ONO PHARMACEUTICAL CO., LTD.

Q1 Financial Results Briefing for the Fiscal Year Ending March 2021

July 31, 2020

[Number of Speakers] 5

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Yukio Tani	Corporate Executive Officer, Head of Corporate Communications

Revenue

Revenue	YoY Change
¥ 74.9 billion	+ 1.3 %

Breakdown of Revenue

(Billion yen)

	FY 2019 Q1	FY 2020 Q1	YoY Change
Revenue of Goods and Products	53.2	53.6	+ 0.8 %
Royalty & other revenue	20.8	21.3	+ 2.5 %
(Opdivo)	(15.4)	(14.0)	(— 9.3 %)
Total	74.0	74.9	+ 1.3 %

Ishizaki: Revenue in the first quarter rose by JPY900 million, or 1.3%, to JPY74.9 billion. While sales of long-term listed products decreased, sales of Opdivo intravenous injection, Forxiga tablets, Orencia subcutaneous injection and Parsabiv injection steadily increased. Sales of products increased by JPY400 million or 0.8% YoY, to JPY53.6 billion. Royalties and other revenue increased by JPY500 million, or 2.5% YoY, to JPY21.3 billion.

Revenue

Sales of Major Products

(Billion yen)

	FY 2019 Q1	FY 2020 Q1	YoY Change
Opdivo	22.3	24.4	+ 9.5 %
Glactiv	6.9	6.5	- 5.9 %
Forxiga	4.4	5.2	+ 17.8 %
Orencia SC	4.9	5.4	+ 10.6 %
Rivastach	2.3	2.0	- 10.0 %
Parsabiv	1.7	1.9	+ 11.1 %
Kyprolis	1.4	1.7	+ 21.3 %
Onoact	1.3	1.0	- 19.1 %
Proemend	0.7	0.7	- 3.1 %
New products（FY2020）	–	0.1	–

By product, sales of the anti-cancer agent Opdivo increased by JPY2.1 billion, or 9.5%, to JPY24.4 billion compared with the same period of the previous fiscal year. This was due to steady use of the product in kidney cell cancer and gastric cancer, as well as the expanded use of the product in esophageal cancer.

Among other major new products, sales of Forxiga for the treatment of diabetes rose by JPY800 million, or 17.8%, to JPY5.2 billion. Orencia for the treatment of rheumatoid arthritis, saw sales increase by JPY500 million, or 10.6%, to JPY5.4 billion. Sales of Parsabiv for the treatment of secondary hyperparathyroidism on hemodialysis, increased by JPY200 million, or 11.1%, to JPY1.9 billion. Sales of Kyprolis for the treatment of multiple myeloma increased by JPY300 million, or 21.3%, to JPY1.7 billion.

Meanwhile, sales of Glactiv for the treatment of Type 2 diabetes amounted to JPY6.5 billion, a decrease by JPY400 million, or 5.9% YoY. Sales of Rivastach for the treatment of Alzheimer's disease, amounted to JPY2 billion, a decrease by JPY200 million or 10.0% YoY.

Revenue

Sales of Long-term Listed Products

(Billion yen)

	FY 2019 Q1	FY 2020 Q1	YoY Change
Opalmon	2.3	**1.5**	- 36.8 %
Emend	2.2	**0.8**	- 64.1 %
Onon capsule	0.9	**0.7**	- 28.4 %
Recalbon	1.4	**0.8**	- 42.5 %

Long-term listed products, such as Opalmon, Emend and Recalbon, recorded a substantial decline in sales, due to the impact of measures to promote the use of generic products.

Operating Profit

Operating Profit	YoY Change
¥ 27.0 billion	+ 35.3 %

Costs, etc.

		(YoY Change)	
・Cost of sales	¥ 20.6 billion	(- 0.8%)	
・R&D expenses	¥ 12.3 billion	(- 22.7%)	①
・SG&A expenses	¥ 14.2 billion	(- 14.3%)	②
①+② Total	¥ 26.5 billion	(- 18.4%)	
・Other income	¥ 0.1 billion	(- 25.8%)	
・Other expenses	¥ 0.9 billion	(+ 0.2%)	

Operating income increased by JPY7.1 billion, or 35.3%, YoY to JPY27 billion. On the cost front, the cost of sales decreased by JPY200 million, or 0.8% YoY to JPY20.6 billion.

R&D expenses decreased by JPY3.6 billion, or 22.7%, YoY to JPY12.3 billion. This was mainly due to a decrease in clinical trial expenses, caused by postponement of enrollment of patients in new clinical trials, suspension of enrollment of patients in ongoing clinical trials due to COVID-19, etc. SG&A expenses, excluding R&D expenses, decreased by JPY2.4 billion, or 14.3%, to JPY14.2 billion compared with the same period of the previous fiscal year. This was mainly due to a decrease in operating expenses, caused by the cancellation or postponement of academic lectures and other events, and voluntary restraint by MRs from visiting medical institutions due to COVID-19.

As a result, operating income increased by JPY7.1 billion YoY, due to an increase in revenue and a decrease in expenses.

Profit before Tax

Profit before Tax	YoY Change
¥ 28.3 billion	+ 33.5 %

Net financial income

+ ¥ 1.3 billion (+ ¥ 0.0 billion)

Finance income :	**¥ 1.3 billion**
(Interest and dividend income received, etc.)	
Finance costs :	**¥ 0.0 billion**
(Interest expense arising from lease obligations and employee retirement benefit, exchange losses, etc.)	

Net financial income was JPY1.3 billion, remaining on the same level from the previous fiscal year. As a result, profit before tax was JPY28.3 billion, an increase by JPY7.1 billion, or 33.5%, from the previous fiscal year.

Profit for the Period
(Owners of the Parent Company)

Profit for the Period (Owners of the Parent Company)	YoY Change
¥ 21.5 billion	+ 31.6 %

Income tax expense

¥ 6.8 billion (YoY Change + 40.7 %)

(Major change factors)

Increase in profit before tax	¥ 7.1 billion
Increase in corporate tax	¥ 2.0 billion

Profit for the period attributable to owners of the parent company increased by JPY5.2 billion, or 31.6%, to JPY21.5 billion compared with the same period of the previous fiscal year, in association with an increase in profit before tax.

There are no revisions on the full-year consolidated earnings forecasts announced on May 12. Regarding the impact of the coronavirus pandemic, we have factored in the impact of voluntary restraint in visiting medical institutions until the end of June 2020.

A slightly negative impact on revenue is expected from July onward, due to voluntary restraints on business activities and medical consultations from patients. However, the impact on operating income is expected to be minimal because suppression on expenditure arising from voluntary restraints on business activities will also occur at the same time.

Development pipeline

Idemitsu: I will explain the status of development.

First, the development status is described on pages 13 to 16 of the financial results summary. This will form the basis of my presentation. The slides consist of a list of oncology areas first, followed by non-oncology areas. I would like to present the updates made since May, when the last financial results were announced.

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

As of July 24, 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*) / In-license
Opdivo Intravenous Infusion / Nivolumab	Additional indication	Esophageal cancer *1	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)

Changes from the announcement of financial results for the fiscal year ended March 2020

*1: An application for Opdivo was approved in Taiwan for the treatment of unresectable advanced or recurrent squamous cell carcinoma of esophageal cancer progressing after fluoropyrimidine- and platinum-based chemotherapy.

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*) : "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
ONO-7643 / Anamorelin	New chemical entities	Cancer cachexia / Ghrelin receptor agonist	Tablet	Japan	In-license (Helsinn Healthcare, S.A.)
ONO-4059 / Tirabrutinib	Additional indication	Waldenstrom macroglobulinemia, Lymphoplasmacytic lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	Japan	In-house
Yervoy Injection * / Ipilimumab	Additional indication	Colorectal cancer (MSI-H)	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Non-small cell lung cancer	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)
Braftovi Capsule / Encorafenib	New chemical entities	Colorectal cancer / BRAF inhibitor	Capsule	Japan	In-license (Pfizer Inc.)
Mektovi Tablet / Binimetinib	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	Japan	In-license (Pfizer Inc.)

★: Combination with Opdivo.

<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	Small cell lung 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)

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In terms of drugs for which approval has been obtained, Opdivo is shown in the top column on page 13. Approval has been obtained in Taiwan for esophageal cancer.

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	Urothelial cancer	Injection	Japan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	Japan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Bladder cancer	Injection	Japan S. Korea Taiwan	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Prostate cancer *2	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	Small cell lung cancer	Injection	Japan 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	Malignant pleural mesothelioma	Injection	Japan	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)

Subsequently, on page 14, the forth item from the top of Opdivo, we can see that Phase III has begun for Opdivo for the indication of prostate cancer.

