.2 billion, -2.4%, to JPY50.9 billion, mainly due to a decrease in operating expenses.

Profit before Tax

Profit before Tax	YoY
¥ 68.7 billion	+ 24.4 %

Net Financial Income

+ ¥ 2.6 billion (- ¥ 0.4 billion YoY)

Finance Income :	**¥ 3.0 billion**
(Interest and dividend income received, etc.)	
Finance Costs :	**¥ 0.4 billion**
(Interest expense arising from lease obligations and employee retirement benefit, exchange losses etc.)	

As for profit before tax, finance income decreased by JPY0.2 billion YoY to JPY3.0 billion and finance costs increased by JPY0.2 billion YoY, resulting in net financial income of JPY2.6 billion. As a result, profit before tax increased by JPY13.5 billion YoY to JPY68.7 billion.

Profit for the Period
(Owners of the Parent Company)

Profit for the Period (Owners of the Parent Company)	YoY
¥ 51.8 billion	+ 20.2 %

Income Tax Expense

¥ 16.7 billion (+ 38.9 % YoY)

(Major Change Factors)

Increase in profit before tax	¥	13.5 billion
Increase in corporate tax	¥	4.7 billion

Profit for the period attributable to owners of the parent company increased by JPY8.7 billion, 20.2% YoY, to JPY51.8 billion.

Next, we will report our earnings forecasts for the fiscal year ending March 31, 2020. Revenue remains unchanged from the previous forecast. Regarding expenses, we have revised down R&D expenses and SG&A expenses by JPY2 billion, respectively, while the previously announced forecast for cost of sales remains unchanged. Regarding details of the revisions, please refer to Page 4 of the Consolidated Financial Results.

(4) Future outlook

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

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

(Millions of yen)

	Revenue	Operating profit	Profit before tax	Profit for the year	Profit attributable to owners of the Company	Basic earnings per share
Previous forecast (A)	290,000	67,000	70,000	53,100	53,000	103.09 yen
Revised forecast (B)	290,000	71,000	73,000	55,100	55,000	108.82 yen
Amount of change (B-A)	—	4,000	3,000	2,000	2,000	
Change (%)	—	6.0	4.3	3.8	3.8	
(Reference) Consolidated results of FY2018	288,634	62,010	65,141	51,679	51,539	100.25 yen

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

Note: The financial forecasts and statements contained in this announcement are made based on information that is available as of the date the announcement is made. Actual results may differ from those set forth in the announcements due to various uncertain factors.

2. Basic Approach to the Selection of Accounting Standards

Our group has applied International Financial Reporting Standards (IFRSs) from the fiscal year ended March 31, 2014, for the purpose of improving comparability by disclosing financial information based on international standards and enhancing the convenience of various stakeholders such as shareholders, investors, and business partners.

Revenue (Forecasts)

Revenue	YoY
¥ 290.0 billion	+ 0.5 %

Breakdown of Revenue

(Billion yen)

	FY 2018 (Result)	FY 2019 (Forecast)	YoY
Revenue of Goods and Products	208.9	202.0	− 3.3 %
Royalty & Other Revenue	79.7	88.0	+ 10.4 %
Total	288.6	290.0	+ 0.5 %

With regard to the consolidated financial results forecast, there is no change in the revenue forecast of JPY290 billion.

Operating Profit (Forecasts)

Operating Profit	YoY
¥ 71.0 billion	＋ 14.5 %

Costs, etc.

(Billion yen)

	FY 2019 (Forecast)	YoY
・Cost of Sales	77.0	(- 8.1 %)
・R&D Expenses	70.0	(- 0.0 %) ①
・SG&A Expenses	70.0	(- 0.0 %) ②
①+② Total	140.0	(- 0.0 %)
・Other Income	0.5	(- 22.6 %)
・Other Expenses	2.5	(- 26.5 %)

We revised operating profit forecast upwardly by JPY4.0 billion, from JPY67 billion to JPY71 billion.

Profit before Tax (Forecasts)

Profit before Tax	YoY
¥ 73.0 billion	+ 12.1 %

Net Financial Income

+ ¥ 2.0 billion (- 36.2 % YoY)

We revised our forecast for profit before tax upwardly by JPY3 billion, from JPY70 billion to JPY73 billion.

Profit for the Period /Owners of the Parent Company (Forecasts)

Profit for the Period (Owners of the Parent Company)	YoY
¥ 55.0 billion	+ 6.7 %

Income Tax Expense

¥ 17.9 billion (+ 33.0 % YoY)

(Major Change Factors)

Increase in profit before tax	¥ 7.9 billion
Increase in corporate tax	¥ 4.4 billion

We revised profit for the period attributable to owners of the parent company upwardly by JPY2 billion, from JPY53.0 billion to JPY55.0 billion.

We plan to pay a year-end dividend of JPY22.5 per share, which remains unchanged.

We have not revised our full-year forecasts for individual products. In fact, sales of Opdivo, Orencia SC, Forxiga, etc. exceeded forecasts.

On the other hand, sales of Glactiv and Rivastach were slightly below the plan. Despite such unexpected trends, we have not made any revision at this time. We would appreciate your attention.

Now, we will explain the progress of our main development pipelines and the prospects for future applications.

We will make updates from the announcement of the Q2 financial results on October 31, 2019. The status of the main development products is shown on pages 14 to 22 of the Financial Results. We will explain the status using this material.

On the material, the situations of the oncology field in Japan, South Korea/Taiwan, and Europe/the United States are described in that order. Subsequently, areas other than oncology are described in the same order.

(4) Main Status of Development Pipelines (Oncology)

As of January 24, 2020

1. Development Status in Japan

<Approved>

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

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

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

<Filed>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
ONO-7643 / Anamorelin	New chemical entities	Cancer cachexia / Ghrelin receptor agonist	Tablet	In-license (Helsinn Healthcare, S.A.)
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Colorectal cancer (MSI-H)	Injection	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Central nervous system lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	In-house
	New chemical entities	Primary macroglobulinemia, Lymphoplasmacytic lymphoma *2 / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	In-house
Yervoy Injection ★ / Ipilimumab	Additional indication	Colorectal cancer (MSI-H) *3	Injection	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Non-small cell lung cancer *4	Injection	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo

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

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

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

*4: An approval application for combination therapy of Opdivo and Yervoy was filed for the treatment of unresectable advanced or recurrent non-small cell lung cancer.

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

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

At the top, Kyprolis for intravenous infusion was approved for multiple myeloma for once-a-week dosage and administration, in addition to the twice-a-week treatment.

As shown in the table below in the third row of ONO-4059, we have submitted an application for the indication of Waldenstrom macroglobulinemia and lymphoplasmacytic lymphoma.

We have also applied for approval for the Yervoy Injection, in combination with Opdivo, for the treatment of microsatellite instability-high (MSI-H) colorectal cancer. In addition, we filed an application for combination therapy of Opdivo with Yervoy for the treatment of non-small cell lung cancer.

