ONO PHARMACEUTICAL CO., LTD.

Financial Results Briefing for the Fiscal Year Ended March 2021

May 12, 2021

[Number of Speakers]	8	
	Gyo Sagara	President, Representative Director, CEO
	Toshihiro Tsujinaka	Member of the Board of Directors, Executive Officer, Executive Director, Corporate Strategy & Planning
	Toichi Takino	Member of the Board of Directors, Executive Officer, Executive Director, Discovery & Research
	Hiroshi Ichikawa	Corporate Senior Executive Officer, Executive Director, Sales and Marketing
	Kiyoaki Idemitsu	Corporate Executive Officer, Executive Director, Clinical Development
	Satoshi Takahagi	Business Unit Director, Oncology Business Division, Sales & Marketing
	Kazuhiro Nagahama	Director, Finance & Accounting
	Yukio Tani	Corporate Executive Officer, Head of Corporate Communications

Revenue

Revenue	YoY
¥ 309.3 billion	+ 5.8 %

Breakdown of Revenue

(Billion yen)

	FY 2019	FY 2020	YoY
Revenue of Goods and Products	205.6	**214.5**	+ 4.3 %
Royalty & other revenue	86.8	**94.7**	+ 9.1 %
Total	292.4	**309.3**	+ 5.8 %

Sagara: Revenue increased by JPY16.9 billion to JPY309.3 billion. This includes an increase of JPY8.9 billion in product sales, to JPY214.5 billion, and an increase of JPY7.9 billion in royalties and other revenue, to JPY94.7 billion.

As shown in the supplementary materials, royalties include JPY59.8 billion from BMS, JPY24.3 billion from Merck, and the rest from others.

Revenue

Sales of Major Products

(Billion yen)

	FY 2019	FY 2020	YoY
Opdivo	87.3	**98.8**	+ 13.2 %
Glactiv	26.1	**25.5**	- 2.1 %
Forxiga	18.1	**22.4**	+ 23.7 %
Orencia SC	19.8	**21.9**	+ 10.4 %
Parsabiv	7.1	**8.1**	+ 13.9 %
Kyprolis	6.0	**7.1**	+ 18.8 %
Onoact	4.9	**4.7**	- 4.2 %
Proemend	2.6	**2.6**	+ 0.2 %
New Product（FY2020）	–	**2.4**	–

By product, sales of Opdivo intravenous infusion increased by JPY11.5 billion to JPY98.8 billion, mainly due to increased sales in the esophageal cancer field.

The sales of Glactiv tablets decreased by JPY 0.6 billion to JPY25.5 billion. The market for DPP-4 inhibitors has peaked and been slightly shrinking. Above all, due to the influence of the sales growth of the combination drugs, the sales of single-drugs is in downward trend. This is a situation.

Sales of Forxiga tablets increased by JPY4.3 billion to JPY22.4 billion. We estimate that about JPY1 billion of these sales are from chronic heart failure.

Orencia subcutaneous injection and Parsabiv intravenous injection for dialysis increased by JPY2.1 billion to JPY21.9 billion and by JPY1 billion to JPY8.1 billion, respectively.

The figure for new products launched in the current fiscal year is JPY2.4 billion. This is JPY2.1 billion for Velexbru tablets and JPY0.3 billion for Ongentys tablets.

Revenue

Sales of Long-term Listed Products

(Billion yen)

	FY 2019	FY 2020	YoY
Rivastach	8.5	**6.6**	- 22.5 %
Opalmon	8.3	**5.5**	- 34.5 %
Recalbon	4.7	**2.9**	- 39.9 %
Onon capsule	3.5	**2.9**	- 15.6 %
Emend	8.1	**2.5**	- 69.6 %

Sales of long-term listed products are continuing to follow the decreasing trend.

Sales of the Rivastatch patch decreased by JPY1.9 billion to JPY6.6 billion, Opalmon tablets decreased by JPY2.9 billion to 5.5 billion, Recalbon tablets decreased by JPY1.9 billion to JPY2.9 billion, Onon capsules decreased by JPY0.5 billion to JPY 2.9 billion, and Emend capsules, which have just included in the long-term listed products, decreased by JPY5.6 billion to JPY2.5 billion.

Operating Profit

Operating Profit	YoY Change
¥ 98.3 billion	+ 26.9 %

Costs, etc.

(Billion yen)

	FY 2020	YoY
・Cost of Sales	85.6	(+ 8.2%)
・R&D Expenses	62.4	(- 6.2%) ①
・SG&A Expenses	69.2	(+ 2.3%) ②
①+② Total	131.6	(- 1.9%)
・Other Income	8.2	(+ 893.1%)
・Other Expenses	1.9	(- 23.1%)

Operating profit increased by JPY20.8 billion to JPY98.3 billion. Cost of sales increased by JPY6.5 billion to JPY 85.6 billion and R&D expenses decreased by JPY4.1 billion to JPY62.4 billion. Due to the impact of the novel coronavirus infection, global clinical trials have been cancelled or reduced. This means that we were unable to proceed as fully planned.

Selling, general and administrative (SG&A) expenses increased by JPY1.6 billion to JPY69.2 billion. Real activities did not go as we expected, and it cost to make up for it by utilizing the web such as IT. In addition, as there was some new product launches and additional indication approval in the previous fiscal year, so costs here have increased. This is in line with our plan. Most of the increase is likely due to web-related costs.

Profit before Tax

Profit before Tax	YoY Change
¥ 100.9 billion	+ 26.6 %

Net financial income, etc.

+ ¥ 2.6 billion (+ ¥ 0.4 Billion YoY)

Finance income :	**¥ 2.7 Billion**
(Interest and dividend income received, etc.)	
Finance costs :	**¥ 0.1 billion**
(Interest expense arising from lease obligations and employee retirement benefit, etc.)	

Profit before tax increased by JPY21.2 billion to JPY100.9 billion.

Profit for the Period
(Owners of the Parent Company)

Profit for the Period (Owners of the Parent Company)	YoY
¥ 75.4 billion	+ 26.3 %

Income tax expense

¥ 25.4 billion		(+ 28.2 % YoY)
Statutory effective tax rate	30.6 %	(30.6 % prior year)
Actual av. burden tax rate	25.2 %	(24.9 % prior year)

(Major change factors)

Increase in profit before tax

Profit for the year attributable to owners of the parent company increased by JPY15.7 billion to JPY75.4 billion.

Regarding the year-end dividend, we are considering an increase of 5 yen per share and plan to increase it to 27.5 yen per share.

Revenue (Forecasts)

Revenue	YoY
¥ 350.0 billion	+ 13.2 %

Breakdown of Revenue

(Billion yen)

	FY 2020 (Result)	FY 2021 (Forecast)	YoY
Revenue of Goods and Products	214.5	245.0	+ 14.2 %
Royalty & other revenue	94.7	105.0	+ 10.8 %
Total	309.3	350.0	+ 13.2 %

I would like to continue with the earnings forecast for the fiscal year ending March 31, 2022.

Revenue is forecast to be JPY350 billion, an increase of JPY40.7 billion. Sales of goods and products will increase by JPY30.5 billion to JPY245 billion. Royalty and other revenue will increase by JPY10.3 billion to JPY105 billion.

In terms of product sales, we expect Opdivo intravenous infusion continue to grow. In addition, Forxiga tablets, Orencia subcutaneous injection, and the new products such as Adlumiz and Joyclu are expected to contribute to sales growth.

As for royalties, we are expecting an increase in royalties from BMS, Merck, Roche, and others.

Revenue (Forecasts)

Sales Forecasts of Major Products

(Billion yen)

	FY 2020 (Result)	FY 2021 (Forecast)	YoY
Opdivo	98.8	120.0	+ 21.4 %
Forxiga	22.4	30.0	+ 34.2 %
Glactiv	25.5	24.5	- 3.9 %
Orencia SC	21.9	22.5	+ 2.7 %
Parsabiv	8.1	8.0	- 0.6 %
Kyprolis	7.1	7.5	+ 5.3 %
Onoact	4.7	4.0	- 14.1 %
Velexbru	2.1	3.5	+ 69.8 %
Braftovi	1.1	3.0	+ 180.6 %
Mektovi	1.0	2.5	+ 150.9 %
Ongentys	0.3	2.5	+ 631.1 %
New sales prospect items	–	7.0	–

I would like to report our sales forecast by product.

Opdivo intravenous infusion is expected to increase by JPY21.2 billion to JPY 120 billion. The main reason for the increase in sales is due to the first-line treatment of lung cancer for which we obtained the approval in the previous fiscal year and have started activities in this area. In addition, the first-line treatment for gastric cancer, which is expected to be approved during the current fiscal year, is expected to be another main source of sales growth.

Sales of Forxiga tablets are forecast to be JPY30 billion, an increase of JPY7.6 billion. Of these, sales for diabetes treatment is expected to account for JPY24 billion to JPY25 billion. In addition to heart failure, chronic kidney disease for which we expect to obtain an indication approval within this fiscal year, are expected to contribute about JPY1 billion.

Sales of Glactiv tablets are forecast to fall by JPY1 billion to JPY 24.5 billion. We expect that products that have recently launched, such as Velexbru tablets, Braftovi capsules, Mektovi tablets and Ongentys tablets will contribute to an overall increase in sales.

The sales of new product items at the bottom of the table, expected to generate about JPY7 billion, are sales of Adlumiz and Joyclu.

Revenue (Forecasts)

Sales Forecasts of Long-term listed products

(Billion yen)

	FY 2020 (Result)	FY 2021 (Forecast)	YoY
Opalmon	5.5	**4.0**	**- 26.7 %**
Rivastach	6.6	**3.0**	**- 54.6 %**
Onon capsule	2.9	**2.5**	**- 14.2 %**

Next, the long-term listed products.

We expect this to remain negative. Sales of Opalmon tablets are expected to fall by JPY1.5 billion to JPY 4billion. Sales of Rivastach will continue to be significantly affected, with a decrease by JPY3.6 billion to JPY3 billion, as generics entered into the market from the middle of the previous fiscal year. Sales of Onon capsules will decrease by JPY0.4 billion to JPY2.5 billion.

Operating Profit (Forecasts)

Operating Profit	YoY
¥ 105.0 billion	+ 6.8 %

Costs, etc.

(Billion yen)

	FY 2021 (Forecast)	YoY
・Cost of Sales	96.0	(+ 12.2 %)
・R&D Expenses	72.0	(+ 15.4 %) ①
・SG&A Expenses	76.0	(+ 9.8 %) ②
①+② Total	148.0	(+ 12.4 %)
・Other Income	1.0	(- 87.8 %)
・Other Expenses	2.0	(+ 3.5 %)

Operating profit is forecast to be JPY105 billion, an increase of JPY6.7 billion from the previous fiscal year.

Cost of sales is expected to increase by JPY10.4 billion to JPY 96 billion due to an increase in the quantity base of products. R&D expenses are expected to increase by JPY9.6 billion to JPY72 billion, considering that it will not be impacted by the coronavirus pandemic this fiscal year as heavily as they were in the previous fiscal year and that necessary clinical studies can be carried forward steadily.

SG&A expenses except for R&D expenses are forecast to increase by JPY6.8 billion to JPY76 billion. This is due to the fact that we will continue to obtain additional indication approval and launch new products this year. In addition, we need to invest for IT and digital projects.

Profit before Tax (Forecasts)

Profit before Tax	YoY
¥ 107.0 billion	+ 6.1 %

Net financial income, etc.

+ ¥ 2.0 billion (- ¥ 0.6 billion YoY)

Profit before tax is forecast to be JPY107 billion, an increase of JPY6.1 billion.

