ONO PHARMACEUTICAL CO., LTD.

Q3 Financial Results Briefing for the Fiscal Year Ending March 2021

February 1, 2021

[Number of Speakers] 6

Toshihiro Tsujinaka	Member of the Board of Directors, Executive Officer/Executive Director, Corporate Strategy & Planning
Hiroshi Ichikawa	Corporate Senior Executive Officer/ Executive Director, Sales and Marketing
Kiyoaki Idemitsu	Corporate Executive Officer/ Executive Director, Clinical Development
Satoshi Takahagi	Business Unit Director, Oncology Business Division, Sales and Marketing
Kazuhiro Nagahama	Director, Finance & Accounting
Yukio Tani	Corporate Executive Officer/Head of Corporate Communications

Tani: Today's meeting is a briefing session on financial results for the third quarter, but I would like to take a moment to talk about the arrest of employees of our company announced on January 27. Mr. Sagara will explain the situation.

Sagara: On January 27, our marketing representatives were arrested on suspicion of bribery by the Tsu District Public Prosecutors Office. We would like to take this opportunity to deeply apologize for causing lots of inconvenience and concern to you all. We take it gravely and seriously that we have caused such a situation.

In order to prevent such event from happening in the future, we will aim to strengthen compliance awareness among employees, and strengthen governance to more strongly ensure the transparency and fairness in the scholarship donation system itself. Considering the facts to be determined through the progress of the investigation, we will set up a proper investigation committee at an appropriate timing in the future to investigate the cause and take measures to prevent recurrence. Should there be any information or event to be disclosed in the future, we will announce them in a timely manner.

We will do our best to regain the trust of our company that was lost due to this matter as soon as possible and meet the expectations of society. We would most appreciate your continued support and guidance.

Revenue

Revenue	YoY
¥ 234.9 billion	+ 4.3 %

Breakdown of Revenue

(Billion yen)

	FY 2019 Q3	FY 2020 Q3	YoY
Revenue of Goods and Products	161.1	165.4	+ 2.7 %
Royalty & Other Revenue	64.2	69.5	+ 8.2 %
(Opdivo)	(46.0)	(44.7)	(– 2.8 %)
Total	225.3	234.9	+ 4.3 %

Nagahama: Revenue in the third quarter of the fiscal year increased by JPY9.6 billion, or 4.3%, YoY to JPY234.9 billion.

Sales of products increased by JPY4.3 billion, or 2.7%, YoY to JPY165.4 billion, due to steady sales of Opdivo, Orencia, Forxiga, Parsabiv, and Kyprolis, despite a decrease in sales of long-term listed products.

Royalties and other revenue increased by JPY5.3 billion, or 8.2%, YoY to JPY69.5 billion. Royalty and other revenue includes royalty income from Bristol-Myers Squibb of JPY44.7 billion, a decrease of JPY1.3 billion YoY, and royalty income from Merck of JPY17.6 billion, an increase of JPY3.8 billion.

Revenue

Sales of Major Products

(Billion yen)

	FY 2019 Q3	FY 2020 Q3	YoY
Opdivo	68.0	**76.3**	+ 12.3 %
Glactiv	20.5	**19.9**	- 3.2 %
Forxiga	13.8	**16.6**	+ 20.3 %
Orencia SC	15.2	**16.8**	+ 10.5 %
Parsabiv	5.5	**6.3**	+ 14.9 %
Kyprolis	4.6	**5.4**	+ 17.3 %
Onoact	4.0	**3.6**	- 10.2 %
Proemend	2.0	**2.0**	- 1.9 %
New products（FY2020）	–	**1.4**	–

By product, sales of the anti-cancer agent Opdivo increased by JPY8.3 billion, or 12.3%, YoY to JPY76.3 billion. This was mainly due to increased use for esophageal cancer, while competition with competitors' products intensified.

In other major new products, sales of Forxiga, for diabetes and heart failure, rose by JPY2.8 billion, or 20.3%, to JPY16.6 billion. Sales of Orencia, for rheumatoid arthritis treatment, increased by JPY1.6 billion, or 10.5%, to JPY16.8 billion. Sales of Parsabiv, for the treatment for secondary hyperparathyroidism in hemodialysis patients, increased by JPY800 million, or 14.9%, to JPY6.3 billion. Sales of Kyprolis, for multiple myeloma treatment, increased by JPY800 million, or 17.3%, to JPY5.4 billion.

On the other hand, sales of Glactiv, for type 2 diabetes treatment, decreased by JPY700 million, or 3.2%, YoY to JPY19.9 billion.