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
ONO-4687 ★ (BMS-986227) / Cabiralizumab	New chemical entities	Pancreatic cancer / Anti-CSF-1R antibody	Injection	II	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Solid tumor (Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma)	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central nervous system lymphoma / Primary testicular lymphoma	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Pancreatic cancer	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Biliary tract cancer *5	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection ★ / Ipilimumab	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4686 ★ (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4482 ★ (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7807 ★ (BMS-986258)	New chemical entities	Solid tumor / Anti-TIM-3 antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483 ★ (BMS-986015) / Lirilumab	New chemical entities	Solid tumor / Anti-KIR antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4578 ★	New chemical entities	Solid tumor / PG receptor (EP4) antagonist	Tablet	I	In-house
ONO-7705 / Selinexor	New chemical entities	Multiple myeloma and non-hodgkin lymphoma / XPO1 inhibitor	Tablet	I	In-license (Karyopharm Therapeutics Inc.)
ONO-7475 ★	New chemical entities	Solid tumor / Axl/Mer inhibitor	Tablet	I	In-house
ONO-7911 ★ (BMS-986321) / Bempegaldesleukin	New chemical entities	Solid tumor / PEGylated interleukin-2	Injection	I	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo

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

*5: Phase II of Opdivo was initiated for the treatment of biliary tract cancer.

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

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

As shown in the fourth row of Opdivo, we have started Phase II trials for bladder cancer.

2. Development Status in South Korea and Taiwan

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Esophageal cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	South Korea	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Bladder cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection ★ / Ipilimumab	Additional indication	Non-small cell lung cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
ONO-7702 / Encorafenib	New chemical entities	Colorectal cancer / BRAF inhibitor	Capsule	III	South Korea	In-license (Pfizer Inc.)
	New chemical entities	Melanoma / BRAF inhibitor	Capsule	III	South Korea	In-license (Pfizer Inc.)
ONO-7703 / Binimetinib	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	III	South Korea	In-license (Pfizer Inc.)
	New chemical entities	Melanoma / MEK inhibitor	Tablet	III	South Korea	In-license (Pfizer Inc.)
ONO-7701 ★ (BMS-986205) / Linrodostat	New chemical entities	Bladder cancer / IDO1 inhibitor	Tablet	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
ONO-7912 *6 (CPI-613) / Devimistat	New chemical entities	Pancreatic cancer / Cancer metabolism inhibitor	Injection	III	South Korea	In-license (Rafael Pharmaceuticals, Inc.)
	New chemical entities	Acute myeloid leukemia / Cancer metabolism inhibitor	Injection	III	South Korea	In-license (Rafael Pharmaceuticals, Inc.)
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Pancreatic cancer	Injection	II	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
ONO-4687 ★ (BMS-986227) / Cabiralizumab	New chemical entities	Pancreatic cancer / Anti-CSF-1R antibody	Injection	II	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)

We began Phase III trials of ONO-7912 in South Korea for the treatment of pancreatic cancer and acute myeloid leukemia.

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

As of January 24, 2020

1. Development Status in Japan

<Filed>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
ONO-2370 / Opicapone	New chemical entities	Parkinson's disease / Long acting COMT inhibitor	Tablet	In-license (Bial)
Orencia IV Orencia SC / Abatacept	Additional indication	Structural damage of the joints in rheumatoid arthritis / T-cell activation inhibitor	Injection	In-license (Bristol-Myers Squibb)
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication	Tachyarrhythmia upon sepsis / β_1 blocker (short acting)	Injection	In-house
ONO-5704 *7 / SI-613	New chemical entities	Osteoarthritis / Hyaluronic acid-NSAID	Injection	In-license (Seikagaku Corporation)

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

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

<Clinical Trial Stage>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Orencia SC / Abatacept	Additional indication	Untreated rheumatoid arthritis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
	Additional indication	Primary Sjögren syndrome / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
	Additional indication	Polymyositis / Dermatomyositis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / β_1 blocker (short acting)	Injection	II / III	In-house
ONO-5704 / SI-613	New chemical entities	Enthesopathy / Hyaluronic acid-NSAID	Injection	II	In-license (Seikagaku Corporation)
ONO-4059 / Tirabrutinib	New chemical entities	Pemphigus / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	In-house
ONO-7269	New chemical entities	Cerebral infarction / FXIa inhibitor	Injection	I	In-house
ONO-4685	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	Injection	I	In-house

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

This page shows non-oncology. In the table of clinical trial stage, you find ONO-5704. This is a compound in-licensed from Seikagaku Corporation. The application was filed on January 6 for the treatment of osteoarthritis.

2. Development Status in Overseas

<Clinical Trial Stage>

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

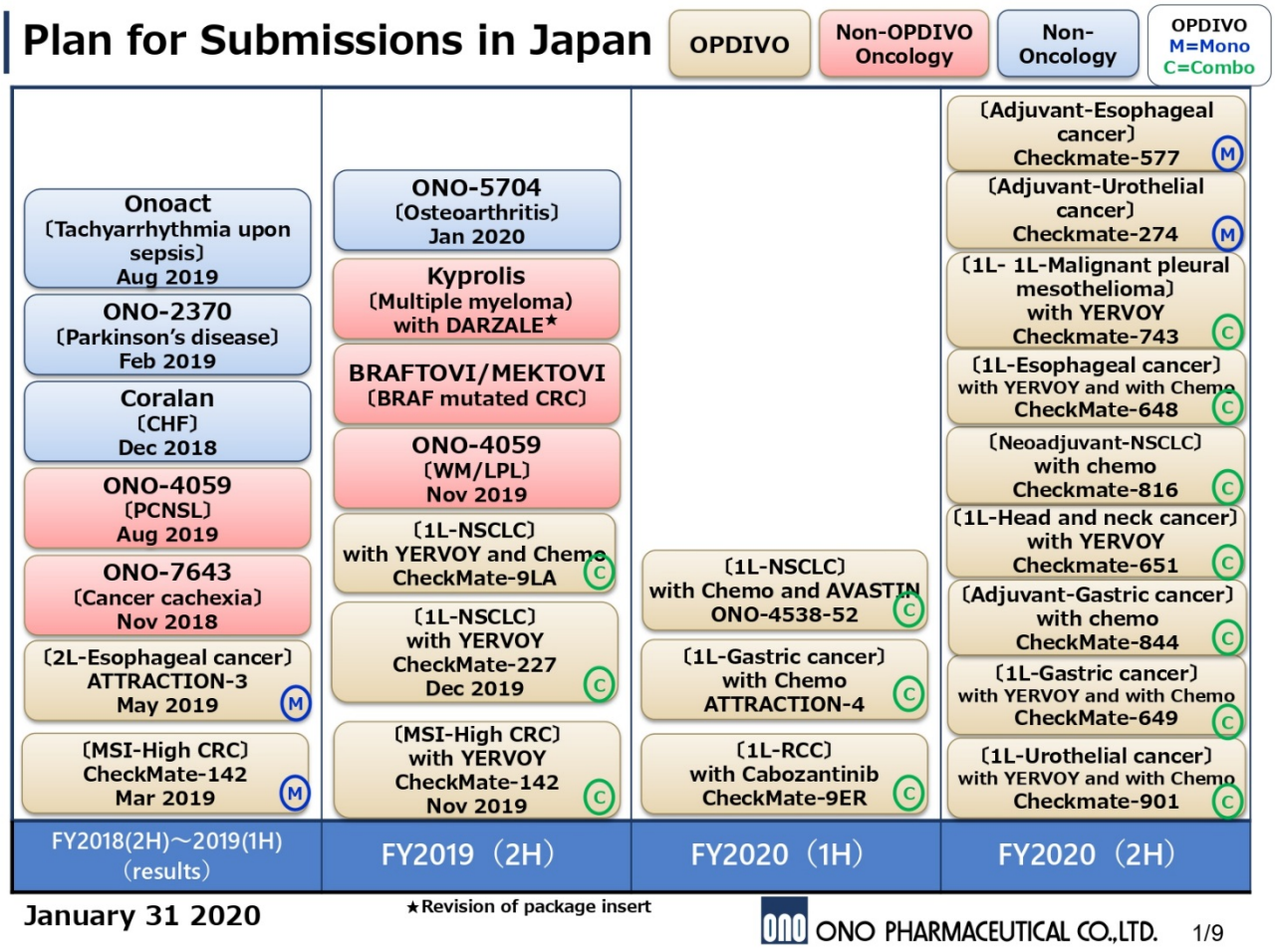
Changes from the announcement of financial results for the second quarter of the fiscal year ending March 2020
*8: Phase I of S1P5 receptor agonist (ONO-2808) was initiated for treatment in healthy adults.
*Phase I of growth hormone secretion inhibitor (ONO-5788) for the treatment of acromegaly was discontinued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

