ONO PHARMACEUTICAL CO., LTD.

Q2 Financial Results Briefing for the Fiscal Year Ending March 2021

October 30, 2020

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

Revenue

Revenue	YoY
¥ 150.5 billion	+ 1.0 %

Breakdown of Revenue

(Billion yen)

	FY 2019 Q2	FY 2020 Q2	YoY
Revenue of Goods and Products	106.8	106.5	- 0.2 %
Royalty & other revenue	42.2	44.0	+ 4.1 %
(Opdivo)	(30.7)	(29.2)	(- 5.1 %)
Total	149.0	150.5	+ 1.0 %

Sagara: As for the outline of the financial results, revenue was JPY150.5 billion, an increase of JPY1.5 billion, or 1.0%, YoY.

The breakdown is as shown on the slides. The result is down JPY300 million YoY for sales of products, and up JPY1.8 billion for royalties and other revenue.

Revenue

Sales of Major Products

(Billion yen)

	FY 2019 Q2	FY 2020 Q2	YoY
Opdivo	46.8	**49.1**	+ 4.8 %
Glactiv	13.3	**13.0**	- 2.3 %
Forxiga	8.7	**10.5**	+ 20.5 %
Orencia SC	10.0	**10.9**	+ 8.9 %
Rivastach	4.4	**4.1**	- 7.0 %
Parsabiv	3.5	**3.9**	+ 11.9 %
Kyprolis	2.9	**3.5**	+ 19.8 %
Onoact	2.4	**2.2**	- 11.2 %
Proemend	1.3	**1.3**	- 1.9 %
New products (FY2020)	–	**0.5**	–

Sales by product are shown in this table.

Sales of Opdivo was up JPY2.3 billion to JPY49.1 billion. Sales of Forxiga, Orencia, Parsabiv, Kyprolis, etc. were all steadily up.

On the other hand, sales of Rivastach Patch, Onoact, etc. were a little behind schedule, as was Glactiv.

At the bottom of this slide, we have added a category for new products to this period, which represent two new products, Velexbru and Ongentys. Sales of these products was JPY500 million.

Opdivo steadily increased in use for patients with renal, gastric and esophageal cancer, with favorable progress in sales.

Revenue

Sales of Long-term Listed Products

(Billion yen)

	FY 2019 Q2	FY 2020 Q2	YoY
Opalmon	4.5	**2.9**	- 35.4 %
Emend	4.6	**1.5**	- 67.8 %
Onon capsule	1.6	**1.2**	- 24.6 %
Recalbon	2.6	**1.5**	- 41.3 %

As for long-term listed products, there was a continuing significant double-digit drop. The drop itself was not so far, but rather greater than we expected.

Operating Profit

Operating Profit	YoY
¥ 52.4 billion	+ 25.1 %

Costs, etc.

(Billion yen)

	FY 2020 Q2	YoY
・Cost of sales	¥41.8	(+ 0.2%)
・R&D expenses	¥25.7	(- 16.8%) ①
・SG&A expenses	¥29.8	(- 11.6%) ②
①+② Total	¥55.6	(- 14.1%)
・Other income	¥0.4	(- 13.0%)
・Other expenses	¥1.1	(- 7.0%)

ONO PHARMACEUTICAL CO.,LTD. 6/17

Operating profit was JPY52.4 billion, with a YoY increase of JPY10.5 billion. The cost of sales remains almost unchanged, increasing by JPY100 million. R&D expenses were JPY30.9 billion in the previous fiscal year, so there was a decrease of JPY5.2 billion.

In addition, SG&A expenses other than R&D expenses decreased by JPY3.9 billion, down from JPY33.7 billion in the previous fiscal year. Combined R&D and other SG&A expenses fell by JPY9.1 billion. This is a factor to increase the profits.

R&D and SG&A expenses are lagging behind schedule. As you know, due to the coronavirus pandemic, recruitment in clinical trials has been discontinued and suspended, or in a state of flux for trials in progress.

As for SG&A expenses, mainly operating expenses, we have been in the situation where we have not yet been able to resume large-scale lectures, and MR activities were still at a lower level than before. While we are moving these activities on an online basis, we are not yet able to work as planned.

In the April to June period, it appeared that limitations would be temporary, and that from July, things would probably return to normal. However, in the July to September period, that return to normality has not taken place.

Profit before Tax

Profit before Tax	YoY
¥ 53.7 billion	+ 24.7 %

Net financial income

+ ¥ 1.3 billion (+ ¥ 0.1 Billion)

Finance income :	**¥ 1.4 Billion**
(Interest and dividend income received, etc.)	
Finance costs :	**¥ 0.1 billion**
(Interest expense arising from lease obligations and employee retirement benefit, exchange losses etc.)	

Profit before tax was JPY53.7 billion before tax, an increase of JPY10.6 billion.

Profit for the Period
(Owners of the Parent Company)

Profit for the Period (Owners of the Parent Company)	YoY
¥ 39.8 billion	+ 21.4 %

Income tax expense

¥ 13.8 billion (YoY + 36.1 %)

(Major change factors)

Increase in profit before tax	¥	10.6 billion
Increase in corporate tax	¥	3.7 billion

Net income was JPY39.8 billion, a YoY increase of JPY7 billion.

Revenue (Forecasts)

Revenue	YoY
¥ 305.0 billion	+ 4.3 %

Breakdown of Revenue

(Billion yen)

	FY 2019 (Result)	FY 2020 (Forecast)	YoY
Revenue of Goods and Products	205.6	214.0	+ 4.1 %
Royalty & other revenue	86.8	91.0	+ 4.8 %
Total	292.4	305.0	+ 4.3 %

The revenue forecast for the full-year is JPY305 billion, up JPY2 billion from the initial plan, and an increase of JPY12.6 billion over the previous year.

Product sales has been revised upward by JPY4 billion, to JPY214 billion. In addition, royalties and other revenue was revised downward by JPY2 billion, to JPY91 billion. So, the revenue forecast is JPY305 billion in total.

Revenue (Forecasts)

Sales Forecasts of Major Products

(Billion yen)

	FY 2019 (Result)	FY 2020 (Forecast)	YoY
Opdivo	87.3	**98.0**	+ 12.2 %
Glactiv	26.1	**25.0**	- 4.1 %
Forxiga	18.1	**22.5**	+ 24.6 %
Orencia SC	19.8	**22.0**	+ 11.0 %
Rivastach	8.5	**7.5**	- 12.0 %
Parsabiv	7.1	**8.0**	+ 13.1 %
Kyprolis	6.0	**7.0**	+ 16.7 %
Onoact	4.9	**5.5**	+ 13.1 %
Proemend	2.6	**2.5**	- 4.8 %
New products（FY2020）	–	**3.0**	–

With respect to sales forecast of major products, sales forecast of Opdivo has been revised upward from JPY90 billion to JPY98 billion, an increase of JPY8 billion. In light of the current situation, we have been revising the sales by products upward or downward in a range between JPY500 million and JPY1 billion for each product.

Regarding the new products launched in the fiscal year in the bottom column, we initially forecast sales of JPY5 billion, but have revised this down to JPY3 billion. In addition to Velexbru and Ongentys, we also expect to add Joyclu and Adlumiz.

Revenue (Forecasts)

Sales Forecasts of Long-term listed products

(Billion yen)

	FY 2019 (Result)	FY 2020 (Forecast)	YoY
Opalmon	8.3	**5.0**	**- 40.0 %**
Emend	8.1	**2.5**	**- 69.1 %**
Onon capsule	3.5	**2.5**	**- 27.6 %**
Recalbon	4.7	**2.5**	**- 47.3 %**

Regarding sales forecasts of long-term listed products, we have revised slightly downward. In total, we had expected the negative trend of long-term listed products in the current fiscal year to amount to around JPY7 billion, but it is likely that the impact will be slightly larger, and we expect that it may be as high as JPY10 billion.

Operating Profit (Forecasts)

Operating Profit	YoY
¥ 87.0 billion	+ 12.3 %

Costs, etc.

(Billion yen)

	FY 2020 (Forecast)	YoY
・Cost of Sales	84.0	(+ 6.2 %)
・R&D Expenses	65.0	(- 2.3 %) ①
・SG&A Expenses	67.0	(- 1.0 %) ②
①+② Total	132.0	(- 1.6 %)
・Other Income	0.5	(- 39.2 %)
・Other Expenses	2.5	(- 0.5 %)

Operating profit forecast was revised upward by JPY7 billion to JPY87 billion, with a YoY increase of JPY9.5 billion.

Forecast of cost of sales was revised JPY4.5 billion, up from the original plan. In addition, R&D expenses are forecast to be JPY4 billion less than originally planned, at JPY65 billion.

Forecast of the cost of sales has been revised upward by JPY 2.5 billion, while forecast of R&D expenses has been revised downward by JPY4 billion and SG&A expenses downward by JPY3 billion. As I mentioned earlier, we expect that forecast of R&D and SG&A expenses will balance out somewhat through the full-year. So, we expect that operating profit will be JPY87 billion.

Profit before Tax (Forecasts)

Profit before Tax	YoY
¥ 88.5 billion	+ 11.0 %

Net financial income

+ ¥ 1.5 billion (- ¥ 0.7 billion YoY)

We forecast that profit before tax will be JPY88.5 billion.

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

Profit for the Period (Owners of the Parent Company)	YoY
¥ 65.0 billion	+ 8.9 %

Income tax expense

¥ 23.3 billion	(+ 17.6 % YoY)

(Major change factors)

Increase in profit before tax	¥ 8.8 billion
Increase in corporate tax	¥ 3.5 billion

We have revised our forecasts for profit for the period to JPY65 billion, an upward revision of JPY4 billion, and a YoY increase of JPY5.3 billion.

Although there are no slides, there are a number of factors contributing to the expansion of business performance in H2 of the fiscal year, or in the next fiscal year. Unfortunately, I do not have time to discuss this in detail, but I will outline some points here.

First, we anticipate that we will be able to obtain approval for first-line treatment of non-small-cell lung cancer by the end of the year. We cannot be exact about the boost to sales, but I think that the I-O market for lung cancer is likely to be about JPY150 billion.