Revenue

Sales of Long-term Listed Products

(Billion yen)

	FY 2019 Q3	FY 2020 Q3	YoY
Rivastach	6.7	**6.0**	- 10.7 %
Opalmon	6.7	**4.3**	- 35.5 %
Emend	6.8	**2.0**	- 70.2 %
Onon Capsule	2.5	**1.9**	- 23.1 %
Recalbon	3.9	**2.3**	- 40.8 %

As for long-term listed product, the sales of products significantly decreased, due to the impact of measures to promote the use of generics. Sales of Rivastach, for the treatment of Alzheimer's dementia, decreased by JPY700 million, or 10.7%, YoY to JPY6 billion. In addition, sales of Opalmon, Emend, Onon and Recalbon all declined significantly.

Operating Profit

Operating Profit	YoY
¥ 82.2 billion	+ 24.4 %

Costs, etc.

(Billion yen)

	FY 2020 Q3	YoY
・Cost of Sales	66.2	(+ 7.5%)
・R&D Expenses	43.8	(- 3.4%) ①
・SG&A Expenses	48.2	(- 5.3%) ②
①+② Total	92.1	(- 4.4%)
・Other Income	7.1	(+1114.3%)
・Other Expenses	1.6	(- 17.6%)

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Operating income increased by JPY16.1 billion, or 24.4%, YoY to JPY82.2 billion. In terms of expenses, cost of sales increased by JPY4.6 billion, or 7.5%, YoY to JPY66.2 billion.

R&D expenses increased due to joint research expenditures with universities and research institutes, as well as milestone payments related to drug discovery alliances with bio-ventures. On the other hand, from June last year, we resumed research and development activities, including subject enrollment, costs related to clinical trials decreased due to the impact of the coronavirus pandemic, resulting in a decrease by JPY1.5 billion, or 3.4%, to JPY43.8 billion YoY.

Selling, general, and administrative expenses decreased by JPY2.7 billion, or 5.3%, YoY to JPY48.2 billion. This was due to a review of academic lectures resulting from the impact of the coronavirus pandemic, as well as a decrease in operating expenses resulting from a reduction in MR visits to medical institutions.

Other income rose by JPY6.5 billion to JPY7.1 billion, as a result of an income of the lump-sum payment of a patent license agreement with Roche relating to anti-PD-L1 antibody concluded in November last year. As a result, operating income increased JPY16.1 billion YoY.

Profit before Tax

Profit before Tax	YoY
¥ 84.7 billion	+ 23.3 %

Net Financial Income

+ ¥ 2.5 billion (- ¥ 0.2 billion YoY)

Finance Income :	**¥ 2.6 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.)	

Finance income amounted to JPY2.6 billion, and finance cost totaled JPY100 million. Finance balance decreased by JPY200 million YoY to JPY2.5 billion. As a result, quarterly profit before tax increased by JPY16 billion, a 23.3% increase from the same period of the previous year, to JPY84.7 billion.

Profit for the Period
(Owners of the Parent Company)

Profit for the Period (Owners of the Parent Company)	YoY
¥ 66.5 billion	+ 28.3 %

Income Tax Expense

¥ 18.1 billion (+ 8.5 % YoY)

(Major Change Factors)

Increase in profit before tax	¥	16.0 billion
Increase in corporate tax	¥	1.4 billion

Quarterly profit attributable to owners of the parent increased by JPY14.7 billion, or 28.3%, YoY to JPY66.5 billion, due to the increase in quarterly profit before tax.

Both revenue and profit at each stage reached record highs for the cumulative third quarter.

Revenue (Forecasts)

Revenue	YoY
¥ 309.0 billion	+ 5.7 %

Breakdown of Revenue

(Billion yen)

	FY 2019 (Result)	FY 2020 (Forecast)	YoY
Revenue of Goods and Products	205.6	215.0	+ 4.6 %
Royalty & other revenue	86.8	94.0	+ 8.3 %
Total	292.4	309.0	+ 5.7 %

Last time, we revised the consolidated full-year earnings forecast announced on October 29 last year. The forecasts for revenue and profit at each stage have been revised. But R&D expenses and SG&A expenses remain unchanged from the previously announced forecast. The details of the revisions are described on page 4 of the financial results report.

The revenue forecast was revised upward by JPY4 billion, from JPY305 billion to JPY309 billion.

Operating Profit (Forecasts)

Operating Profit	YoY
¥ 94.0 billion	+ 21.3 %

Costs, etc.

(Billion yen)

	FY 2020 (Forecast)	YoY	
・Cost of Sales	88.0	(+ 11.3 %)	
・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	8.0	(+ 873.0 %)	
・Other Expenses	3.0	(+ 19.4 %)	

The operating profit forecast was revised upward by JPY7 billion, from JPY87 billion to JPY94 billion.