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

Profit for the Period (Owners of the Parent Company)	YoY
¥ 83.0 billion	+ 10.0 %

Income tax expense

¥ 23.9 billion	(- 5.9 % YoY)

(Major change factors)

Increase in profit before tax	¥ 6.1 billion
Decrease in corporate tax	¥ 1.5 billion

Profit for the year attributable to owners of the parent company is expected to be JPY83 billion, an increase of JPY7.6 billion from the previous fiscal year.

We plan the annual dividend of JPY56 per share for FY2021. We plan the dividend of 28 yen for the interim period and 28 yen for the end of the term.

Status of Reduction of Cross-shareholdings

➢ Reduction plan
The number and amount (market value basis) of cross-shareholdings held by the company as of the end of March 2018 will be reduced by 30% over the three-year period from November 2018.

	End of March 2018	End of March 2021	Reduction	Reduction rate
Number of listed brands	111	**70**	**41**	**- 36.9 %**
Balance sheet accounting amount	¥ 167.1 bil	¥ 137.0 bil	¥ 30.1bil	-18.0 %
Market price at the end of March 2018	**¥ 167.1 bil**	**¥ 119.2 bil**	**¥ 47.9 bil**	**-28.7 %**

We will now move on to the status of reduction of cross-shareholdings.

The reduction of cross-shareholdings started in November 2018. The number and amount of stocks held as of the end of March 2018 are shown in the slide. The main focus is on the monetary figure. We have been working to reduce it by 30%. At present, after 2 and a half years, we have achieved 36.9% in terms of the number of brands and 28.7% in terms of value. We would like to report here that the remaining about 1% will be completed as scheduled by September.

Future Plan for reduction of Cross-shareholdings

- Medium to long-term plan
  Aiming at less than 10% of net assets

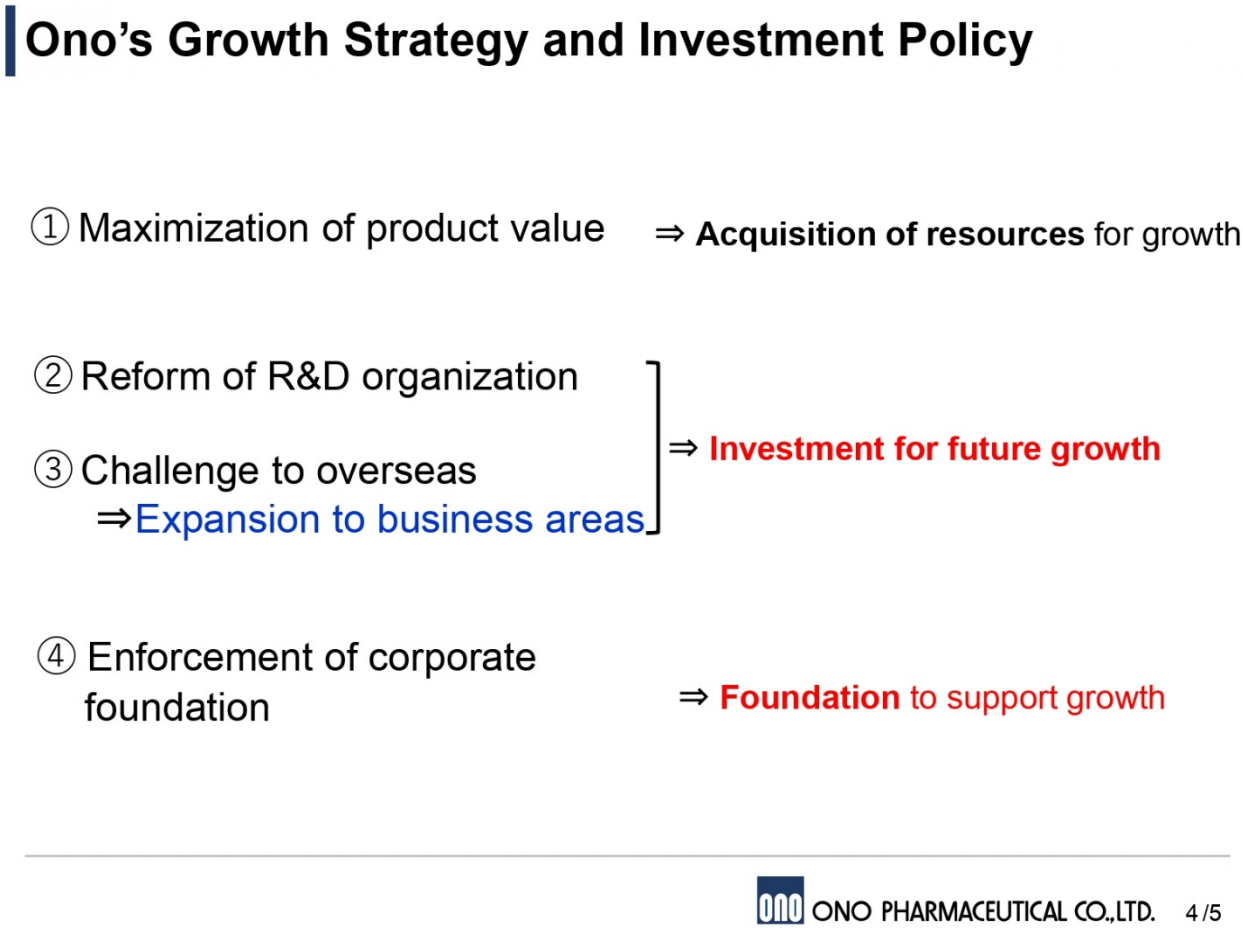
- The next reduction plan (three-year plan) will be presented at the financial results announcement scheduled for November 2021.
  * Reduced to less than 20% of net assets by the end of March 2022

	End of March 2018	End of March 2021	**End of March 2022**
Net assets amount	¥ 529.6 bil	¥ 641.2 bil	¥ 650 - 700 bil
Cross-shareholdings (BS accounting base)	¥ 167.1 bil	¥ 137.0 bil	¥ 127.0 bil
Ratio	32%	21%	**18 – 20%**

As for the future reduction plan, our medium- to long-term goal is to reduce our cross-shareholdings to less than 10% of our net assets.

After the current 3-year plan, we are currently planning to set another 3-year period plan to reduce them. We will make a specific announcement at the financial results briefing for the second quarter of this fiscal year.

In addition, we are currently planning to reduce the amount to less than 20% of net assets by the end of March 2022. As you may be aware, the ISS standard is less than 20%. The 10% of net assets figure is the standard proposed by Glass Lewis, and we are currently aiming for that level.



Also, as many investors have pointed out, financial assets will increase as a result of this cross-shareholdings reduction policy. The Company has had a strong cash position to begin with, and from that state, profits have been increasing year by year, and internal reserves will be added. In addition, the cash will come in by releasing the cross-shareholdings. We have been asked what we are going to do with such cash.

About the Item 1, maximization of product value, we consider that it is necessary to maximize product value, which is associated with costs for promotion in the market.

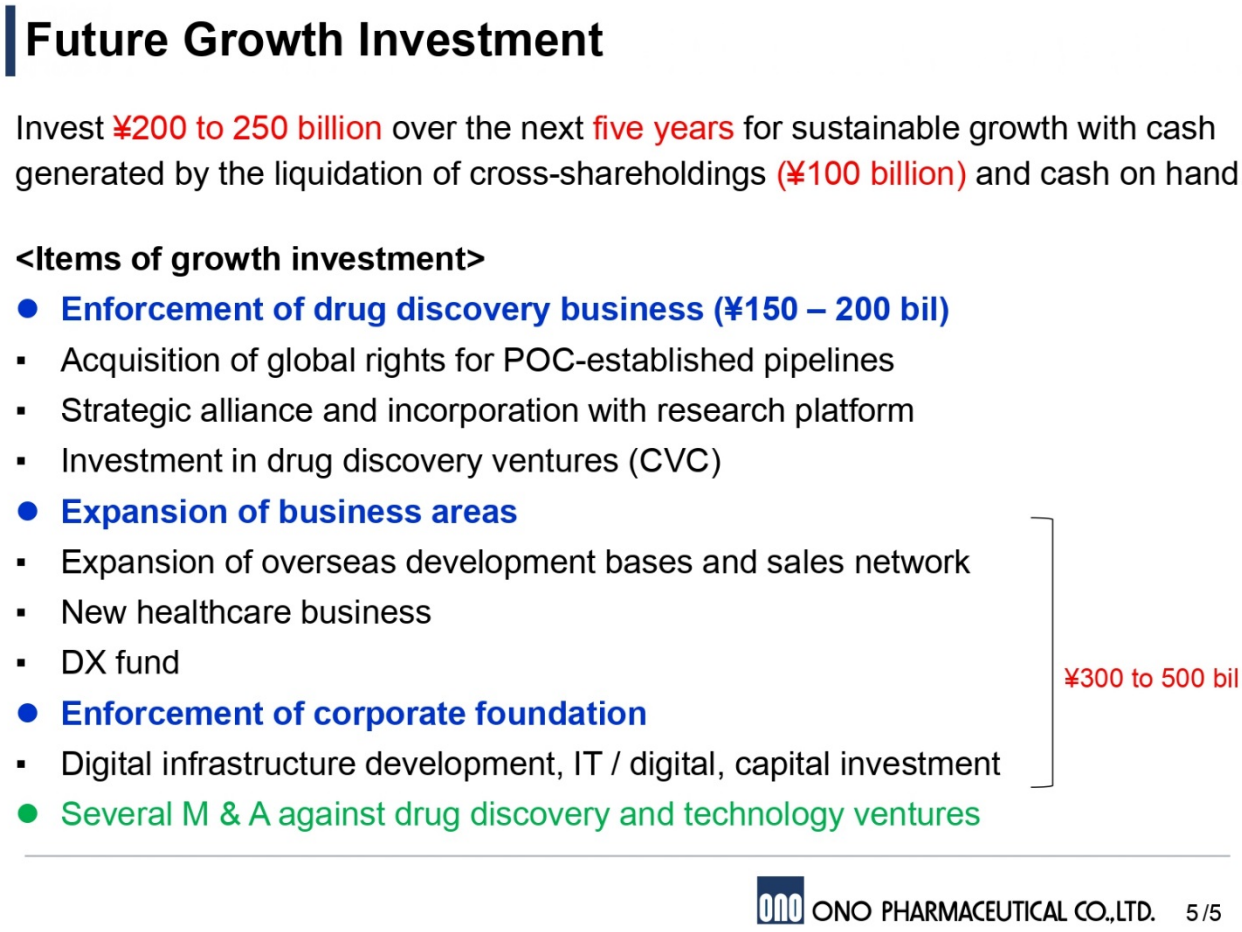
The 2nd item, reform of R&D organization and the 3rd item, challenge to overseas are more significant. As for our R&D activities, we are working with various academia and venture companies, etc., in setting up collaboration on drug discovery alliances, technology and basic research alliances, in order to make more and better compounds coming out of our own in-house research. We are aiming to do this on a larger scale.

Regarding the challenge for overseas, we established a new US office in Cambridge neighboring to Boston, where we have made a fresh start to conduct clinical trials, obtain approvals and then move forward with marketing and post-marketing activities. A certain amount of money is necessary to invest for these activities.

In relation to items 2 and 3, we would like to make efforts to in-license new compounds more actively than before. Whereas we have obtained the rights only for Japan, South Korea and Taiwan, we would like to take global rights in the future, and think that considerable amount of money will be needed for this investment.

The fourth point is to strengthen our corporate infrastructure, including digital.

In addition, although it is not mentioned here, we naturally keep in mind the need to return profits to our investors and shareholders.