Opdivo's second-line treatment for lung cancer is expected to generate sales of about JPY20 billion. If we obtain the indication of first-line treatment and take about 30% of the total, we think that it will be about JPY50 billion. That is, assuming that we are able to take a third of the market.

As for first-line treatment of gastric cancer, we anticipate that approval will be around the end of this fiscal year or the beginning of next fiscal year. Opdivo now accounts for about 70% of gastric cancer cases treated with third-line treatment. If we are able to obtain the same level in first-line treatment, the market would be worth around JPY80 billion. Again, this depends on how much market share we are able to secure.

The next point is the schedule for applications in the next fiscal year. Regarding the application for adjuvant treatment in gastric cancer, at present, 24,000 patients per year undergo surgery for gastric cancer. If Opdivo is used as adjuvant treatment in about 4,000 patients per year, that would constitute a market of about JPY40 billion.

Similarly, in the application as adjuvant treatment for urothelial cancer, the market overall is worth roughly JPY20 billion to JPY30 billion. Again, this depends on how much of market share we will take.

Next, regarding Forxiga, we had recommendation of approval yesterday in the 1st committee on drugs and expect to obtain approval for chronic heart failure in November. We plan to announce our sales target when we obtain approval. There are 1.6 million patients with chronic heart failure. Strictly speaking, we expect that half of them, or 800,000 people will be target population. If we can obtain 30% to 40% share of the target patients, the market will be worth up around JPY10 billion. We expect this to add between JPY10 billion and JPY15 billion.

As you know, we are currently conducting clinical trials in AstraZeneca for dilated heart failure, so we are hoping to see additional indication in both types.

Although this is a little further down the road, we are also conducting trials for chronic kidney disease (CKD). Here, we estimate that the number of patients is about 2.7 million.

We anticipate to obtain approvals and launch of Joyclu for the treatment of osteoarthritis and Adlumiz for cancer cachexia by the end of the fiscal year.

In addition, we expect to obtain approval for the combination treatment with Braftovi and Mektovi for second-line treatment of colorectal cancer. If we can obtain approvals as scheduled, we expect that there will be a total market of around JPY10 billion.

This is a brief summary of the market outlook. I am confident that we will be able to obtain solid market share in these areas. This is also the middle term forecast.

Status of Cross-shareholdings

	End of March 2018	End of September 2020	YoY
Number of listed brands	111	**79**	**(- 28.8 %)**
Balance sheet amount	¥ 167.1 billion	¥ 142.5 billion	(- 14.7 %)
the market price at the end of March 2018	¥ 167.1 billion	**¥ 132.0 billion**	**(- 21.0 %)**

As of March 2018, the Company held strategic cross-shareholdings of JPY167.1 billion. In terms of the number of stock names, 111 stock names will be released, and over the three-year period from October 2018, 30% will be released. As this is 30% of JPY167 billion, we are basing this on the market price at that time. This was originally a reduction of JPY50 billion, but now two years have passed, a reduction of approximately JPY35 billion. We would like to proceed with the remaining JPY15 billion as scheduled next year. Currently, we are making steady progress. We are reducing the number of stock names by 32.

The above is a report on progress at the two-year point.

Development pipeline

Idemitsu: I would like to explain the progress of development.

The status of the development products is described on pages 3 to 4 of the financial results summary. It is also described on pages 6 to 9 of the Financial Results Supplement. Today, this supplementary material will be used to explain the updates since Q1 FY2021.

Regarding the composition of the materials, first the oncology field is described, followed by areas other than oncology. In addition, items will be described in the order of approval, submission and clinical development stage (Phase 3 followed by advanced stages).

I. Main Status of Development Pipelines (Oncology)

As of October 27, 2020

<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*1 / In-license
Yervoy Injection ★ / Ipilimumab	Additional indication	Colorectal cancer *1 (MSI-High)	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Waldenstorm macroglobulinemia, Lymphoplasmacytic lymphoma *2 / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	Japan	In-house

★: Combination with Opdivo.
Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2021
*1: An application was approved in Japan for combination therapy of Opdivo and Yervoy for the treatment of microsatellite instability-high (MSI-High) unresectable advanced or recurrent colorectal cancer that has progressed following chemotherapy.
*2: An application was approved in Japan for Velexbru Tablets for the treatment of waldenstorm macroglobulinemia and lymphoplasmacytic 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*1 / In-license
ONO-7643 / Anamorelin	New chemical entities	Cancer cachexia / Ghrelin receptor agonist	Tablet	Japan	In-license (Helsinn Healthcare, S.A.)
Yervoy Injection ★ / Ipilimumab	Additional indication	Non-small cell lung cancer	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma *3	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)
Braftovi Capsules / Encorafenib	New chemical entities	Colorectal cancer / BRAF inhibitor	Capsule	Japan	In-license (Pfizer Inc.)
Mektovi Tablets / Binimetinib	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	Japan	In-license (Pfizer Inc.)

★: Combination with Opdivo.
Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2021
*3: An approval application for combination therapy with Opdivo and Yervoy was filed in Japan for the treatment of unresectable advanced or recurrent malignant pleural mesothelioma.

<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	Gastro-esophageal junction cancer and esophageal cancer	Injection	Japan 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	Glioblastoma	Injection	Japan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	Japan	III	In-house (Co-development with Bristol-Myers Squibb)

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First of all, the oncology field. This is page 6 of the Supplementary Materials for the Financial Results, listing the products which approval has been obtained. In September, we received approval for combination Opdivo and Yervoy in MSI-High colorectal cancer.

Below that, Velexbru tablets received approval for the treatment of Waldenstrom macroglobulinemia and lymphoplasmacytic lymphoma in August.

Next, in the third line of 2nd column under filing, we made an application this week for combination Opdivo and Yervoy in malignant pleural mesothelioma.

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	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	Solid tumor (Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma)	Injection	Japan	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central nervous system lymphoma / Primary testicular lymphoma	Injection	Japan	II	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	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	Non-small cell lung cancer	Injection	S. Korea Taiwan	III	In-license (Co-development with Bristol-Myers Squibb)
	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)

Last time, we presented the Phase III for Opdivo monotherapy and Opdivo and Yervoy combination therapy for small-cell lung-cancer. However, the development was discontinued and these have been removed from the tables on pages 6 and 7.

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
ONO-4686 ★ (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4482 ★ (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-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-4578 ★	New chemical entities	Solid tumor / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
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)

<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-7702 / 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.)
ONO-7703 / 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.)
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.)

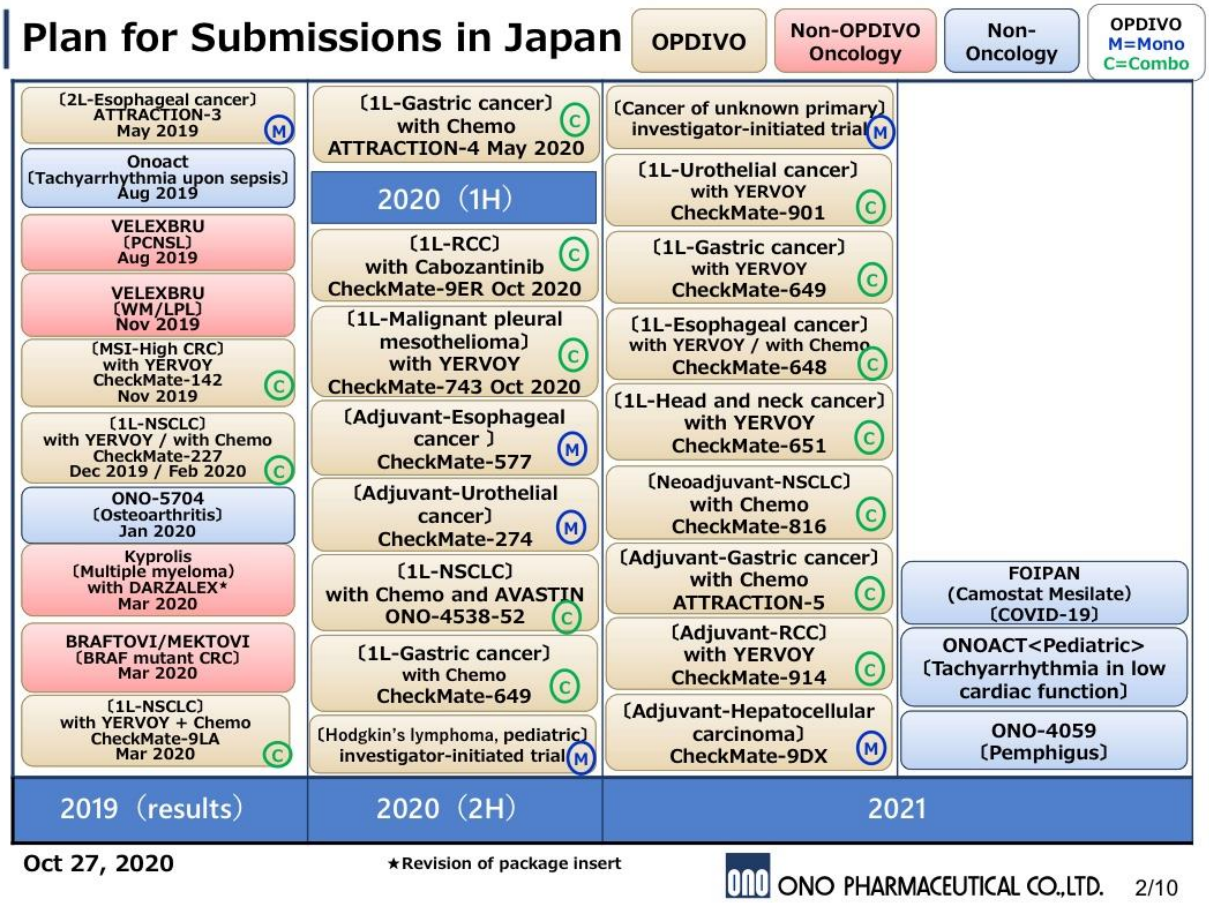
★: Combination with Opdivo.