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

Overseas clinical trials. You find ONO-2808 at the bottom, a new compound from our research laboratory. This is a S1P5 receptor agonist for the treatment of neurodegenerative diseases. We initiated Phase I study.

In addition, we discontinued clinical trials of ONO-5788, an oral agonist for somatostatin receptor, for strategic reasons.

This is the update, but we have also updated the progress of each pipeline posted on our website. Please refer to it later.

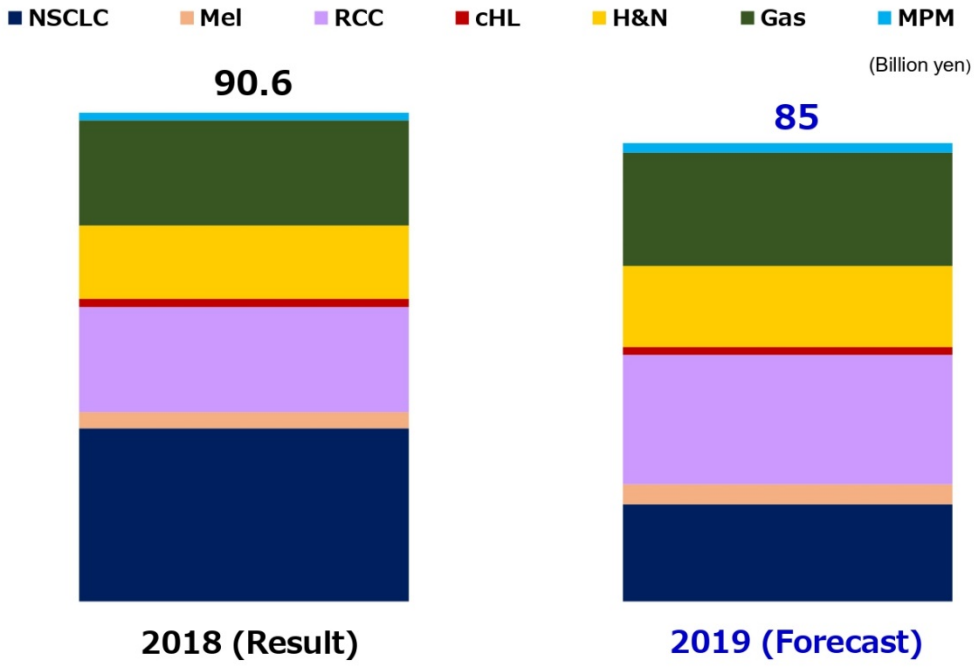


We slightly changed the method of presenting future application schedules.

Previously, it was divided into two colors, but this time it is divided into three colors: yellow is Opdivo, red is non-Opdivo oncology, and blue is non-oncology.

As before, for Opdivo, M is indicated at the right end for single agent, and C is indicated at the right end for combined use. In the case of Opdivo, the names of the study code have been added. Please check the details later.

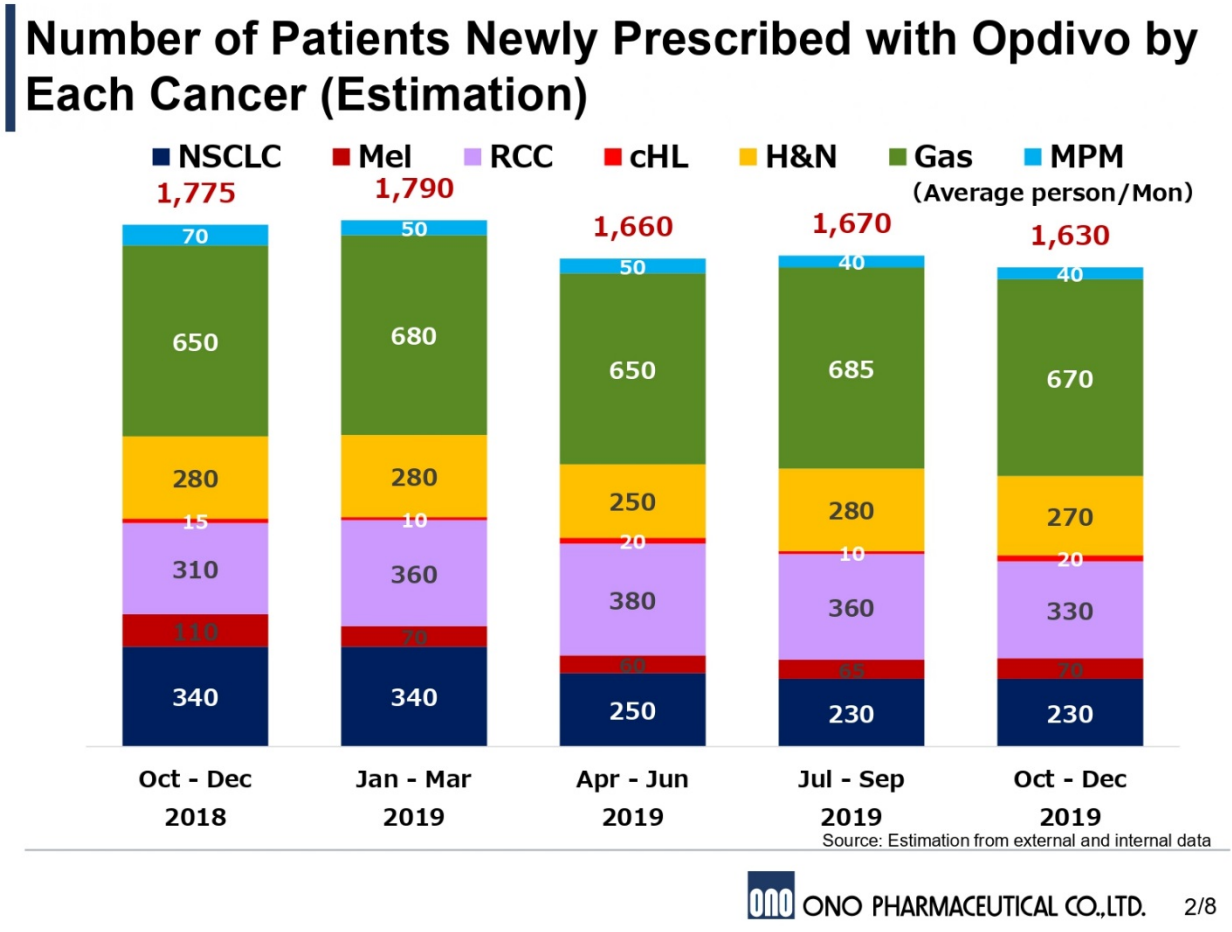
Sales of Opdivo by Each Cancer (Estimation)



