ONO PHARMACEUTICAL CO., LTD.

Financial Results for Q2 FY2021

November 2, 2021

[Number of Speakers] 7

Gyo Sagara	President, Representative Director, CEO
Toshihiro Tsujinaka	Member of the Board of Directors, Senior Executive Officer, Executive Director of Corporate Strategy & Planning
Toichi Takino	Member of the Board of Directors, Senior Executive Officer, Executive Director of Discovery & Research
Kiyoaki Idemitsu	Member of the Board of Directors, Corporate Executive Officer, Executive Director of Clinical Development
Satoshi Takahagi	Executive Director of Sales and Marketing
Kazuhiro Nagahama	Director of Finance and Accounting Department
Yukio Tani	Corporate Executive Officer, Head of Corporate Communications

Revenue

Revenue	YoY Change
¥ 174.1 billion	+ 15.7 %

Breakdown of Revenue

(Billion yen)

	FY 2020 Q2	FY 2021 Q2	YoY Change
Revenue of Goods and Products	106.5	119.2	+ 11.9 %
Royalty & other revenue	44.0	54.9	+ 24.8 %
Total	150.5	174.1	+ 15.7 %

Sagara: I would now like to report on our business results for the second quarter.

First of all, sales revenue increased by JPY23.6 billion YoY to JPY174.1 billion. This is a 15.7% increase in sales. Sales of products increased to JPY119.2 billion, an increase of 11.9% YoY. Royalties and other revenue was JPY54.9 billion, an increase of 24.8% YoY.

Revenue

Sales of Major Products

(Billion yen)

	FY 2020 Q2	FY 2021 Q2	YoY Change
Opdivo	49.1	**56.1**	**+ 14.3 %**
Forxiga	10.5	**15.6**	**+ 49.3 %**
Glactiv	13.0	**12.7**	**- 1.7 %**
Orencia SC	10.9	**11.2**	**+ 3.3 %**
Parsabiv	3.9	**4.5**	**+ 15.6 %**
Kyprolis	3.5	**4.2**	**+ 18.6 %**
Velexbru	0.5	**2.9**	**+ 497.2 %**
Onoact	2.2	**2.3**	**+ 8.8 %**
Braftovi	0.3	**1.4**	**+ 301.0 %**
Mektovi	0.3	**1.1**	**+ 234.9 %**
Ongentys	0.1	**0.9**	**+1477.7 %**
New Products（FY2021）	–	**0.5**	–

Next, sales by product.

Opdivo, Forxiga, Parsabiv, Kyprolis, and Velexbru have contributed to the increase in sales.

Sales of Opdivo increased by JPY7 billion, or 14.3% YoY. This increase was mainly due to the expansion use for first-line treatment of non-small cell lung cancer, and second-line treatment of esophageal cancer.

Sales of Forxiga increased by JPY5.2 billion, or 49%, due to the sales contribution by additional indication approvals for chronic heart failure and chronic kidney disease, in addition to the existing indication of diabetes.

In addition, we believe that the sales of products such as Braftovi and Mektovi have got a certain amount of sales share. Sales of Velexbru, for which clinical trials have started in the US, is also in a favorable situation.

Revenue

Sales of Long-term Listed Products

(Billion yen)

	FY 2020 Q2	FY 2021 Q2	YoY Change
Opalmon	2.9	**2.4**	- 16.8 %
Rivastach	4.1	**1.6**	- 61.7 %
Onon capsule	1.2	**1.8**	+ 49.6 %

Next, long-term listed products.

This time, there are a number of points of note. Sales of Opalmon is gradually shrinking. For Rivastach, there was a large decrease in sales due to the generics entry on the market. As for Onon, the downward trend has not changed, but there was a slight increase due to a supply shortage in generic companies.

Operating Profit

Operating Profit	YoY Change
¥ 58.2 billion	+ 11.0 %

Costs, etc.

(Billion yen)

	FY 2021 Q2	YoY Change	
・Cost of Sales	¥ 45.6 billion	(+ 9.1%)	
・R&D Expenses	¥ 32.6 billion	(+ 26.5%)	①
・SG&A Expenses	¥ 37.7 billion	(+ 26.3%)	②
①+② Total	¥ 70.2 billion	(+ 26.4%)	
・Other Income	¥ 0.7 billion	(+ 83.1%)	
・Other Expenses	¥ 0.8 billion	(- 29.0%)	

Operating income was JPY58.2 billion, up JPY5.8 billion, or 11%, from the same period of the previous fiscal year.

Cost of sales showed a slight improvement, with 1.6% to 26.2%.

Research and development expenses increased by JPY6.8 billion, YoY. In clinical trials, the utilization rate of medical institutions has increased, and activities have recovered. In addition, investment in laboratories and research departments has been steadily increasing.

In terms of selling, general and administrative (SG&A) expenses excluding R&D expenses, we are continuing to aggressively promote web-based meetings, explanatory meetings, lectures, and other events due to the impact of the coronavirus pandemic. Actual visitation activities are increasing, but is not yet sufficient. Using the web a lot, it will cost more. As a result, SG&A expenses increased by JPY7.8 billion YoY to JPY37.7 billion.

Profit before Tax

Profit before Tax	YoY Change
¥ 59.2 billion	+ 10.4 %

Net financial income, etc.

+ ¥ 1.1 billion (YoY Change - ¥ 0.2 Billion)

Finance income :	**¥ 1.4 Billion**
(Dividend income received and gain on sale of investment securities, etc.)	
Finance costs :	**¥ 0.4 billion**
(Loss on valuation of investment securities and exchange losses, etc.)	

Profit before tax increased by JPY5.8 billion to JPY59.2 billion.

Profit for the Period
(Owners of the Parent Company)

Profit for the Period (Owners of the Parent Company)	YoY Change
¥ 46.3 billion	+ 16.2 %

Income tax expense

¥ 12.9 billion (YoY Change - 6.4 %)

(Major change factors)

Increase in profit before tax	¥ 5.6 billion
Decrease in corporate tax	¥ 0.9 billion

Profit for the period was JPY46.3 billion, an increase of 16.2%.

For the first half of the fiscal year, both sales and profits reached record highs.

As for dividends, we plan an annual dividend of JPY56 per share. In the interim period, we will pay a half dividend of JPY28.

These are the financial results of the period.

Revenue (Forecasts)

Revenue	YoY Change
¥ 345.0 billion	+ 11.5 %

Breakdown of Revenue

(Billion yen)

	FY 2020 (Result)	FY 2021 (Forecast)	YoY Change
Revenue of Goods and Products	214.5	240.0	+ 11.9 %
Royalty & other revenue	94.7	105.0	+ 10.8 %
Total	309.3	345.0	+ 11.5 %

We will continue with our full-year earnings forecast.

Immediately after the announcement of financial results made in May, we revised our sales forecast to JPY345 billion. This forecast remains unchanged. Both revenue of goods and products, and royalties and other revenue also remain unchanged.

Revenue (Forecasts)

Sales Forecasts of Major Products

(Billion yen)

	FY 2020 (Result)	FY 2021 (Forecast)	YoY Change
Opdivo	98.8	110.0	+ 11.3 %
Forxiga	22.4	35.0	+ 56.6 %
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 %
Velexbru	2.1	5.0	+ 142.6 %
Onoact	4.7	4.0	- 14.1 %
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	–	2.5	–

The sales forecast by product also remains unchanged.

Revenue (Forecasts)

Sales Forecasts of Long-term listed products

(Billion yen)

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

As for the sales forecast of the long-term listed products, the situation remains unchanged.

Operating Profit (Forecasts)

Operating Profit	YoY Change
¥ 103.0 billion	+ 4.7 %

Costs, etc.

(Billion yen)

	FY 2021 (Forecast)	YoY Change
・Cost of Sales	95.0	(+ 11.0 %)
・R&D Expenses	72.0	(+ 15.4 %) ①
・SG&A Expenses	74.0	(+ 6.9 %) ②
①+② Total	146.0	(+ 10.9 %)
・Other Income	1.0	(- 87.8 %)
・Other Expenses	2.0	(+ 3.5 %)

Forecast of operating income is also unchanged.

Profit before Tax (Forecasts)

Profit before Tax	YoY Change
¥ 105.0 billion	+ 4.1 %

Net financial income, etc.

+ ¥ 2.0 billion (YoY Change - ¥ 0.6 Billion)

Forecast of profit before tax is also unchanged.

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

Profit for the Period (Owners of the Parent Company)	YoY Change
¥ 81.5 billion	+ 8.1 %

Income tax expense

¥ 23.4 billion (YoY Change - 7.8 %)

(Major change factors)

Increase in profit before tax	¥ 4.1 billion
Decrease in corporate tax	¥ 2.0 billion

There is no change in forecast of profit for the period.

This concludes my report on the interim financial result and full-year forecasts.

Results of Reduction of Cross-shareholdings

- Reduction plan (published on November 1, 2018)
  - Over the next 3 years, the company will reduce its cross-shareholdings by about 30% as of the end of March 2018 (111 brands, 167.1 billion yen).

- **Results of reduction**
  - **Number of listed brands : 40 brands (36.0%)**
  - **Amount (based on Market price at the end of March 2018) : ¥ 50.3bil (30.1%)**

	End of March 2018	End of September 2021	Reduction	Reduction rate
Number of listed brands	111	**71**	**40**	**- 36.0 %**
Balance sheet accounting amount	¥ 167.1 bil	¥ 141.8 bil	¥ 25.3bil	-15.1 %
Market price at the end of March 2018	**¥ 167.1 bil**	**¥ 116.8 bil**	**¥ 50.3 bil**	**-30.1 %**

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Sagara: I would like to touch on 2 other topics today.

The first topic is the reduction of our strategic cross-shareholdings. Starting from the strategically held shares as of the end of March 2018, we have proceeded with the goal of reducing the amount by 30% in the three years until the end of September this year. First, I will show the results.

The results are as shown in this slide. The amount of JPY167.1 billion at market price shown in the bottom row was reduced by 30% to JPY116.8 billion. This is based on the unit price as of the end of March 2018. The amount recorded on the balance sheet is JPY141.8 billion, and the actual reduction amount is JPY25.3 billion, which is about half.

The number of brands held has decreased by 40 to 71.

Future Plan for reduction of Cross-shareholdings

➢ **Next reduction plan**

・Period: October 2021 to March 2025 (3 and a half years)

・Details of reduction plan:

30% reduction from the end of September 2021 (141.8 billion yen)

※The company plans to reduce its cross-shareholdings to less than 20% of its net assets by the end of March 2022.