Changes from the announcement of financial results for the first quarter of the fiscal year ending March 2021

* Phase III of combination therapy of Opdivo and Yervoy for the treatment of small cell lung cancer was discontinued due to strategic reasons.
* Phase II of ONO-4687 (BMS-986227) / Cabiralizumab (Anti-CSF-1R antibody) for the treatment of pancreatic cancer was discontinued.

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

We were also conducting Phase II for the anti-CSF-1R antibody, ONO-4687 (cabiralizumab), for the treatment of pancreatic cancer, but the trial was discontinued and removed from the I-O related tables on page 8.



I will introduce the updated parts using the material on the progress of the development pipeline on our website. The information is summarized on the slide 2.

In the table, Opdivo is in beige, oncology items other than Opdivo are in red, and non-oncology items are in blue.

M is for monotherapy items and C is for combination items.

The composition of the table has changed slightly from the previous time. The previous report was divided into four categories: FY2019 results on the left, then FY2020 H1, H2, and FY2021. For ease of presentation, H1 and H2 of FY2020 are summarized on the left, and the items for which applications will be submitted in FY2021 are in the right two columns.

Then, I will explain the changes from the July earnings announcement.

First, as for the left-hand side representing FY2019 (actual results), we have already received approval for the following three cases from above: Opdivo for second-line treatment of esophageal cancer, Onoact for tachyarrhythmia upon sepsis, and Velexbru for primary central nervous system lymphoplasmacytic lymphoma, as reported previously.

Regarding Velexbru, the product was launched in May. An additional indication for Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, which is described in the fourth section from above, was approved in August.

As I mentioned earlier, we received approval in September for combination Opdivo and Yervoy in MSI-High colorectal cancer.

At the item below and the bottom column, there are two items for the first-line treatment of non-small-cell lung cancer with Opdivo. In CheckMate-227 and CheckMate-9LA, we have submitted applications for three types of regimes: combination Opdivo, Yervoy and chemotherapy, combination Opdivo and Yervoy, and combination Opdivo and chemotherapy. They will be referred to the subcommittee to be held today.

In addition, the following items will be referred to the subcommittee meeting today; combination Kyprolis and Darzalex for multiple myeloma and Braftovi/Mektovi for BRAF-mutant colorectal cancer.

Next, we will explain the updated parts for H2 of FY2020, one from the left.

First of all, regarding H1 of FY2020, we submitted an application this week for combination of Opdivo and cabozantinib for the first-line treatment of renal cell carcinoma.

In addition, the application for combination Opdivo and Yervoy in malignant pleural mesothelioma was also submitted this week, as previously mentioned.

That concludes my update on applications and approvals.

Next, I would like to introduce the results of clinical trials.

First, five findings on Phase III of Opdivo were released at the last ESMO. The first is the result of the ATTRACTION-4 for the first-line treatment of gastric cancer. Second, the results of CheckMate-9ER with cabozantinib for the first-line treatment of renal cell carcinoma. As I mentioned earlier, we have already submitted the applications for these indications.

Next is the result of the Checkmate-577 for adjuvant treatment of esophageal cancer. The forth is the result of ONO-4538-52, which is Avastin combination trial for the first-line treatment of non-small-cell lung cancer. The fifth is the result of CheckMate-649 for the first-line treatment of gastric cancer trial. In all of these trials, the primary endpoint was met.

Regarding the first-line treatment of gastric cancer, PFS was achieved in ATTRACTION-4 conducted in Asia, by which we have already filed an application. In addition, a significant difference was observed in OS in the global CheckMate-649 study.

This concludes the ESMO presentations.

Furthermore, we have obtained two new trial results since ESMO. The first is the adjuvant trial for urothelial cancer, Checkmate-274. The results of the interim analysis showed a significant difference in disease-free survival (DFS).

Second, in Checkmate-816 for the neo-adjuvant treatment of non-small-cell lung cancer, a significant difference in pathological complete response was observed.

Considering the time to be required for preparing an application, including consultation with the authorities, these applications were scheduled to be filed in H2 of FY2024 in the previous material, but have been changed to FY2021.

The schedule for ATTRACTION-5, for adjuvant treatment of gastric cancer was also changed from H2 of FY2020 to FY2021. It has been changed due to the event occurrence status.

Three new projects have been added. The first is the bottom line of H2 of FY2020, with an indication of pediatric Hodgkin Lymphoma with Opdivo. The second is for use of Opdivo for cancer of unknown primary.

The third is a project targeting COVID-19 with Foipan. Foipan is a product that was launched for chronic pancreatitis more than 30 years ago, and several generics have already been launched. Following the release of papers on basic experiments suggesting its efficacy against COVID-19, we believe that it is our responsibility to confirm whether it will indeed be effective in human, and we are currently developing it. We are currently preparing for Phase III.

Development pipeline in Japan (Oncology, other than OPDIVO)

As of Oct 27, 2020

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Approved】		
VELEXBRU (Tirabrutinib)	Primary macroglobulinemia Lymphoplasmacytic lymphoma	BTK inhibitor
【Filed】		
ONO-7643 (Anamorelin)	Cancer cachexia (in all types of cancer)	Ghrelin mimetic
BRAFTOVI (Encorafenib)	BRAF-mutant colorectal cancer	BRAF inhibitor
MEKTOVI (Binimetinib)	BRAF-mutant colorectal cancer	MEK inhibitor
【Phase Ⅰ】		
ONO-4578*	Solid tumor	PG receptor (EP4) antagonist
ONO-7475*	Solid tumor	Axl / Mer inhibitor
ONO-7913	Solid tumor	Anti-CD47 antibody
ONO-7912	Pancreatic Cancer	Cancer metabolism inhibitor

*Combination with Opdivo.

Red: Update after May 2020

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Major developments in Opdivo and developments in oncology other than Opdivo are listed. In addition, this section describes pipelines outside the oncology field. The part in red has been updated since May 2020. I will update you now on the other items.

ONO-7912, from Rafael. Phase I was launched for pancreatic cancer.

Development pipeline in Japan (Non-oncology) (1)

As of Oct 27, 2020

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Approved】		
ONGENTYS (Opicapone)	Parkinson's disease	Long acting COMT inhibitor
ONOACT (Landiolol hydrochloride)	Tachyarrhythmia upon sepsis	Short-active selective β_1 blocker
【Filing】		
ONO-5704・SI-613	Osteoarthritis	Hyaluronic acid-NSAID
【Phase Ⅲ】		
ORENCIA SC (Abatacept)	Polymyositis/Dermatomyositis	T-cell activation inhibitor
【Phase Ⅱ/Ⅲ】		
ONOACT (Landiolol hydrochloride)	Tachyarrhythmia in low cardiac function <Pediatric>	Short-active selective β1 blocker

Red: Update after May 2020

Ongentys was approved for Parkinson's disease in June and launched in August.

Development pipeline in Japan (Non-oncology) (2)

As of Oct 27, 2020

Product name/ Development code (Generic name)	Target indication	Pharmacological action
【Phase Ⅱ】		
ONO-5704・SI-613	Enthesopathy	Hyaluronic acid-NSAID
VELEXBRU (Tirabrutinib)	Pemphigus	BTK inhibitor
【Phase Ⅰ】		
ONO-7269	Cerebral infarction	FXIa inhibitor
ONO-4685	Autoimmune disease	PD-1×CD3 bispecific antibody
ONO-2910	Peripheral nerve disorder	Enhancement of Schwann cell differentiation
FOIPAN（Camostat mesilate）	Novel coronavirus infection	Protease enzyme inhibitor

Red: Update after May 2020

ONO PHARMACEUTICAL CO.,LTD. 9/10

ONO-2910 is a new compound with Schwann cell differentiation-promoting effect. We expect that it will be effective for peripheral neuropathy. Phase I was started.

As mentioned about Foipan earlier, Phase III is currently being prepared for COVID-19, but prior to that, we had implemented Phase I to confirm high-dose safety.

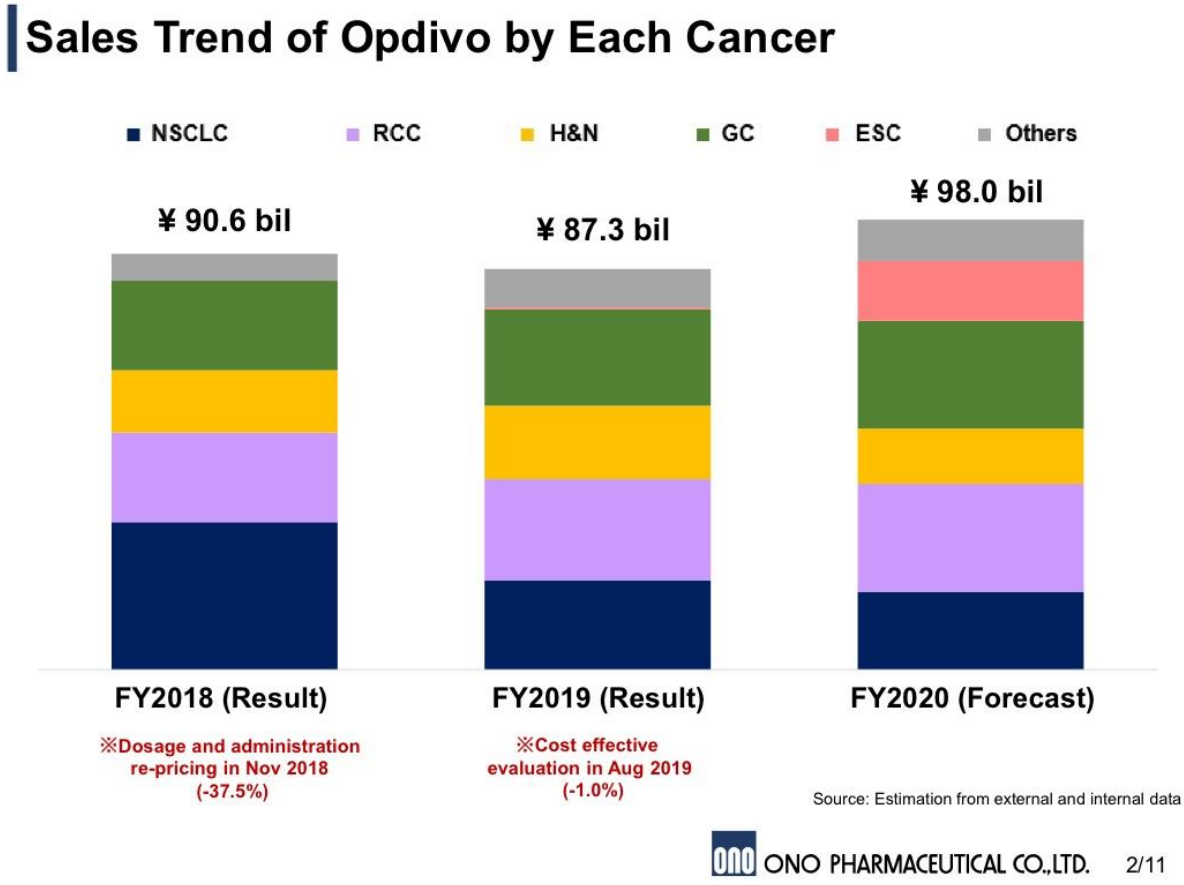
Global development projects (Other than OPDIVO)