<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-4687 * (BMS-986227) / Cabiralizumab	New chemical entities	Pancreatic cancer / Anti-CSF-1R antibody	Injection	Japan S. Korea Taiwan	II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4686 * (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4482 * (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7807 * (BMS-986258)	New chemical entities	Solid tumor / Anti-TIM-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483 * (BMS-986015) / Lirilumab	New chemical entities	Solid tumor / Anti-KIR antibody	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-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.)
	New chemical entities	Pancreatic cancer *1 / Cancer metabolism inhibitor	Injection	Japan	I	In-license (Rafael Pharmaceuticals, Inc.)
ONO-7475	New chemical entities	Acute leukemia / Axl/Mer inhibitor	Tablet	USA	I	In-house

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On page 15, the second item form the bottom of the table, Others, we have ONO-7912, in-licensed from Rafael Pharmaceuticals. Phase I has been started for pancreatic cancer.

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
ONO-7913 / Magrolimab	New chemical entities	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 fiscal year ended March 2020
*2: Phase III of Opdivo was initiated in Japan, South Korea, and Taiwan for the treatment of prostate cancer.
*3: Phase I of cancer metabolism inhibitor (ONO-7912) was initiated in Japan for the treatment of pancreatic cancer.

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

(5) Main Status of Development Pipelines (Areas other than Oncology)

As of July 24, 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*) / In-license
ONO-2370 *4 / Opicapone	New chemical entities	Parkinson's disease / Long acting COMT inhibitor	Tablet	Japan	In-license (Bial)
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication	Tachyarrhythmia upon sepsis *5 / Short-acting selective β_1 blocker	Injection	Japan	In-house

Changes from the announcement of financial results for the fiscal year ended March 2020
*4: An application was approved for a catechol-*O*-methyltransferase (COMT) inhibitor (ONO-2370) for the improvement of the end-of-dose motor fluctuations (wearing-off phenomenon) in parkinson's disease in combination with levodopa-carbidopa or levodopa-benserazide hydrochloride.
*5: An application was approved for a short-acting selective β_1 blocker (Onoact for Intravenous Infusion) for the treatment of tachyarrhythmia associated with sepsis (atrial fibrillation, atrial flutter and sinus tachycardia).

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*) : "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
ONO-5704 / SI-613	New chemical entities	Osteoarthritis / Hyaluronic acid-NSAID	Injection	Japan	In-license (Seikagaku Corporation)

<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
ONO-5704 / SI-613	New chemical entities	Enthesopathy / Hyaluronic acid-NSAID	Injection	Japan	II	In-license (Seikagaku Corporation)

As is shown on page 16, we have made major progress in non-oncology fields. We have received approval for the COMT inhibitor, ONO-2370 or opicapone for the treatment of Parkinson's Disease.

Also, Onoact has been approved for tachyarrhythmia associated with sepsis.

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*1 / In-license
ONO-4059 / Tirabrutinib	Additional indication	Pemphigus / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	Japan	II	In-house
ONO-7269	New chemical entities	Cerebral infarction / FXIa inhibitor	Injection	Japan	I	In-house
ONO-4685	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	Injection	Japan	I	In-house
ONO-7684	New chemical entities	Thrombosis / FXIa inhibitor	Tablet	Europe	I	In-house
ONO-2808	New chemical entities	Neurodegenerative diseases / S1P5 receptor agonist	Tablet	Europe	I	In-house
ONO-2910 *6	New chemical entities	Peripheral neuropathy / Schwann cell differentiation promoter	Tablet	Japan	I	In-house
Foipan Tablets *7 / Camostat mesilate	Additional indication	Novel coronavirus infection (COVID-19) / Protease enzyme inhibitor	Tablet	Japan	I	In-house

Changes from the announcement of financial results for the fiscal year ended March 2020
*6: Phase I of Schwann cell differentiation promoter (ONO-2910) was initiated for healthy adult male subjects.
*7: Clinical trials were initiated on protease enzyme inhibitor Foipan Tablets as a treatment for COVID-19.

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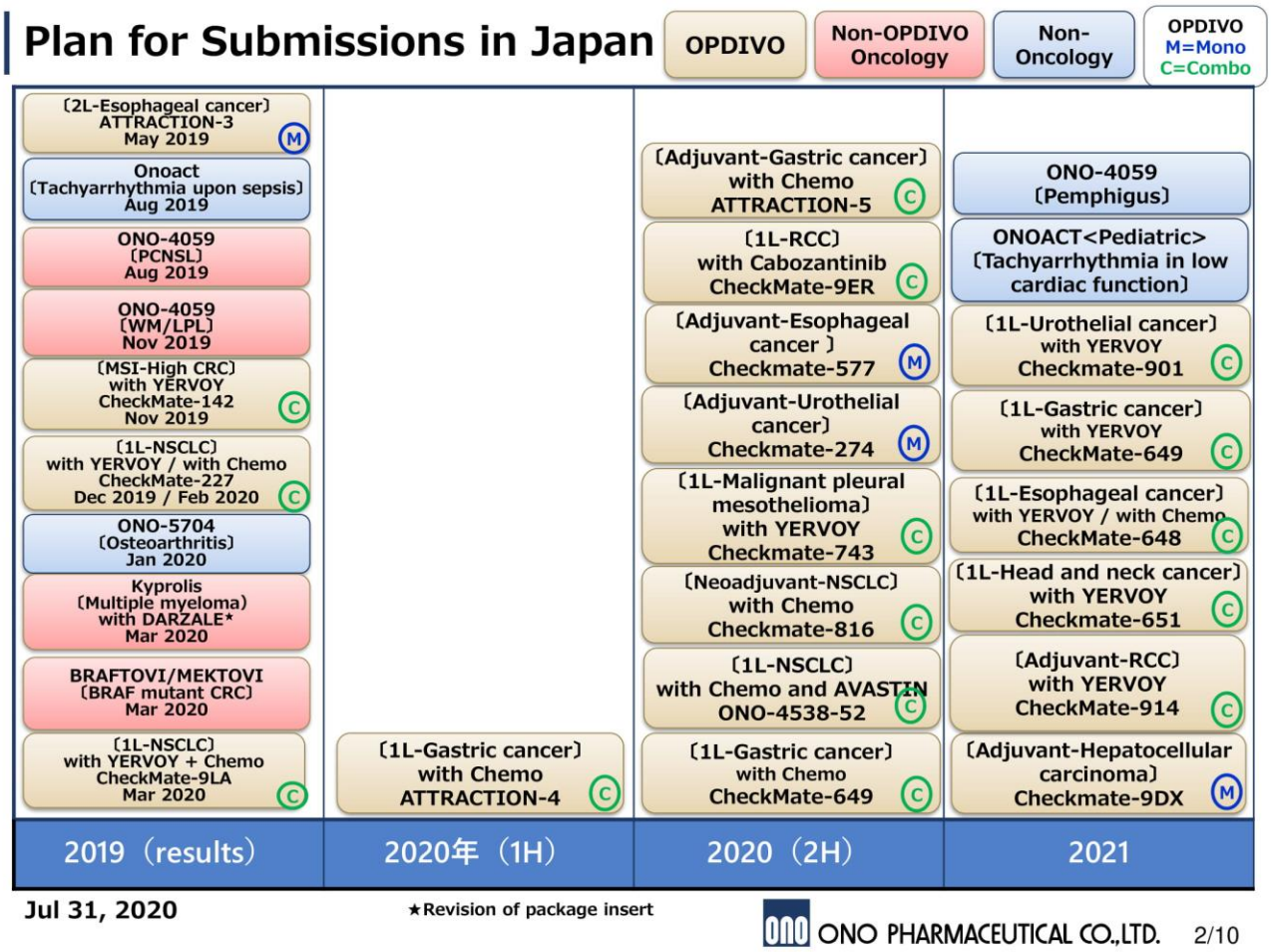
The table at the bottom of the page shows products that are undergoing trials. The second compound from the bottom is ONO-2910, a compound that promotes the differentiation of Schwann cells. This compound is in Phase I.

Then, we have started clinical study with Foipan for the treatment of COVID-19.



Next, we are also updating the development pipeline on our website. Of these, I would like to explain our plans for filing in the future.