	End of September 2021	Expected at the end of March 2025	Plan	
			Reduction	Reduction rate
Market price at the end of September 2021	¥ 141.8 bil	¥ 99.3 bil	¥ 42.5 bil	-30.0%

➢ **Medium-to long-term plan**

We aim for the ratio of strategic shareholdings to net assets (on a balance sheet basis) to be less than 10%.

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We have formulated a future reduction plan starting from the market price of JPY141.8 billion as of the end of September this year.

With the goal of the end of March 2025, we will reduce by JPY42.5 billion, which is equivalent to 30%, over a period of three and a half years. Assuming that the stock price is fixed, we plan to reduce it to JPY99.3 billion.

The reason why we set the period at three and a half years this time is because it is easier to compare each period in the annual securities report and the settlement of accounts will be better separated, if we set the goal at the end of the period.

As three and a half years is a relatively long period, we have set one milestone. We are planning to reduce this JPY141.8 billion to less than 20% of net assets by the end of March 2022. If it is reduced by about JPY10 billion from JPY141.8 billion in 6 months, it will reach less than 20% of net assets.

However, there may be slight fluctuations depending on how net assets increase and stock price level, so we would like to proceed with that in mind. As you know, the ISS standard for exercising voting rights is less than 20% of net assets for the fiscal year ending March 31, 2022, so we would like to clear this requirement.

We would like to start with a reduction of about JPY10 billion in the first 6 months. This has been an outline of the new plan to reduce cross-shareholdings.

Sagara: The other topic is the prevention of the recurrence of inappropriate incidents and the strengthening of compliance. We have already been working diligently to establish an internal system to address this, and determined to strengthen compliance.

Regarding the system, we have set up a compliance officer who is an executive director class of each division.

In addition, we have established compliance managers at all of our offices, numbering 85 in total. These managers will promote the enhancement of the compliance system under the direction of the compliance officer.

In particular, the sales division will strengthen the system by appointing assistant managers in the organization belonging to the offices. In addition, the training system has been greatly strengthened compared to that last year.

In terms of organization, the Compliance Promotion Department is the main department responsible for this. Under this organization, we would like to proceed with compliance by establishing three organizations, the Compliance Promotion Office, which promotes company-wide compliance, the Assessment Office, which strengthens the local compliance system, and the Medical Review Office, which supervises promotion.

What I have just mentioned is something that all other companies are working on earnestly. We have strengthened our efforts in this area.

In addition to this, we have started to reflect compliance activities in personnel evaluations. Starting in the second half of FY2021, from October to March next year, we have clearly included compliance items in individual and organizational evaluations for all job grades.

Additionally, scholarship donations have been suspended for this fiscal year.

We are currently examining the method for next year and beyond, and as I have said in the past, we will come to a conclusion on how to handle scholarship donations for the next fiscal year and beyond by the end of December this year. What is clear is that we cannot resume the way in the way we did until last year. If we resume it, we will employ a new method.

Regarding academic society donations, general donations and support membership fees except for scholarship donations, we are making company-wide donations.

Since the social significance of these donations except for scholarship donations is clear and obvious, we decided to continue this in a fair and transparent way, and restarted it in October this year.

However, we have resumed the donation process with a policy that the sales department will not be involved in donations at all, nor will it relay them in the process. Therefore, I believe that we have been able to eliminate as much as possible the likelihood of seeing a repeat of the Mie University bribery incident.

A few final discussion points remain for the next fiscal year, but for now, we will proceed as reported here.

This concludes my report.

Development pipeline

Idemitsu: First of all, in pages 3 to 4 of the summary of Consolidated Financial Results, you can see the main progress of the development products. In addition, pages 6 to 10 of the Supplementary Materials describe the main progress of development products.

Today, I will provide an update from the FY2022 Q1 March presentation.

The structure of the document is as follows: first, the oncology field, and then the non-oncology field. They are listed in order of development stage: application filed, Phase 3, Phase 2, and Phase 1.

I. Main Status of Development Pipelines (Oncology)

As of October 22, 2021

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

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	In-house*) / In-license
Yervoy Injection ★ / Ipilimumab	Additional indication	Malignant pleural mesothelioma *1	Injection	Taiwan	In-license (Co-development with Bristol-Myers Squibb)
Braftovi Capsules / Encorafenib	Additional indication	Colorectal cancer *2 / BRAF inhibitor	Capsule	S. Korea	In-license (Pfizer Inc.)
Opdivo Intravenous Infusion / Nivolumab	Additional indication for pediatric use	Hodgkin lymphoma *3	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)

★: Combination with Opdivo.

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2022

*1: An application was approved in Taiwan for combination therapy of Opdivo and Yervoy for the treatment of unresectable malignant pleural mesothelioma.

*2: An application was approved in South Korea for Braftovi Capsules / Encorafenib for use in combination therapy with cetuximab for the treatment of adult patients with advanced or recurrent $BRAF^{V600E}$-mutant colorectal cancer after prior therapy.

*3: An approval for Opdivo was obtained in Japan to expand the use for the treatment of pediatric patients with recurrent or refractory classical hodgkin lymphoma.

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

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	In-house*) / In-license
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Urothelial cancer	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Cancer of unknown primary	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection ★ / Ipilimumab	Additional indication	Esophageal cancer *4	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2022

*4: Approval applications were filed in Japan for combination therapy of Opdivo and Yervoy and combination therapy of Opdivo and chemotherapy for the treatment of unresectable advanced or recurrent esophageal cancer.

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First, the oncology field. As you can see in the table of approved products on page 6, Yervoy was approved for the treatment of malignant pleural mesothelioma in combination with Opdivo in Japan in May, in South Korea in June, and in Taiwan in September.

Below, approval for Braftovi was obtained in South Korea for the treatment of BRAF-mutant colorectal cancer.

Next, the dosage and administration of Opdivo for pediatric indication was approved in Japan for the treatment of Hodgkin lymphoma.

Please refer to the table below for products under applications.

In September, we submitted an application for Opdivo and Yervoy combination therapy, and Opdivo and chemotherapy for the first-line treatment of esophageal cancer, as shown at the bottom of the table.

<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-7475 ★	New chemical entities	Solid tumor / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-7911 ★ (BMS-986321) / Benpegaldesleukin	New chemical entities	Solid tumor / PEGylated IL-2	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4578 ★	New chemical entities	Colorectal cancer / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Pancreatic cancer / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Non-small cell lung cancer / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Solid tumor ・ Gastric cancer / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
ONO-7913 ★ /Magrolimab	New chemical entities	Pancreatic cancer / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
	New chemical entities	Colorectal cancer / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
ONO-7119 ★	New chemical entities	Solid tumor *5 / PARP7 inhibitor	Tablet	Japan	I	In-license (Ribon Therapeutics, Inc.)

In the bottom row of the I-O related table, we can see ONO-7119, which is a PARP7 inhibitor in-licensed from Ribon Therapeutics. Phase 1 study in combination with Opdivo has been initiated for solid tumors.

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

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
ONO-7912 (CPI-613) / Devimistat	New chemical entities	Pancreatic cancer / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, Inc.)
	New chemical entities	Acute myeloid leukemia / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, Inc.)
Braftovi Capsules / Encorafenib	Additional indication	Thyroid cancer / BRAF inhibitor	Capsule	Japan	II	In-license (Pfizer Inc.)
Mektovi Tablets / Binimetinib	Additional indication	Thyroid cancer / MEK inhibitor	Tablet	Japan	II	In-license (Pfizer Inc.)
ONO-4059 /Tirabrutinib Hydrochloride	New chemical entities	Primary central nervous system lymphoma / BTK inhibitor	Tablet	USA	II	In-house
ONO-7475	New chemical entities	Acute leukemia / Axl/Mer inhibitor	Tablet	USA	I / II	In-house
	New chemical entities	EGFR-mutated non-small cell lung cancer / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-7912 (CPI-613) / Devimistat	New chemical entities	Pancreatic cancer / Cancer metabolism inhibitor	Injection	Japan	I	In-license (Rafael Pharmaceuticals, Inc.)
ONO-7913 / Magrolimab	New chemical entities	Solid tumor / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
	New chemical entities	Myelodysplastic syndromes (MDS) / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)
ONO-4578	New chemical entities	Hormone receptor-positive, HER2-negative breast cancer*6 / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
ONO-4685	New chemical entities	T-cell lymphoma*7 / PD-1 x CD3 bispecific antibody	Injection	USA	I	In-house

★: Combination with Opdivo.

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2022
*5: Phase I of combination therapy of Opdivo and ONO-7119 was initiated in Japan for the treatment of solid tumor.
*6: Phase I of ONO-4578 was initiated in Japan for the treatment of hormone receptor-positive, HER2-negative breast cancer.
*7: Phase I of ONO-4685 was initiated in the USA for the treatment of T-cell lymphoma.
* Phase III of Braftovi Capsules and Mektovi Tablets for the treatment of melanoma was discontinued in South Korea due to strategic reasons.
* Phase III of Mektovi Tablets for the treatment of colorectal cancer was discontinued in South Korea 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.

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ONO-4578 is an EP4 antagonist. We have started Phase 1 study in patients with hormone receptor-positive, HER2-negative breast cancer.

Below that, at the bottom. ONO-4685 is a bispecific antibody for PD-1 and CD3. We have started Phase 1 study for T-cell lymphoma in the US.

Please note that there is a change in the table for Braftovi capsules and Mektovi tablets from the previous version. In the previous document, it was stated that the combination treatment with Braftovi and Mektovi is in Phase 3 for BRAF-mutant malignant melanoma in South Korea. However, due to strategic reasons, the development for malignant melanoma has been discontinued.

As for Mektovi, we were conducting a Phase 3 study in South Korea for the treatment of BRAF-mutant colorectal cancer in combination with Braftovi. As I mentioned earlier, Braftovi was approved in South Korea, while Mektovi was discontinued for strategic reasons.