As of Oct 27, 2020

Development code (Generic name)	Target indication	Pharmacological action	Area
【Phase Ⅲ】			
BRAFTOVI (Encorafenib)	BRAF-mutant colorectal cancer	BRAF inhibitor	KR
	BRAF-mutant melanoma		KR
MEKTOVI (Binimetinib)	BRAF-mutant colorectal cancer	MEK inhibitor	KR
	BRAF-mutant melanoma		KR
ONO-7912・CPI-613 (Devimistat)	Pancreatic cancer	Cancer metabolism inhibitor	KR
	Acute myeloid leukemia		KR
【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

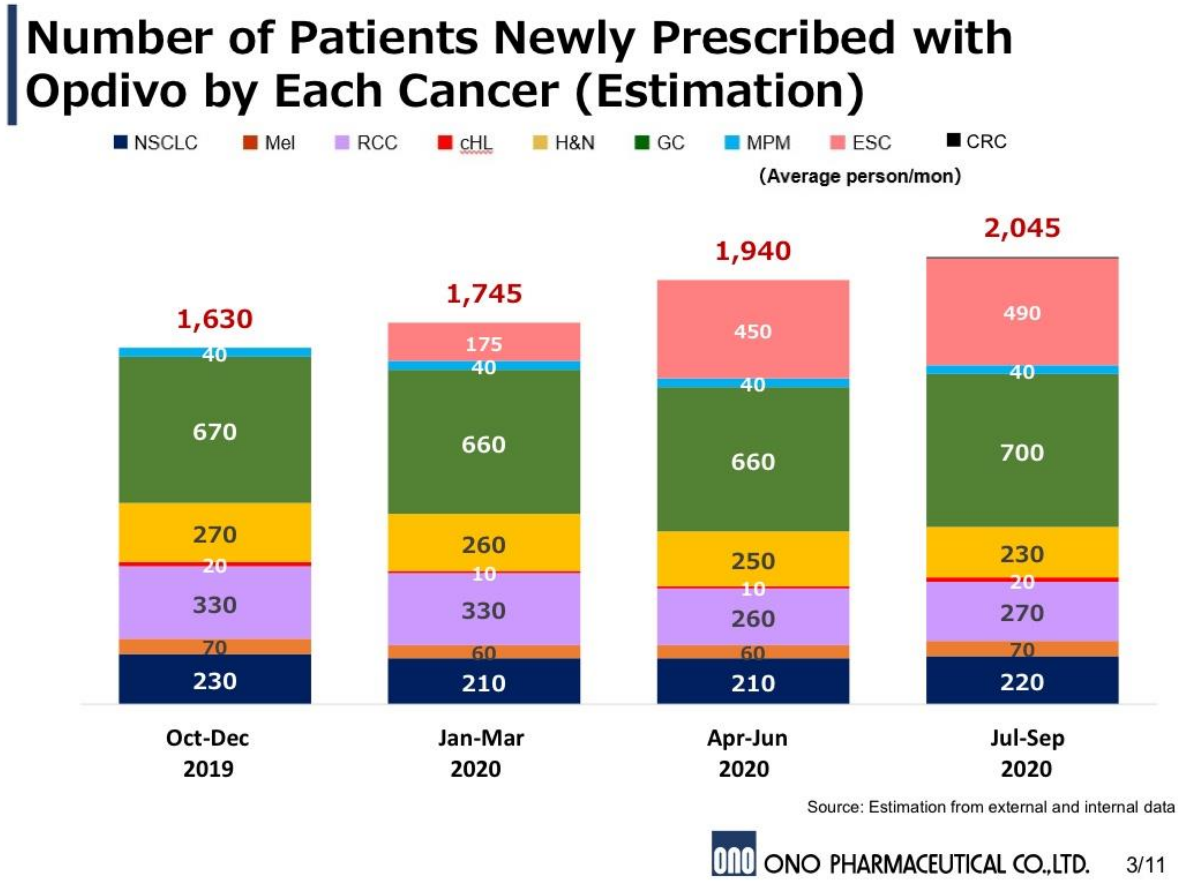
*Combination with Opdivo.
Red: Update after May 2020

Finally, ONO-7475 is an inhibitor of Axl/Mer. We had been conducting Phase I for acute leukemia, and we have been conducting Phase I-II to evaluate its effectiveness.



Takahagi: I would like to talk about an overview of trend of Opdivo, as well as a breakdown by cancer type.

From the bar graph on the left, the results for FY2018, FY2019, and the forecast for FY2020 are shown. In the current fiscal year, we forecast sales of JPY98 billion, taking into account positive factors, such as an increase in new prescriptions in esophageal cancer and promising entry of the first-line treatment of lung cancer.

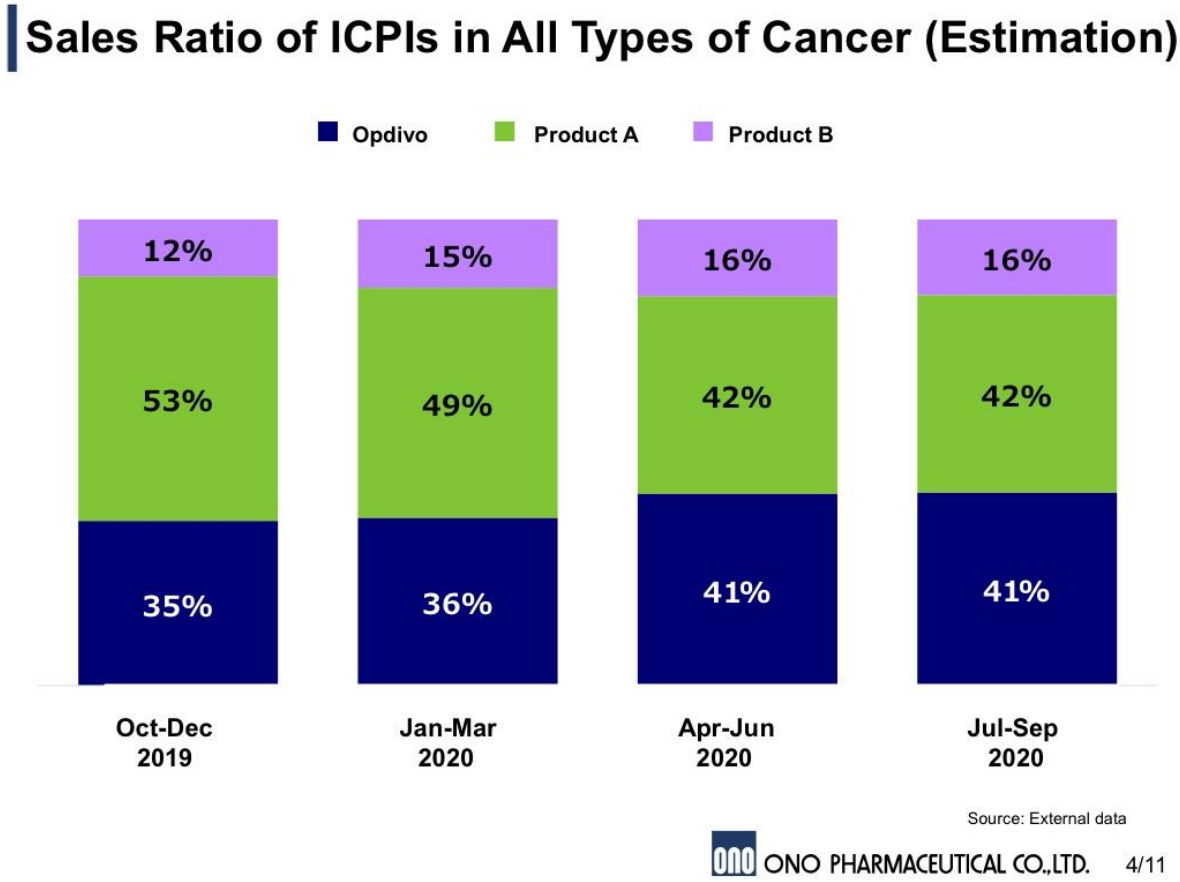


This slide shows the number of new prescriptions for Opdivo by each cancer type.

From the bar graph on the left, the average number of patients per month is shown quarterly from October to December in FY2019 to July to September in FY2020.