Please have a look at Page 2, or Page 3 when the cover page is counted. In this table, beige color shows Opdivo. Red is for oncology other than Opdivo. Blue is for non-oncology areas. In addition, for Opdivo, the "M" denotes monotherapy and "C" denotes combination therapy. I will explain the changes made since the last financial results announcement in May.

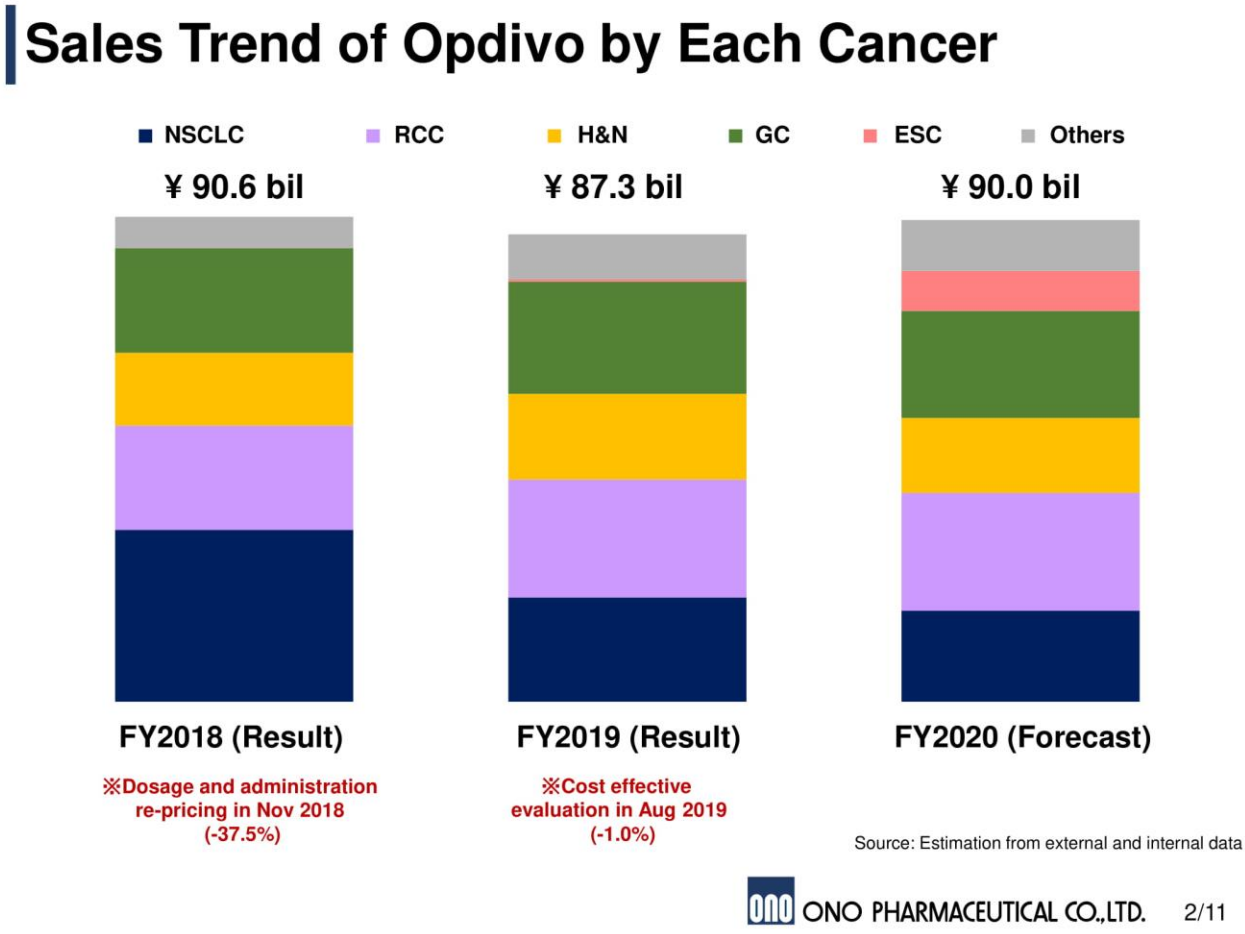
In the second column from the left, the first half of FY2020, the application was filed in May for Opdivo in combination with chemotherapy for first-line treatment of gastric cancer.

Next column to the right side, the second half of FY2020, regarding the second item from the top, we changed the schedule for application for combination of Opdivo and cabozantinib for first-line treatment of renal cell cancer from the first half of FY2020 to the second half.

Next, second item from the bottom, we have changed the schedule for application for Opdivo in combination with Avastin and chemotherapy for first-line treatment of non-small cell lung cancer from the first half of FY2020 to the second half.

Next, in the right column for FY2021, regarding the third item, Checkmate-901 where we have evaluated the combination treatment of Opdivo and Yervoy, and the combination treatment of Opdivo and chemotherapy for first-line treatment of urothelial cancer, we changed our application schedule for the combination with Yervoy from the second half of FY2020 to FY2021. Regarding the combination with chemotherapy, this was moved to FY2022.

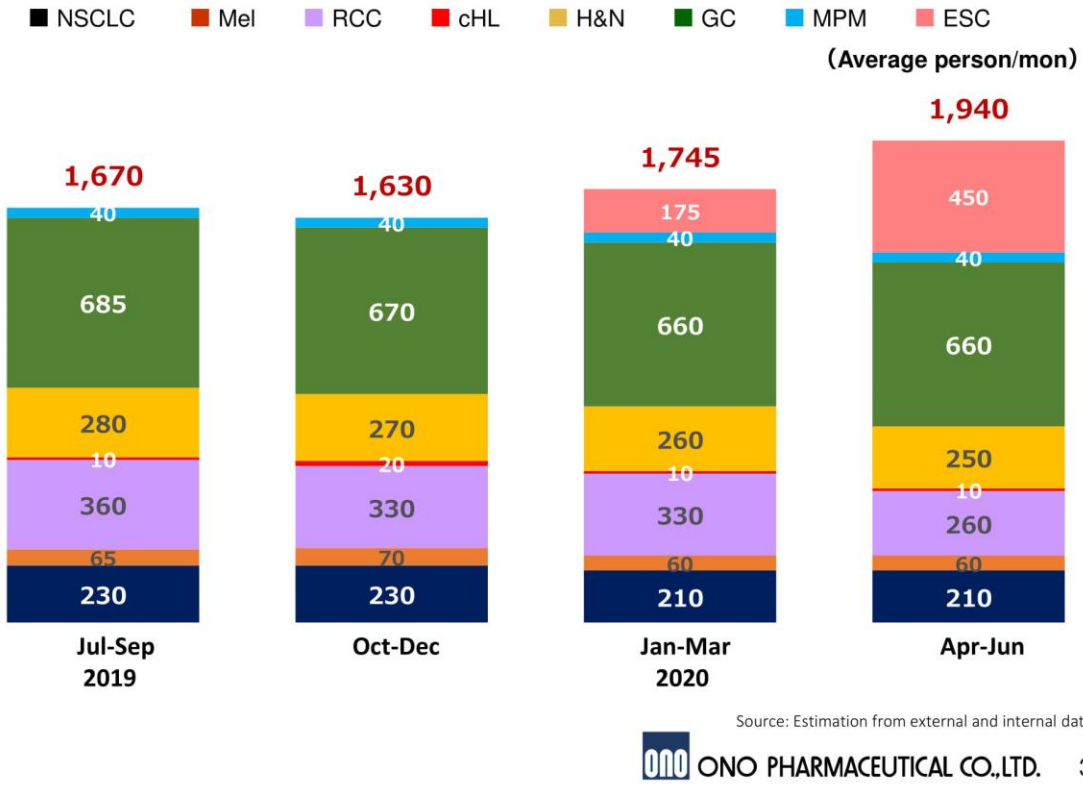
Finally, the forth item from the top, regarding the CheckMate-649 where we have evaluated the combination treatment of Opdivo and chemotherapy, and Opdivo and Yervoy for first-line treatment of gastric cancer, we have changed our application schedule for combination treatment with Opdivo and Yervoy from the second half of FY2020 to FY2021. Regarding the combination with chemotherapy, there is no change in the schedule, remaining in the bottom of the second column from the right side, in the second half of FY2020.



Takahagi: We will now briefly explain trend of Opdivo. In this section, we will introduce the overall situation and the status of Opdivo by cancer type. The second page of the document is about sales of Opdivo. Starting from the left, the bar graphs show sales for FY2018, those for FY2019, and estimates for FY2020.