Dosage and administration re-pricing in Nov 2018 (-37.5%)

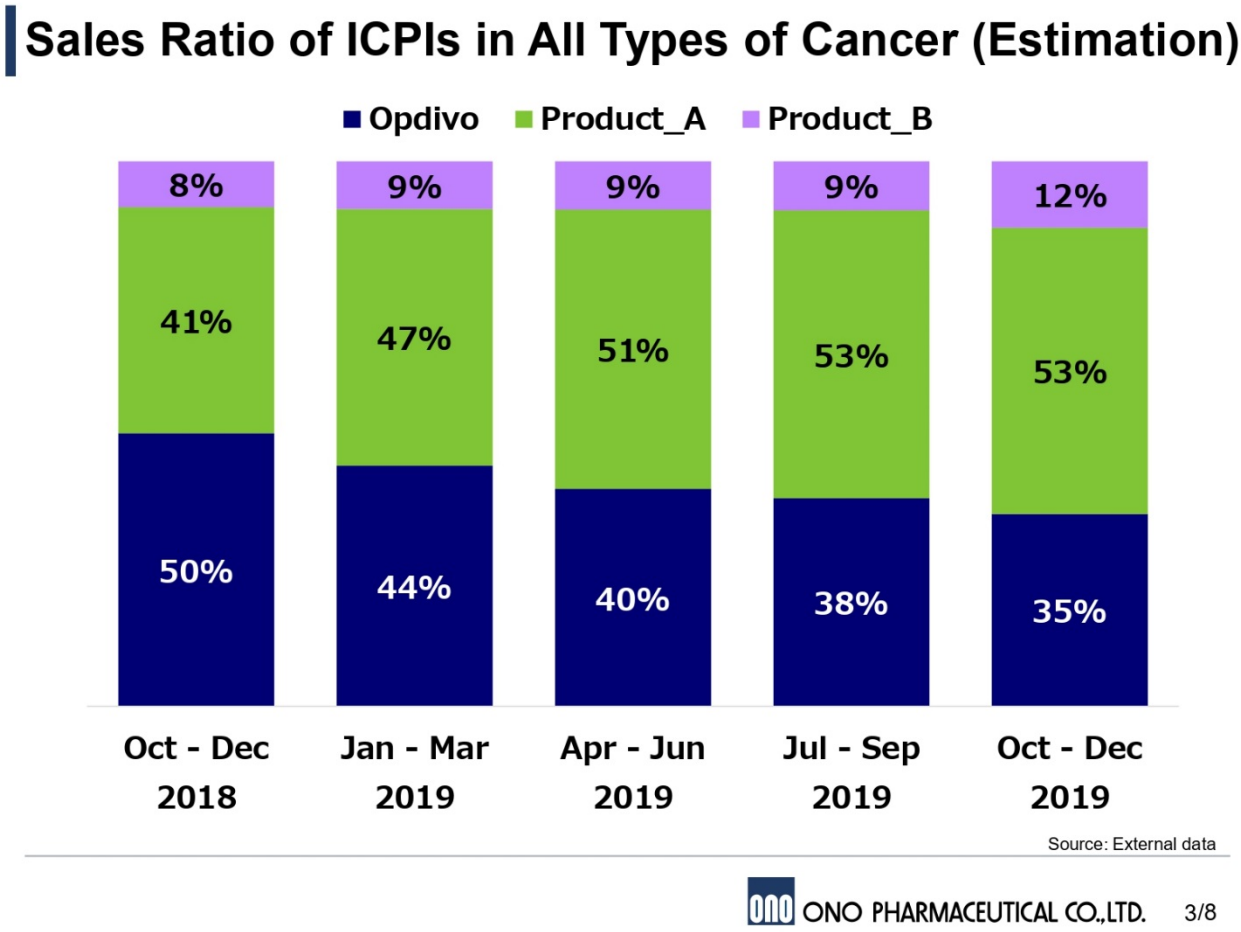
Source: Estimation from external and internal data

I will introduce the sales of Opdivo. You see the result of FY2018 on the left and the forecast for FY2019 on the right. In FY2019, we are expanding our prescriptions for renal cell cancer and other cancers. However, the impact of the drug price revision in November 2018 and the decline in new prescription acquisition for lung cancer are expected, and we expect JPY85 billion in FY2019.



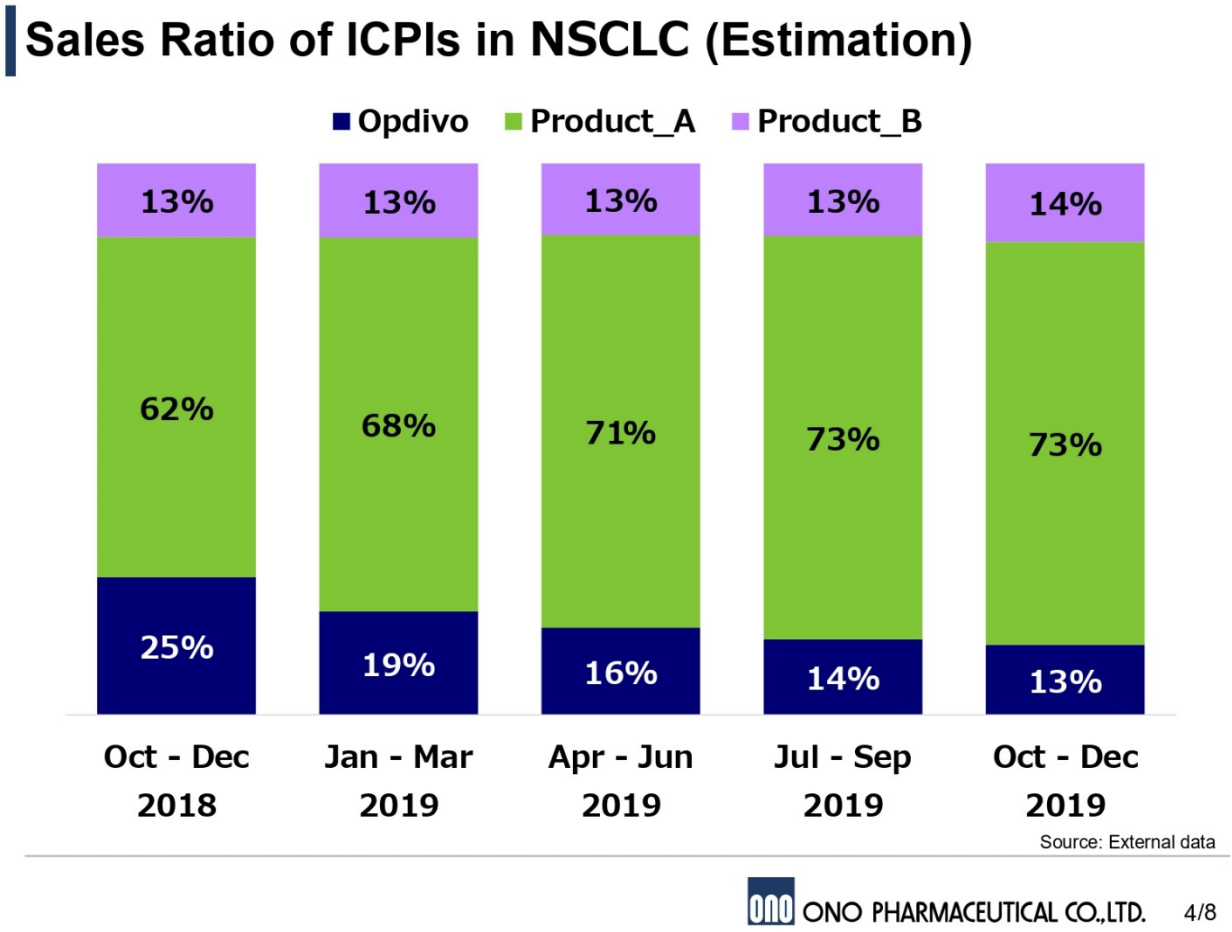
This slide shows estimation for changes in the number of newly prescribed patients for Opdivo by cancer type. It shows the average number of patients per month, divided by quarter from the quarter October to December 2018 to the quarter October to December 2019.