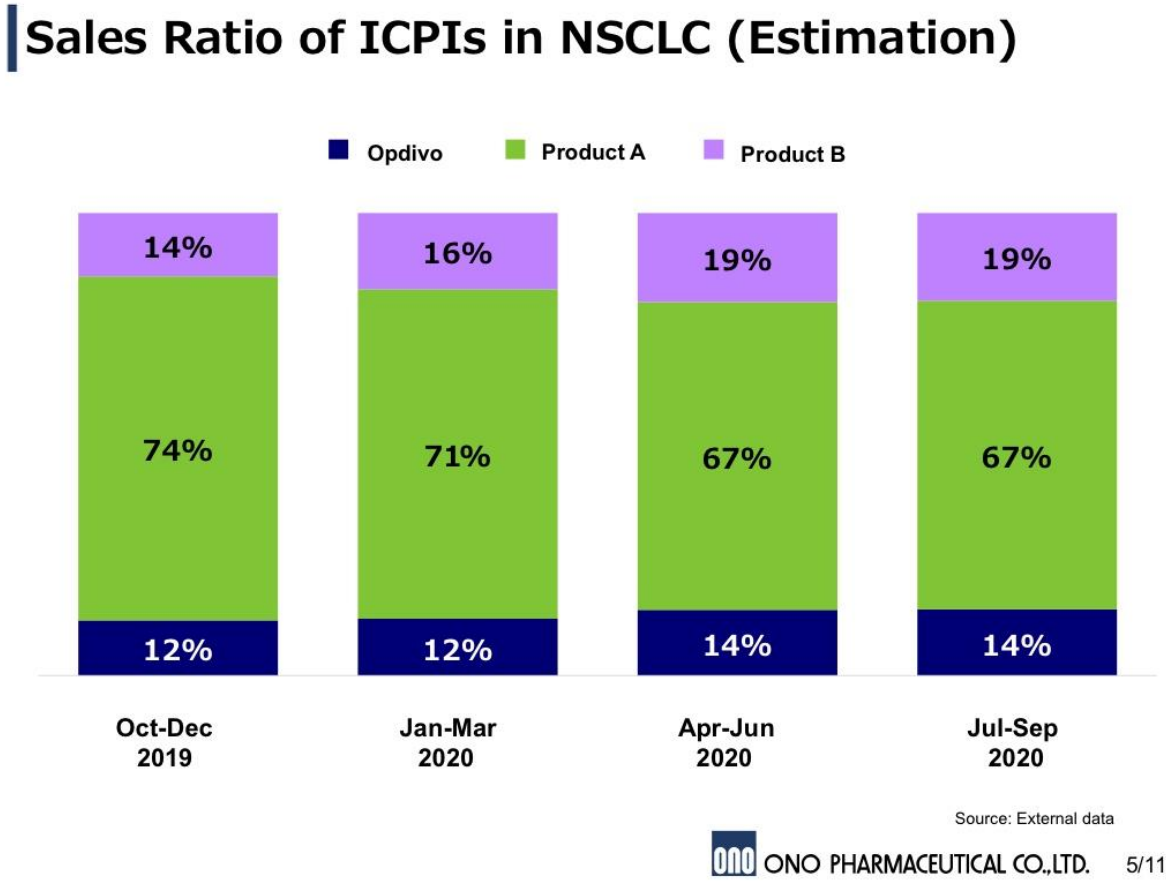
These are estimates. In July to September 2020, the drug was used in 700 cases of gastric cancer and in 270 cases of renal cell carcinoma. In July to September 2020, as for esophageal cancer, it was used in second- or third-line treatment in 490 cases, and we have obtained 3,400 prescriptions including waiting patients since approval.

In July to September, the average monthly number of new prescriptions exceeded 2,000 cases.



The percentages of sales accounted for by the major immuno-checkpoint inhibitors, Opdivo and its competitors are shown on a quarterly basis from October to December FY2019 to July to September FY2020

In July to September 2020, Opdivo held a 41% share among the major immuno-checkpoint inhibitors.

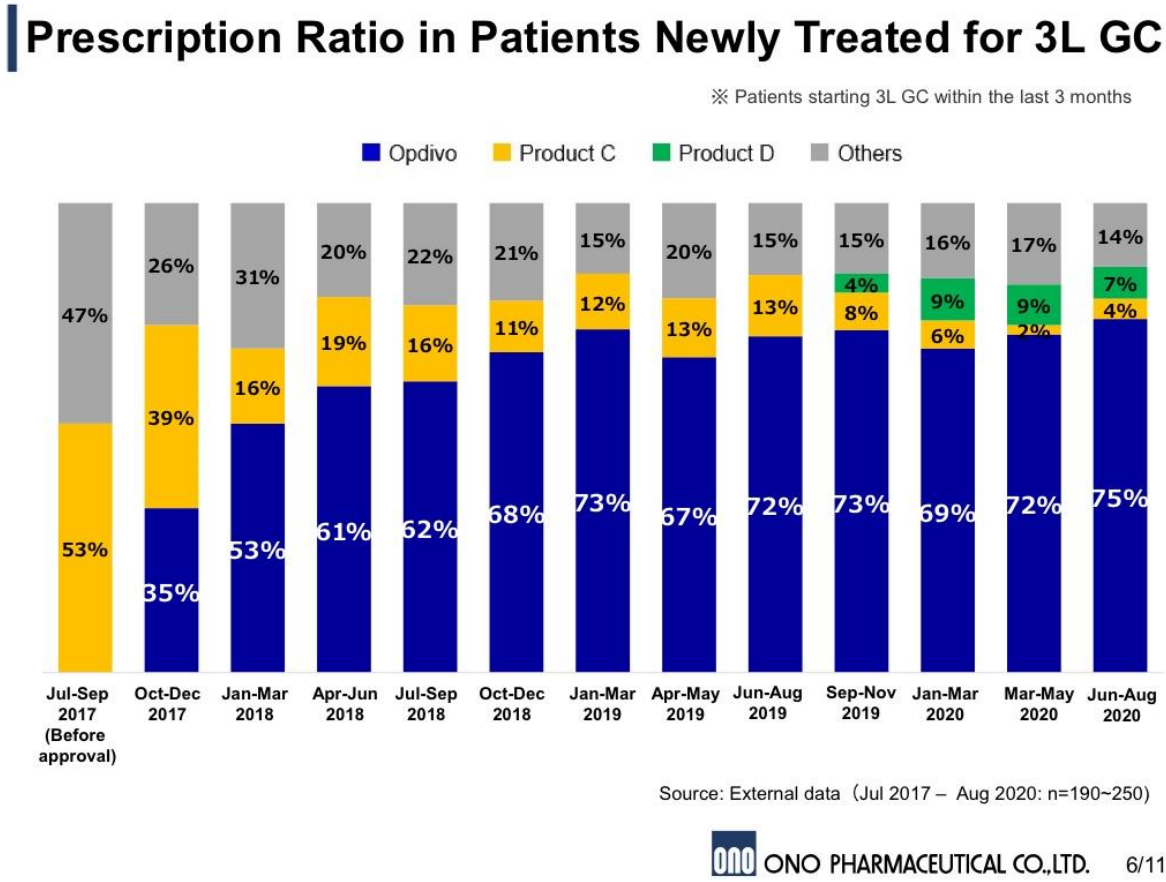


We introduce the figures by cancer type.

First, non-small-cell lung cancer (NSCLC). This slide shows the sales composition ratio of immuno-checkpoint inhibitors in all treatment lines, including first-line, second-line, and third-line treatment for major immuno-checkpoint inhibitors for NSCLC.

Similar to the graph above, the bars on the left are shown separately on a quarterly basis.

Opdivo is currently 14% share, and we intend to enter the first-line treatment field of NSCLC to regain the market share in the future.



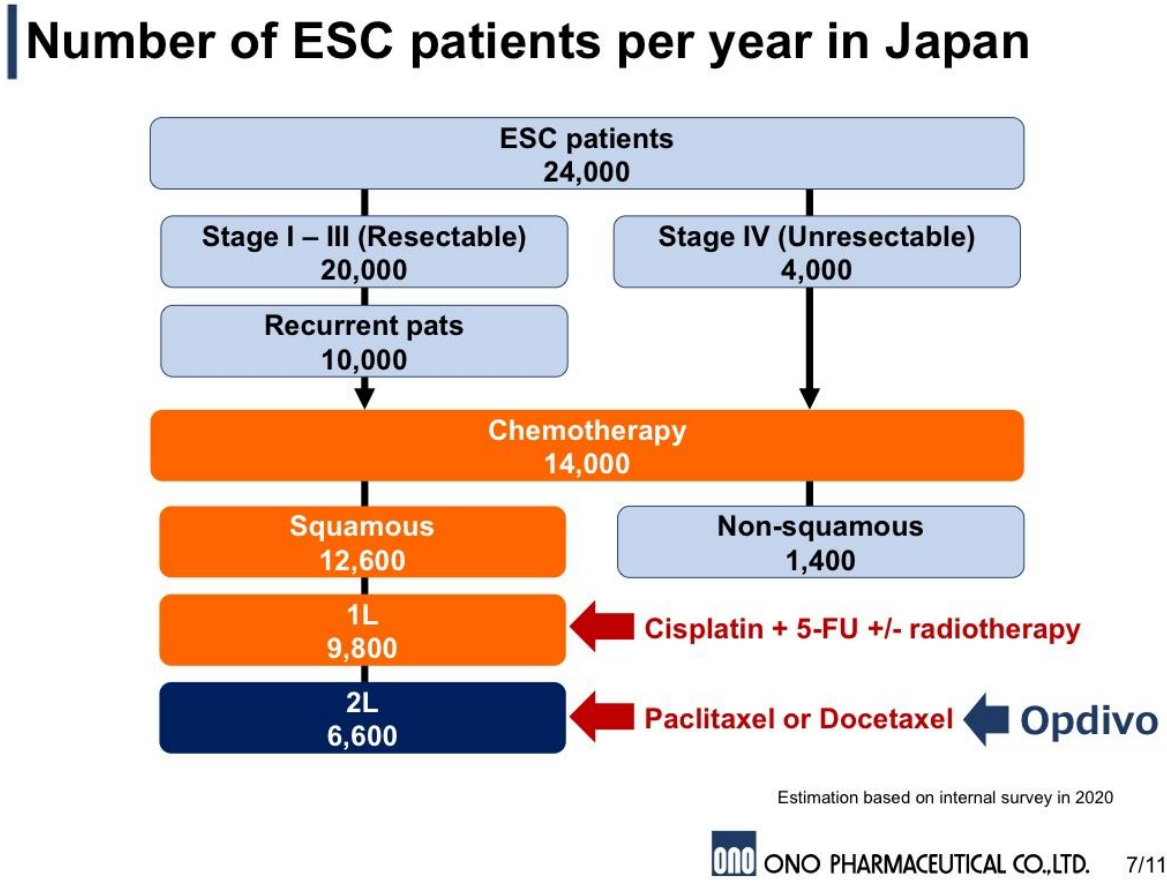
Next is the gastric cancer field. Changes in the share of prescriptions for new patients in third-line treatment of gastric cancer are shown here.