This fiscal year, we expect sales of JPY90 billion, taking into account factors such as the increase in new prescriptions for esophageal cancer, the positive factor of entry into the first-line treatment of lung cancer, and negative factor of entry by competitive products.

Number of Patients Newly Prescribed with Opdivo by Each Cancer (Estimation)



Source: Estimation from external and internal data

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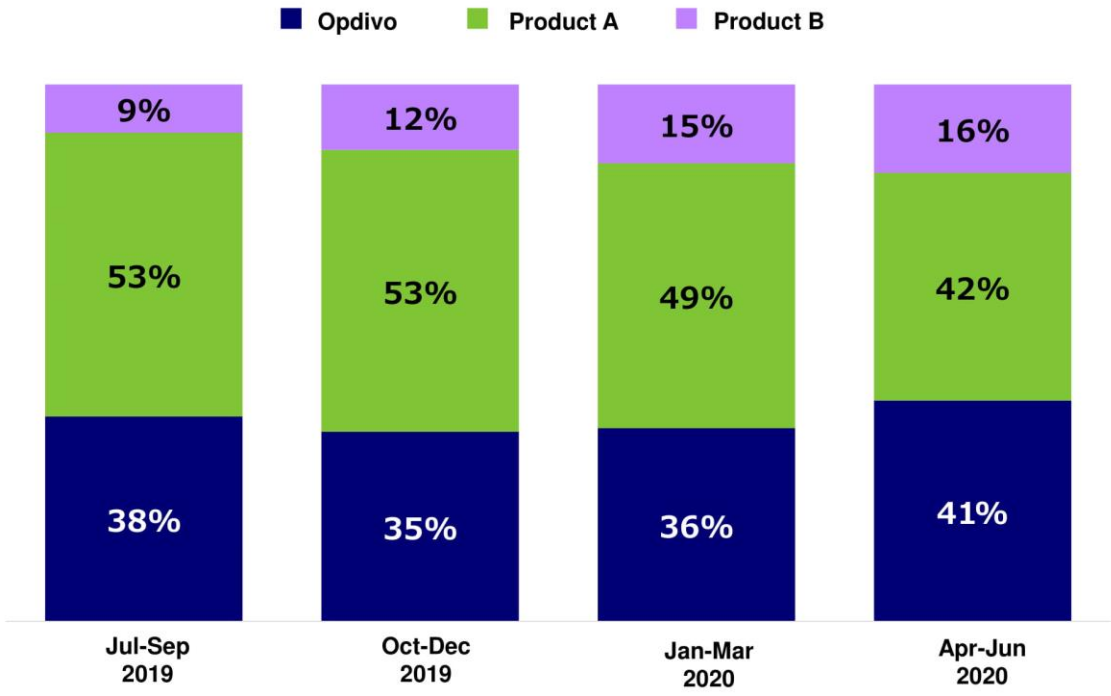
Changes of the number of new prescriptions of Opdivo by cancer type are shown on a quarterly basis, starting on the left in the July to September 2019, and continuing to the April to June 2020. The monthly average figure is shown.

It is estimated that in April to June 2020, 660 patients were prescribed for gastric cancer and 260 for kidney cell cancer. Opdivo was approved for esophageal cancer in February, and prescribed for esophageal cancer in 450 patients from April to June. The monthly average of patients in new prescriptions for all cancers was 1,940.

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



Source: External data

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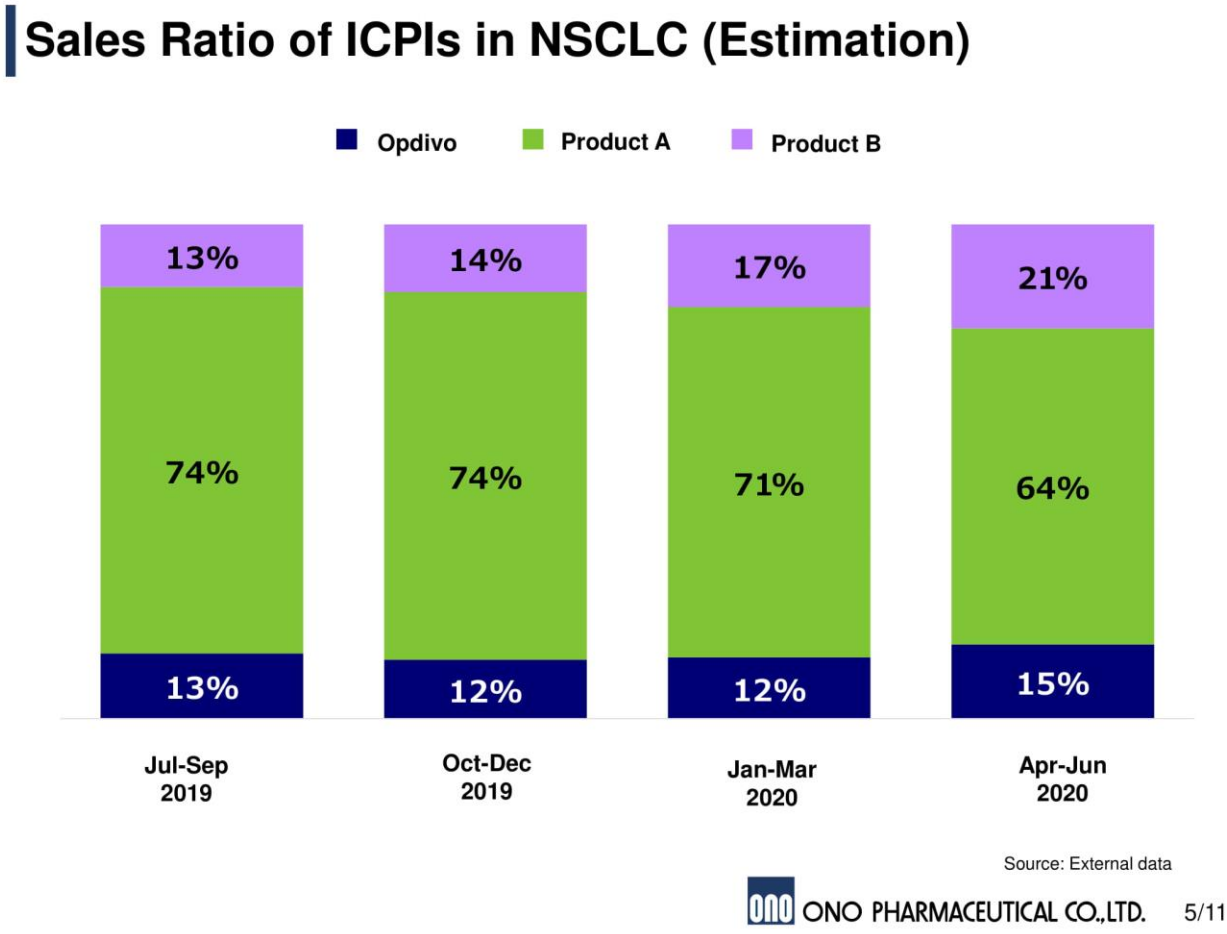
The sales ratio of major immune checkpoint inhibitors is shown in the bar chart for all cancers, separated quarterly from July to September 2019.