We estimate that 670 patients were prescribed for gastric cancer and about 330 patients were for renal cell cancer in the quarter October to December 2019, and the monthly average number of new prescriptions was 1,630.



This shows the sales ratio of major immune checkpoint inhibitors that compete with Opdivo, in total for all types of cancer, by quarter.

In October to December 2019, Opdivo had a 35% share of the major immune checkpoint inhibitor market.



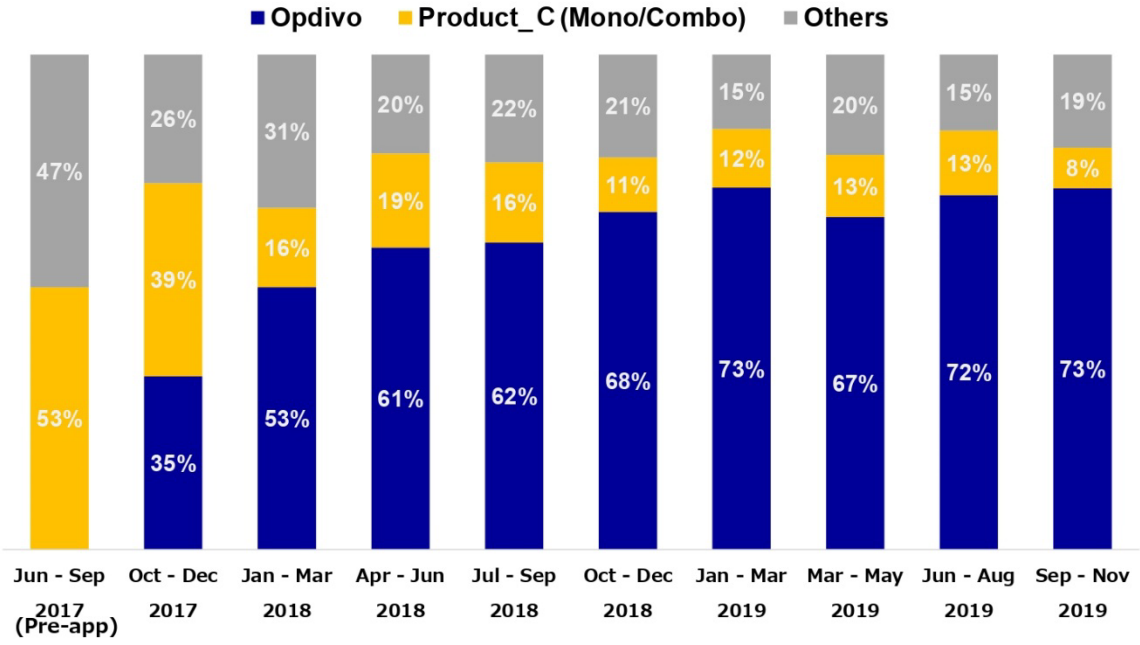
We will report on each type of cancer. This is for lung cancer. The graph shows the sales ratio of immune checkpoint inhibitors for non-small-cell lung cancer, including first line, second line, and third line treatments. We estimate that the total amount of immune checkpoint inhibitors in the lung cancer field will be around JPY150 billion a year on a drug price basis.

It is divided by quarter from October to December 2018 to October to December 2019. In addition to the first line treatment for non-small-cell lung cancer, the indication of combination therapy has been added to other companies' immune checkpoint inhibitors and the market share has been expanding. However, Opdivo maintains its market share at 13% only for indication after the second line treatment. For the new share of second line treatment alone, our share is 30%.

We expect that the full-year plan for Opdivo will be achieved in the area of lung cancer, and hope to make preparations for the entry into the first line treatment in the future.

Prescription Ratio in Patients Newly Treated for 3rd Line Gastric Cancer

※ Patients starting 3rd line treatment of gastric cancer within the last 3 months



Source: External data (Jul 2017 – Nov 2019: n=190~250)

Next, we would like to explain the area of gastric cancer. We entered into the third line treatment market for Opdivo in September 2017. We are working to acquire 70% share of the new prescriptions and 65% transition rate from the second line to the third line as our goal.

Changes in the share of new patients in the third line treatment are presented. Since approval of Opdivo, the share of new prescriptions has steadily increased, and we continue to maintain our target of 70% or more.

On the other hand, as for the transition rate, which had been an issue, at the outset, the rate of transition remained at a peak of around 55%. Recently, however, it has risen to 61%, approaching the target of 65%.