Profit before Tax (Forecasts)

Profit before Tax	YoY
¥ 95.5 billion	+ 19.8 %

Net financial income

+ ¥ 1.5 billion (- ¥ 0.7 billion YoY)

The forecast of profit before tax was revised upward by JPY7 billion, from JPY88.5 billion, to JPY95.5 billion.

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

Profit for the Period (Owners of the Parent Company)	YoY
¥ 74.0 billion	+ 23.9 %

Income tax expense

¥ 21.3 billion	(+ 7.5 % YoY)

(Major change factors)

Increase in profit before tax	¥	15.8 billion
Increase in corporate tax	¥	1.5 billion

The forecast of profit attributable to owners of the parent was revised upward by JPY9 billion, from JPY65 billion to JPY74 billion.

The year-end dividend is planned to be JPY22.5 per share, which remains unchanged at present.

Development pipeline

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

The status of the development products is described on pages 13 to 17 of the financial results report. First, I will present the updates since Q2 FY2021 by using this report.

Regarding the composition of the report, the materials are divided into oncology area followed by non-oncology area. In addition, items are listed in order of development stage, for example, approval, submission for approval, Phase III .

(4) Main Status of Development Pipelines (Oncology)

As of January 25, 2021

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Yervoy Injection ★ / Ipilimumab	Additional indication	Non-small cell lung cancer *1	Injection	Japan S. Korea	In-license (Co-development with Bristol-Myers Squibb)
Braftovi Capsules / Encorafenib	Additional indication	Colorectal cancer *2	Capsule	Japan	In-license (Pfizer Inc.)
Mektovi Tablets / Binimetinib	Additional indication	Colorectal cancer *2	Tablet	Japan	In-license (Pfizer Inc.)
Adlumiz Tablets / Anamorelin	New chemical entities	Cancer cachexia *3 / Ghrelin receptor agonist	Tablet	Japan	In-license (Helsinn Healthcare, S.A.)

★: Combination with Opdivo.
Changes from the announcement of financial results for the second quarter of the fiscal year ending March 2021
*1: Applications were approved in Japan and South Korea for combination therapy of Opdivo and Yervoy for the treatment of unresectable advanced or recurrent non-small cell lung cancer.
*2: Applications for Braftovi Capsules and Mektovi Tablets were approved in Japan for the treatment of unresectable advanced or recurrent BRAF-mutant colorectal cancer that has progressed following chemotherapy.
*3: An application was approved in Japan for Adlumiz / Anamorelin for the treatment of cancer cachexia in patients with malignant tumors (non-small cell lung cancer, gastric cancer, pancreatic cancer or colorectal cancer).

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Yervoy Injection ★ / Ipilimumab	Additional indication	Malignant pleural mesothelioma	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)

★: 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	Hepatocellular carcinoma	Injection	Japan S. Korea	III	In-house (Co-development with Bristol-Myers Squibb)
	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)

First, the oncology field.

At the top of the approved development products list is Yervoy. In November, we obtained approval for combination treatment with Opdivo for non-small cell lung cancer in Japan and South Korea. In November, we received approval for Braftovi and Mektovi, for treatment of BRAF-mutant colorectal cancer. We received approval of Adlumiz in January for cancer cachexia.

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	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 *4	Injection	Japan S. Korea Taiwan	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	Japan S. Korea Taiwan	I / II	In-house (Co-development with Bristol-Myers Squibb)

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
Yervoy Injection ★ / Ipilimumab	Additional indication	Non-small cell lung cancer	Injection	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)
ONO-4686 ★ (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)

Next, listed in the section for products under development, we launched Phase II study for Opdivo for gallbladder cancer in Japan, South Korea, and Taiwan.

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
ONO-4482 ★ (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-7807 ★ (BMS-986258)	New chemical entities	Solid tumor / Anti-TIM-3 antibody	Injection	Japan	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483 ★ (BMS-986015) / Lirilumab	New chemical entities	Solid tumor / Anti-KIR antibody	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-7475 ★	New chemical entities	Solid tumor / Axl/Mer inhibitor	Tablet	Japan	I	In-house
ONO-7911 ★ (BMS-986321) / Bempegaldesleukin	New chemical entities	Solid tumor / PEGylated IL-2	Injection	Japan	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4578 ★	New chemical entities	Colorectal cancer *5 / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Pancreatic cancer *5 / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Non-small cell lung cancer *5 / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house
	New chemical entities	Solid tumor・Gastric cancer / PG receptor (EP4) antagonist	Tablet	Japan	I	In-house