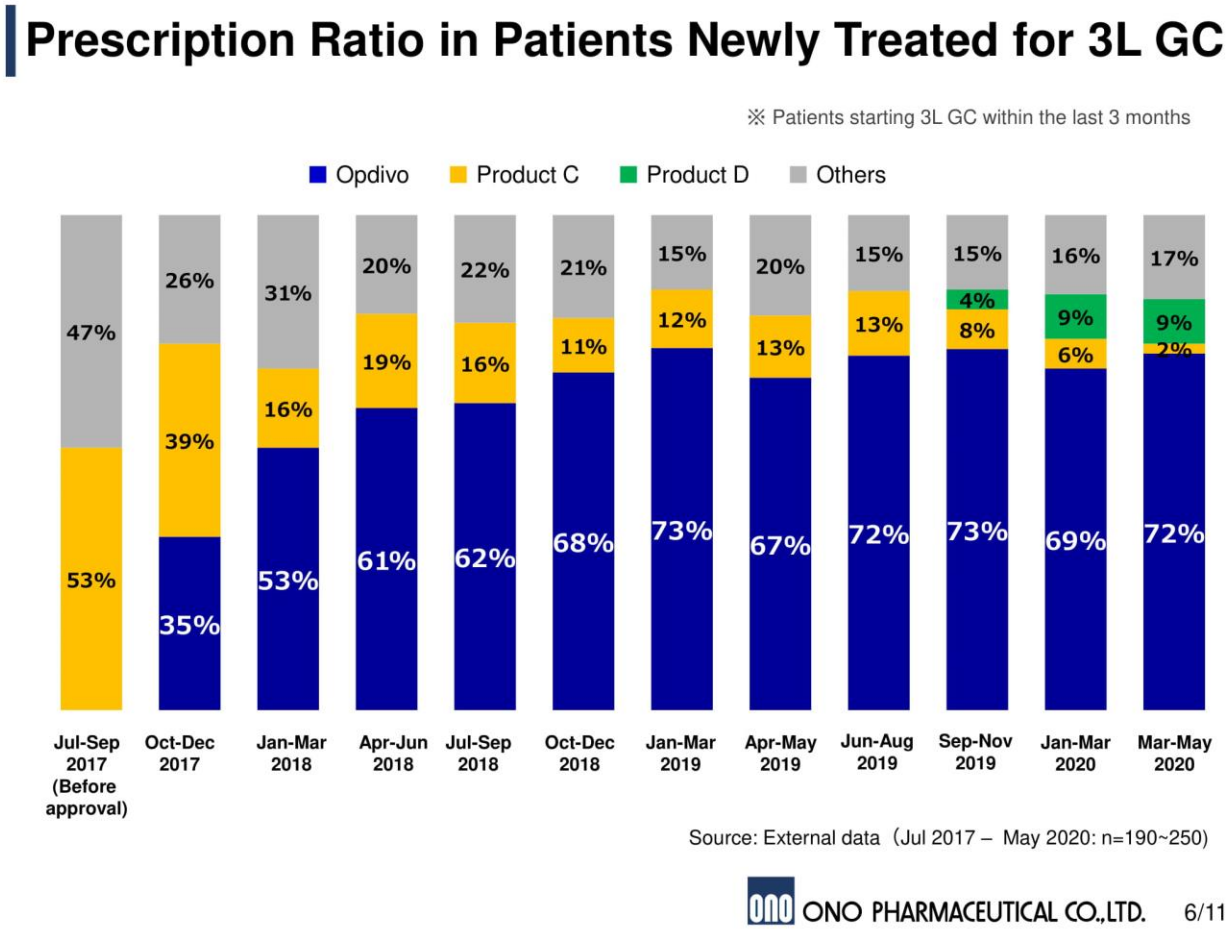
In April to June 2020, Opdivo had a 41% share among the main immune checkpoint inhibitors.



I will explain the sales ratio of immune checkpoint inhibitors by type of cancers.

This graph shows the sales composition ratio of immune checkpoint inhibitors for non-small cell lung cancer (NSCLC) as a whole, including first, second, and third treatment of NSCLC.

From the bar on the left, the figures are divided quarterly from July to September 2019 as before. Market share is expanding due to the entrance of competitors into first-line treatment of NSCLC. Opdivo makes up 15% of share with the only second-line treatment of NSCLC. We will make steady progress in entering into first l-line treatment within this year, and are committed to regaining the market share in this field.

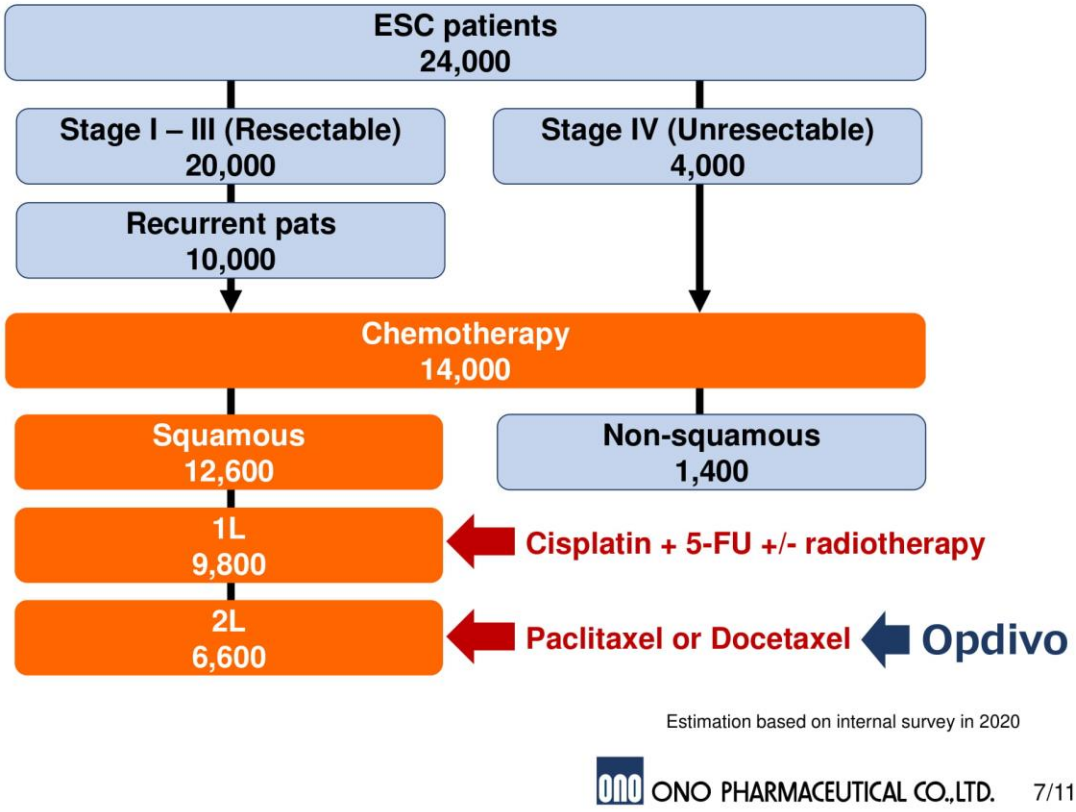


I will explain the gastro-intestinal cancers, gastric cancer and esophageal cancer.

This graph shows the share of prescriptions for new patients in third-line treatment of gastric cancer. Opdivo share of new prescriptions for third-line treatment remains at our target of 70%.

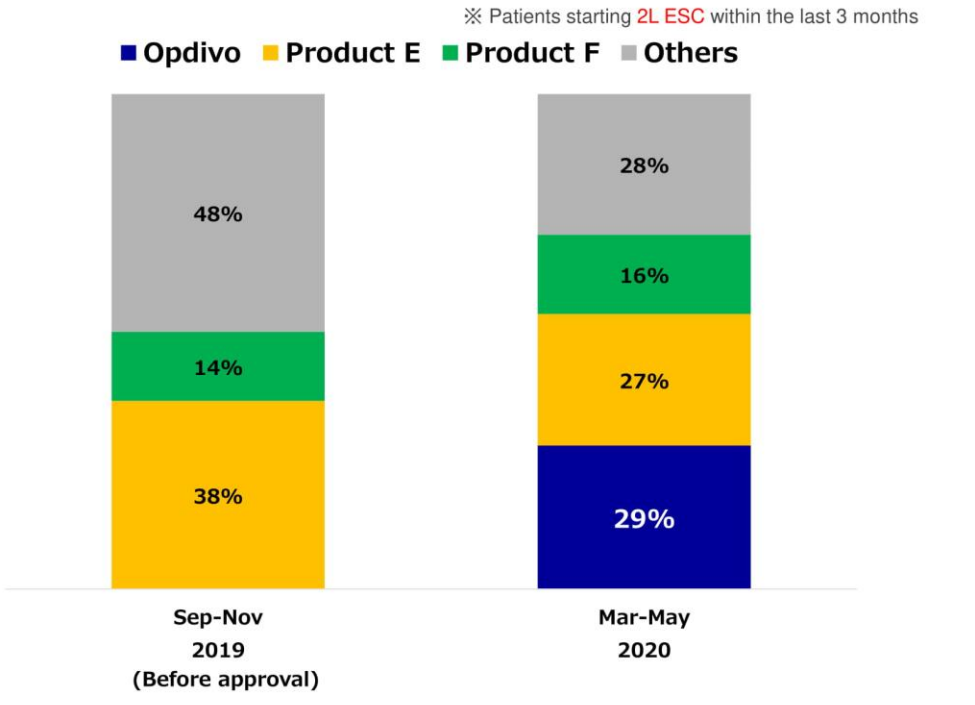
Competitor products entered the market in August last year in the field of third-line gastric cancer treatment, but Opdivo is firmly maintaining its established position.