This shows sales trends from July 2017, before the indication approval, to the period of June to August 2020.

Competitors have been entering the market share of new prescriptions in Opdivo's third-line treatment of gastric cancer field. However, Opdivo firmly maintained 75% of the market share, exceeding our target of 70%.

On the other hand, regarding the rate of treatment transition for gastric cancer, the rate of transition from the second line to the third line, has remained unchanged with 61%.

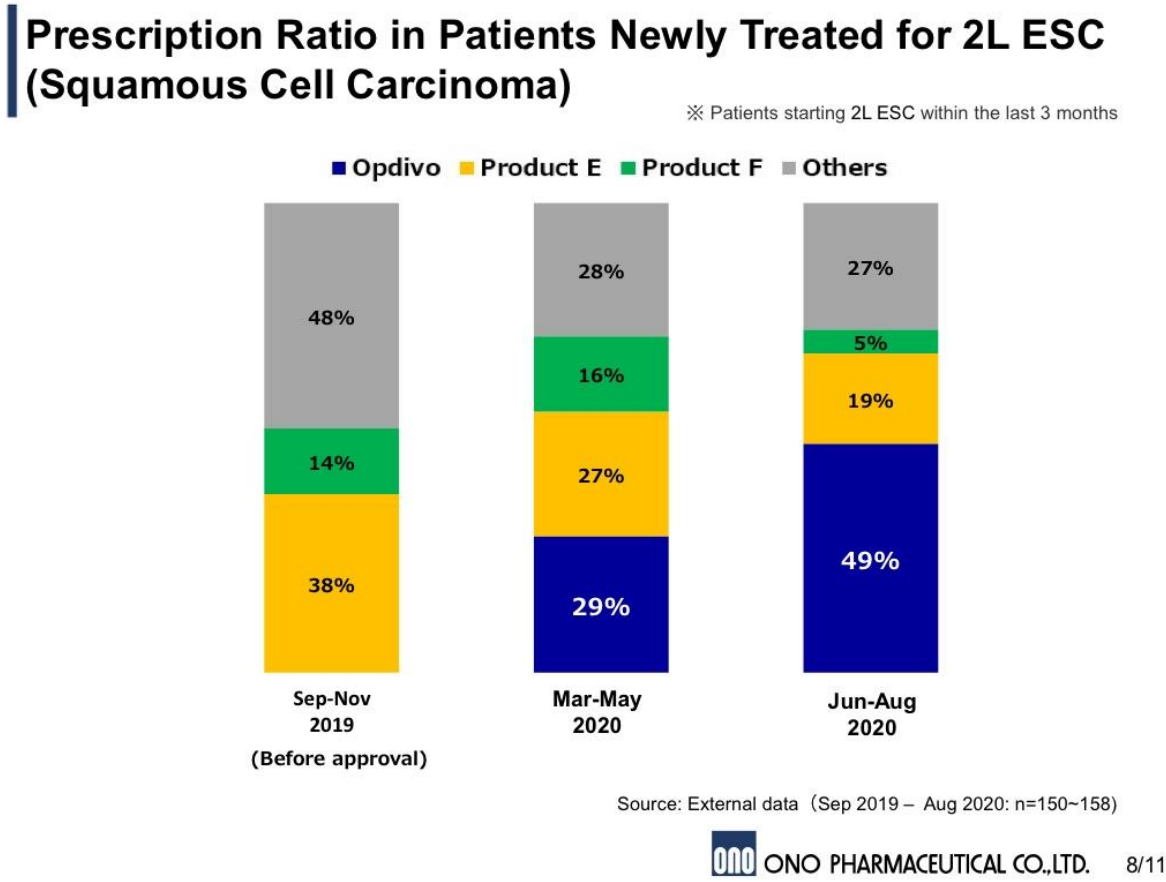
Going forward, we intend to maximize the therapeutic significance of the immuno-checkpoint inhibitor in the field of gastric cancer, by which we want to make use of Opdivo as a first-line treatment in the future.



For esophageal cancer, approval was granted in February of this year, and we are currently working on this indication.

We have a total of 6,600 target patients for Opdivo's second-line treatment of esophageal cancer.

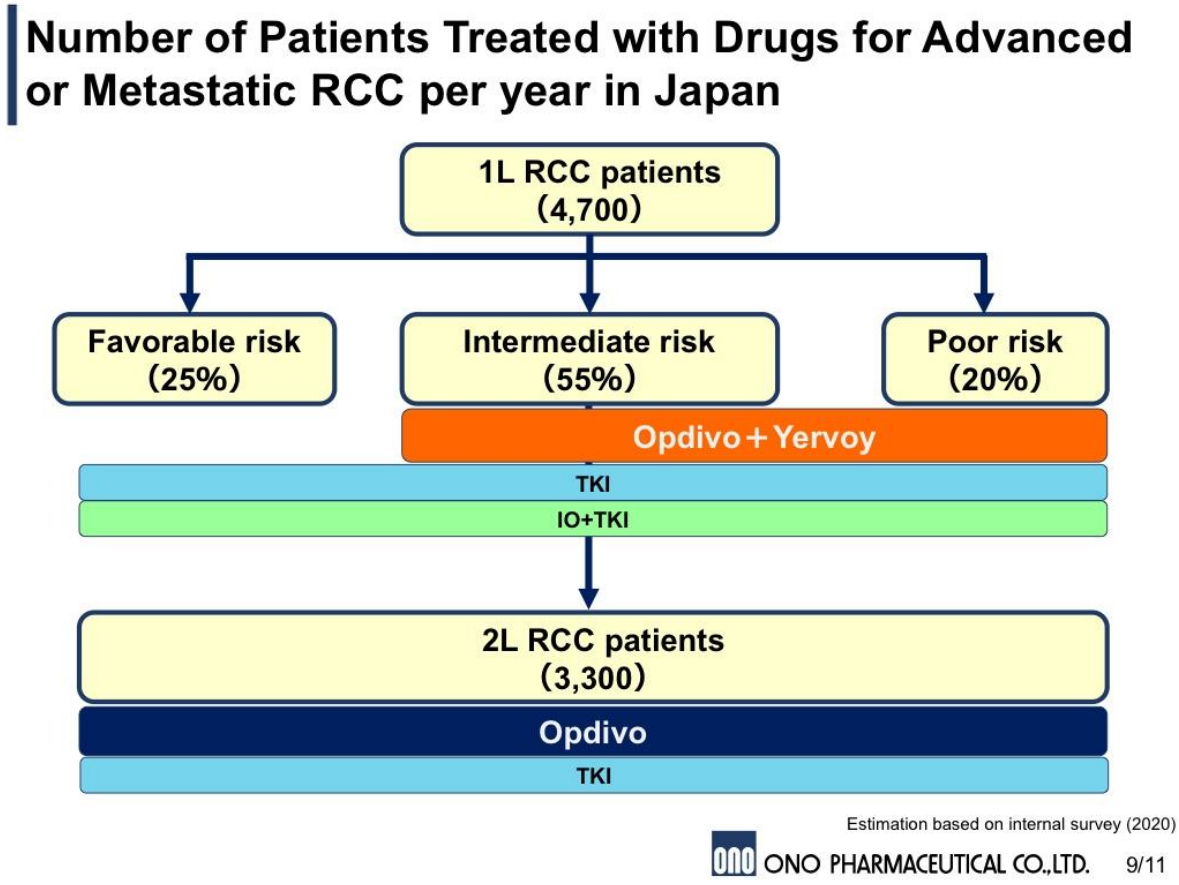
Previously, the treatment of esophageal cancer has been very limited with those such as FP therapy, S-1, and taxanes, and there have been no new therapeutic drugs available. This is an area where the unmet needs of patients and healthcare professionals have been extremely high. In this context, we obtained additional indication of esophageal cancer, leading to a rapid penetration of Opdivo, as I mentioned before, with 3,400 estimated prescription cases since its approval.



This slide shows trends in the share of new patient prescriptions for second-line treatment.

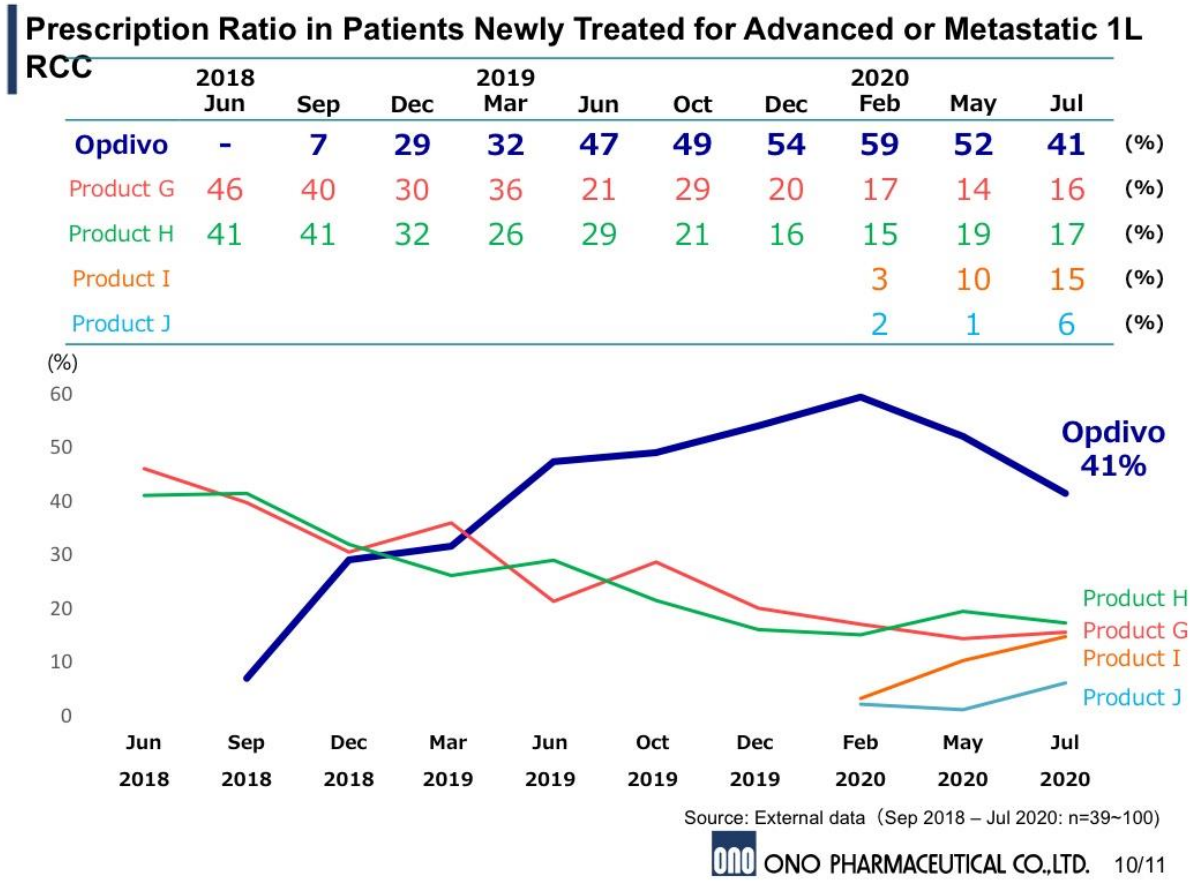
In the gastrointestinal field, we started activities in the gastric cancer field and believe that they were successfully passed over to the field of esophageal cancer. In this area, Opdivo has gained an extremely high reputation.