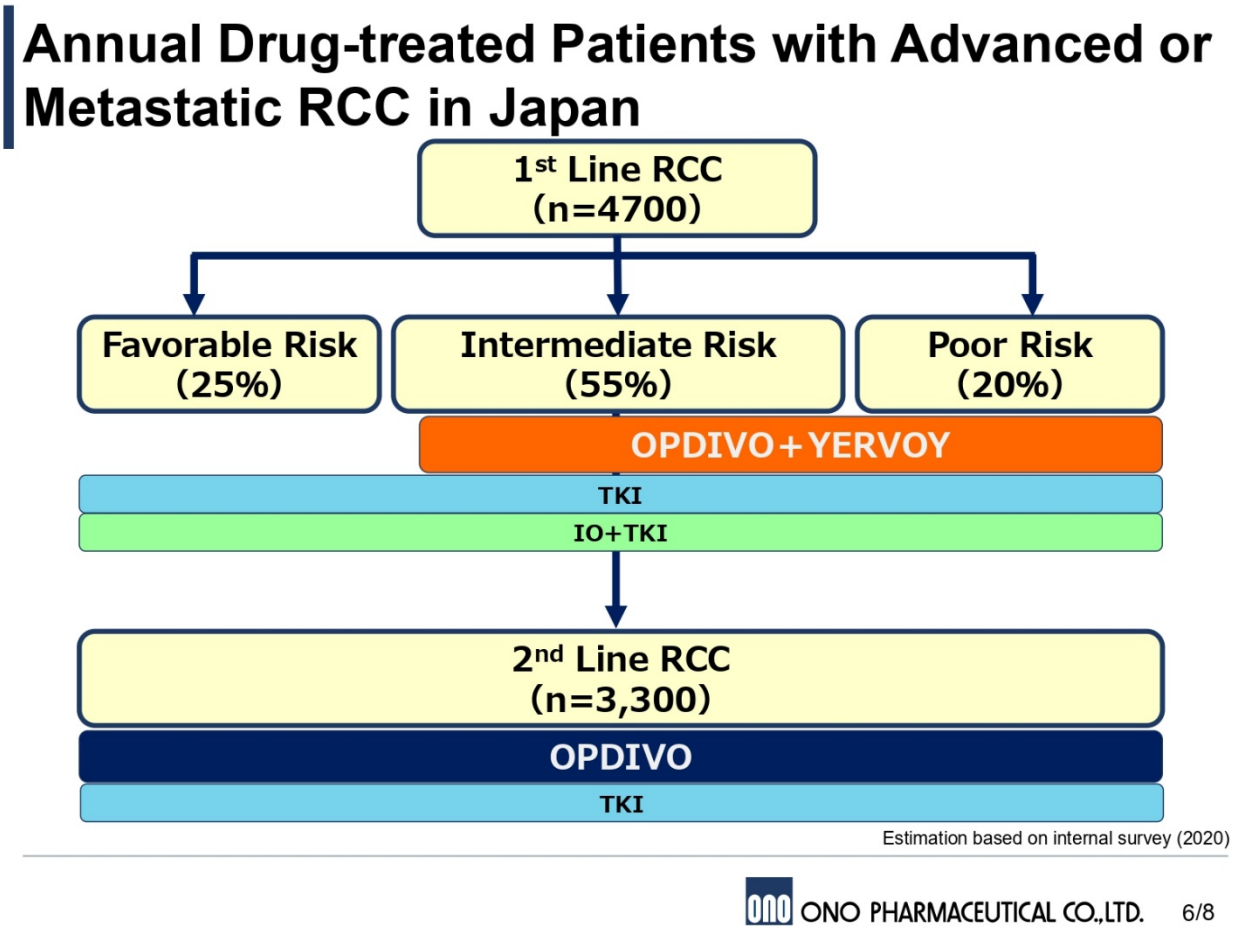
In August last year, a competitor entered the third line treatment. For Opdivo, however, we will strive to win prescriptions without giving up our position.

A three-year follow-up results from a Phase III ATTRACTION-2 study for the third line treatment of gastric cancer were also published in last month's ASCO-GI. The three-year survival rate was 5.6 in the Opdivo group and 1.9 in the placebo group, indicating the superiority of Opdivo for OS even in the three-year follow-up.

In addition, the three-year OS rate by the best overall category was 35.5% in the Opdivo group in CR/PR cases, and clear long-term survival benefits were demonstrated in CR/PR cases.

In the safety of the three-year follow-up, no new signal of side effects has been observed.

In the field of gastric cancer in Opdivo, healthcare professionals expect long-term survival benefit based on the results from ATTRACTION-2 study. Going forward, we will continue to develop activities aimed at solidifying our position with the standard treatment for the third line treatment of gastric cancer and promoting awareness of the significance of the third line treatment.



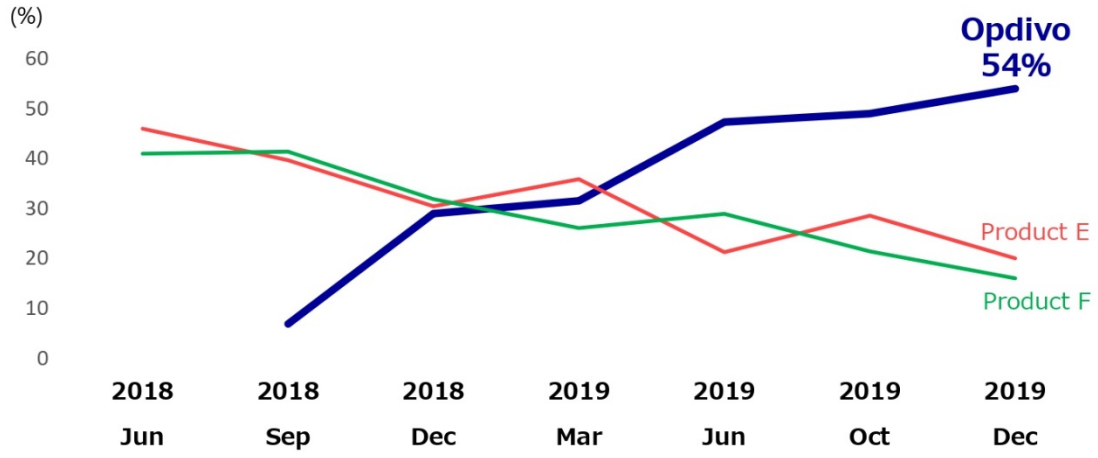
Next, I will explain the area of renal cell cancer. In 2016, Opdivo was approved for additional indication of the second-line treatment of renal cell cancer, followed by the first-line treatment of renal cell cancer in combination with Yervoy in August 2018.

The number of patients eligible for Opdivo is shown. There are approximately 4,700 patients per year in the first line treatment. Among them, the combination therapy of Opdivo and Yervoy are indicated for patients with intermediate/poor risk. We assume that these patients account for about 70% or more.

We have appealed Opdivo's efficacy and safety data to our doctors in the field of the first line treatment.

Prescription Ratio in Patients Newly Treated for Advanced or Metastatic 1st Line RCC

	2018 Jun	Sep	Dec	2019 Mar	Jun	Oct	Dec	
Opdivo	-	7	29	32	47	49	54	(%)
Product E	46	40	30	36	20	29	20	(%)
Product F	41	41	32	26	28	21	16	(%)



Source: External data（Sep 2018 - Dec 2019: n=39~100)

This slide shows change in the prescription ratio until December last year. Since the approval, the acquisition of prescriptions for the combination of Opdivo and Yervoy for the first line treatment has progressed as planned, and approximately 1,700 new patients have been acquired since the additional approval by the end of December.

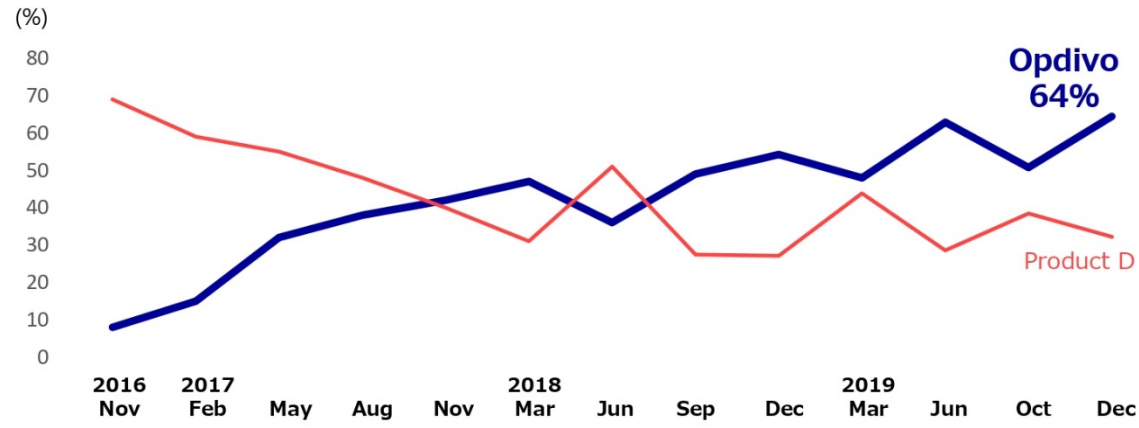
As of December, new prescriptions accounted for 54% of all first line treatment. Targeting at the intermediate/poor risk alone, we captured more than 70% prescription share.