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

As of October 22, 2021

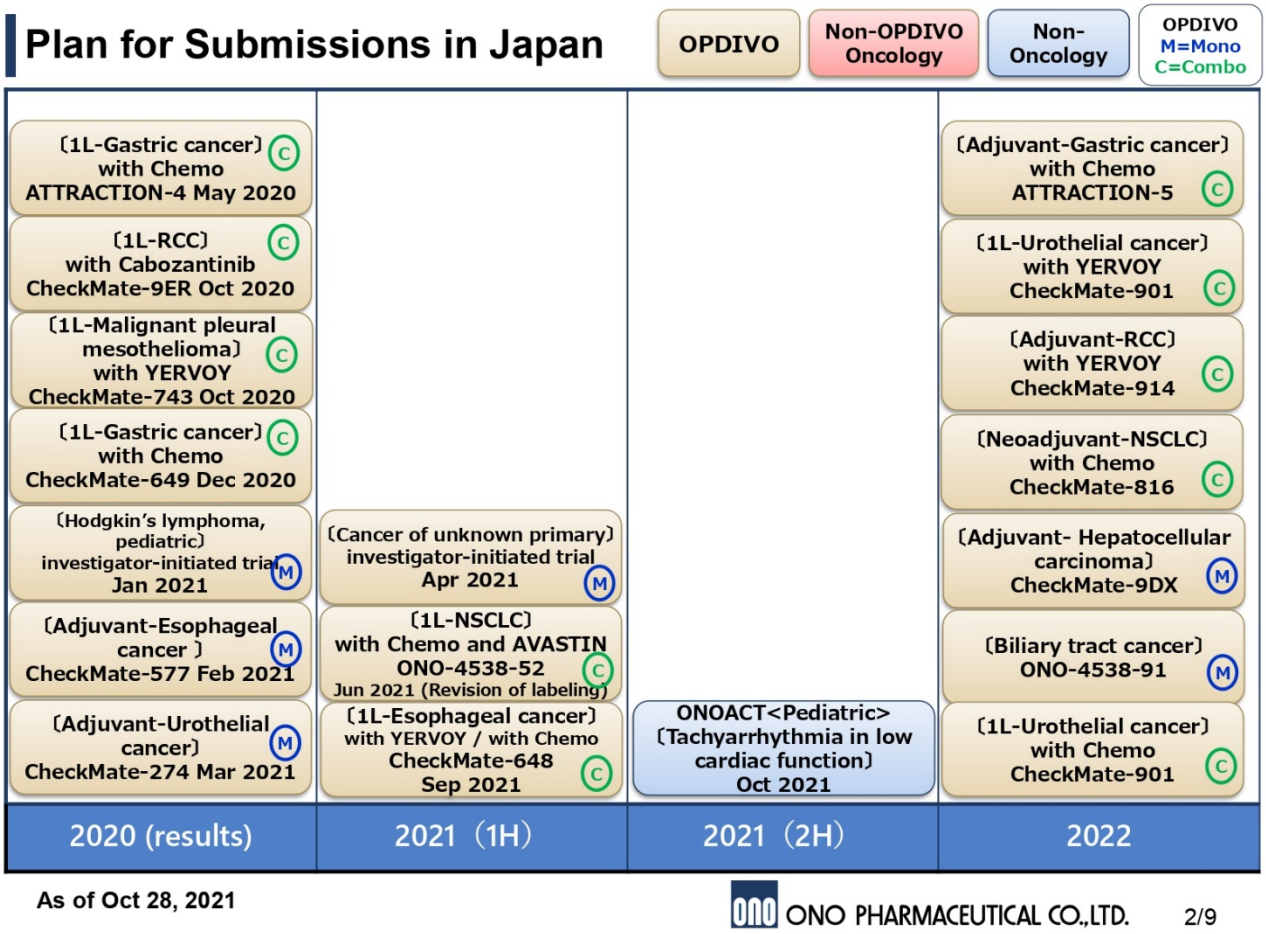
<**Clinical Trial Stage**>　　*) : "In-house" compounds include a compound generated from collaborative research.

Product Name / Development Code / Generic Name	Classification	Target Indication / Pharmacological Action	Dosage Form	Area	Phase	In-house*) / In-license
Orencia SC / Abatacept	Additional indication	Polymyositis・Dermatomyositis / T-cell activation inhibitor	Injection	Japan	III	In-license (Co-development with Bristol-Myers Squibb)
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / Short-acting selective 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 / Schwann cell differentiation promoter	Tablet	Japan	II	In-house
ONO-4685	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	Injection	Japan Europe*8	I	In-house
ONO-7684	New chemical entities	Thrombosis / FXIa inhibitor	Tablet	Europe	I	In-house
ONO-2808	New chemical entities	Neurodegenerative disease / S1P5 receptor agonist	Tablet	Japan Europe	I	In-house
ONO-2909	New chemical entities	Narcolepsy / PG 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 first quarter of the fiscal year ending March 2022

*8: Phase I of ONO-4685 was initiated in Europe for the treatment of autoimmune disease.

ONO-4685, which is slightly below the middle of the table, is a bispecific antibody for PD-1 and CD3. We have started Phase 1 study for autoimmune disease in Europe.



Please refer to the plan for submissions in Japan on page 2 of this document.

First of all, in this table, the beige column indicates Opdivo, and the blue column indicates non-oncology. For Opdivo, the bottom right corner of the column shows M for mono-therapy and C for combination therapy.

The timing of the application is based on the earliest possible date, assuming all goes according to plan, and is subject to change.

This table, in order from left to right, shows the results for FY2020, then FY2021, with the results for the first half of the year, the plans for the second half of the year, and finally, on the far right, the plans for FY2022.

I will now focus on the changes that have been made since the previous presentation on July 30.

First of all, on the far left, starting with the results for FY2020, it has been decided that first-line treatment for gastric cancer will go up to the Second Committee on Drugs to be held on November 4.

The second item from the bottom, the postoperative adjuvant treatment of esophageal cancer, will also go up to the meeting to be held on November 4.

The third item from the bottom, the pediatric indication for Hodgkin lymphoma, was approved in September.

Next, I will talk about the first half of FY2021.

As I mentioned earlier, for first-line treatment of esophageal cancer, the bottom row, we submitted an application on September 14 for Opdivo and Yervoy combination therapy, and also for Opdivo and chemotherapy combination therapy.

Next, in the second half of FY2021, we submitted an application on October 28 for Onoact for the treatment of tachyarrhythmia in pediatric patients with low cardiac function.

Next, in FY2022, the application for combination Opdivo and Yervoy in first-line treatment for urothelial carcinoma was supposed to be submitted in the second half of FY2021, but we have changed the timing of the application to FY2022, due to event delays.

In addition, the application for the once-weekly KRd regimen with Kyprolis for multiple myeloma, which was listed in FY2022 in the previous document, has been shifted to beyond FY2022, and has been removed from this table.

Global development projects (Other than OPDIVO)

As of Oct 28, 2021

Product name/ Development code (Generic name)	Target indication	Pharmacological action	Area
【Approved】			
BRAFTOVI (Encorafenib)	BRAF-mutant colorectal cancer	BRAF inhibitor	KR
【PhaseIII】			
ONO-7912 (Devimistat)	Pancreatic cancer	Cancer metabolism inhibitor	KR
	Acute myeloid leukemia		KR
【Phase II】			
ONO-4059 (Tirabrutinib)	Primary central nervous system lymphoma	BTK inhibitor	US
【Phase I / II】			
ONO-7475	Acute leukemia	Axl / Mer inhibitor	US
【Phase I】			
ONO-7684	Thrombosis	FXIa inhibitor	EU
ONO-2808	Neurodegenerative disease	S1P5 receptor agonist	EU
ONO-4685	T-cell lymphoma	PD-1 x CD3 bispecific antibody	US
	Autoimmune disease		EU

Red: Update after May 2021

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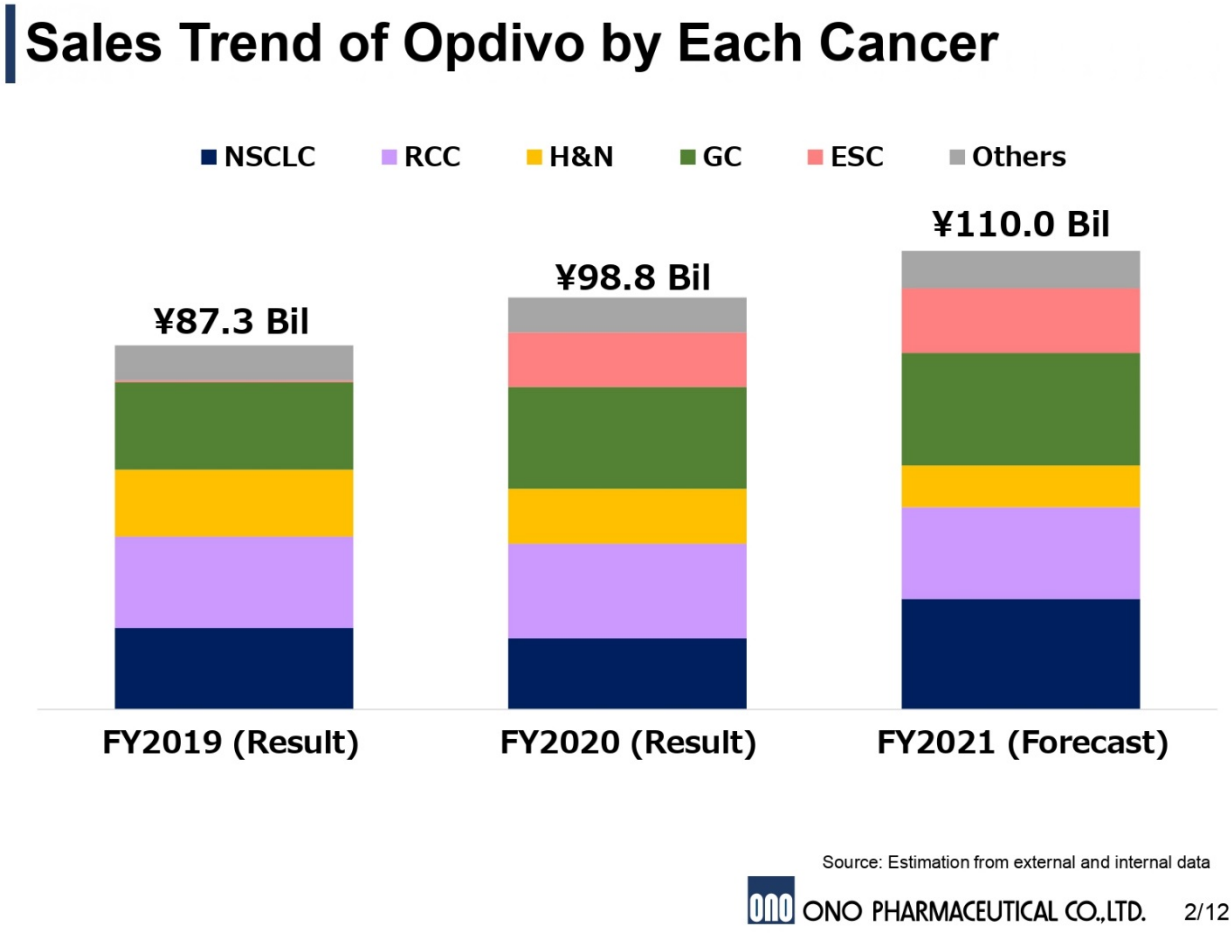
I'll say a few words about page 9. This shows the overseas development status.