The share of new prescriptions of Opdivo for the second-line treatment is currently 49%, showing a rapid start-up. We intend to continue delivering this product to patients who are affected by esophageal cancer.



Finally, renal cell carcinoma.

There is evidence supporting first-line treatment with combination Opdivo and Yervoy, and for the second-line treatment and thereafter with Opdivo monotherapy. We are working to ensure that Opdivo can be available to all patients with renal cell carcinoma.

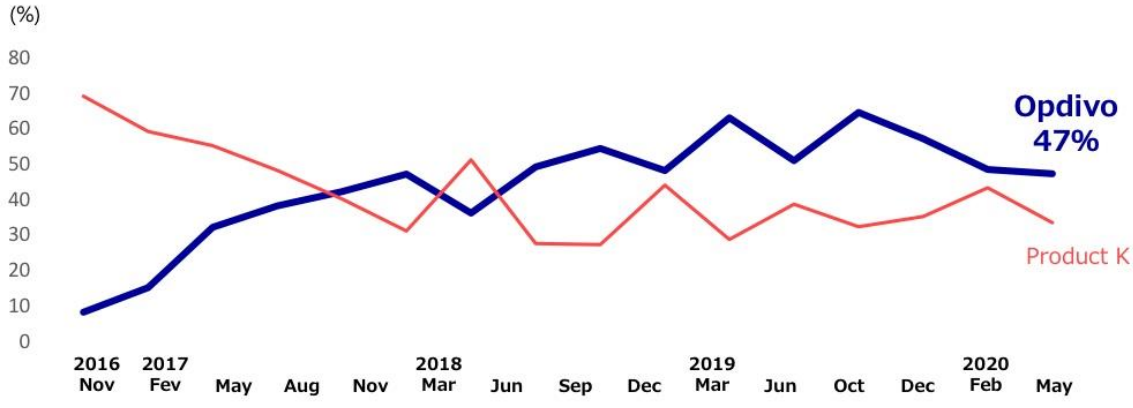


This slide shows the trends in new patient prescription share in the first-line treatment of renal cell carcinoma.

In first-line treatment, combination I-O and TKI therapies have entered the market, and prescriptions are gradually expanding. The share of new prescriptions in first-line treatment for combination Opdivo and Yervoy is 41%, but the share of new prescriptions is more than 50% when we look at medium- and high-risk groups. We believe that the business is performing preferably.

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

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



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

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With the increase of I-O inhibitors for first-line treatment and the decrease of I-O inhibitors in patients with previously untreated with I-O inhibitors in second-line treatment, the current share of Opdivo is 47%.

Focusing only on patients who have not been treated with an immuno-checkpoint inhibitor, Opdivo's prescription share is high with 75%. As I mentioned earlier, we intend to continue our activities to deliver Opdivo to all patients with renal cell carcinoma.

In the European Society for Clinical Oncology, ESMO 2020, the data that strongly supports our activities in combination Opdivo and Yervoy for the first-line treatment of renal cell carcinoma.

While competitive I-O inhibitors are entering the market in combination with TKI products, we are strengthening our activities by delivering such information to medical professionals.

The following three slides provide further data.

This data is from CheckMate-214, with which we obtained approval for combination Opdivo and Yervoy treatment. This is the four-year follow-up data.

In Japan, with the progress of treatment of renal cell carcinoma, there has been a significant increase in the number of doctors and patients who are eager to see the long-term follow-up data. Four-year follow-up data has been published for combination Opdivo and Yervoy therapy.

The median OS was prolonged compared to the control group, and the difference in OS rates and hazard ratio at each landmark point was maintained throughout the long-term observation period.

In terms of the characteristics of Opdivo, the response has been maintained in patients who was responsible, and long-term response can be expected. This information has been rated highly by our experts.

In addition, the PFS showed a tail plateau of about 35%, showing the clear usefulness of Opdivo and Yervoy combination therapy in the four-year follow-up data. Going forward, we will continue to proceed with our activities to deliver Opdivo treatment opportunities to all patients with renal cell carcinoma.

I will show an estimated market expansion following the additional approval of Opdivo shown here.

To begin with, regarding a post-operative adjuvant treatment of esophageal cancer, we estimate that there are 800 patients per year in Japan who undergo pre-operative radiation and chemotherapy, based on the inclusion criteria for CheckMate-577. However, depending on the future approval status and positioning of standard therapy, we estimate it will expand to around 4,000 cases.

Furthermore, as for the post-surgery adjuvant therapy for urothelial cancer, we estimate that the number of patients with a higher risk of recurrence, which is an inclusion criteria of CheckMate-274, is around 3,000 in Japan.

In addition, regarding the neo-adjuvant therapy for NSCLC, we estimate that the number of cases eligible for pre-operative chemotherapy for NSCLC, which is an inclusion criteria for CheckMate-816 will be around 4,000 per year.

Currently, there are no standard therapies in these cancer types, and unmet needs are high. Depending on the status of approval and the positioning of standard therapies for Opdivo, we believe that Opdivo will be a potential product for these types of cancers.

We will continue to deliver the benefits of Opdivo monotherapy and combination therapy with Opdivo and Yervoy therapy to cancer patients in the future.

Question & Answer

Q: Regarding an expanded indication of Opdivo for the first-line treatment of non-small-cell lung cancer to be referred to in today's subcommittee meeting for, does this include not only the 227 trial regimen but also 9LA trial regimen?

Idemitsu: That understanding is correct.

Q: During the presentation, there was an explanation of the sales potential of Opdivo in the event that approval for adjuvant treatment is granted.

What do you think about the potential for cannibalization of the market for other advanced or recurrent types of cancer when approval is granted for treatment as an adjuvant?

Is it possible to use Opdivo once again in case of reoccurrence after the adjuvant or neo-adjuvant treatment? In some cases, if Opdivo is used during the surgical period, I suppose that there is a tendency to choose treatment option with another I-O products in case of recurrence.

The situation may differ depending on the cancer type, but I would particularly like to hear your opinions with respect to this for significant treatment of cancers such as lung cancer or gastric cancer to the company.

Takahagi: To summarize your question, you are asking if Opdivo is use for the adjuvant treatment, can Opdivo be used again for the treatment of advanced or recurrent cancer. Or would other drugs be used?

I think there are a variety of patterns, as you mentioned, where Opdivo works well or does not work for postoperative adjuvant treatment, and also cancer recurs after adjuvant treatment. I think we need to think about various patterns in the future.

First, we need to follow up patients treated with Opdivo for post-operative adjuvant treatment, and scrutinize the data from Opdivo treatment carefully. We want to show which patients can be helped with Opdivo in case of a recurrence.

This does not just apply to Opdivo, but more generally speaking, some professionals say that the treatment drugs will be decided in the recurrent cases, judging from the cases who received adjuvant treatment and recurred within or after 6 months.

In the future, we will continue discuss and consider this issue with such experts.

That may be slightly vague, but does that answer your question?

Q: For example, it was mentioned earlier that there is a capacity of about JPY80 billion for first-line treatment of gastric cancer, if Opdivo is approved, and about JPY40 billion if Opdivo can be used for adjuvant treatment. Can we simply add these together to get JPY120 billion?

Takahagi: It may be difficult to simply add them up. I would like to carefully examine the data that we will generate in the future.

Q: Finally, regarding the application for the 816 study. This is a neo-adjuvant treatment of small-cell lung cancer. In the current press release, the significant difference is observed in pathological complete response alone. Can you file an application based on this data alone? Is it necessary to wait for event-free survival data?

Idemitsu: We will consult with the authorities, including whether or not it is necessary to wait.

Q: If you need data on the event-free survival, can you apply in the next fiscal year?

Idemitsu: I'm sorry, but I cannot make a comment about the timing. We believe that the results of event-free survival will come out in the not-too-distant future. We will consult with the authorities the timing of data availability to determine the timing of our application.

Q: First of all, about Opdivo's first-line for non-small-cell lung cancer. As mentioned, the competing product with the first line therapy is Keytruda. I think Keytruda is almost a leading product for this market at present. Opdivo will enter that kind of market, and I think you will scrutinize a lot of data.

At present, I think that there are various combinations, such as combination with Yervoy, combination with chemotherapy, and single-agent therapy. How will your company approach this strategically? Do you have any specific thoughts on this matter?

I would also like to ask about the SG&A and R&D expenses, as spending here has been low. In particular, there has been a downward revision to R&D expenses. Financial results are not available for all other companies yet, but are there any specific factors that have exacerbated this for your company?

At present, there are quite a lot of products in development, but given the low R&D spending, is there a risk that there will be a delay in development in the future? How is your company planning to deal with this?