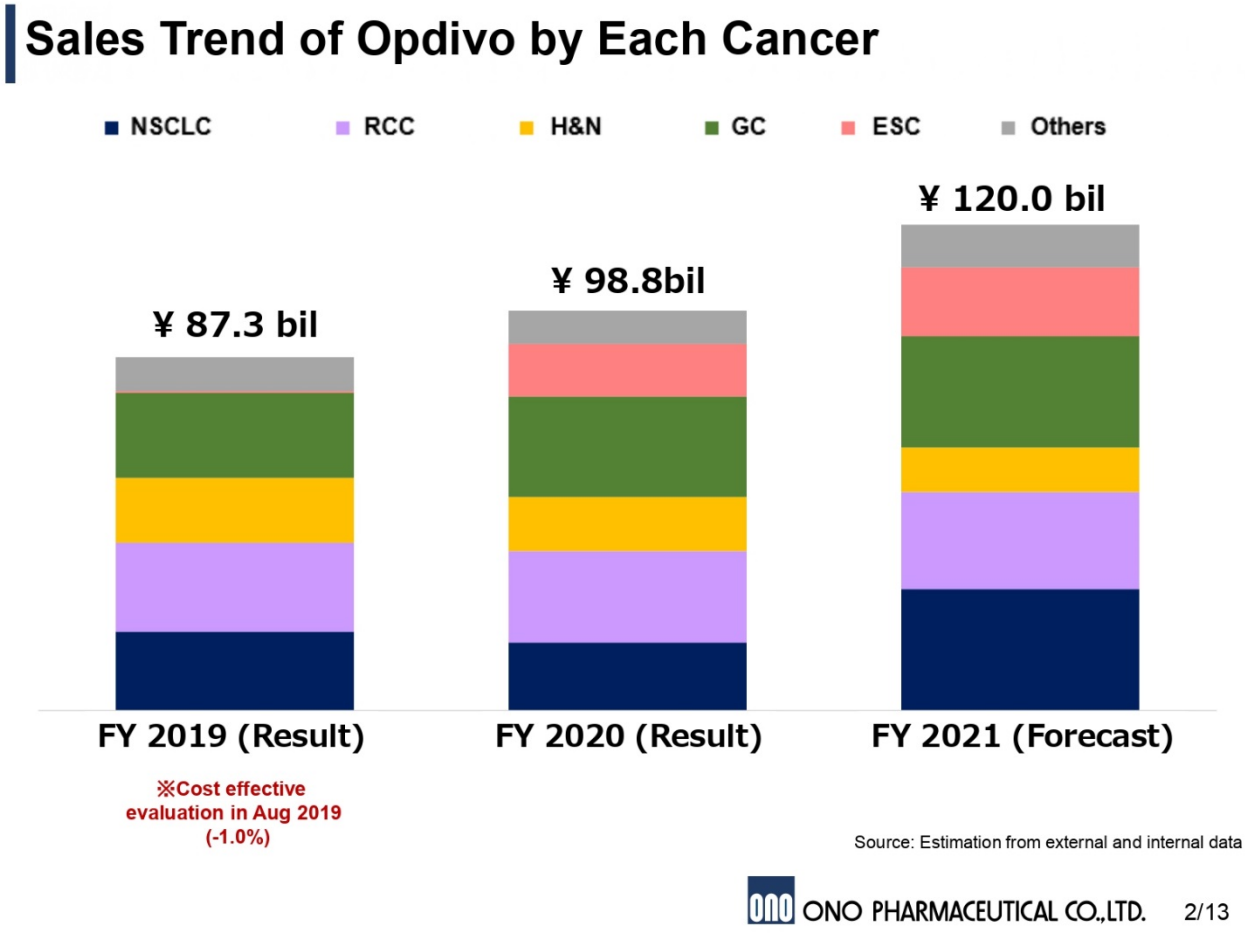


As a rough estimate, we would like to invest JPY150 billion to JPY200 billion in the reform of R&D organization (Item 2), including in-licensing activities. For challenge to overseas (Item 3) and enforcement of corporate foundation (Item 4), we consider that we need to invest between JPY30 billion and JPY50 billion.

Naturally, while we have spent more than JPY70 billion each year in R&D, we would like to extend the R&D expenses to about JPY100 billion as at early opportunity as possible. Apart from that, we would like to make such an investment.

In addition, we would like to positively consider M&A opportunities for venture companies that target technologies, drug discovery, and chemical compounds.

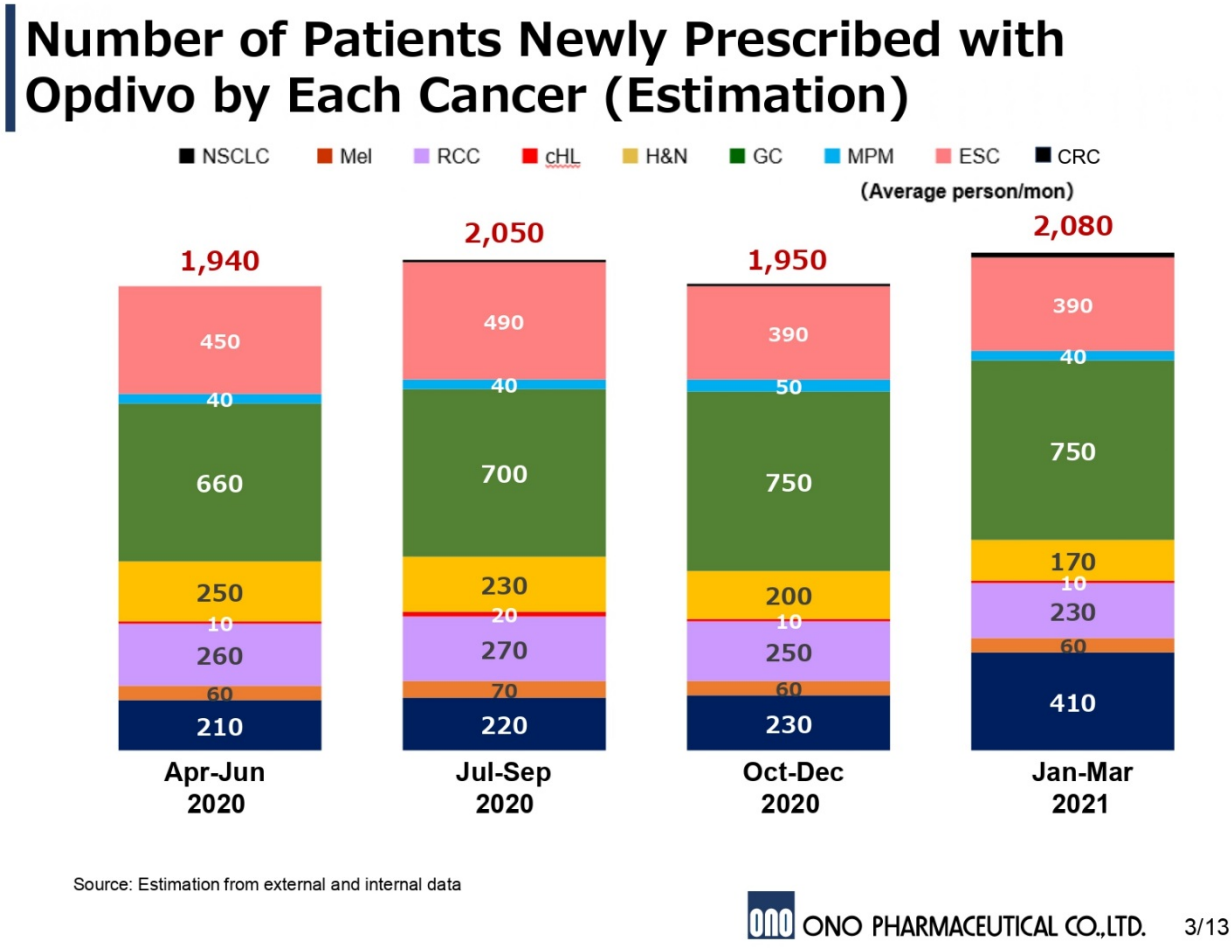
That’s a rough outline of what we’re considering at this time.



Takahagi: I would like to talk about Opdivo trends.

I will talk about the general situation, sales trends, new patient prescription trends, and the composition ratio of I-O inhibitors. As for the status by cancer type, I would like to talk about the growth drivers of Opdivo: lung cancer, gastric cancer, esophageal cancer and renal cell carcinoma.

Regarding sales of Opdivo, from the bar graph on the left, the results for FY2019, FY2020, and the forecast for FY2021. In FY2020, sales increased by JPY11.5 billion over the previous year to JPY98.8 billion. For the current fiscal year, we forecast sales of JPY120 billion.



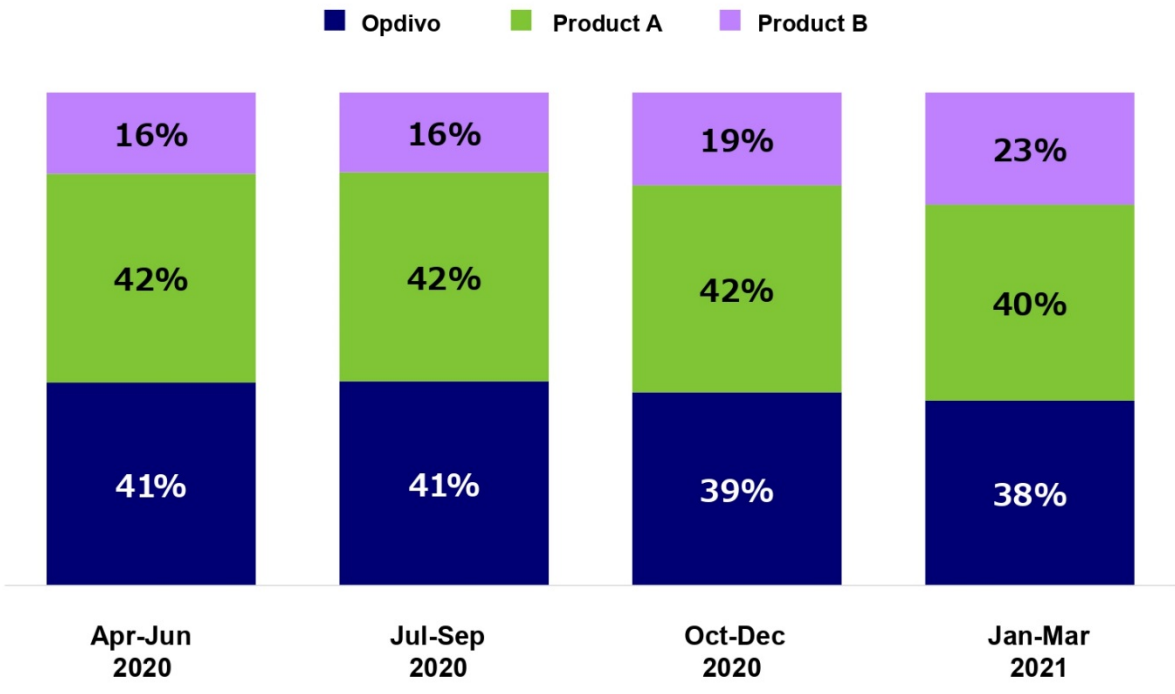
The number of new prescriptions for Opdivo by cancer type is shown in the bar graph from the left, broken down by quarter for FY2020, with the average number of patients per month.

This is only an estimate, but from January to March 2021, prescriptions were obtained for 750 cases of gastric cancer and 230 cases of renal cell carcinoma, and for 390 cases of esophageal cancer, including second- and third-line treatments. For lung cancer, 410 prescriptions per month were obtained, including in first- and second-line treatments.

For Opdivo as a whole, we have acquired an average of 2,080 new prescriptions per month.