In the middle of the page, in Phase 2, we have started a study of ONO-4059, tirabrutinib, for primary central nervous system lymphoma in the United States.

Regarding ONO-4685, which is at the bottom of the table, we have started Phase 1 study for T-cell lymphoma in the US and Phase 1 study for autoimmune diseases in Europe.

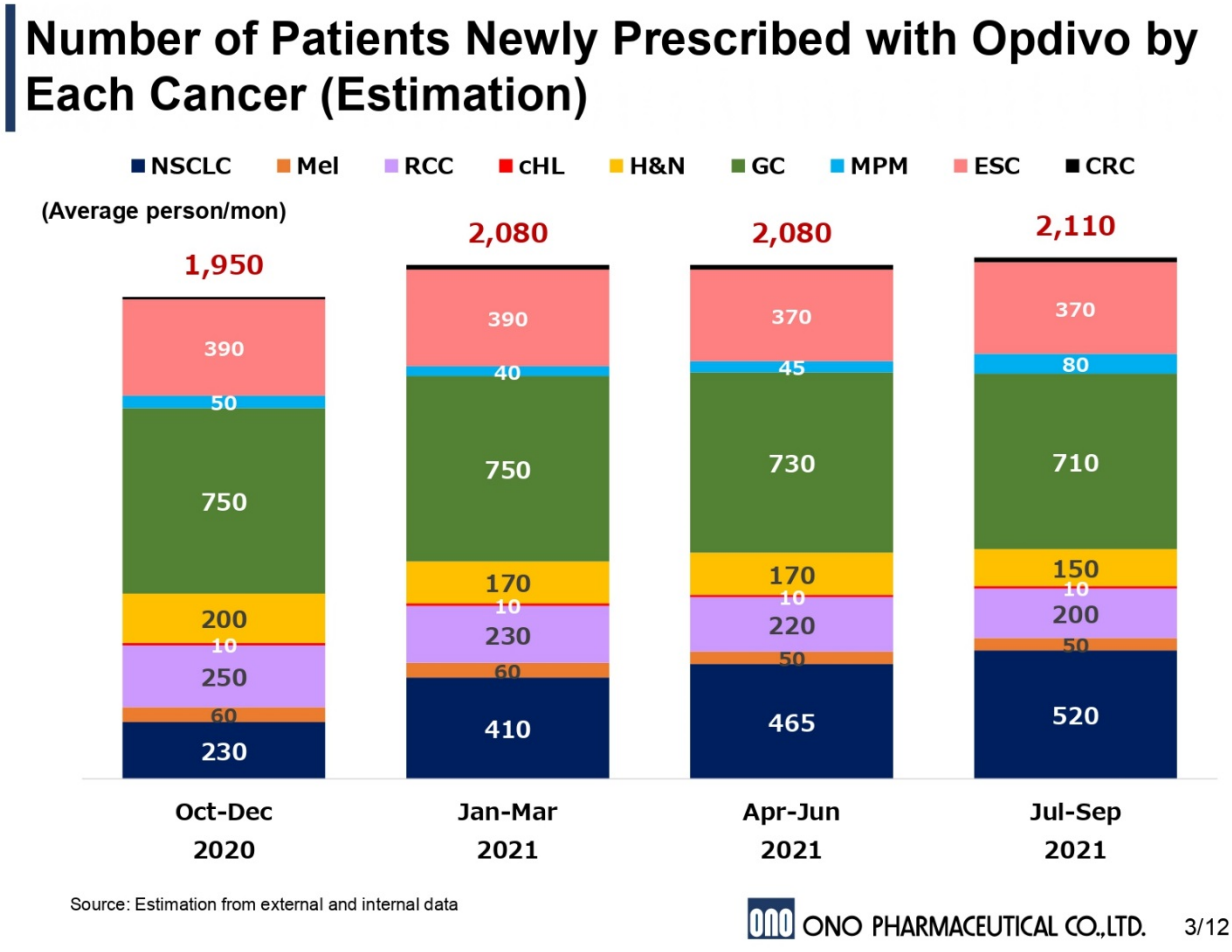
Trend of Opdivo

Takahagi: Regarding trend of Opdivo, I would like to report on general status, sales trends, change in the number of newly prescribed patients, composition ration of I-O inhibitors sales, the situation by cancer type of lung cancer, gastric cancer, esophageal cancer and renal cell carcinoma.



Takahagi: From the bar graph on the left are the results for FY2019, FY2020, and the forecast for FY2021.

Following sales of JPY98.8 billion in FY2020, we expect sales of JPY110 billion in the current fiscal year.



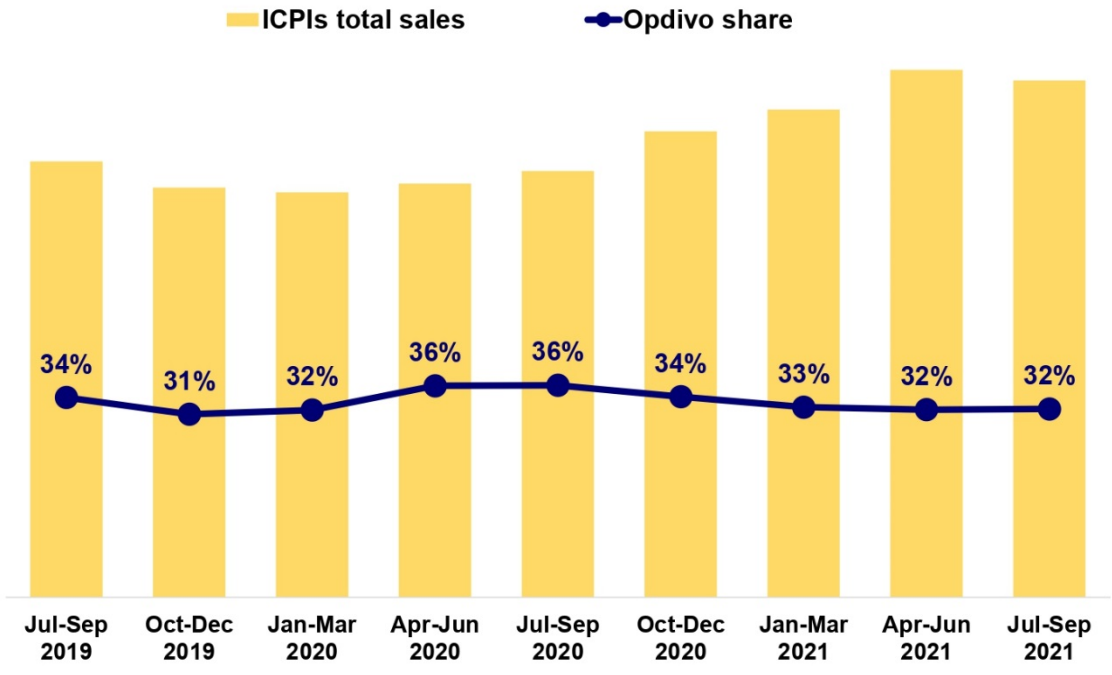
From the left, the bar graphs show the estimated number of new prescriptions for Opdivo by cancer type, broken down by quarter from October-December of FY2020 to July-September of FY2021, with the average number of patients per month.

Although it is an estimate, in the July-September period of FY2021, the drug was used in 710 cases of gastric cancer and 370 cases of esophageal cancer, and in lung cancer, it was newly prescribed in an average of 520 cases per month for first- and second-line treatment and beyond. On average, we get 2,110 new prescriptions per month.

In particular, the number of new prescriptions for the first-line treatment of lung cancer was 2,700 from December of last year to June of this year.

We estimate that the average number of cases during the period from July to September was 350 for first-line treatment and 170 for second-line treatment and beyond.

Trend of total sales of ICPIs and Opdivo share

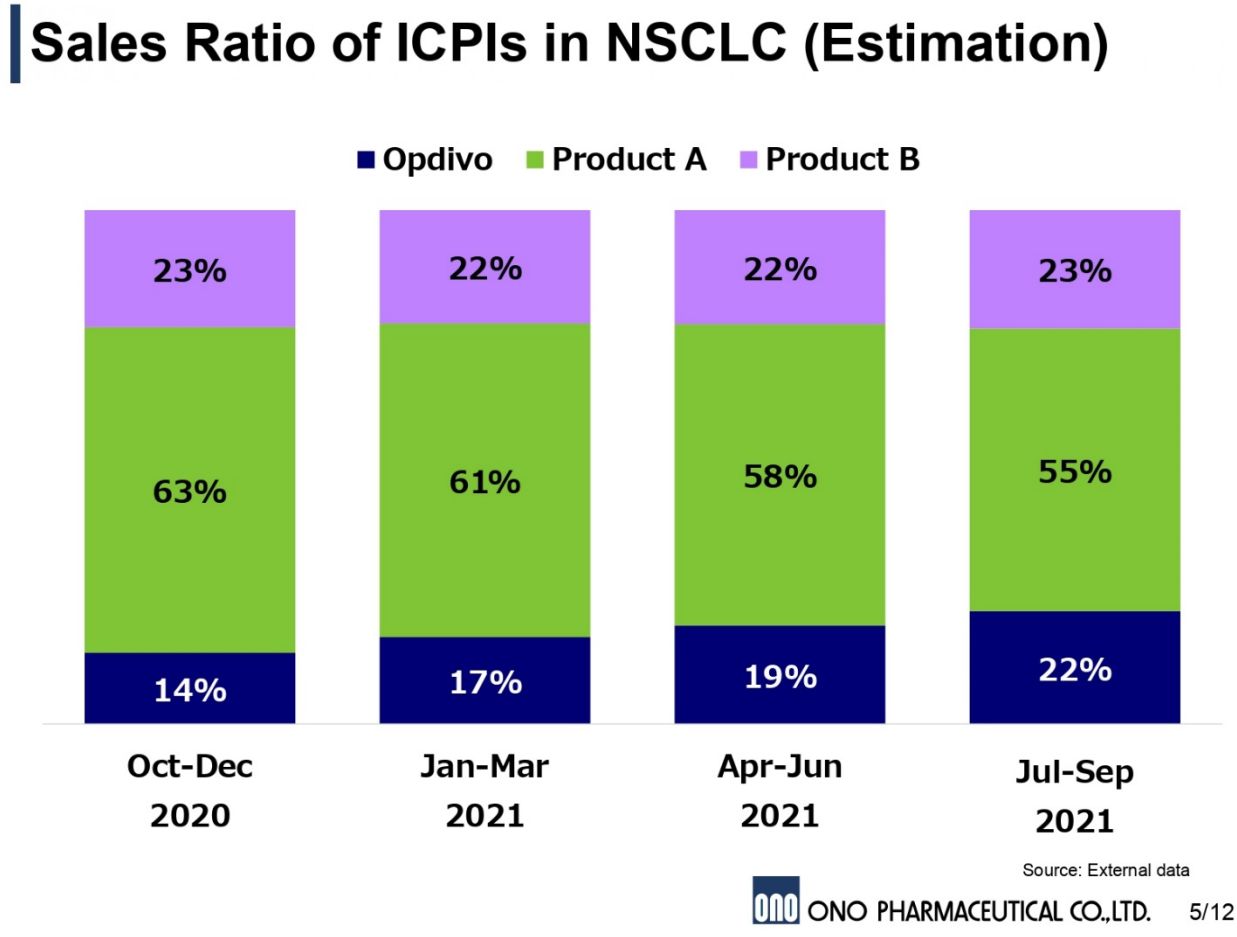


Source: External data

This slide shows the sales trend of all immune checkpoint inhibitors launched in Japan and the market share of Opdivo.