Regarding combination therapy of Opdivo and Yervoy, at the time of approval, many doctors of urology were concerned about irAEs (immune-related adverse events), and we felt that it would be very difficult to obtain prescriptions. However, from the outset of these activities, we have been promoting in-house management to ensure early detection and early treatment of irAEs, and collaboration with doctors in other departments that provide irAEs treatment. We believe that this has helped to dispel concerns about irAEs and lead to the acquisition of prescription shares.

A competitive product has entered into the market in first line treatment of renal cell cancer. However, we intend to maintain a certain market share by clearly conveying the efficacy and safety of the combination therapy of Opdivo and Yervoy.

Prescription Ratio in Patients Newly Treated for Advanced or Metastatic 2nd Line RCC

	2016 Nov	2017 Feb	May	Aug	Nov	2018 Mar	Jun	Sep	Dec	2019 Mar	Jun	Oct	Dec	
Opdivo	8	15	32	38	42	47	36	49	54	48	63	51	64	(%)
Product D	69	59	55	48	40	31	51	27	27	44	29	38	32	(%)



Source: External data (Sep 2018 - Dec 2019: n=32~57)

The steady activities for the first line treatment of Opdivo has boosted the reputation for I-O, and as a result we secured a 64% share of the second line treatment.

We assume that the combined use of I-O and TKI for the first line treatment will lead to a higher ratio of I-O use in the first line treatment, perhaps to around 90%.

As a result, cases for I-O in the second line treatment are expected to decrease, and opportunities for use of Opdivo in the second line treatment are expected to decrease. However, Opdivo can be used even in and after the third line treatment, and also for Opdivo, combination therapy with TKI is being developed in the first line treatment.

We expect approval in the future, and we will continue to steadily increase our presence in the urology field.

Finally, Opdivo is expected to enter new areas in 2020, and expected to be approved for the treatment of esophageal cancer and MSI-High colorectal cancer in the near future. Given the addition of new cancer to the gastrointestinal field, where we have been active with gastric cancer, we believe that we will be able to fully utilize the experience we have gained so far. In particular, we intend to rapidly expand the market share in the field of esophageal cancer.

We also believe that the market in which Opdivo can be used will continue to expand. It is expected to expand particularly in the lung cancer and gastric cancer field. Competitors are leading the way in the first line treatment of lung cancer. However, we are currently investigating the needs of doctors, and believe that unmet needs still remain in markets of PD-L1 weakly positive and negative, and that we may be able to respond to these needs.

We believe that we will be able to recover the share in the first line treatment field with the CheckMate-227 regimen and the CheckMate-9LA regimen.

We also expect that unmet needs for the first line treatment of gastric cancer will be fully met with the combination of Opdivo and Chemo.

In the future, we expect the combination therapy of Opdivo and Yervoy, and the combination therapy of Opdivo and Chemo to be applied to other cancers as well. We want to deliver the benefits of Opdivo to cancer patients.

I have reported on trends in Opdivo. We will continue to strive to respond to unmet needs of cancer patients.

Question & Answer

Q: The first is about Opdivo. I think Keytruda was approved for head and neck cancer and renal cell cancer on December 20. What are your thoughts on its impact on Opdivo? Please tell us the reputation of doctors, if any.

A: I would like to comment about head and neck cancer first.

I would like to explain that indications of Opdivo and Keytruda are different.

Opdivo is indicated for the treatment of platinum resistance, relapse within six months after platinum treatment. Keytruda's evidence is for platinum sensitivity, replace after six months of platinum treatment. Evidence for each drug is different.

Currently, we assume that approximately 30% to 40% of the market for Opdivo is for platinum resistance.

Prior to the launch of Keytruda, Opdivo was used for the first line treatment of platinum-resistance, and also for and after the second line treatment of platinum sensitivity.

I believe that the reduction in I-O naive patients due to the use of Keytruda prior to the second line treatment of platinum sensitivity may have a negative impact of dozens of percent on head and neck cancer.

On the other hand, in the field of renal cell cancer, Opdivo is indicated for intermediate/poor as described earlier.

On the other hand, Keytruda can be used in combination with axitinib for all first line treatment including favorable and intermediate/poor.

In particular, we believe that Opdivo and Keytruda will compete for intermediate risk. Considering this competitive situation, we believe that this will have an impact of around 10%.

Regarding comments from doctors, the indication was added in December last year, and actual use has just started in January. Doctors will gradually use the drug and accumulate clinical experiences, so we have not yet been able to gather responses.

Q: The second point is about Adulmiz (anamorelin). You said at the briefing on November 1 that this was scheduled to be released in the 1H of next fiscal year, and you would response at the next subcommittee. According to media reports, this was not dealt with in the subcommittee. I would like to ask for your comments on the future outlook.

A: As you have pointed out, since it was decided to be continuously deliberated at the subcommittee meeting on August 29 last year, we have been in discussions with PMDA, including the preparation of responses to the items pointed out at the subcommittee. As soon as the preparations are made, a re-discussion at the subcommittee will be made, but there is no clear plan yet. We would like to receive approval in the 1H of the next fiscal year.

As for the specific content with PMDA, we will refrain from answering this question due to the regulatory issue..

Q: Do you mean that the new clinical trial data remains to be unnecessary?

A: Yes. We recognize so.

Q: First of all, I think Coralan was launched in November. Could you please comment on the launch status?

A: As you know, we should proceed cautiously in this area. However, it was expected to reach JPY150 million this fiscal year, and I believe that it will be beyond JPY5.5 billion at its peak.

We will target younger doctors specializing in this area. We have developed a strategy to gather responses while ensuring safety, and we believe that this is within our assumptions.

Q: How about the number of cases?

A: The target number has been achieved. We have received more accounts than we expected.

Q: I understand. As for the full-year forecast, the R&D expenditure has been revised, but it is planned that around JPY10 billion are to be used in Q4. Do you have any forecasts for licensing? Or do you plan more projects?

A: It does not mean that there are any licenses planned for Q4 in the future, for example.

Q: But you plan to spend around JPY25 billion in Q4, or not?

A: Yes. With regard to R&D expenses, there may be some delays, so we expect that amount in Q4.

Q: I understand. Finally, regarding ovarian cancer for Opdivo, what will happen in the future? Will you stop the development for ovarian cancer?

A: We will review the results of Phase III and consider what we will do in the future.

Trials for the combination use have already been partially initiated, and in addition to that, we have to consider what we will do in the future.

Q: As for the overview of Q3's business performance, operating profit increased by 27%, JPY13.9 billion. Operating profit for Opdivo increased by JPY7.5 billion, including the royalties received from Merck. Simply subtracted, the remaining is JPY5.9 billion, and R&D expenses decreased by about JPY5.8 billion.

Does this mean that profit from the sales of existing products, excluding royalties, has remained almost unchanged?

A: This is true when looking only at the figures.

Q: I understand. Then, in terms of revenue and forecast of individual products, not only the quarterly revenues of Kyprolis and Parsabiv, but also of Glactiv and Rivastach, which have been relatively struggling, are rising toward Q3. Is it better to see that this is just in reaction to the drug price revision and the trend has not changed?

A: About half is due to the reaction to the price revision. In the latter half of the fiscal year, we believe that there will be a positive impact due to the change of ingredient of Rivastach, for example. Sales of Glactiv are usually increased in the second half, so we did not make revisions.