In particular, the number of newly prescribed patients for the first-line treatment of lung cancer, for which approval was obtained on November 27, 2020, reached a cumulative total of 750 cases from December last year to March this year, with 260 new prescriptions obtained in March.

Sales Ratio of ICPIs in All Types of Cancer (Estimation)

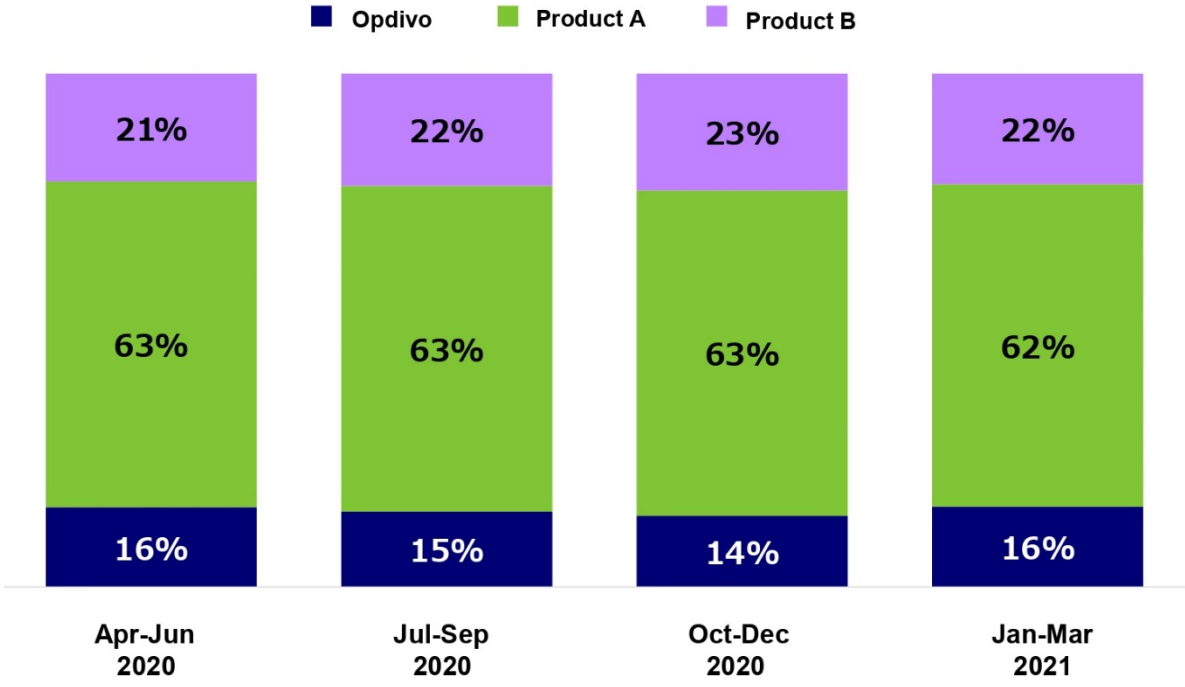


Source: External data

The graph shows the sales composition of major immune checkpoint inhibitors that compete with Opdivo across all cancer types, broken down by quarter for fiscal 2020, starting with the bar graph from the left.

In January to March 2021, Opdivo had a 38% market share among the major immune checkpoint inhibitors.

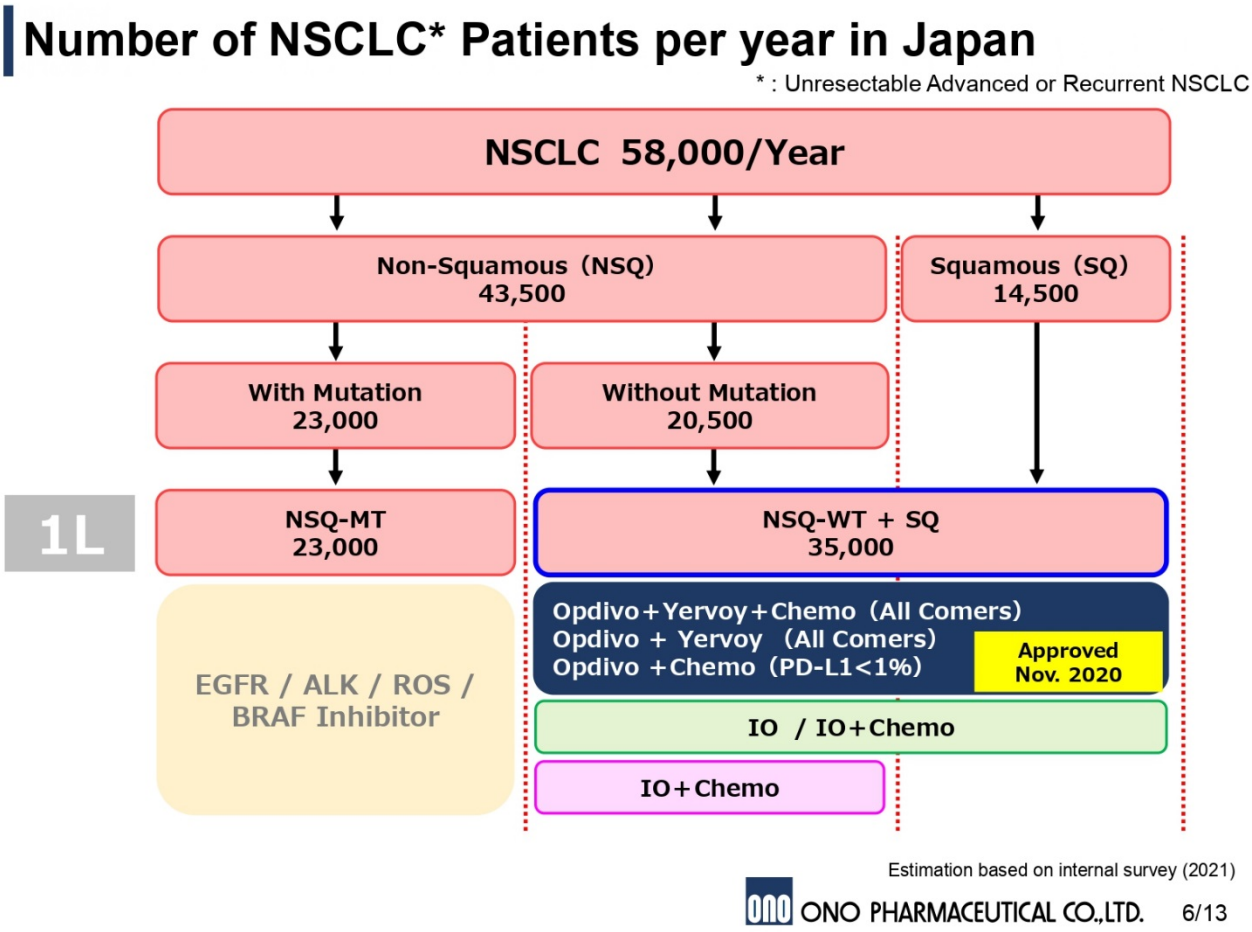
Sales Ratio of ICPIs in NSCLC (Estimation)



Source: External data

The graph shows the sales composition of immune checkpoint inhibitors in all lines of non-small cell lung cancer.

The bar graph from the left shows FY2020 broken down by quarter. Opdivo had a 16% market share in January to March 2021 marking the start to recover the share with the first-line treatment of lung cancer.



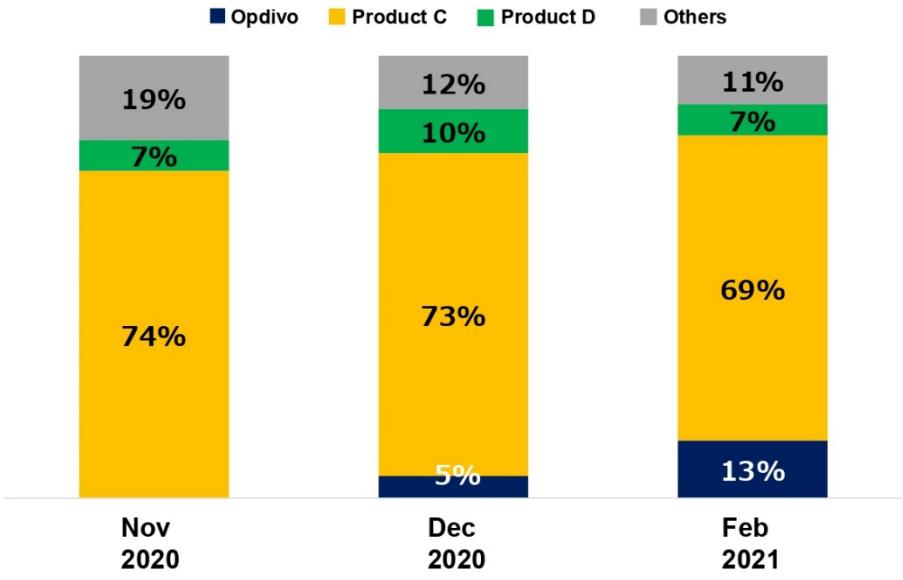
The annual number of patients with unresectable advanced or recurrent non-small cell lung cancer is estimated to be around 58,000 per year in our own estimate.

As you know, non-small cell lung cancer is divided into non-squamous cell carcinoma and squamous cell carcinoma by histological type, and non-squamous cell carcinoma is further divided by diagnosis with or without genetic mutation. In the first-line treatment of lung cancer, immune checkpoint inhibitors such as Opdivo are used to treat squamous cell carcinoma and non-squamous cell carcinoma without genetic mutation. It is estimated that number of target patients is 35,000 per year, which is a very large market.

Currently, various immune checkpoint inhibitors have been approved as monotherapy or combination therapy with other drugs, and the competitive environment is intense. We entered the market in November last year with Opdivo and Yervoy combination therapy, etc.

Prescription Ratio in Patients Newly Treated for 1L NSCLC

※Patients starting 1L treatment within the last 1 months (Except Driver Mutation)



Source: External data (Nov 2020 – Feb 2021: n=193~245)

As of February, Opdivo's share of new patient prescriptions was 13%, and we are currently striving to achieve 30%.

I would like to introduce the field of gastric cancer. As in the case of lung cancer, I will show you the annual number of patients with gastric cancer.

The annual number of patients with unresectable advanced or recurrent gastric cancer is estimated to be 27,000 per year in our own in-house estimate. Before starting treatment, HER2, which is involved in the growth of cancer cells, is tested. Patients are classified into positive and negative, and the first-line treatment is initiated. Opdivo is currently being used in the third-line setting. The number of patients is thought to be about 12,000 per year.