The yellow bar graph shows the total sales of all immune checkpoint inhibitors, and the dark blue line graph shows the market share of Opdivo.

As you can see, sales of immune checkpoint inhibitors have been steadily increasing, and in FY2020, the total sales of all 5 products will exceed JPY300 billion on a NHI price basis. Of this, Opdivo will secure a share of more than 30%.

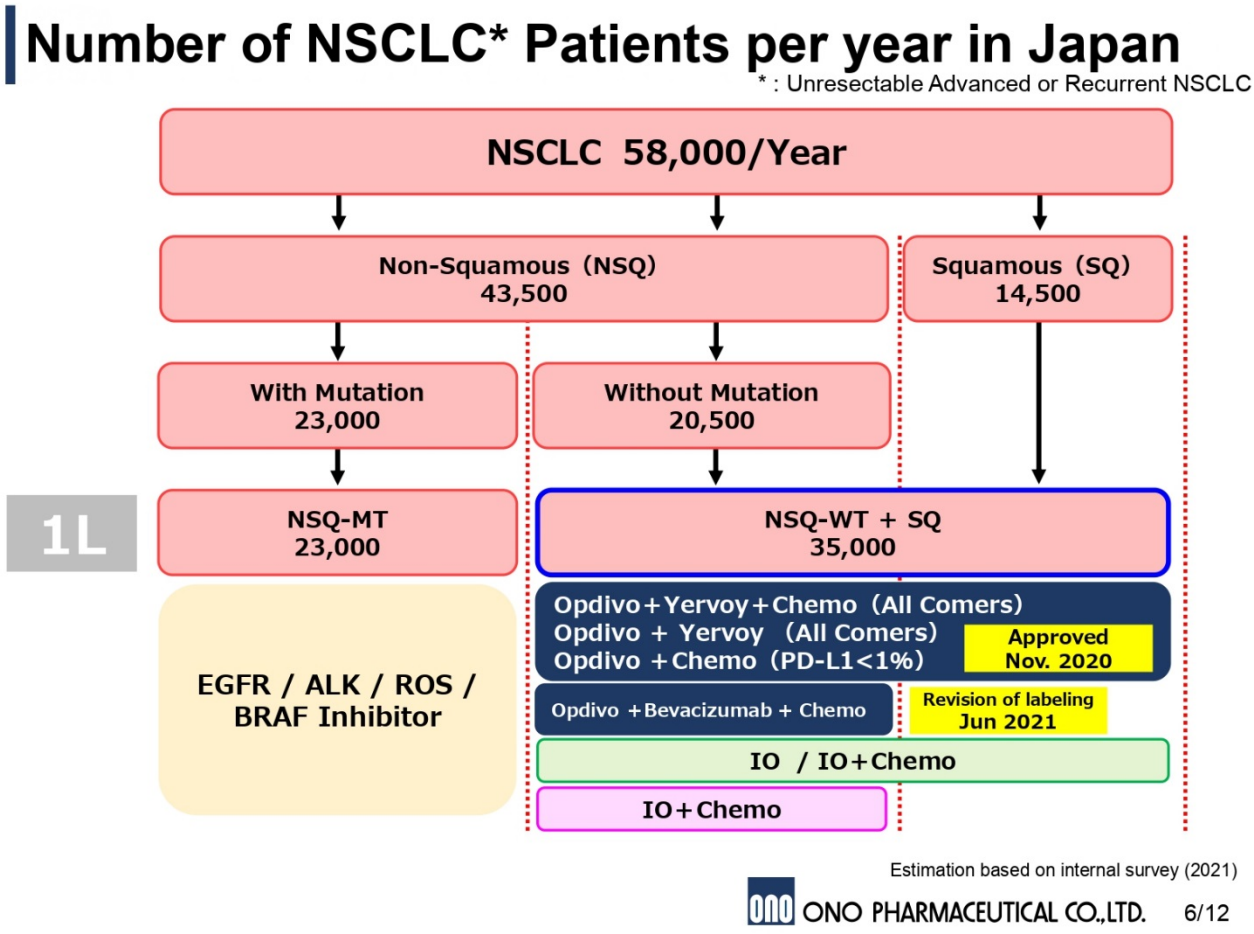


Here is an introduction by cancer type.

First, let's take a look at the area of lung cancer. The bar graphs shows the sales composition ratio of immune checkpoint inhibitors for all non-small cell lung cancer, including first-line treatment and second-line treatment and beyond, as well as new patients and patients under treatment.

From the left, the bar graphs shows the period from October-December 2020 to July-September 2021, broken down by quarter.

Opdivo share, in dark blue, is at 22%. We are trying to gain ground in the first-line treatment of lung cancer.



The annual number of patients with non-small cell lung cancer is shown.

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

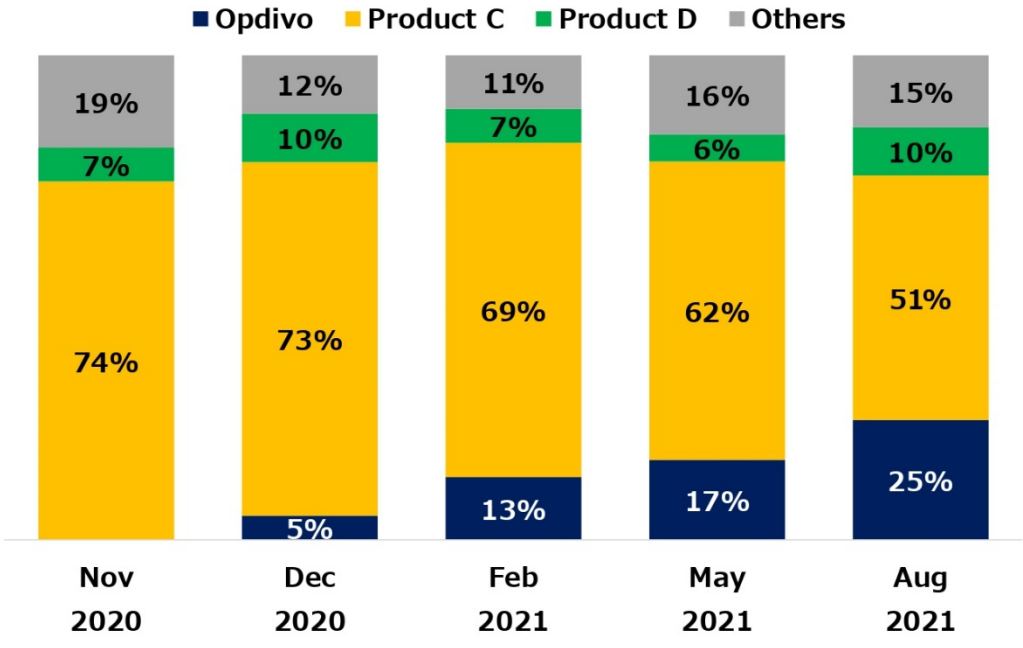
Non-small cell lung cancer is divided into non-squamous cell carcinoma and squamous cell carcinoma by histological type, and non-squamous cell carcinoma is further divided by diagnosis with or without genetic mutation.

The market is very large for immune checkpoint inhibitors such as Opdivo in the first-line treatment of lung cancer target squamous cell carcinoma and non-squamous cell carcinoma without genetic mutation. The market is estimated to be 35,000 patients per year.

Although the current environment is quite competitive, we entered the market last year with Opdivo and Yervoy combination therapy. Since June this year, we have also been working in the first-line treatment area using a combination with bevacizumab.

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 – Aug 2021: n=167~245)