Q: I understand. The figures for Opdivo remain unchanged. Does this also reflect the competitive situation of esophageal and colorectal cancer?

A: We have not factored in the impact of competitor's products, esophageal cancer and colorectal cancer.

Q: I would like to ask you about CM -227 study. On the weekend, Bristol-Myers withdrew 227 applications in Europe. I would like to know if there is any risk that this will affect the application in Japan. Please also let me know the background. I know about the Priority Review in the United States.

A: As you have pointed out, BMS has withdrawn the application for first line treatment of non-small-cell lung cancer for combination therapy with Opdivo and Yervoy.

Regarding the impact on Japan, the same application for the first line treatment of non-small-cell lung cancer for Opdivo and Yervoy combination has already been made in Japan, and this case has also been reported to the authorities. We intend to respond appropriately by providing explanations to the authorities as necessary. The impact will be confirmed in the future.

Q: Do you mean that you have informed the authorities before this weekend that Europe will withdraw the application, and the Japanese authorities have not particularly said anything?

A: We plan to inform the authorities after the announcement. We explained the background to this withdrawal in Europe to the authorities in advance.

Q: Is it difficult to explain it to us now?

A: As written here, after there have been several changes to the protocols, the European authorities, CHMP, have decided not to approve them.

Q: I understand. I would like to see you organize your thinking for the next fiscal year in terms of positive and negative factors. In my understanding, Opdivo will grow in Japan. Royalty for Merck will increase. Both R&D and SGA expenses will not significantly increase or decrease. Is this understanding correct?

A: We would like to explain about the next fiscal year at the time of our full-year financial results. At the very least, in terms of Opdivo, as I mentioned earlier, the additional indications for esophageal cancer and partly for colorectal cancer will be positive factors.

On the other hand, as we received a few questions, the situation of competing products will be added, so I think that will be a negative factor.

On the other hand, regarding non-Opdivo, in addition to the Coralan tablet mentioned above, there are also new products and indications that are expected to be added. Therefore, we believe that the primary area as a whole will work positively.

Regarding expenses, we explained from the beginning that research and development expenses will increase slightly. As a result of the revision, we expect R&D expenses to reach JPY70 billion in the current fiscal year, without an increase from JPY70 billion in the previous fiscal year.

In the next fiscal year, we will basically see a slight increase, but we will continue to scrutinize this issue.

In terms of SG&A expenses, operating expenses related to the new launch of Adulmiz, which was originally expected for the current fiscal year, have been postponed to the next fiscal year and beyond. Therefore, in principle, SG&A expenses will not increase significantly. As we have explained so far, there is a possibility that SG&A expenses will increase for this portion in the next fiscal year.

In any event, we would like to scrutinize it for the announcement of financial results in May, and I would like to ask for your understanding.

Q: I think that cost of sales after deducting royalties and other items is quite different from quarter to quarter. Q3 has fallen considerably, and Q4 seems to be rising to around 50%.

I know costs fluctuate every quarter, but royalties rise steadily. So, I would like to ask if there are other factors that could cause costs to fluctuate widely.

Mr. Ishizaki mentioned that there was a contribution for the active pharmaceutical ingredients of Opdivo last year. I think this is a talk about last year, so what happened until Q3 of the fiscal year under review? Also, as much as possible, can you explain what you anticipate in Q4?

A: The biggest factor is the absence of one-time payments for the stable supply of the active pharmaceutical ingredients of Opdivo in the same period of the previous fiscal year, as explained by Mr. Ishizaki, Director, Finance & Accounting Department.

Q: The question I asked is not the comparison with the previous fiscal year, but the absolute value of the cost ratio for the current fiscal year.

A: In Q3, there is only one factor that was not in Q2 or Q1. The reserve portion has not increased in Q3 from Q2. As explained earlier, this is included in cost of sales, so this contributed to the cost reduction in Q3.

Other details are an accumulation of small parts.

Q: Then, can I understand that the cost will jump again in Q4?

A: Are you asking about the cost ratio every three months?

Q: Yes. I know that it fluctuates, but it's so volatile this fiscal year.

A: Without accumulation, when separated by quarter, the cost ratio in Q1 was 28%, and Q2 was 27.9%, which is almost the same. Although the ratio fell to 26.1% in Q3, as explained by Tani, this is due to the provision and, as I mentioned earlier, in the previous fiscal year, the lump-sum payment associated with active pharmaceutical ingredient of Opdivo was included in the cost of sales, but it has disappeared in the fiscal year under review.

In Q4, our current forecast is around 24%, but there is no major factor.

Q: Understood. Next, as for Braftovi and Mektovi, the application is planned to be submitted in the 2H of FY2019 in this document. Will the application be submitted in combination? I think that in the US, Pfizer made an application for Braftovi alone. This appears to be due to the fact that ESMO data were not very favorable. Will your Company apply for combination in Japan? This relates to Erbitux.

A: Erbitux will be the basis. Pfizer applied for with one additional drug. We were originally conducting clinical trials with three drugs, and we are currently preparing to apply for the application for three drugs or two drugs, while consulting with the regulatory authorities. I regret that we would like to refrain from answering at this point. Please understand that we are proceeding while thoroughly consulting with the authorities.

Q: Then, is it two or three drugs?

A: That's true.

Q: I think you said in November that the timing of the application for CheckMate-9LA would be 1H of the next fiscal year, but it is now planned in the 2H of the current fiscal year. Please tell us the background. In addition, I think that data on this is not published yet. Will the data be released after the application?

A: As you have pointed out, the application was originally planned in the 1H of FY2020, but by efficiently advancing the data preparation, we are now in the process of preparing for the application in this 2H.

Rather than saying that there has been a major change in the situation, we are now in a position to quickly prepare for the application by the end of this fiscal year. In addition, we plan to submit an application based on the results of the interim analysis, and we are still in discussions with BMS regarding the data release, but we think it will be a little later.

Q: I would like to briefly review the development plan for 7912, for which Phase III was launched in South Korea. I believe you mentioned at the R&D briefing that you were conducting a study of AVENGER 500 abroad. What are your plans for development in Japan today?

A: As for Japan, it is necessary to first confirm the tolerance in Japanese people, and we are currently considering what package should be prepared for filing an application as soon as possible. Incidentally, for the Phase III in South Korea and Taiwan, this is not what we are doing, but Rafael is doing.

Q: Understood. Then, do you mean, regarding the development plan in Japan, your leadership has not changed since the previous explanation?

A: Yes. That's right.

Q: Understood. Next, regarding S1P5 receptor agonist that entered Phase I this time. Please tell us about the features of this product to the extent that you can. I think that other drugs may cause side effects by combining with various S1P subtypes. What are the concepts and characteristics of the drug?

A: S1P5 is one of subtypes of sphingosine-1-phosphate receptor, a lipid mediator. S1P5 has been highly expressed in nervous system cells. Our experimental studies provide data that suggest an improvement in neurodegenerative diseases. We have not disclosed the details, so we cannot explain them. However, we hope that our data will show the efficacy on various neurodegenerative diseases.

Q: What are the characteristics in comparison with other drugs?

A: We understand that there are not many S1P5 selective compounds yet.

Q: Understood.

A: Some compounds targeting S1P5 are undergoing early-stage clinical studies, but the approved products are not S1P5 selective ones.