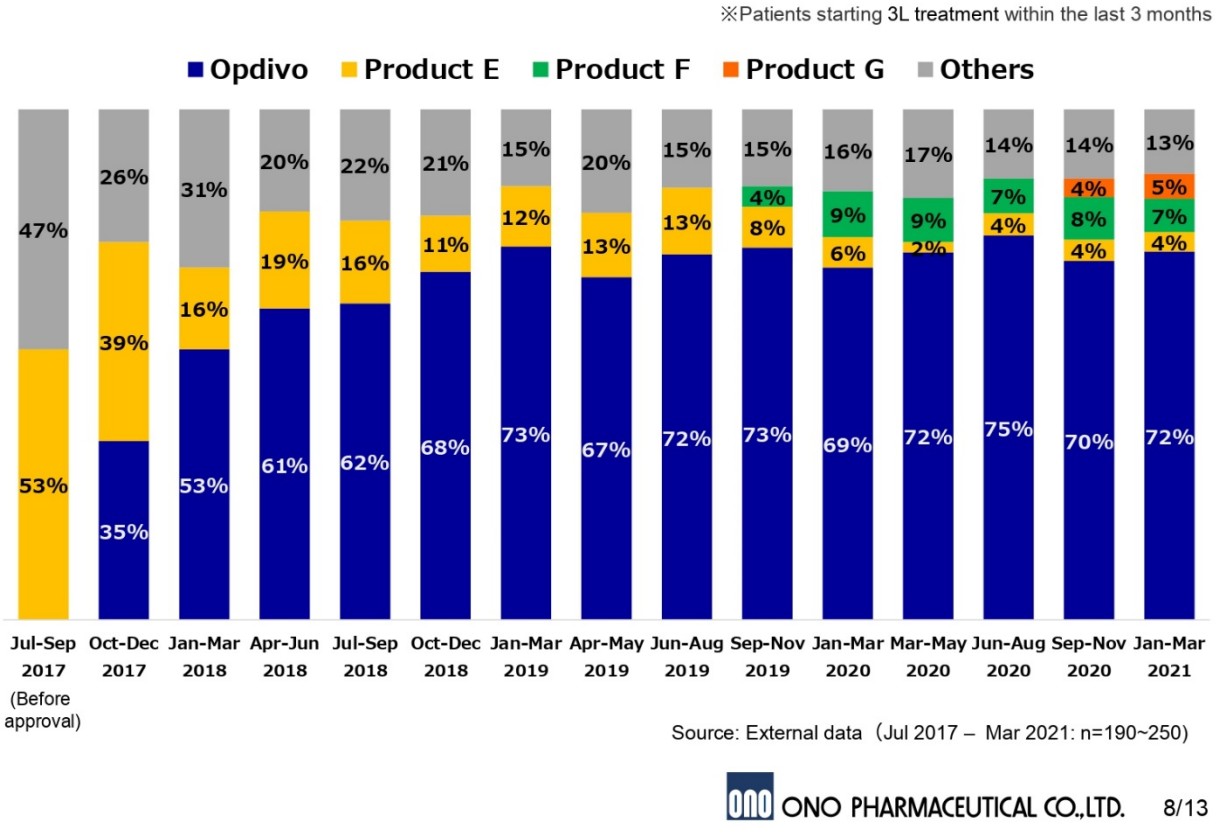
Here, I would like to introduce the gastric cancer treatment guidelines.

Recommended chemotherapy regimens for unresectable, advanced or recurrent gastric cancer in the Guidelines are shown in the slide.

In recent years, there have been well-recommended drugs for HER2-positive patients in the first-line treatment, as well as in the second-line treatment.

Opdivo was approved for the third-line treatment in September 2017, and has been recommended as a Category A, where the evidence is very high, but recently there have been a number of competing products entering the market.

Prescription Ratio in Patients Newly Treated for 3L GC



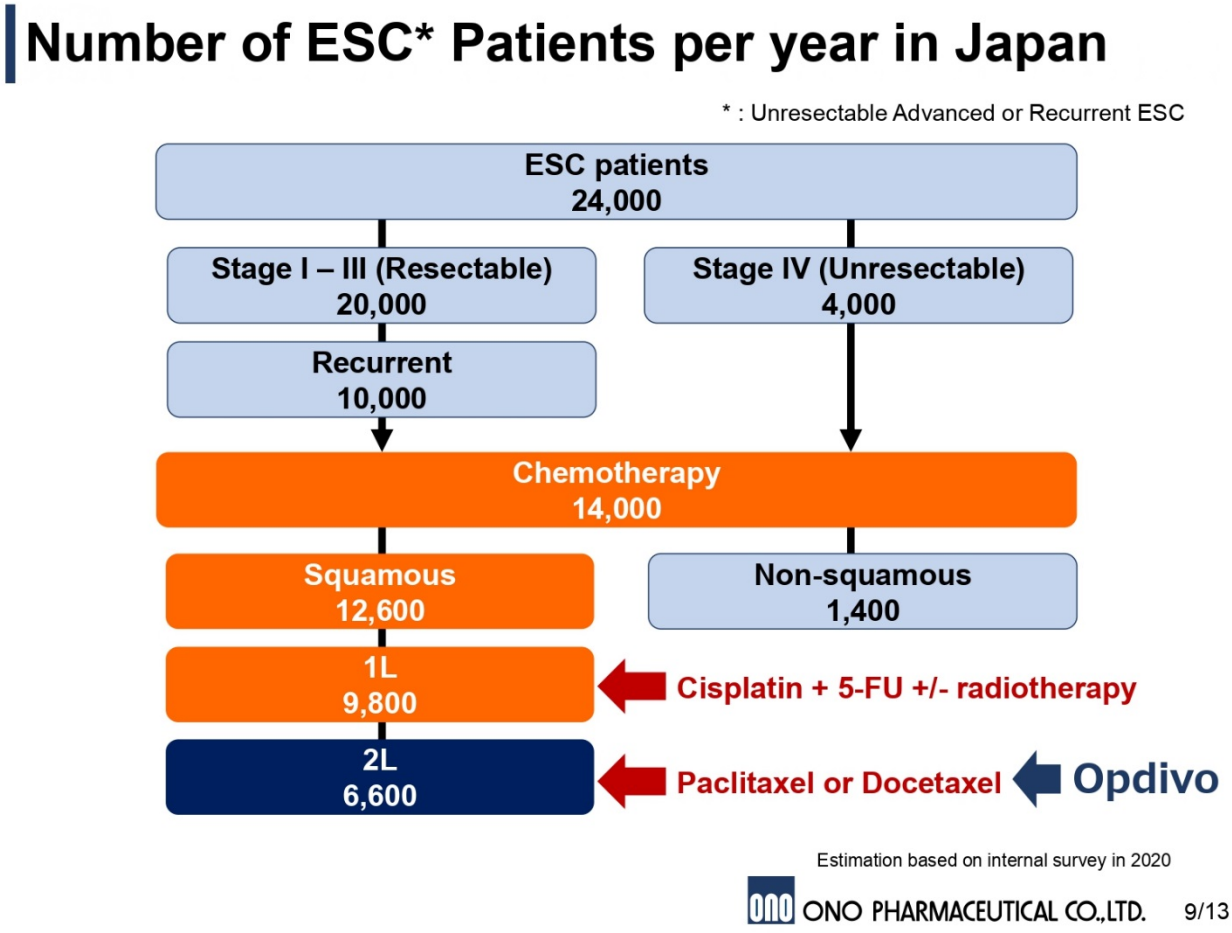
Source: External data（Jul 2017 – Mar 2021: n=190~250）

ONO PHARMACEUTICAL CO.,LTD. 8/13

The market share of new prescriptions for third-line treatment with Opdivo has remained at the target level of 70%, despite the entry of competing products.

In addition, as I mentioned earlier in the guidelines for clinical practice of gastric cancer, it is recommended to use up for the treatment, and we believe that it is important to increase the rate of transition to the next line of treatment.

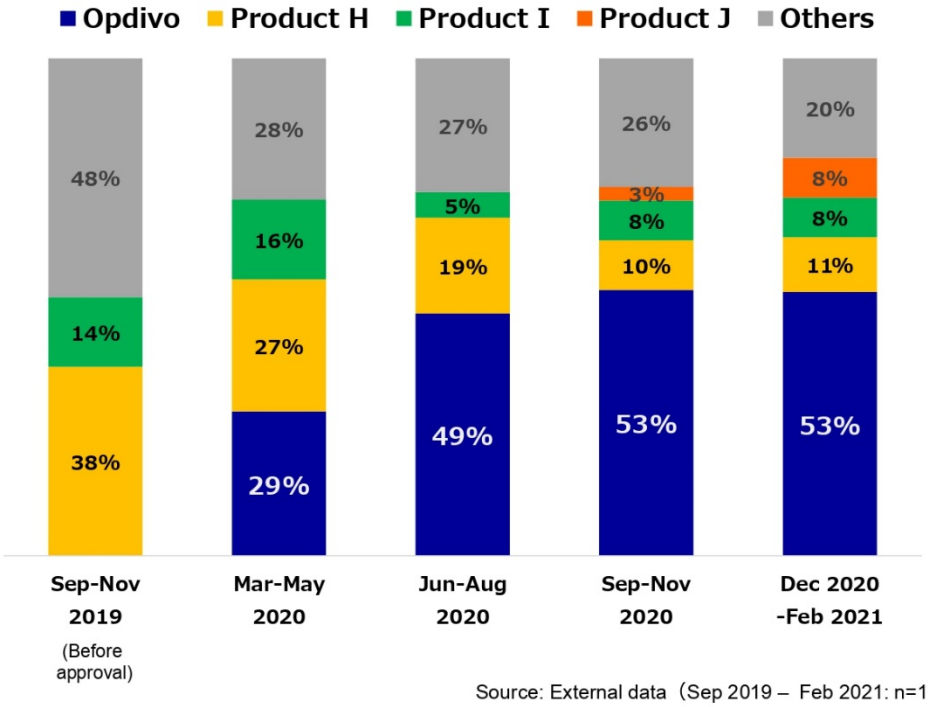
In this context, the transition rate of treatment lines for gastric cancer, especially from second line to third line treatment, has been maintained at over 60%. We would like to continue to improve in this area.



In February 2020, Opdivo was approved for the second-line treatment of unresectable advanced or recurrent esophageal cancer. We estimate that Opdivo has been used in approximately 5,700 patients by the end of this March since the approval.

Prescription Ratio in Patients Newly Treated for 2L ESC (Squamous Cell Carcinoma)

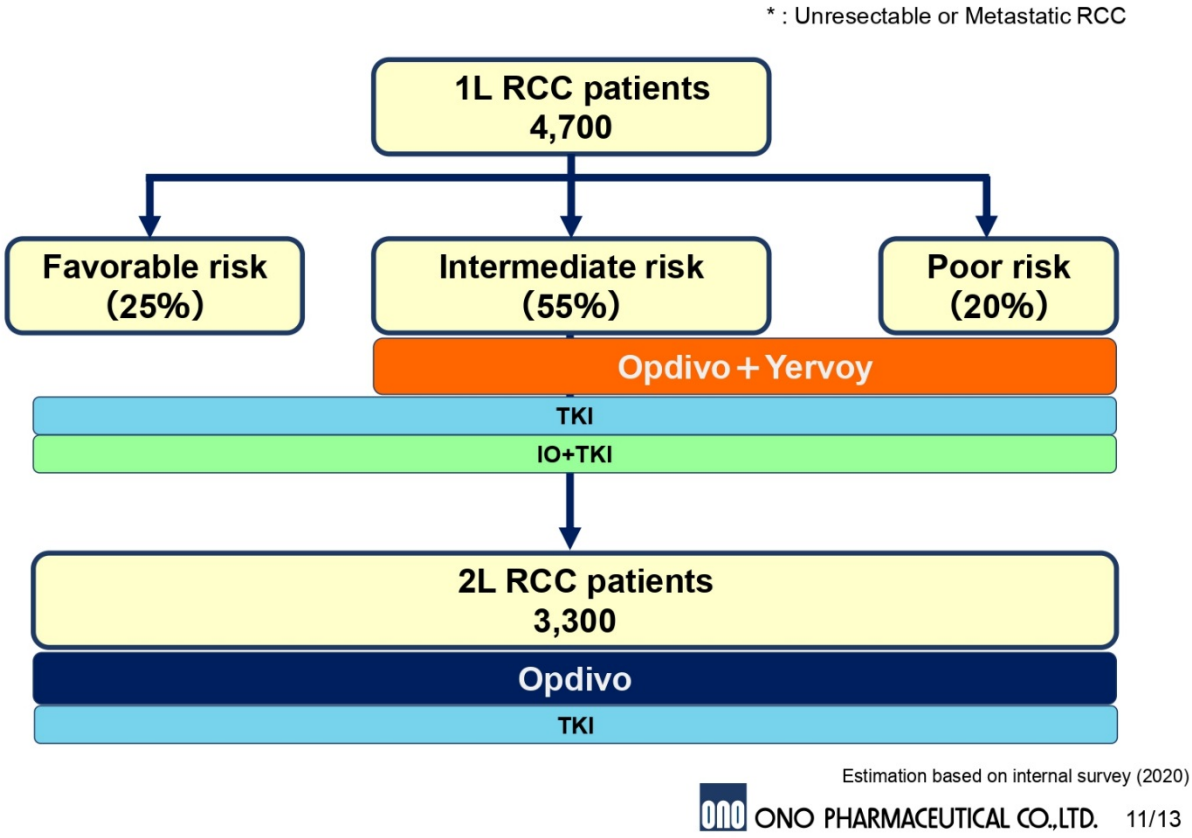
※ Patients starting 2L ESC within the last 3 months



Source: External data（Sep 2019 – Feb 2021: n=150~158)

Opdivo has 53% of the market share in the second-line treatment and beyond. We will continue to raise awareness of the effectiveness of Opdivo on gastric and esophageal cancers in this gastrointestinal field.