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
Braftovi Capsules / Encorafenib	New chemical entities	Colorectal cancer / BRAF inhibitor	Capsule	S. Korea	III	In-license (Pfizer Inc.)
	New chemical entities	Melanoma / BRAF inhibitor	Capsule	S. Korea	III	In-license (Pfizer Inc.)
Mektovi Tablets / Binimetinib	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	S. Korea	III	In-license (Pfizer Inc.)
	New chemical entities	Melanoma / MEK inhibitor	Tablet	S. Korea	III	In-license (Pfizer Inc.)
ONO-7912 (CPI-613) / Devimistat	New chemical entities	Pancreatic cancer / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, Inc.)
	New chemical entities	Acute myeloid leukemia / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, Inc.)
Braftovi Capsules / Encorafenib	Additional indication	Thyroid cancer *6 / BRAF inhibitor	Capsule	Japan	II	In-license (Pfizer Inc.)

In the I-O section, on the second line from the top of the table on page 15, we have ONO-4578, which is an EP4 antagonist. We commenced Phase I study for combination treatment with Opdivo, for colorectal cancer, pancreatic cancer, and non-small cell lung cancer.

Also listed on page 15 are Braftovi and Mektovi. We also launched Phase II study for Braftovi and Mektovi for BRAF-mutant thyroid cancer.

Unfortunately, the development for glioblastoma has been discontinued because it was determined that the expected effect could not be obtained. It was deleted from the table

In addition, regarding ONO-4059, or Velexbru, we have out-licensed to Gilead for the development focusing on Europe and the US. However, Gilead returned the right in the oncology area. Gilead still holds rights in the non-oncology field.

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

As of January 25, 2021

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

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
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)
Foipan Tablets / Camostat mesilate	Additional indication	Novel coronavirus infection (COVID-19) *7 / Protease enzyme inhibitor	Tablet	Japan	III	In-house
Onoact for Intravenous Infusion / Landiolol Hydrochloride	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / Short-acting selective β_1 blocker	Injection	Japan	II / III	In-house
ONO-5704 / SI-613	New chemical entities	Enthesopathy / Hyaluronic acid-NSAID	Injection	Japan	II	In-license (Seikagaku Corporation)
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Pemphigus / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	Japan	II	In-house
ONO-4685	New chemical entities	Autoimmune disease / PD-1 x CD3 bispecific antibody	Injection	Japan	I	In-house
ONO-7684	New chemical entities	Thrombosis / FXIa inhibitor	Tablet	Europe	I	In-house
ONO-2808	New chemical entities	Neurodegenerative diseases / S1P5 receptor agonist	Tablet	Japan *8 Europe	I	In-house
ONO-2910	New chemical entities	Peripheral neuropathy / Schwann cell differentiation promoter	Tablet	Japan	I	In-house
ONO-2909	New chemical entities	Narcolepsy *9/Prostaglandin receptor (DP1) antagonist	Tablet	Japan	I	In-house
Velexbru Tablets / Tirabrutinib Hydrochloride	Additional indication	Systemic scleroderma *10 / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	Japan	I	In-house

Changes from the announcement of financial results for the second quarter of the fiscal year ending March 2021
*7: Phase III of Foipan Tablets was initiated in Japan for the treatment of COVID-19.
*8: Phase I of S1P5 receptor agonist (ONO-2808) was initiated in Japan.
*9: Phase I of prostaglandin receptor (DP1) antagonist (ONO-2909) was initiated in Japan for healthy adult subjects and for the treatment of narcolepsy.
*10: Phase I of Velexbru Tablets (Btk inhibitor) was initiated in Japan for the treatment of systemic scleroderma.
* Development of FXIa inhibitor (ONO-7269) for the treatment of cerebral infarction was discontinued in Japan due to strategic reasons.

The status of development products other than oncology, which are described on page 17.