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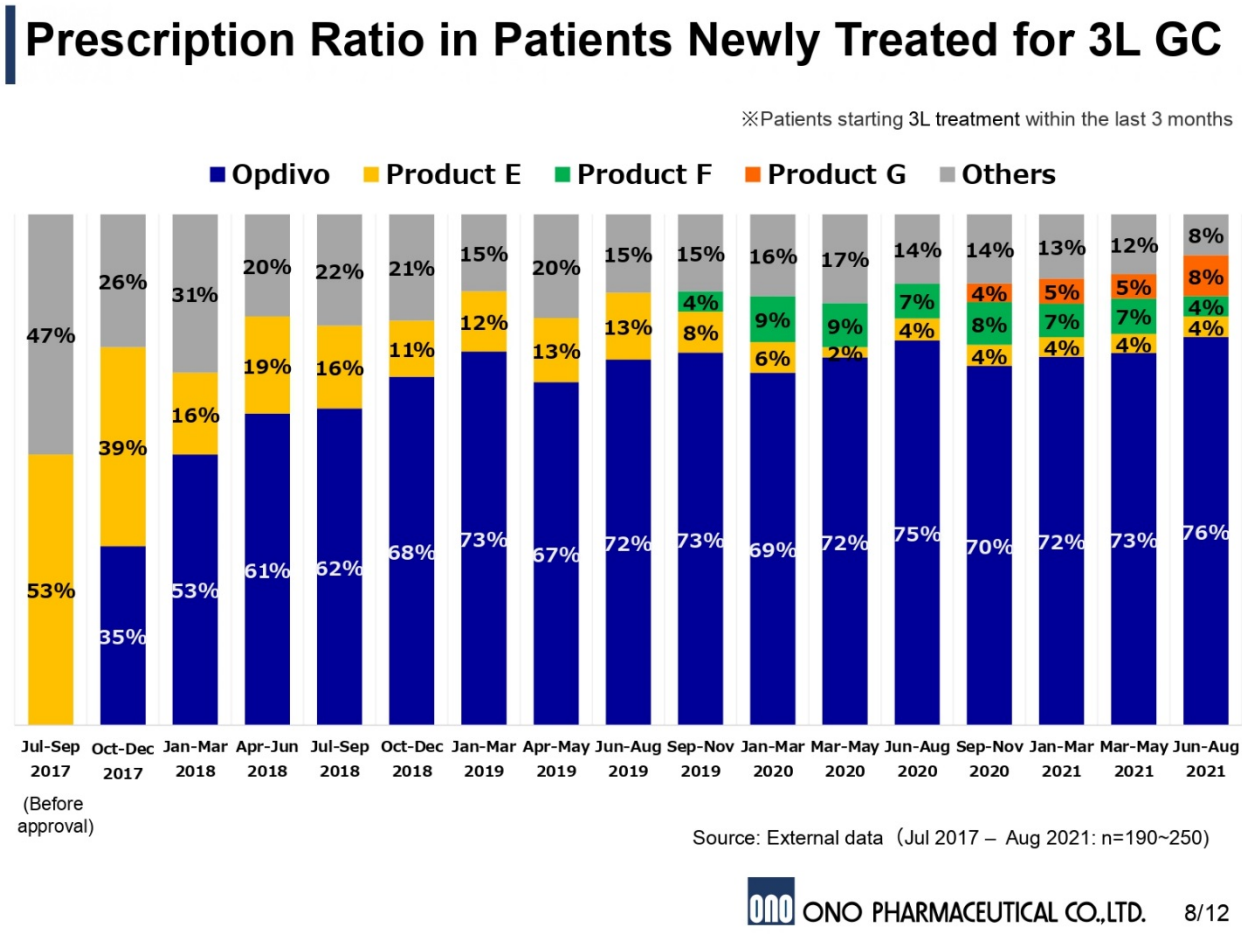
The bar graphs shows changes in the share of new patient prescription in the first-line treatment of non-small cell lung cancer.

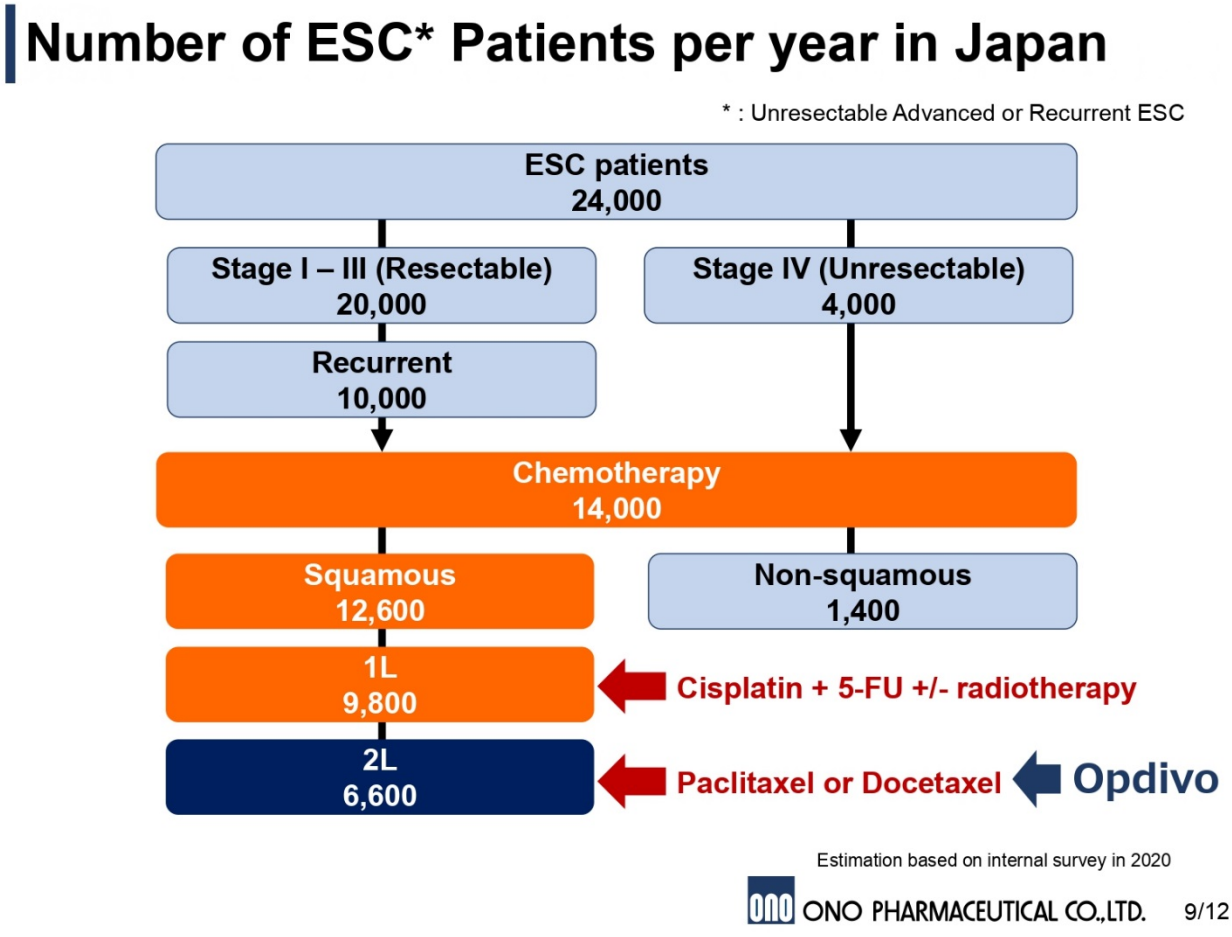
The share of new patient prescriptions for Opdivo was 25% as of August, and we will continue our activities to achieve 30% this fiscal year.



Here is an introduction of gastrointestinal cancers.

First, I would like to show you the trend in the share of new patient prescriptions in third-line treatment for gastric cancer. In gastric cancer, we entered the market in 2017, and have been steadily expanding its market share.

The market share of new patient prescriptions for Opdivo, shown in dark blue, for third-line treatment has exceeded the target of 70% and is still at 76%, despite the entry of competing products.

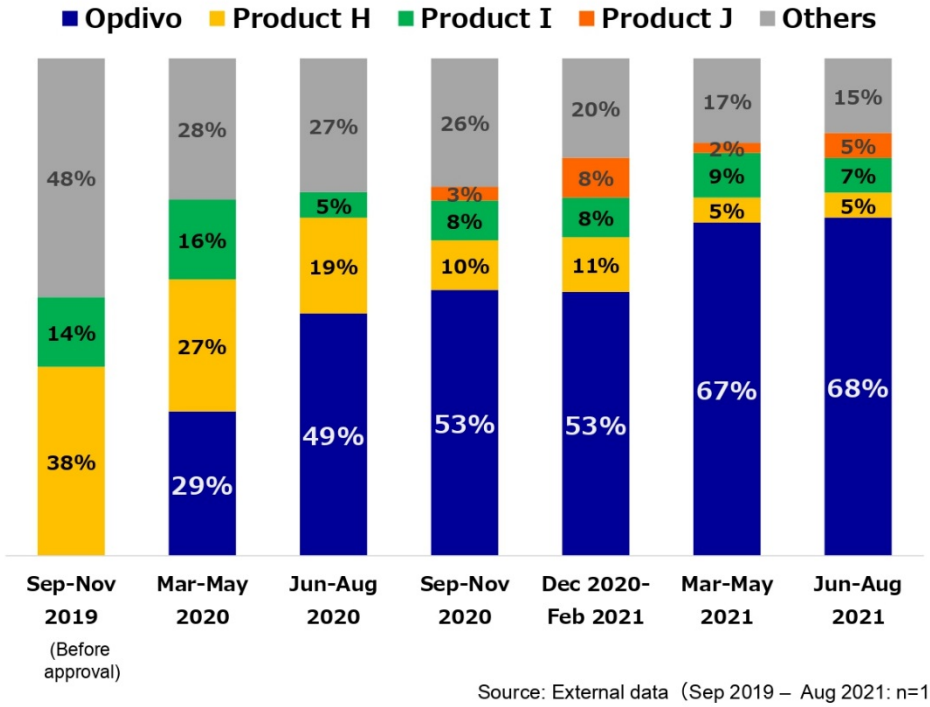


Next, let's take a look at esophageal cancer.

In the second-line treatment of unresectable advanced or recurrent esophageal cancer, we believe that prescriptions of Opdivo have been steadily increasing since its approval in February 2020.

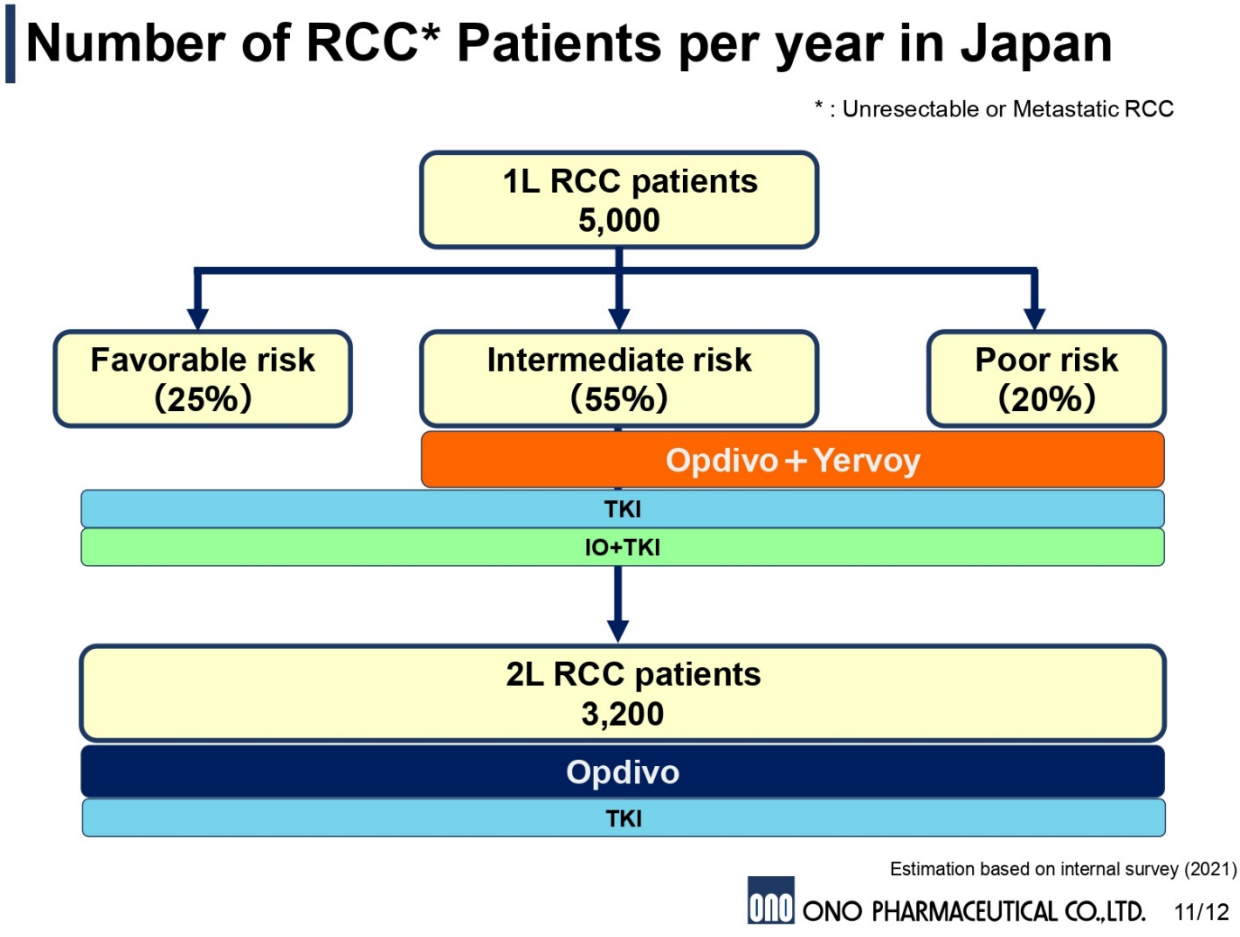
Prescription Ratio in Patients Newly Treated for 2L ESC (Squamous Cell Carcinoma)