Number of RCC* Patients per year in Japan

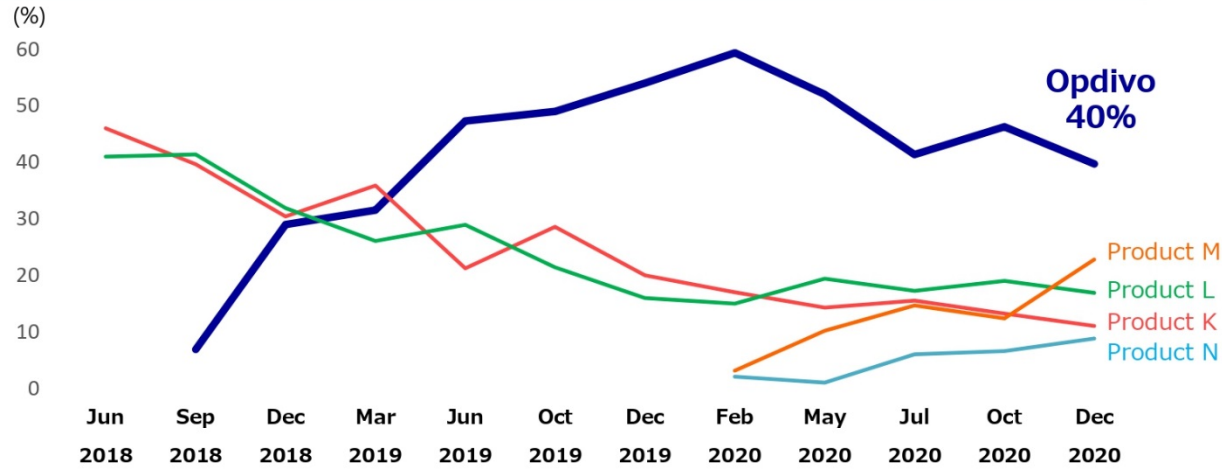


Estimation based on internal survey (2020)

Opdivo has an evidence in the first- and second-line treatments, and we are working to bring Opdivo to all renal cell carcinoma patients.

Prescription Ratio in Patients Newly Treated for 1L RCC

	2018 Jun	Sep	Dec	2019 Mar	Jun	Oct	Dec	2020 Feb	May	Jul	Oct	Dec	
Opdivo	**-**	**7**	**29**	**32**	**47**	**49**	**54**	**59**	**52**	**41**	**46**	**40**	(%)
Product K	46	40	30	36	21	29	20	17	14	16	13	11	(%)
Product L	41	41	32	26	29	21	16	15	19	17	19	17	(%)
Product M								3	10	15	12	23	(%)
Product N								2	1	6	7	9	(%)



Source: External data（Jun 2018 – Dec 2020: n=39~100)

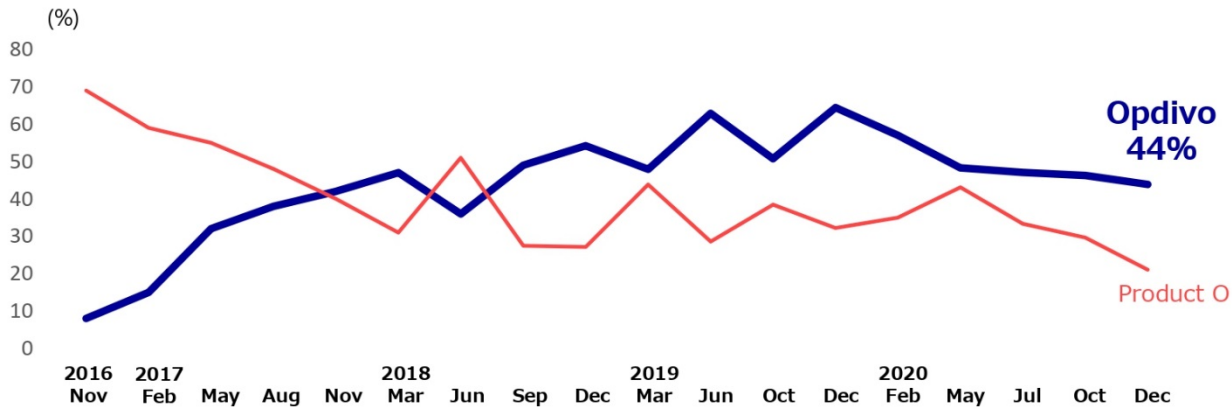
ONO PHARMACEUTICAL CO.,LTD. 12/13

In the first-line treatment, the combination therapy of I-O + TKI has entered the market, and prescriptions are gradually increasing, with 70% of first-line treatments now being I-O therapy.

The share of new patient prescriptions for the combination therapy of Opdivo and Yervoy has been maintained at 40%. Looking at the intermediate- and high-risk patients in whom Opdivo and Yervoy combination therapy is granted, the share of new patient prescriptions for the combination therapy of Opdivo and Yervoy has remained at more than 50%.

Prescription Ratio in Patients Newly Treated for 2L RCC

	2016 Nov	2017 Feb	May	Aug	Nov	2018 Mar	Jun	Sep	Dec	2019 Mar	Jun	Oct	Dec	2020 Feb	May	Jul	Oct	Dec	
Opdivo	8	15	32	38	42	47	36	49	54	48	63	51	64	57	48	47	46	44	(%)
Product O	69	59	55	48	40	31	51	27	27	44	29	38	32	35	43	33	30	21	(%)



Source: External data（Nov 2016 – Dec 2020: n=32~58)

ONO PHARMACEUTICAL CO.,LTD. 13/13

Earlier, I showed you that the I-O therapy in first-line treatment is expanding. Although the number of patients who have not been treated with immune checkpoint inhibitors in second-line therapy is decreasing, the share of new patient prescriptions for monotherapy with Opdivo in second-line therapy is currently 44%.

If we focus on previously untreated patients with I-O, the share of prescriptions exceeds 70%, and we will continue to work to ensure that Opdivo is available to all patients in the renal cell carcinoma field.

In the current fiscal year, we will first try to regain the market share by pushing forward with our activities in the first-line treatment of lung cancer, for which we obtained approval last year.

In adjuvant treatment for gastric cancer, we estimate that the number of patients who receive preoperative radio chemotherapy, which is an inclusion criteria in CheckMate-577, is around 800 per year, but we believe that number of target patients will expand to around 4,000, based on the approval condition or if it is positioned as a standard treatment.

In adjuvant treatment for urothelial carcinoma, the number of patients at high risk of recurrence, which is an inclusion criteria in CheckMate-274, is estimated to be around 3,000.

Also, cancer of unknown primary, the first-line treatment for malignant pleural mesothelioma, and pediatric Hodgkin lymphoma are rare cancers, and unmet needs are high. Therefore, we will make efforts to provide information, including disease awareness.

We will continue to deliver the benefits of Opdivo as a monotherapy and combination therapy with Yervoy and other therapies to cancer patients.

Development pipeline

Idemitsu: I will explain the progress of the development products.

First, I would like to start with an explanation using the supplementary materials.

As for the materials, pages 3 to 5 of the financial results report show the main progress of the development products. Pages 7 to 10 of the supplementary materials of the financial results report also show the main progress of the development products.

I. Main Status of Development Pipelines (Oncology)

As of April 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	Non-small cell lung cancer *1	Injection	Taiwan	In-license (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

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

*1: An application was approved in Taiwan for combination therapy of Opdivo and Yervoy for the treatment of unresectable advanced or recurrent non-small cell lung cancer.

<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
Yervoy Injection ★ / Ipilimumab	Additional indication	Malignant pleural mesothelioma	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Urothelial cancer *2	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer *3	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

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

*2: An approval application for Opdivo was filed in Japan for the adjuvant therapy of resected urothelial cancer.

*3: An approval application for Opdivo was filed in Japan for the adjuvant therapy of esophageal cancer.

<Clinical Trial Stage>

<Opdivo>

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

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
Opdivo Intravenous Infusion / Nivolumab	Additional indication	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)

<Yervoy> ***) :** "In-house" compounds include a compound generated from collaborative research.

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
Yervoy Injection ★ / Ipilimumab	Additional indication	Head and neck cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	Japan S. Korea Taiwan	I / II	In-license (Co-development with Bristol-Myers Squibb)

<I-O Related> ***) :** "In-house" compounds include a compound generated from collaborative research.

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
ONO-7701 ★ (BMS-986205) / Linrodostat	New chemical entities	Bladder cancer / IDO1 inhibitor	Tablet	Japan S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
ONO-4686 ★ (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4482 ★ (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7807 ★ (BMS-986258)	New chemical entities	Solid tumor / Anti-TIM-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483 ★ (BMS-986015) / Lirilumab	New chemical entities	Solid tumor / Anti-KIR antibody	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-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

<Others> ***) :** "In-house" compounds include a compound generated from collaborative research.

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
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-7475	New chemical entities	Acute leukemia / Axl/Mer inhibitor	Tablet	USA	I / II	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.)

★: Combination with Opdivo.

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

* Development of Opdivo for the treatment of solid tumor (cervix carcinoma, uterine body cancer, soft tissue sarcoma) was discontinued in Japan due to strategic reasons.
* Development of Opdivo for the treatment of central nervous system lymphoma / primary testicular lymphoma was discontinued in Japan due to strategic reasons.

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

First of all, I will use the supplementary materials of this financial report to explain the updated portions after the third quarter of fiscal year ending March 31, 2021.

The materials are organized in the following order: oncology and non-oncology. They are also listed in order of development stage: approval, application, Phase III, II and I.

The first area is oncology on page 7. Regarding Yervoy, following the approvals in Japan and South Korea, we received approval in Taiwan in combination with Opdivo for non-small cell lung cancer in February.

Next is the section on development products under application. The second one from the top of the table, the application of Opdivo for approval as an adjuvant treatment for urothelial cancer was filed in March.

We filed an application of Opdivo for approval as an adjuvant treatment for esophageal cancer in February.

Below that is the section on products under development in clinical trials, which continues on page 9. See the note below the table on page 9. Phase II studies of Opdivo for cervix carcinoma, uterine body cancer, and soft tissue sarcoma, as well as central nervous system lymphoma and primary testicular lymphoma, have been terminated for strategic reasons and have been removed from this document.