Number of ESC patients per year in Japan



In February this year, Opdivo received approval for second-line treatment of esophageal cancer. In March, a guideline was issued by the Japan Esophageal Society. For the first time, the guideline strongly recommended Opdivo as second-line treatment, with an evidence class of “A”. In addition, there has been comment that Opdivo is strongly recommend regardless of PD-L1 expression status. We would like to position Opdivo as a standard-of-care treatment.

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



Source: External data（Sep 2019 – May 2020: n=150~158)

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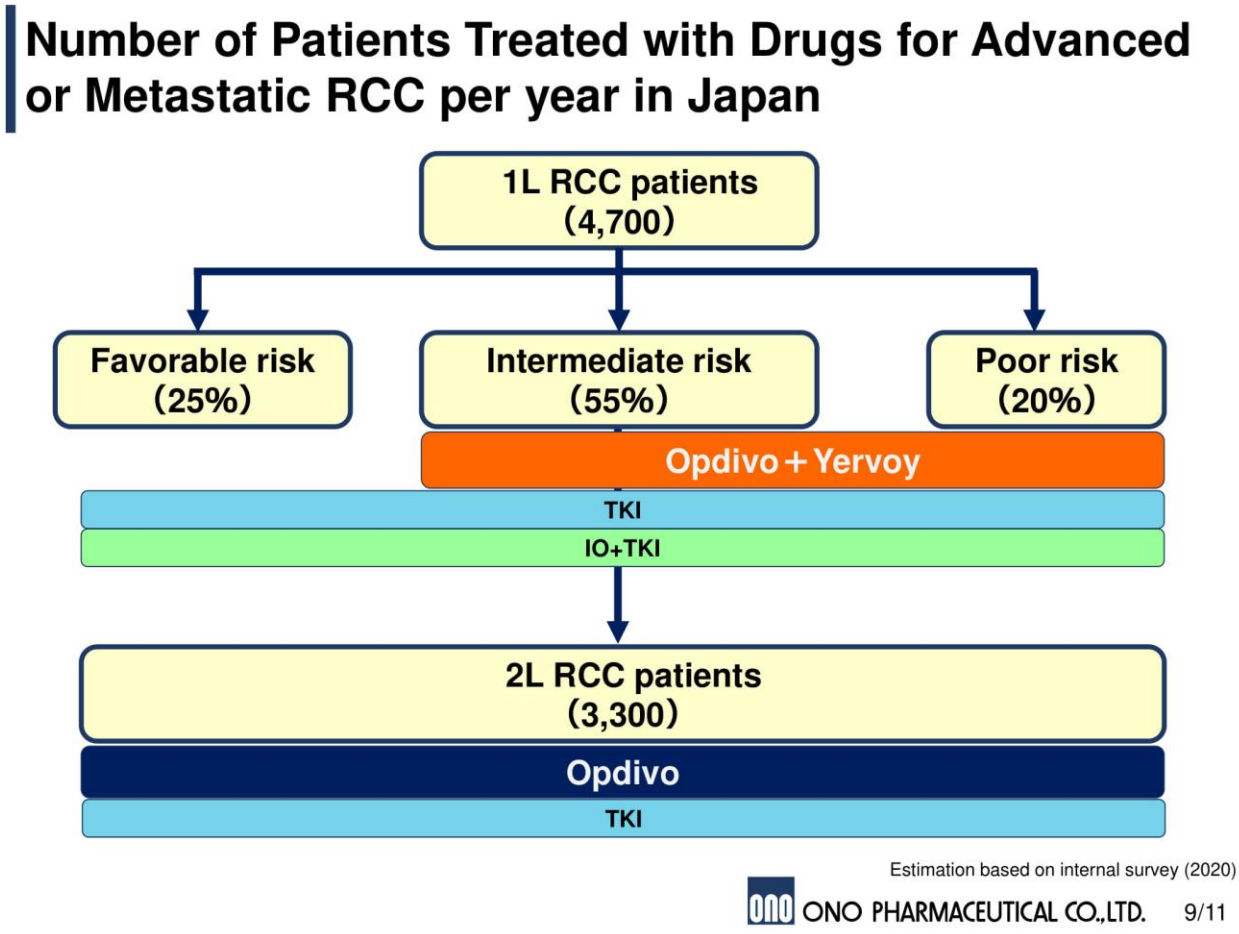
This slide shows the share of new prescriptions for second-line treatment of esophageal cancer.

Opdivo has a 29% share of the new patient prescriptions in the three months after approval and has seen a rapid start up similar to the case when it entered into a third-line treatment for gastric cancer.

From approval to the end of June, it is estimated that, we have acquired new prescriptions in 1880 patients including standby patients, and we believe that this is showing a favorable start-up.

We are confident that by the end of March 2021, we will be able to achieve our target share of 55%. We will strive to promote our activities in gastric cancer and esophageal cancer and strengthen our presence in the gastro-intestinal field.

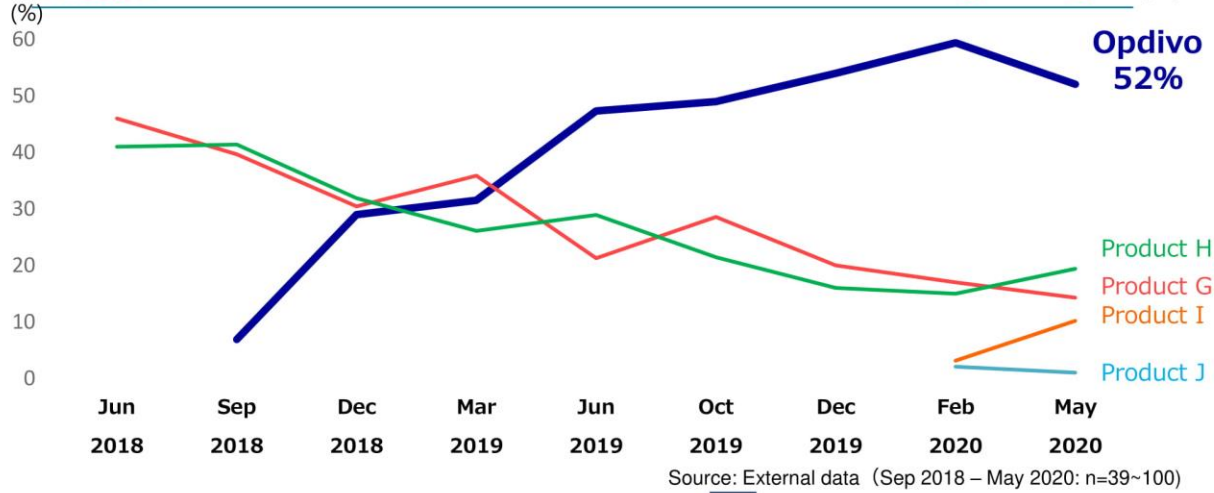


Finally, I would like to mention the figures for renal cell carcinoma.

There is evidence for the use of Opdivo for intermediate and poor risk of first- and second-line treatment, and we are working to deliver Opdivo to many patients with renal cell carcinoma.

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

	2018 Jun	Sep	Dec	2019 Mar	Jun	Oct	Dec	2020 Feb	May	
Opdivo	**-**	**7**	**29**	**32**	**47**	**49**	**54**	**59**	**52**	(%)
Product G	46	40	30	36	21	29	20	17	14	(%)
Product H	41	41	32	26	29	21	16	15	19	(%)
Product I								3	10	(%)
Product J								2	1	(%)



Source: External data (Sep 2018 – May 2020: n=39~100)

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The table shows trends in the share of new prescriptions in the first-line treatment of renal cell carcinoma.

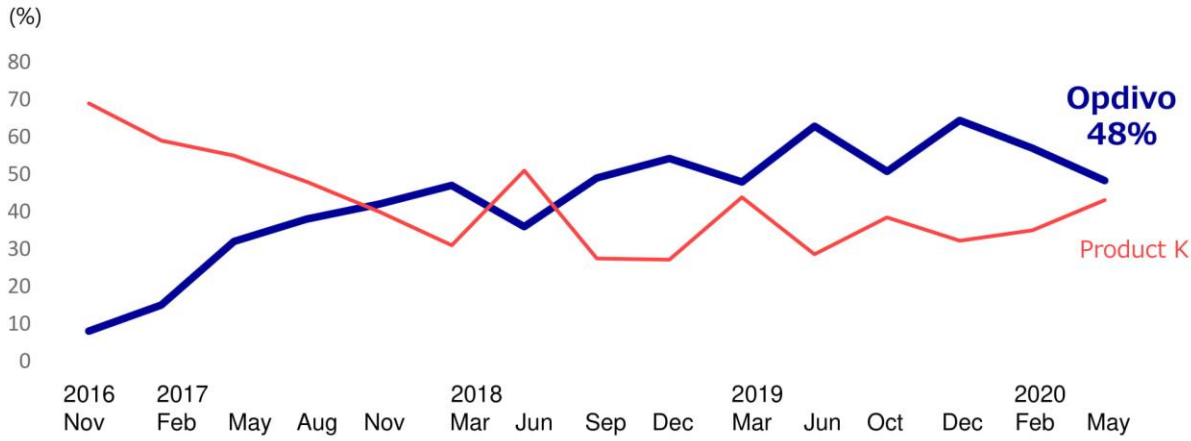
Last December, combination treatment of IO products and molecule target products entered the market for favorable, intermediate, and poor risk in renal cell carcinoma. Currently, the share of prescriptions is increasing, mainly in the favorable risk patients.