※ Patients starting 2L ESC within the last 3 months



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

Amid the entry of competing products, our share of new patient prescriptions for second-line treatment of esophageal cancer is 68%, and we will continue to develop our activities to achieve our target share of 70%. We will continue to raise awareness of the benefits of Opdivo in the gastrointestinal field.

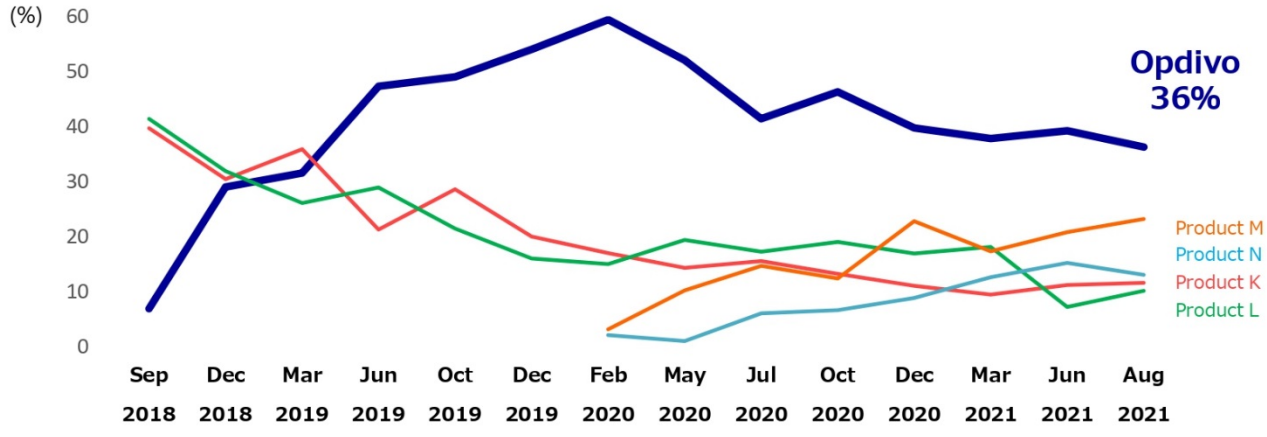


Next, renal cell carcinoma.

As you know, there is evidence for Opdivo in first-line treatment, second-line treatment and beyond. We are working to bring Opdivo to all renal cell carcinoma patients.

Prescription Ratio in Patients Newly Treated for 1L RCC

	2018		2019				2020				2021				
	Sep	Dec	Mar	Jun	Oct	Dec	Feb	May	Jul	Oct	Dec	Mar	Jun	Sep	
Opdivo	**7**	**29**	**32**	**47**	**49**	**54**	**59**	**52**	**41**	**46**	**40**	**38**	**39**	**36**	(%)
Product K	40	30	36	21	29	20	17	14	16	13	11	9	11	12	(%)
Product L	41	32	26	29	21	16	15	19	17	19	17	18	7	10	(%)
Product M							3	10	15	12	23	17	21	23	(%)
Product N							2	1	6	7	9	13	15	13	(%)



Source: External data（Sep 2018 – Aug 2021: n=46~100)

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This slide shows the changes in the share of new patient prescriptions for the first-line treatment of renal cell carcinoma. In first-line treatment, combination therapy of I-O and TKI has entered the market, and prescriptions are gradually expanding, with I-O therapy becoming the main treatment with over 70% share of first-line treatment.

The share of new patient prescriptions in first-line treatment with Opdivo and Yervoy combination therapy is 36%. If we narrow down the target group to intermediate and poor-risk patients who are eligible for the combination therapy with Opdivo and Yervoy, the share of new patient prescriptions is more than 50%.

In August this year, Opdivo was also approved for use in combination with Cabometyx, a TKI. We consider to expand the market share in the favorable-risk patients in the future.

I have just reported the trend of Opdivo, the current general situation on the area of non-small cell lung cancer, gastric cancer, esophageal cancer and renal cell carcinoma.

We will continue to push forward with our activities to meet the unmet needs of cancer patients.

Question & Answer

Questioner 1: I have a question about Opdivo. First of all, you mentioned that you have reached 25% share of new prescriptions in the NSCLC first line, and that if you can reach a 30% share, you can expect JPY50 billion at peak. Given the current situation, I think 30% is already in your sights, and JPY50 billion or more can be realized. I think there are issues such as the period of use, so can I assume that this is the kind of momentum that you are aiming for? That's the first question.

Takahagi: We believe that 30% share of new prescriptions is within our reach. Therefore, we would like to aim for JPY50 billion or more, but at the same time, we still have some issues to be solved for strongly positive PD-L1 (more than 50%), so we will make efforts to provide information to the doctors. We will do our best.

Questioner 1: Is the actual period of use longer or shorter than expected in your activities?

Takahagi: It has been less than a year since the first-line has been approved, so it is difficult to make firm comments in terms of the use period, but based on clinical data, it is about 5.7 months, and so within half a year. Judging from the response of the doctors, who are using the product, and MRs' feedback, and if we include patients who have stopped using the medication, I don't think there is significant deviations. However, for the future, we believe that the regimen is capable of achieving long-term survival, so we will continue to monitor it closely.

Questioner 1: The second question is first-line treatment for gastric cancer and adjuvant treatment of esophageal cancer that will be discussed at the second committee meeting this week. Mr. Sagara said previously that the potential for the first-line treatment for gastric cancer would be JPY80 billion, and the adjuvant treatment of esophageal cancer would be JPY20 billion. At the study session at the end of last year, I think Dr. Muro said that the use of Opdivo could exceed 80% of first-line treatment of gastric cancer. I know you have not yet got the approval, but based on preliminary discussions with specialists and KOLs, do you have a good feeling that you can go further than the initial forecast, or do you want to aim for this goal first? I would appreciate it if you could give me a sense of the expected sales.

Sagara: Expectations are very high, but in reality, we will have a second committee meeting on November 4, and after that, we are expecting approval around the end of this month, following various reviews. I think we will be able to talk about the outlook once the approval is given. At the moment, although expectations are high as I mentioned, we do not know whether actual sales will be a little higher or lower. Therefore, I would like to refrain from making any new comments at this time.

Questioner 1: By the way, may I understand that there will not be another price reduction in the NHI price revision based on this additional indication?

Sagara: No, we do not think so.

Questioner 2: I am aware that there has been no change to the full-year forecast based on the results for the first half of the fiscal year. While new products seem to have been a little slow out of the blocks, there are clearly some products such as Onon Capsules that are performing better with sales of more than half than expected. Please advise us about the products with which sales will be higher or lower than expected, including Opdivo.

Tani: As shown in the supplementary materials for the financial results, with regard to Opdivo, there is the impact of the NHI drug price revision, so I guess that the sales of JPY110 billion is within our expectation and we will have to wait and see how the additional indications will exceed the expectation of JPY110 billion.

As for Forxiga, we raised the forecast of sales from JPY30 billion to JPY35 billion at the time of the announcement of the financial results for the first quarter. We believe that this JPY35 billion is well within its expected range. I think we are around the expected figure for Glactiv.

For Parsabiv, there is no doubt that we are above the forecast. The full-year plan was a JPY100 million decrease, while we have seen a JPY600 million increase in the first half of the fiscal year. As for Velexbru, although we revised the forecast upward by JPY1.5 billion in the first quarter, the current progress is JPY2.9 billion against the full-year forecast of JPY5 billion, so we are also making upward progress.

As for Onoact, the first-half figure was JPY2.3 billion against a full-year plan of JPY4 billion. The coronavirus pandemic had an impact here, but I hear that surgeries are coming back, so we are making progress on the upside here as well.

On the other hand, for new products, Joyclu and Adlumiz, launched in the current fiscal year, these have the sales of JPY500 million against a full-year forecast of JPY2.5 billion. We will have to see how well Adlumiz can perform in the second half of the year.

Questioner 2: I just want to confirm one point about Opdivo. Is the first-line treatment for gastric cancer included in the sales forecast, or not?

Takahagi: It is included.

Questioner 2: I have questions on the two compounds in your pipeline. Regarding ONO-4685, T-cell area overseas is a bit of a niche area. Are you planning to develop it in-house? Or, are you going to license it someone else?

Idemitsu: We have been developing it in-house, and plan to continue to do so in the future.

Questioner 2: I remember that LAG-3 was a breakthrough overseas, and I think some data was released by Bristol. I think many companies, including your company are struggling to develop an Opdivo Plus α. Do you see any direction for the development of LAG-3?

Idemitsu: We are co-developing an anti-LAG-3 antibody called relatlimab with BMS. Regarding melanoma, BMS has filed an application for the combination treatment with Opdivo and relatlimab based on the Phase 3 results in the US and Europe. The development for melanoma in Japan is currently under review, and we are currently discussing with BMS how to develop other types of cancer.