II. Main Status of Development Pipelines (Areas other than Oncology)

As of April 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
Joyclu Intra-articular Injection / ONO-5704 / SI-613	New chemical entities	Osteoarthritis *4 / Hyaluronic acid-NSAID	Injection	Japan	In-license (Seikagaku Corporation)

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

*4: An application for Joyclu Intra-articular Injection / ONO-5704 / SI-613 was approved in Japan for the treatment of osteoarthritis (knee joint and hip joint).

<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)
Foipan Tablets / Camostat mesilate	Additional indication	Novel coronavirus infection (COVID-19) / Protease enzyme inhibitor	Tablet	Japan	III	In-house
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / Short-acting selective β_1 blocker	Injection	Japan	II / III	In-house
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 *5 / 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 / 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

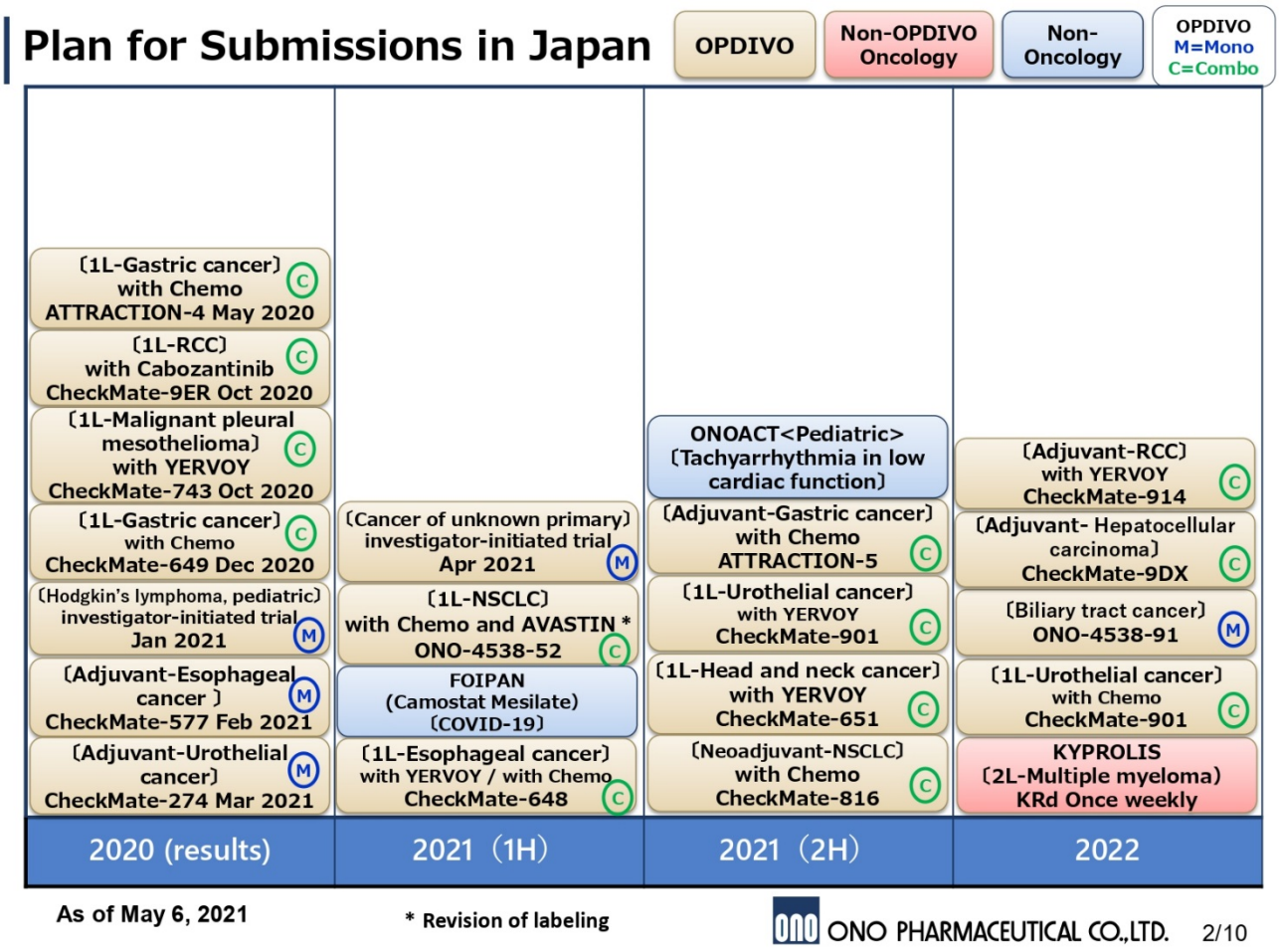
Changes from the announcement of financial results for the third quarter of the fiscal year ended March 2021

*5: Phase II of Schwann cell differentiation promoter (ONO-2910) was initiated in Japan for patients with diabetic polyneuropathy.

Next, from page 10, we show the progress of development in areas other than oncology.

In the approved items list, we have Joyclu, which is a compound that combines the anti-inflammatory analgesic diclofenac with hyaluronic acid. It was licensed from Seikagaku Corporation. It was approved in March for the treatment of osteoarthritis.

Next is ONO-2910, which is a compound that promotes the differentiation of Schwann cells. These cells form the myelin sheath that covers nerve axons. A Phase II study for diabetic polyneuropathy has been initiated.



Opdivo is shown in beige, oncology areas other than Opdivo are shown in red, and non-oncology areas are shown in blue.

For Opdivo, as shown in the upper right corner, M is used for monotherapy and C for combination therapies. Please note that the timing of the application is based on the earliest possible schedule, assuming things go as planned, and is subject to change.

From left to right, the results for FY2020, the plan for the first half of FY2021, the plan for the second half of FY2021, and finally, on the far right, the plan for FY2022.

I will now focus on the changes from the previous earnings announcement in February. First of all, in the FY2020 results on the far left, the second from the bottom is for the adjuvant treatment of Opdivo for esophageal cancer, and the bottom row is for the adjuvant treatment for urothelial cancer.

Next, the second one from the left, the first half of FY2021, as shown in the top row, we submitted an application for Opdivo for cancer of unknown primary in April.

Under this, the package insert will be revised for the combination of chemotherapy and Avastin for the first-line treatment of non-small cell lung cancer. Compared to the previous presentation, the timing has been moved from the second half of FY2020 to the first half of FY2021. This is because, unlike the case of additional indications, the timing of the revision of the package insert cannot be indicated in the form of an application for approval. In other words, the procedure itself is proceeding as planned.

The third from the top, Foipan, is currently in Phase III for COVID-19. Patient recruitment has been completed and administration and observation is expected to be completed by the end of May. We are preparing to fix the data so that the results can be obtained as soon as possible.

We recently obtained the results of CheckMate-648 for the first-line treatment of esophageal cancer. This is shown in the bottom row. The combination of Opdivo and chemotherapy, as well as the combination of Opdivo and Yervoy, was found to be effective in terms of overall survival. We are currently preparing the application.

Next, regarding the second half of FY2021. At the top, we are planning to file an application for pediatric use of Onoact.

As for Opdivo, the results of the adjuvant treatment of gastric cancer are expected to come out around this time. The third from the top is for the first-line treatment of urothelial cancer, and the fourth is for the first-line treatment of head and neck cancer, both of which are combination trials of Opdivo and Yervoy. If we get the results as expected, we will file applications in sequence.

At the bottom is the study on neoadjuvant treatment of non-small cell lung cancer. Pathological CR results have already been obtained, and we plan to submit an application in the second half of FY2021.

Finally, the last column for FY2022. First, there is Opdivo, which is in the top row, that's for renal cell carcinoma, second is for hepatocellular carcinoma as an adjuvant treatment, third is for biliary tract cancer, and fourth is for urothelial cancer in combination with chemotherapy. The results of these studies are expected to come out, and if the expected results are obtained, the application will be submitted sequentially.

In addition, in the bottom row is the KRd Kyprolis combination for multiple myeloma. K, carfilzomib, R, lenalidomide, and d, dexamethasone are used. We are planning to file an application for once a week based on the results of the ongoing study.

Clinical trials in combination therapy
OPDIVO & other Immuno-Oncology compounds

As of May 6, 2021

Development code (Generic name) Pharmacological action	Cancer type	Japan	US/EU	KR/TW
ONO-7701 （Linrodostat） IDO1 inhibitor	Bladder cancer	Ⅲ	Ⅲ	Ⅲ
ONO-4686 Anti-TIGIT antibody	Solid tumor	Ⅰ／Ⅱ	Ⅰ／Ⅱ	-
ONO-7807 Anti-TIM-3 antibody	Solid tumor	Ⅰ／Ⅱ	Ⅰ／Ⅱ	-
ONO-4482 (Relatlimab) Anti-LAG-3 antibody	Melanoma	Ⅰ／Ⅱ	Ⅱ／Ⅲ	-
ONO-4483 (Lirilumab) Anti-KIR antibody	Solid tumor	Ⅰ	Ⅰ／Ⅱ	-
ONO-4578 * PG receptor (EP4) antagonist	Solid tumor, Gastric cancer	Ⅰ	Ⅰ／Ⅱ	-
	Colorectal cancer	Ⅰ	-	-
	Pancreatic cancer	Ⅰ	-	-
	Non-small cell lung cancer	Ⅰ	-	-
ONO-7475 Axl/Mer inhibitor	Solid tumor	Ⅰ	-	-
ONO-7911 (Bempegaldesleukin) PEGylated IL-2	Solid tumor	Ⅰ	Ⅰ／Ⅱ	-
	Melanoma	-	Ⅲ	-
	Renal cell carcinoma	-	Ⅲ	-
	Bladder cancer	-	Ⅲ	-

Red: Update after May 2020

*ONO-4578 was out-licensed to BMS in 2017, but the rights were returned.

ONO PHARMACEUTICAL CO.,LTD. 6/10

As for the status of our development projects, there is one point that I would like to explain. ONO-4578, the third drug from the bottom of page 6, is an EP4 receptor antagonist. In 2017, we out-licensed the drug to BMS mainly for the US and European rights, but the rights were returned to us and Ono will develop the compound in the US and Europe. We are currently expanding the Phase I study to include various types of cancer.

Question & Answer

Q: Thank you very much. 2 quick questions.

The first one is the premise of the earnings forecast. The NHI price recalculation for Opdivo was announced yesterday or today in association with the one for the competitive drug. Is it correct that this is not included in your earnings forecast?

Since it was announced yesterday, I don't really want to criticize what was announced, but I understand that the rules are a bit opaque, and I would like to know what you think about that.

Since the rate will be lowered by 11.5% from August, please tell us how your company plans to reflect this, including the timing.

Sagara: First of all, the current forecast does not reflect the price cut of Opdivo from August 1. I am aware that the decision will be made based on the results of today's meeting of the Central Social Insurance Medical Council. Therefore, based on this, I would like to make corrections as soon as possible if they are necessary.

One more thing is the rules for market expansion recalculation due to the one for the other drug. It is complicated and difficult to understand.

Basically, there are two types of the recalculation rules, the typical market expansion recalculation rule and the special recalculation rule where there is criteria for huge amount of over JPY100 billion or over JPY150 billion. As for the typical recalculation rule, the drug price is recalculated based on the comparison between sales and the peak sales forecast, for example, if the sales exceeds JPY15 billion and is more than double of the peak sales forecast, or otherwise the sales reached more than JPY35 billion.

In the current rules, the normal recalculation will cause the recalculation of other drugs. In the recalculation based on huge sales amount, the recalculation is applicable to the products that were launched later than the recalculated product, but not with Opdivo. If Keytruda is recalculated, Tecentriq, Bavencio, and Imfinzi receive the recalculation, while Opdivo does not.