On the other hand, as for combination treatment of Opdivo and Yervoy, the share of new patient prescriptions in first-line treatment as a whole is currently 52%. If we focus on the intermediate- and poor-risk patients targeted for the combination of Opdivo and Yervoy, the share of new prescriptions is 64%, indicating that the impact of competitive products is negligible.

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
Opdivo	**8**	**15**	**32**	**38**	**42**	**47**	**36**	**49**	**54**	**48**	**63**	**51**	**64**	**57**	**48**
Product K	69	59	55	48	40	31	51	27	27	44	29	38	32	35	43

(%)



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

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Prescriptions of combination Opdivo and Yervoy in first-line treatment are increasing, and those of other IO treatment are also increasing. Among these, the number of untreated patients in the second-line treatment with immune checkpoint inhibitors is decreasing, and the current share of prescriptions for new patients is 48%.

However, if we focus only on those previously untreated patients in second-line treatment with immune checkpoint inhibitors, Opdivo share of prescriptions for second-line treatments is 80%, and we intend to continue to work firmly in this area. We will strive to deliver the opportunity of Opdivo therapy to all renal cell carcinoma patients.

Looking ahead, we expect to see a significant growth in the field of first-line treatment for lung cancer and gastric cancer.

This concludes my presentation on the trends of Opdivo overall and by cancer type.

Question & Answer

Q: At first, the general impression is that coronavirus is having some effect on some products、 but not others. Please clarify whether there has been any impact on Opdivo due to COVID-19. This is only looking at the April to June period, and I think there would have been a big impact on some products in May in particular. I know that in April, there were delays in prescriptions, or increased prescription durations, and other similar aberrant events.

Have there been any other distinctive events during this period? If so, could you please tell us about them?

Ichikawa: First of all, I will touch on Opdivo in terms of oncology in general. There have been cases where cancer patients have had delays in surgery and outpatient therapy. However, I think that the impact on Opdivo is negligible.

In terms of chronic diseases and diabetes, there has been a slight effect on the dementia drug Rivastach. We think the product receives a slight impact in terms of visiting hospital and nursing care facilities.

However, as you have pointed out, there is some cases of longer prescription periods. While there is uncertainty, we believe that the impact is high in the field of dementia, and may be small in the area of diabetes.

Q: Second question. There were some items in the application schedule for development that were slightly behind schedule for Opdivo. In particular, there was a slight gap in clinical trials evaluating the combination treatment with Yervoy and with chemotherapy. Is this due to COVID-19, or any other factors? Could you explain how this gap came about?

Idemitsu: There are several factors. We temporarily stopped registering patients due to the effect of COVID-19. I do not think that this effect will be seen much in this type of late-stage study. That is to say, registration is almost complete in those studies.

On the other hand, there has been a slight impact on visits to institutions due to COVID-19. So, we have slightly changed the schedule for data fixing. For example, regarding ONO-4538-52 study (listed in the second half of FY2020) evaluating Opdivo in combination with Avastin and chemotherapy in the first-line treatment of NSCLC, we have changed the data fixing time for 2 months behind.

As for combination therapy of Opdivo and cabozantinib described on the second item from the top in the second half of 2020, we have also changed the schedule. We have already got the results from the study and are now preparing for the submission. As we originally scheduled a submission with the fastest target date in this table. This time, the schedule was shifted into the second half of FY2020, due to one or two-month delay by re-scheduling the submission date.

Regarding the combination treatment with Yervoy and with chemotherapy for urothelial cancer and gastric cancer, we have re-scheduled the submission date in association with the change of each study and treatment group. For example, in case of urothelial cancer, the change in schedule for combination with Yervoy is limited, but the schedule for chemotherapy combination is greatly changed by increasing the number of the patients. In either case, these changes are not due to the impact of COVID-19.

I apologize that my answer may be somewhat difficult to understand, and the effect differs by study, but essentially, it cannot be said that the schedule changes are entirely due to COVID-19.

Q: Finally, can you tell us when the first-line treatment of gastric cancer data will be released?

Idemitsu: There are two Opdivo gastric cancer studies. One is ATTRACTION-4, for which we have already submitted an application. The other one is a global study, we are now fixing the data and expect to make the data available for the combination treatment with chemotherapy soon.

Q: When will ATTRACTION-4 data be disclosed?

Idemitsu: We have been making adjustments with the academic conferences, and would like to disclose it as soon as possible.

Q: This is another question about ATTRACTION-4. Can we see the data at medical meeting to be held in the first half of FY2020? Or better to anticipate to have it in the second half of FY2020? Can you advise us, in the first half of the fiscal year or the second?

Idemitsu: We would like to disclose it at the end of the first half or the beginning of the second half.

Q: I think it is around the meeting to be held in Madrid. I would like to ask you about ONO-4538-52 study, the combination with Avastin. This trial is conducted mainly in Japan or by your Company. So, if the result is positive, like the ATTRACTION-4, is it correct to say that we can see the result at the announcement for good results or for submission?

Idemitsu: The filing schedule for ONO-4538-52 described in this table is on the basis that a positive result is obtained in the interim analysis. If the good result is obtained from the interim analysis, we are likely to announce it at that time.

Q: So, if the positive top line result comes out, we can see it in the press release.

Idemitsu: Yes, the results will be fixed soon.

Q: Lastly, in the slides, it seems that all companies are spending less due to coronavirus in the April to June period. As you may have said a little while ago, in terms of spending, in your company's case, the R&D budget will be spent at the very end, but is it better to think that there is a possibility that there will be a surplus in SG&M expenses if sales costs remain relatively unchanged?

Tani: We originally anticipate that new products will appear in the second half of the year, and that the impact due to coronavirus will continue until June. So, I think it is reasonable to understand that the cost, R&D investment, and SG&A expenses will not significantly change from this prospect. Therefore, if you look at the full year, you will see that there is no change.

Q: What is the situation with Opdivo in renal cell carcinoma? Looking at the slide on page 3, it seems that the number of new patients has fallen by 20% against the previous quarter.

As for the competitor products, you explained that you are not affected by competitors very much. What would be the best way to understand these numbers in the context of this statement?

Takahagi: I apologize for my slightly insufficient explanation. Regarding first-line treatment, we are now at least 60% of the IO market, including those of competitor products and Opdivo.

Thus, the number of IO-naïve patients who go to the second-line treatment is decreasing. The number of new patient acquisitions for Opdivo in second-line treatment has decreased. This is a major factor behind the decline when comparing the previous data with the number of prescriptions this quarter.

Q: In the conference call for the third quarter of the previous fiscal year, you thought that the impact of the approval of the combination of Keytruda and Inlyta had a negative impact of about 10% or so, but was this 20% reduction also anticipated? I believe the figure mentioned was in the 10% range. Could you clarify what that was referring to?

Takahagi: At the time, we explained that we anticipated a decline in the 10% range in the intermediate and poor risk groups in the first-line treatment for Opdivo and Yervoy combination therapy.

Looking at the April to June period data, it can be seen that while there is no effect on the intermediate or poor risk groups, IO competitive products can be used for favorable risk group, resulting in an increase of prescription for favorable group.

In second-line treatment, Opdivo was used in the favorable-risk patients who have not been treated with IO products. Due to IO naïve market shrinkage, there is about 20% reduction in the second line treatment.

Q: So the current situation is just as expected?

Takahagi: Yes, that's correct.

Q: About the situation with esophageal cancer, in your plan at the beginning of the fiscal year, it was expected that the average administration period would be about 4.2 months. Is any data about this available at present?