Questioner 2: Lastly, I am sure you have been asked a lot about the strategically held shares. In many ways, I think the stock price is struggling a little, but I think the financial structure is very good right now. Externally, it seemed to me that the timing is right for shareholder returns, including share buybacks. Could you tell us what you think about it at the moment?

Sagara: To put it simply, stock buyback is always on our minds as a way of returning profits to shareholders, and we are considering it. You say that the timing is good right now, but I would like to consider this as an extension of the fact that we are always considering it. Not long ago, many companies were buying back their own shares, and I think there was a time when people thought this was not the right time. Do you think it is not such a situation now but a good timing?

Questioner 2: Yes, that's a factor. There are many companies that don't have the money. In the case of your company, there was the Mie University issue, but I think it is probably on its way to being resolved. I thought it would be a good time for your company to send out a message that the price is low, because the stock price is relatively in a struggling situation.

Sagara: Thank you for sharing your opinion on this. I would really like to hear feedback. Our policy has not changed, and based on recent results, we buy back our own shares about once every 2 years. We will consider various aspects, including shareholder returns and reduction of strategic cross-shareholding, as well as the question of how to use the cash coming in from them.

Questioner 3: On page 3 of the Opdivo trend section, there is a chart of new prescriptions by cancer type. I understand that this is an estimate, but I have the impression that the number of patients is moving quite a bit in the July to September period. The number of patients with non-small cell lung cancer at the bottom of the bar is gradually increasing due to the strengthening of the first-line treatment, but on the other hand, gastric cancer, which had looked strong so far, is decreasing. Also, I am curious about the increase in mesothelioma. Is this related to the respiratory symptoms of the coronavirus pandemic?

Takahagi: Considering gastric cancer, compared to the October-December period of last year, there were about 40 cases difference. Considering the monthly average number of patients at that time, we do not think that there will be a significant change. As for mesothelioma, the first-line treatment of mesothelioma was approved this fiscal year, and at present, prescriptions for first-line treatment of mesothelioma are being expanded more than for second-line mesothelioma. On the other hand, in head and neck cancer, Keytruda was additionally approved for the first-line treatment of platinum-sensitive head and neck cancer. Opdivo has been used in the second-line, but the number of I-O naïve patients is decreasing because of the introduction of Keytruda in the first line treatment. The number of head and neck cancer patients for Opdivo is gradually moving in a negative direction.

Questioner 3: Could you comment on the renal cell carcinoma figures?

Takahagi: In renal cell carcinoma, there is of course a great deal of competition in the first-line market, but originally there were a large number of new prescription patients in the second-line market. As you can see, the share of the first-line in new prescription patients is increasing to 70% of all I-O, and the number of I-O naive patients who fall into the second-line is decreasing significantly. As a result, the number of second-line Opdivo patients is decreasing, which is a slight negative impact.

Questioner 3: Is it correct to say that in mesothelioma, it will completely overtake Alimta in terms of pace?

Takahagi: For mesothelioma, we believe that with full use of first-line drugs, second-line prescriptions will disappear in the future.

Questioner 3: I think it has been treated with Alimta up to now.

Takahagi: Yes. I think the first-line regimen, Alimta, was the most common, but it is now being replaced by combination Opdivo and Yervoy therapy.

Questioner 3: There has been a lot in the mass media about Dr. Honjo reconciliation. I don't know if you can talk about the recent situation and future prospects, but I would like to ask you to comment on the situation to the extent that you can.

Sagara: As we have said in the past, we are willing to proceed to a settlement as long as it is at an appropriate level, and this has not changed. On top of that, I hope you will bear with me as to what the current situation is, because of all the times this could be discussed, this is the time when I am least able to talk about it. I'm sorry. What I can say is that nothing has been decided yet that needs to be reported or announced.

Questioner 3: I wonder if that's still in flux, including the timeline.

Sagara: Yes, that's right.

Questioner 3: Please do your best to resolve the issue as soon as possible, because I think that will probably have quite an impact on the stock price.

Sagara: What impact do you expect?

Questioner 3: Well, the problem has been identified, or that's how I see it, at least. For the industry as a whole, it would be unfortunate if the goalposts were moved, so I think they want you to do your best.

Sagara: Yes, thank you very much.

Questioner 4: The first question is about SG&A expenses. Progress to the full-year forecast of JPY74 billion was 50.9% in the first half of the fiscal year. I think that you are spending more than usual. I'm wondering if it will be within this JPY74 billion against the full-year plan. Even if it isn't, I feel that sales have been quite strong, so I think it would be possible to meet your full-year operating profit plan as a whole. What do you think about the current progress toward the JPY74 billion forecast and what should we expect in the second half?

Sagara: As you know, we have reached the halfway point in terms of the standard progress, but the progress is usually a little bit slower, and I think you are probably thinking it will be increasing in the second half of the year. This time, I believe that SG&A expenses will be almost in line with the budget.

Questioner 4: So we should understand that the balance between the first half and the second half will be a little different than those in previous years.

Sagara: Yes, you're right.

Questioner 4: Next, in the first-line treatment of renal cell carcinoma, Opdivo is now being used in combination with Cabometyx for favorable-risk patients, I think. Could you comment on this?

Takahagi: The first-line treatment for renal cell carcinoma in combination with Cabometyx was approved at the end of August, and we have been working on it since then, so it has been about 2 months now. In the initial response, there were various reactions from doctors, but among the TKIs, there were some who said that this segment was very good for Cabometyx. We believe that if we continue to provide the information diligently, we will be able to expand the prescription of Cabometyx even in favorable-risk patients, so we would like to advise about the use the combination of Opdivo and Yervoy in intemediate- and poor-risk patients, and the use Cabometyx in combination with Opdivo in favorable-risk patients. We would like to acquire the number one position in the first line treatment of renal cell carcinoma with Opdivo Regimen. We will probably be able to report on the response next time.

Questioner 4: Last but not least, ONO-4578. I think you are starting a trial for breast cancer this time, but I thought it was more promising for GI cancers, relatively gastric cancer, that have already been treated, since you said at the previous R&D briefing that prostaglandin expression is high in the digestive system. I would like to know the background why you have started for breast cancer, and also your plan about trials for gastric cancer, colorectal cancer, pancreatic cancer, lung cancer which are now in Phase 1, and breast cancer this time. Will all these cancers be moved to Phase 2, or will they be narrowed down to the more promising ones? I was wondering if you could comment on future development plans. Also, if you could tell us anything about the time line, I'd appreciate it.

Idemitsu: As for breast cancer, unlike other cancer types, it is not used in combination with Opdivo. Based on the information of non-clinical study such as the involvement of EP4 in breast cancer growth by M2 macrophages, this trial has been started. To be honest, we will not know for which cancer types it will work until we try it. We would like to start a PoC trial for each cancer in order that the efficacy is confirmed.

Questioner 4: Which will be the first indication to get a PoC?

Idemitsu: In terms of progress, I feel that gastric cancer and colorectal cancer are making progress right now.

Questioner 4: Can you tell me when the PoC will be known?

Idemitsu: It depends on the progress and results of the trials. I'm afraid it is not appropriate to reply to you about the time line lightly, because we may need to consider a little further. So please forgive me.

Questioner 5: The first question is about Opdivo for the first-line treatment of gastric cancer. In the US, it was approved for all-comers. In Europe, it was approved only for PD-L1-positive patients with a CPS of 5 or higher, so I think the decision is different between the US and Europe. What do you think will be the direction of approval in Japan at the day after tomorrow's meeting?

Idemitsu: I would like to refrain from answering this question, as it is related to the strategic issue.

Questioner 5: Is it correct to say that in terms of planning and the comments that you have made up until now, it has been based on the assumption of all-comers?

Idemitsu: The application itself was filed for all-comers. We are aiming for approval for all-comers.

Questioner 5: Regarding the use of cash obtained from the reduction of shares held for policy purposes, I think you clearly stated that you would like to use the cash obtained from the reduction for long-term growth investment. Is it correct to say that the additional funds to be acquired this time will be used for growth investment as before?

Sagara: Yes, that's right. In addition to investment in growth, we have always said that we will return profits to shareholders. We prioritize R&D investment, capital investment, and shareholder return in order, and I would like you to understand that the same applies to the reductions we will implement over the next three and a half years.

Questioner 5: Lastly, regarding the settlement discussion with Dr. Honjo, you said that you would be willing to settle if the level was appropriate. I would like to understand how much the appropriate level is, and whether or not there is a large deviation, but is it appropriate to think that the range has already allocated is the upper limit of the appropriate level? Or is this a level that seems to fall somewhere in between the appropriate levels? In other words, even if the case is settled at an appropriate level, what is the likelihood that additional expenses will be incurred?

Sagara: I have to decline to comment on this at this time. We are not in a position to say what an appropriate level is.

Questioner 6: Regarding Opdivo, I am looking at pages 3 and 7 of the document, and I reviewed the information about Keytruda for head and neck cancer. If you look at page 3, you can see that it is first-line for lung cancer. If you look at page 7, you can see that it is very apparent and growing. I don't know how the analysis is made, but I found some NHI-based figures for September, and it says that Keytruda has reversed the trend. Is it correct to assume that the first line for lung cancer has increased further in September and October, if you would take this Keytruda’s share?

Takahagi: Lung cancer is also positioned as the biggest growth driver for Opdivo this fiscal year, and we would like to expand prescriptions in this area and contribute to sales growth. We believe that the reason for the growth of Opdivo is the accumulation of cases in non-small cell lung cancer, which has had a significant positive impact on the market.

Questioner 6: Regarding long-term listed products, the progress rate for Onon capsules is high at 72%. While generic manufacturers have issues related to supply system, consumer trust and product quality, you have

not updated the forecast here. But if we look at the current situation of generics, can we assume that progress will be high in the third quarter and fourth quarter?

Takahagi: We will continue to monitor the shipment adjustments made by generic drug manufacturers, and will consider these issues as they arise.

Questioner 6: I would like to conclude by saying about receipt of royalties, especially with respect to Keytruda. The figure has grown by 30% in the second quarter alone, with the royalty from Bristol Myers Squibb growing steadily. The growth rate for the second quarter was 25%, and the forecast for the full year is unchanged at JPY105 billion. At the current pace, can we expect this to be revised upwards? Or, since it's still a royalty, should I assume that there will be shifts or advance payments?

Sagara: At this point, we would like to wait a little longer before making any revisions for the full year. It is true that we are making good progress, and if we continue at this pace, we will probably surpass the target, but we would like to see how much more we can do.