My third question is related to reducing cross-shareholdings. As this goes ahead, will it lead to an accumulation of cash? Are approaches such as share buybacks, dividend increases, or shareholder returns being considered? This seems to be something that could be decided and announced quickly, separate from the mid-term plan. Are there any plans to do this?

Takahagi: Regarding the question about first-line Opdivo and Yervoy combination therapy for lung cancer, and the 9LA and 227 trials. First of all, Keytruda is mainly used for the first-line therapy in combination with chemotherapy. In this context, we consider I-O/I-O as one of our strengths. We believe that the greatest characteristics and advantages are that Opdivo and Yervoy can be used together. The first part of our strategy is to explain this benefit to health professionals. Especially in the case of Yervoy, as we have shown the data on renal cell carcinoma in combination with Opdivo, we believe that we can expect long-term survival, tail plateau. We intend to hold discussions with specialists, focusing on these areas.

In the 9LA regimen, there was a decline in PFS at an early stage with I-O therapy and a cross with the control group. This is a very distinctive feature of this 9LA regimen, where only the first two cycles of chemotherapy have been combined, and the decline in that part has been eliminated.

We will explain this efficacy of combination Opdivo and Yervoy to specialists. We want to regain the market share in the area of lung cancer by appealing the efficacy.

Idemitsu: This is regarding the research and development expenses, and there are two major impacts of coronavirus on development.

One is the collection and fixation of data from trials for which case collection has already been completed, and the other is case collection.

Regarding the former part, we have made full use of various methods to collect and fix the data under the limited visits to medical institutes. Therefore, we believe that the impact on our latest filing schedule is limited.

Recruiting, on the other hand, has been delayed due to limitations on visits to facilities. In some countries, these limitations are so strict that it is substantially impossible to conduct trials. We reduced the budget due to this six-month delay, but in the future, we would like to proceed with recruitment by selecting countries and facilities where we can move forward. We are considering this reduction in development costs to be temporary.

Sagara: I would like to answer the questions with regard to our approach to shareholder returns.

As you said, we have made a reduction of JPY35 billion, and we have the cash from those transactions. This is a matter that we will be considering in the near future. I am not able to discuss any details at this time.

With regards to R&D expenses, I do not feel that there are any missed opportunities here. It is conceivable that there may be delays in scheduling, say, three to four years or five to six years from now, but it is still possible to recover. While the current situation is unfortunate, we intend to make a solid recovery.

Q: Are you able to tell us any more about the status of the review for first-line treatment in gastric cancer?

To expand a bit, the result of ATTRACTION-4 was a bit disappointed in terms of OS. 649 succeeded in terms of OS, but it was not all comer because it was CPS1 or beyond. I understand that you are currently presenting this heterogeneous data to the PMDA, but could you please tell us a little more about how it will be authorized?

Idemitsu: There are two types of data. The first was the Asian results of ATTRACTION-4. The other is CheckMate-649, which was global.

Regarding ATTRACTION-4, the primary, PFS, was met, but unfortunately, OS was not met. Although the primary of CheckMate-649 is PD-L1 positive cases, the OS was significantly improved in the all-comer analysis results.

In short, PFS was met, but unfortunately OS was not in all comer in one study. In the other study, both PFS and OS were met in all comer. We have already applied with ATTRACTION-4, and are currently discussing with authorities how to handle with CheckMate -649 data.

Q: Likewise, for TASUKI-52 study, first line lung cancer with Avastin. The data was great, but I think only PFS is on hand now. Are you able to apply with this data?

To be sure, I think approval was obtained for combination Avastin and Tecentriq with OS data. I know the data is great, but could you tell me the application strategy here?

Idemitsu: As OS data is immature for the TASUKI-52 trial for non-small-cell lung cancer in combination with Avastin, we would like to file an application on the basis of the PFS, but we need to consult with the authorities on this point.

There is the committee meeting today, where Opdivo will be consulted for the first line treatment of non-small cell lung cancer. Opdivo will be used in several ways for lung cancer. Based on the results of the approval, I think it is first necessary to consult with the authorities the medical strategy on how to use it with Avastin.

Q: Finally, although sales of BTK inhibitors was JPY500 million in H1 of the fiscal year, it seems that they are selling well. Could you please explain whether this is due to strong demand or a transitory element?

Takahagi: Am I correct in understanding that you are asking about Velexbru?

It was approved for indications of PCNSL and WM, both of which are rare diseases.

In PCNSL, it was approved for second-line treatment. There are about 330 to 400 cases per year. There are 240, or less than 300 cases per year.

However, we heard that many patients have difficulties with conventional therapies, and that hospitalization is necessary, because chemotherapy is taken as existing therapies.

On the other hand, since Velexbru is an oral drug, the convenience and safety of this drug have been evaluated, we believe that we are proceeding almost as planned. We are currently acquiring prescriptions as expected.

Q: The filing date for ATTRACTION-5 has changed from H2 of the current fiscal year to the next fiscal year. Is it assumed that the timing of the top-line emergence has been pushed back slightly?

Idemitsu: As you can imagine, there may be a slight delay in obtaining data due to event occurrence status.

Q: In the slides, there is no breakdown of H1 and H2 for the coming fiscal year, but can I assume that it will be in H1 of the next fiscal year?

Idemitsu: I'm sorry, I cannot comment on that.

Q: I would like to confirm some of the figures given by Mr. Sagara earlier in the meeting. One was the first-line indication for gastric cancer. At present, it has a 70% share as a third-line treatment. If it took 70% share as a first-line treatment, the market share was estimated as JPY80 billion. Is that JPY80 billion for the first line alone, or for the total?

Sagara: I would like to confirm that we are showing market capacity rather than forecasting sales, so the figure was based on the first level alone.

Q: Also, for lung cancer, it was stated that taking 30% would result in JPY50 billion. There was discussion today about the expansion of several indications. Is this 30% figure based solely on passing at the committee meeting, or does it include the combination of Avastin?

Sagara: In the first place, after understanding that we will talk a little roughly, this is about three indications.

Q: Two things this time.

Sagara: Yes.

Q: I have two questions. The first concerns the cultivation of adjuvant patients. We thank you for your detailed disclosure of the number of patients this time. For example, for some indications, there are 3,000 cases in the country, such as urothelial cancer, and 4,000 cases of neo-adjuvant in non-small-cell cancer per year. If Opdivo is approved, how many patients is this likely to increase by? If you have any estimates of this at this time, I would be grateful if you could share them.

The second issue is your strategy for growth investment. I think that the growth of Opdivo at home and abroad has improved dramatically over the past six months to a year. In this context, what kind of growth investment will you make in the future when you look ahead to the post-Opdivo era in 2030 and beyond?

I am asking about things like joint ventures or an in-house pipeline. How has the strategy for growth investment changed in light of the improvement in the prospects of Opdivo over the past six months?

Takahagi: To be sure, for the area of adjuvants, as there are some cancer types with no standard treatment, there are significant unmet needs.

Presumably, if the data of Opdivo and others are available in the future, this will be appreciated by specialists, and the degree of recommendation in the guidelines may well increase. This would have an associated upside.

However, as we do not have any data or other materials relating to this at present, I would like to refrain from responding to any questions on this point.

Sagara: You asked about investment strategies based on the expiry of the Opdivo patent. You are aware of the circumstances. As a result of the failure of the 026 study, we have to do a robust test in East Asia, and we have to recover. We have invested in the development of Opdivo as first-line treatment for gastrointestinal and lung cancer.

It is also true that we will meet an extra cliff around 2030. Filling the space beyond that and growing further is a big task, but that is what we have to do.

I will talk today about the strengthening of our own R&D, and also the overseas sale of our products, as well as the launch of our own products. We hope to do this.

Overseas, we have already started the clinical trial with ONO-7475, and some compounds are in preparation to start. With these compounds, I think we have started from the area of rare diseases in the US market, and I would like to expand our reach in this market.

In addition, we are looking at ventures for investment in research and development, and we are now implementing a variety of initiatives. We will strive to bring out good compounds from our laboratories, although I recognize that there is not an overabundance of time.

Q: I have a question about the progress of anamorelin. I understand that it is expected to be approved by the end of this fiscal year, so I do not think it will be a great delay. The question now is what kind of issues are delaying the process? Is there any possibility that additional trials may be necessary? Can you tell us anything else about options moving forward?

Idemitsu: I am very sorry to inform you that we cannot discuss the details of the process regarding anamorelin. Regarding the specific question of additional trials, we think that additional trials will not be necessary.

Q: I suspect you will advise me to ask MSD about this, but I think they probably won't answer me. I think your company is already seeing what trials your competitors are doing, so I would like you to tell me your thoughts on this.

There are two trials, KEYNOTE-859 and 585 trials. I think the former was first line and the latter was adjuvant gastric cancer. There is a common theme here. Perhaps Merck is not so familiar with TS-1, but the combination of capecitabine and cisplatin.

I'm sorry for my very lack of knowledge. Given that TS-1 and platinum formulations are the main products for gastric cancer in Japan, if their trial gives similar data with CAPOX therapy, your company, which uses TS-1, is more familiar to the Japanese market.

In short, I think that their results will be delayed, and if the results are not stellar, it seems as if the share for your company will be strong. Is this a fair assessment of the situation?

Idemitsu: I'm sorry, I think we should avoid discussing hypotheticals about what others may be thinking.

Q: The other day, it was announced in the Lancet that in KEYNOTE-426, combination pembrolizumab and axitinib were relatively ineffective in favorable risk patients.

This is just the question of whether Ono's successful CheckMate-9ER result will prevent the renal cell carcinoma share from decreasing in the future.

Takahagi: To be sure, we expect very much the regimen in 9ER. In particular, Opdivo and Yervoy combination therapy has been approved for the treatment of with intermediate- and poor-risk patients. As indicated in the data section, we emphasize that we can expect long-term survival.

On the other hand, in first-line treatment, Opdivo and Yervoy combination treatment has not been approved for the treatment of favorable risk patients. We believe that 9ER result can cover those patients. In the future, 9ER will be characterized by its high success rates, and morbidity will be controlled. We intend to appeal to experts the high response and disease control rate which are characteristics in 9ER trial and want to regain the share especially in favorable risk area.