Takahagi: Not yet. However, in the future, data on items such as MDVs will not be available until they are accumulated in one year or two years. We intend to examine this data moving forward.

Q: The first question is about Opdivo. I think that sales of Opdivo in the April-June period were solid at JPY24.4 billion. From that result, it seems that the company's full-year forecast of JPY90 billion is a little on the low side. Are you anticipating some negative factor in the July-September period?

As explained earlier, the first-line market share for renal cell carcinoma seems to have been maintained, as expected. So, I don’t anticipate that there is any risk from July to September onwards. What are your thoughts on this point?

I have heard that people who have contracted coronavirus should not take Opdivo. Is this something that you are concerned about?

Takahagi: Let me begin by talking about the first point. As you said, we are satisfied with the results from April to June.

The reason for this strong performance is certainly growth in the area of esophageal cancer. As I explained earlier, the factors that have exceeded our expectations are that competitor products have failed to achieve the market penetration we were expecting in the areas of renal cell carcinoma, gastric cancer, and also head and neck cancer. I think that this is a positive factor for Opdivo.

With regard to these factors, and given more time to observe the changes in Opdivo sales, we may be in a position to make an announcement at some time in the future regarding our forecasts for the current fiscal year.

Q: Would it be correct to say that there is not believed to be a risk of a worsening in the clinical course of coronavirus infection associated with Opdivo administration?

Takahagi: We have not been aware of such a problem. In addition, there is no clinical data suggesting that Opdivo administration increases the risk of enhancing infectious diseases. However, if we have received any queries about this from medical professionals, our MRs would respond to them precisely.

Q: The second question concerns royalties. The figure is JPY21.3 billion for the April-June period. I had the impression that the royalties related to Opdivo in particular are a little low. Is this progress in line with your company's plan?

If you look at Bristol-Myers Squibb sales of Opdivo for the period, it looks like a difficult situation. Do you have any concerns about this?

Tani: Regarding the royalties, it will be left up to Bristol-Myers Squibb, but I think the current situation is still somewhat challenging. However, as part of the plan, we have expected the contribution to the sales in first-line treatment of lung cancer market by Bristol-Myers Squibb after its approval. As we expect that the sales will contribute in the second half of FY2020, we do not think that the plan itself will be significantly out of line.

Q: Finally, I would like to ask about the clinical study of Foipan for coronavirus. I think that patients are registered for Phase I. Please tell us about the future development schedule up to the launch of the product. Even if you receive the approval for this disease, there are generics, so it seems as if your Company's profitability on this product will not be very high. Could you comment on this?

Idemitsu: Looking at the data for Foipan, we think that higher dosage than 600 mg/day used for the treatment chronic pancreatitis is needed for COVID-19 treatment. We have been conducting Phase I study in healthy volunteers with higher doses.

After confirming the safety and pharmacokinetics with higher doses in healthy volunteers, we will consider trials in patients.

Tani: Regarding the development schedule, we will decide by the end of August whether we will be able to move to the next step based on the Phase I result.

The next step will naturally be Phase III, but this is not known unless we look at the patient situation, so we cannot make precise statements at this time.

Finally, in terms of profits, as you said, the patent has expired, so I believe that the contribution to profits is limited.

Q: First, I would like to ask you two things that are not very relevant to your Company's business performance. I believe that the Company's performance has now become fairly stable, as Opdivo contribution to profits is clearly visible. I am not sure how to interpret the statement to the press by Company President Sagara mentioning the development of Opdivo in Asia.

I believe it was said that as the rates of gastric and other gastrointestinal cancers are relatively high, there are expectations in this area. Looking at the development list in the summary, Taiwan and South Korea are both listed, but I think progress has been written for some time. China is the territory of Bristol-Myers Squibb, and there was talk of expectations, but I have heard that progress in the area of hepatocellular cancer did not work very well. In terms of this development in Asia, is there anything that we need to pay attention to in the future?

Tani: As you mentioned, our territories are Japan, South Korea, and Taiwan. Of course, the explanation given here is that there are many patients with digestive cancer in Japan, South Korea, and Taiwan, so if they were to obtain approval in advance, the contribution to sales and profits would be greater.

Of course, if we obtain approval for digestive cancer in China ahead of schedule, Bristol sales will also contribute, and our royalty income will increase. The main focus is sales expansion in Japan, South Korea, and Taiwan.

Q: So, as a number, it's not so much at the stage where it can be incorporated yet. Is it right?

Tani: As you know, there is still less type of cancers for which reimbursement by the health insurance is granted in South Korea and Taiwan.

Q: Opdivo has made a positive contribution to profits, and the question of the unwinding of the cross-shareholding has not been mentioned at this time, including the unwinding of the so-called cross-shareholding in your company's balance sheet. Since there has been work on this initiative, will there be any release of figures relating to this in the medium- to long-term vision?

When the patents for Forxiga and Opdivo expire, there is a need to clarify the risk aspect, and how to address that. You may say that I should ask President Sagara directly, but I am not able to meet him at this time of year, so I am asking now. I would like you to consider this matter at the level of IR, too. What do you think?

Because of the future patent cliff risks, there is also the question of enhancing returns with buybacks. Could you comment on this?

Tani: With regard to our medium- to long-term vision, we always welcome the opinions of shareholders, so as in the past, we are working on a mid-term plan internally. The company is examining ways to release this.

For the time being, in the Corporate Report, which we are currently preparing, we are working to make it possible to do so as much as possible. Although I cannot expand on this today, we will proceed with the deliberations in the future, based on your opinions.

Regarding shareholder returns, in the same way, we have been returning profits to shareholders through dividends and share buybacks. We intend to proceed with thorough examinations of both of these matters while taking into account the current state of affairs. We would appreciate your understanding.

Q: I am saying that I am a little impatient, saying that the consideration stage has already passed, so I hope that you will take that into account as well.

Tani: I understand.

Q: First of all, I would like to talk about the financial results as a whole, but the financial results look very good, with revenue up by 1.3% and operating income up by 35%. Looking at the progress rate, sales are nearly 25%, and operating income is 34%. Do you think that the aforementioned upside in profits will have a considerable impact due to coronavirus?

Tani: Yes. R&D expenses and other SG&A expenses in the first quarter were lower than in the previous year due to the impact of coronavirus. These factors are contributing to the overshoot in profits.

Q: The overshoot is JPY7 billion profit, and expenses reduction is JPY6 billion, but this JPY6 billion decrease is due to the considerable impact of coronavirus.

Tani: That’s correct.

Q: After that, Opdivo increased by nearly double digits to JPY2.1 billion, but the number of patients has changed. Could you say, even just in qualitative terms, how much of this increase is due to use in esophageal cancer?

Takahagi: There are sales growth or decrease by type of cancers. So it is difficult to give a single figure. Looking at the overall picture, the number of patients increased by about 8% compared to last year. Focusing esophageal cancer alone, we believe that it is a positive factor with about 10% of the increase.

Q: Last of all, there were some questions that were announced yesterday. For coronavirus, Foipan is better than ONO-5334, but Foipan is now a medical guide, so I think it's necessary to do it. It seems that ONO-5334 is very good on paper, but does your company's analysis suggest a less positive view?

Idemitsu: As you pointed out, it was written in the press release. In April, we got information before the review of the paper, and based on that, we have provided the sample with external institutions to evaluate the possibility of ONO-5334. Based on the results, we reached the conclusion that Foipan is more promising in its effectiveness and that ONO-5334 is rather difficult.

Q: Then, there was a lot of talk about Foipan generics, but before that, you said that you would like to adjust the inventory in the industry paper. What's your level like now? And what is the image of the market share?

Tani: We are adjusting the current distribution of Foipan. We are working hard to ensure that supply for existing use of Foipan is maintained. Our market share is about 20% of the total market share.

Q: If Foipan is approved for COVID in the future, is this going to be an exclusive? Otherwise, generics may be used for COVID instead of Foipan.

Tani: I think this needs to be examined. However, on the other hand, there is a question about whether our Company alone would be able to meet demand.

Q: If anything, that's the problem.

Idemitsu: However, if Foipan shows its efficacy, global demand will increase. If emergent measure is taken, we will collaborate with our authorities an approval and exclusive marketing period. If we have a positive result, we will discuss the supply of the product with our authorities and other concerned people.

Q: Well, if it can’t be supplied, it is open for talks, but if it can be supplied, generics might not be an option, right?

Tani: Basically, generic products of Foipan cannot be used for COVID-19 during the re-examination period. However, as I said earlier, the profit is limited because the drug price itself is extremely low.