There is a rule that if Bavencio receives the recalculation for a huge sales amount, Tecentriq and Imfinzi will receive the same one, but Opdivo and Keytruda will not. As Bavencio is excluded for the recalculation this time, all competitive drugs are not subject to the recalculation. So, there is still discussion on a possibility of future recalculation for Opdivo, but Opdivo will not receive the recalculation in terms of the special recalculation due to huge sales expansion.

There is a possibility of the normal recalculation. Since the recalculation of Keytruda and Tecentriq has already been completed, if the normal recalculation of Bavencio and Imfinzi occurs, and if they are recognized as the one for the competitive drugs, there is still a risk. I can only give a brief explanation, but I am aware that this is the rule.

Q: About your plan for research and development expenses, there is an increase of JPY9.6 billion. I would like to know how the increase or decrease relates to Opdivo and the other drugs.

I would also appreciate it if you could give us a breakdown of the total JPY72 billion, for Opdivo and other than Opdivo.

Tani: We can't disclose individual details. However, if you look at the balance between research and development, until about 2 years ago, the ratio was one for research and 2 for development, but now it is 4 to 6.

Q: I believe that the combination of Keytruda and Lenvima has been filed as first-line therapy for renal cell carcinoma. Also announced was the successful completion of a Phase III study for adjuvant treatment with Keytruda monotherapy. How do you think these factors will affect sales of Opdivo?

Takahagi: Regarding the combination therapy with Lenvima and Keytruda for renal cell carcinoma, an I-O+TKI therapy has been already on the market, so this is the second regimen for Keytruda. However, we will be participating in the I-O+TKI combination therapy with cabozantinib and Opdivo in the future, and we would like to push forward with it.

Regarding adjuvant therapy for renal cell carcinoma, we have confirmed the data, but we are still examining how it will have the impact on the market. We will provide the information when it becomes available.

Q: Regarding the drug price of Opdivo, Mr. Sagara said earlier that he would like to reflect the 11.5% revision when it is made official. On the other hand, looking at the breakdown, gastric cancer first line hardly appears in the forecast for this fiscal year. It looks as if there is only about JPY5 billion included at most.

What I would like to say is that, for example, at the timing of the first quarter in August and the second quarter in November, I wonder if there is really a need to lower the forecast because of the NHI price revision. If the first line is in there quite conservatively, I think it will be fine. What are your thoughts on that?

Sagara: We have not made clear the current breakdown of the JPY120 billion. It is certainly possible to interpret it the way you suggested. However, we would like to consider the matter promptly, including whether or not to revise it based on total consideration.

Q: I understand. I am also interested in the medium- to long-term potential of Opdivo adjuvant treatments.

Your company has already applied for 2 adjuvant treatments, and from the table you gave us, I think we will see the results of many adjuvant treatments in the next 1 or 2 years, such as lung cancer, stomach cancer, RCC and HCC. If we assume that the NHI price will not change, how much potential impact do you think it will have?

Takahagi: Regarding the potential, there are some very difficult aspects based on approval conditions, so it may be difficult to give an answer.

For example, if we can gain approval for the adjuvant treatment in gastric cancer, we can expect about 8,000 patients per year. What percentage we can obtain among them will depend on the data, but if it becomes very large, we can expect even larger sales than the current sales of gastric cancer.

Q: Other than gastric cancer, there are some adjuvant treatments. Do you think that the adjuvant treatment of HCC is quite interesting? Looking at the adjuvant treatments by organs, do you have any idea in which type of cancer the adjuvant treatment is effective or in which cancer the adjuvant treatment is stiff on the market?

Takahagi: It is true that there is no standard adjuvant treatments of each type of cancer, such as non-small cell lung cancer and urothelial cancer. While it will depend on the data from Opdivo, we believe that there is a high unmet need, so we have high expectations.

Sagara: I'll add a few things. I don't know how much share we can obtain for the adjuvant treatment of gastric cancer, but I hope to get the share of twice as large as the current gastric cancer market. Esophageal cancer may be half of that at most. As for urothelial cancer, it is somewhere in between.

This is subject to various conditions at the time of approval, so it may change, but that is the general idea at the moment.

Q: I have 2 simple questions.

As for the composition of the projected sales of Opdivo, looking at the sales by cancer type, the third line share of gastric cancer, as you can see on the slide, has been estimated to be around 75%. I think that is the situation.

In that case, as you mentioned, the future growth areas for Opdivo will naturally include adjuvants, but how much growth we see in the first line of esophageal cancer, lung cancer, for example, will determine whether or not the JPY120 billion for this fiscal year will go up or down. I don't think there will be a swing down, but I think that will be a deciding factor. That is the first point.

Takahagi: As you said, our main focus for this fiscal year is lung cancer. As I mentioned earlier, we would like to achieve a 30% share of new patient prescriptions for lung cancer. I believe that the success of this project will determine whether or not we can reach our goal of JPY120 billion.

In addition, we believe that esophageal cancer, for which we received approval last year, will continue to grow. As for the prescription share, it is currently 53%, but if more than 60% of patients receive the drug, we can expect a further increase. I don't know when the first-line treatment of gastric cancer will be approved, but I think it is a positive factor. Taking these factors into account, we would like to aim for JPY120 billion at the current NHI price.

Q: One more thing. On page 5 of the first presentation that President Sagara used, there is a section on investment for future growth.

The time frame for this is 5 years from now, and if we say 5 years from now, it will be 2026. When I think about the Opdivo cliff, the royalties from Merck will start to decline in about 2023. Then I have an image that this Opdivo cliff will be pretty sluggish.

In order to deal with that, you need to make a big investment at a very early stage, for example, to expand business in the US. Also, I know in-license strategy is going well based on your track record, but I wanted to ask you more about what is going on in the Minase Research Institute in terms of increasing productivity?

I don't think you can answer all of these questions today, but if you could touch on them at some point. I think you mentioned something a little nuanced at the end, but please tell us something about the opportunities that you are envisioning for the future.

Sagara: It’s quite a rough outline of growth strategy investment over a 5-year span. Naturally, as you pointed out, there is not much slack, so it would be desirable to actually realize this investment as early as possible in this 5-year period, and that is what we are aiming for.

Also, as for the Opdivo cliff, as you mentioned, we need our own in-house product and it is not sufficient to have in-license products. Regarding the marketing of our products overseas, starting from the US and in Europe, we will soon start clinical trials in the US for several our own compounds. We will continue to work on the projects that we have already started.

There are also compounds in the late stages of development in the laboratory that do not yet have a development code, so we will continue to work on those.

Q: The first question is about selling and administrative expenses. The plan is for a large increase of about JPY7 billion compared to the previous year, and it was explained that this is IT investment. How many of them

are so-called one-off items that will only occur this period? In other words, how should we think about the outlook for SG&A expenses in the next fiscal year and beyond?

Sagara: There will be a large increase in the SG&A expenses for this fiscal year. There will be 2 major new products, Adlumiz and Joyclu, for which we have high expectations. This is also a major factor.

The rest is digital-related and IT-related investments. Although some of these expenses are recorded in a single year and some will continue for several years, we do not have the image that these SG&A expenses excluding R&D expenses, will continue to increase. I have an image that there will be years when we spend this much, or we will spend less, and that will continue in the medium term in the near future.

Q: In terms of the sales ratio, it has dropped from about 25% level in the past to about 22%. In that sense, if sales of Opdivo and new products continues to grow, is your view basically that SG&A expenses will go down? Or will it remain at a level of around 20%?

Sagara: I don't have a definite answer, and it's hard to estimate. We have an image that the ratio will go down.

Q: My last question is about lung cancer with Opdivo.

You mentioned earlier that you expect the share in the first line market will be 30%. Does this mean a 30% share of the so-called 35,000 people? Do you foresee a market opportunity of, say, JPY100 billion for the first-line lung cancer treatment? I would like to ask you a little bit about the expectation of peak sales in this first line lung cancer, and the assumption of a 30% share.

Takahagi: As I explained earlier, there are currently 35,000 patients in the lung cancer market. In this context, the current criteria for initiation of treatment are as follows: PD-L1 is defined as negative, 1-49% (low positive), or 50% or more (high positive).

In this context, our strength is that we have solid data for Opdivo/Yervoy in 1-49% and negative cases. These patients cover roughly 60% to 70% of the market, so we are aiming for half of that, or 30%, which is our current target.

As a result, if the number of new prescription patients increases, sales in lung cancer will gradually expand.

Q: Regarding the future strategic investment that you introduced here, what is your approach to overseas expansion? You mentioned that you are going to invest JPY30 billion to JPY50 billion to expand your sales network, but will the base case be to receive royalties as you are doing now, or will you have to acquire other companies in order to expand your own business?

Or, if it is a specialized area to some extent, can you tell us about your strategic thinking on whether it is possible to start up by yourself from the JPY30 billion to JPY50 billion?

Sagara: Basically, the purpose for this investment is our own marketing. Considering the characteristics of the compound, there is possiblity to earn royalties through out-licensing in the future, but the investment we are talking about now is to obtain our own approval and sell the product by ourselves.

Q: Are you thinking of making an acquisition to enter the market?

Sagara: I am not sure if that is an option. Basically, we believe that technologies, compounds will be targeted at the present time. In relation to this case of our own marketing overseas, I do not deny that it is a possibility, if it is at all possible.

Q: I'll just ask one question.

The financial results are very good, and as for the profit for this fiscal year, sales are up 13.2%, and Opdivo is expected to grow. I understand that royalties will also increase by over JPY10 billion, but is the reason why profits do not increase much in relation to sales revenue simply because R&D will increase by nearly JPY10 billion and amortization will increase? Or do you think that the profitability of the other areas is a bit difficult?

Sagara: One possible reason is that it is a rebound caused by the fact that we were able to generate a lot of profit due to lower costs, including R&D expenses that we had planned to spend but were unable to in the previous fiscal year. R&D investment will increase by nearly JPY10 billion, and that means other SG&A expenses will also increase.

Also, we received one-time income from Roche in the previous year, which boosted operating income by several billion yen. Billions of yen in the second half. I think that is why I am looking at it in the same way as you.

Q: I understand that you have not announced the breakdown of the JPY21.2 billion increase in sales of Opdivo this fiscal year, but from the explanation you gave earlier, I get the impression that a large part of the increase is due to lung cancer, followed by gastric cancer and others.

Sagara: Yes. We believe that the main reason for the JPY21.2 billion increase in sales is the contribution from first line lung cancer and first line gastric cancer, which will be approved in the second half of the fiscal year.

Q: Would you give me a little insight into the outlook for R&D expenses? Today's discussion made me think that your company will have to aggressively invest in R&D in the future, even considering P/L. Although you mentioned JPY72 billion for this fiscal year, I believe that the amount will increase further when overseas assets, etc. are added. Please tell us how much you are planning to increase the amount.

Sagara: In the near future, as soon as possible, we would like to become a company that is capable of investing JPY100 billion in research and development.

Our sales forecast is roughly JPY350 billion right now, but for example, with sales of JPY400 billion and R&D expenses of JPY100 billion, we would be investing about 25%. We are aiming for this 20% to 25% window, and we would like to increase the amount from the current JPY72 billion. We want to become a company that can invest JPY100 billion a year in R&D in the near future.

Q: In that case, the degree of change of expenses will also increase in the next fiscal year and the fiscal year after that.

Sagara: I'm not talking about JPY100 billion next fiscal year.

Q: I don't think it will be JPY100 billion next fiscal year, but is it safe to assume that the increase will be reasonably large next fiscal year and the year after that?

Sagara: We will try to make it so in the near future, as soon as possible.

Q: I would like to know one more thing briefly. I think the application based on the results of ATTRACTION-5 was moved from the first half to the second half of the fiscal year in this document. What is the factor?

Idemitsu: We are still waiting for the results. The timing is revised due to a slight delay in getting the results.