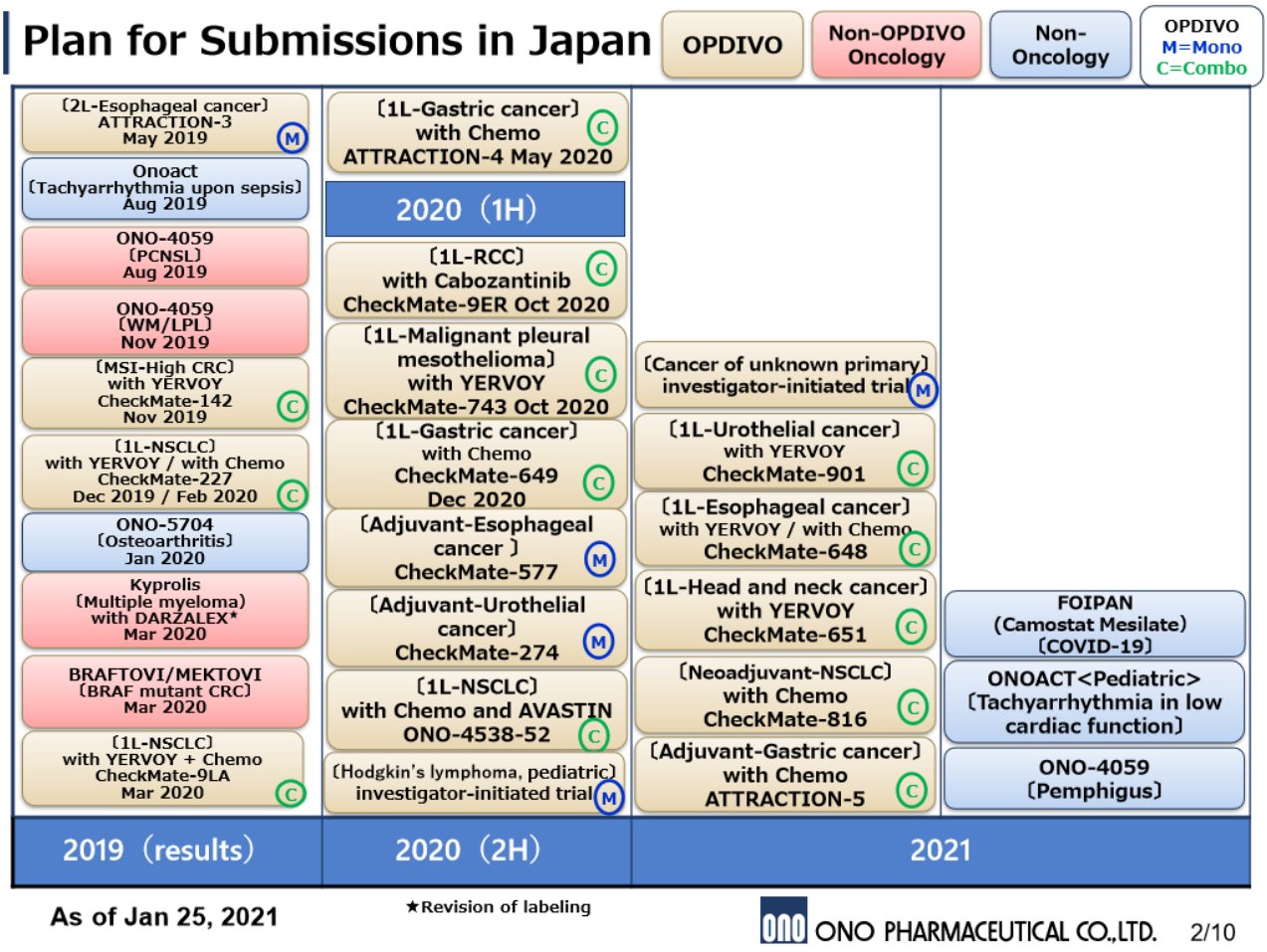
The second line in the table showing products under development in clinical trials is Foipan. We have begun Phase III study for the treatment of COVID-19.

Let me add a little background. Foipan is a drug launched more than 30 years ago for chronic pancreatitis, and generics have already been launched. Following the publication of a paper suggesting its efficacy against COVID-19, we believe that it is our responsibility to confirm whether it is effective in humans, and therefore, we have begun developing it. We believe that we need a higher dose than the dose for chronic pancreatitis.

At the time of the previous earnings announcement, we had implemented Phase I study with higher doses, and were able to confirm the safety in the study, so we launched Phase III study in November last year.

Fourth from the bottom of the same table is ONO-2808. This is a SIP5 receptor agonist. In addition to Phase I study being implemented in the UK, we have also started Phase I study in Japan. Furthermore, the second from the bottom is ONO-2909. This is an antagonist of DP, a PGD_2 receptor. We are considering narcolepsy as a target indication. Phase I study has begun.

The bottom entry is Velexbru. We have started development for generalized scleroderma. Regarding the injectable FXIa inhibitor ONO-7269, we have been conducting and considering development in Japan for the treatment of cerebral infarction. However, the development was discontinued for strategic reasons. It has been removed from the table.



I would like to explain about the future application schedule.

First of all, Opdivo is shown in beige, oncology other than Opdivo is shown in red, and non-oncology in blue. In addition, for Opdivo, “M” is for monotherapy, and “C” is for combination therapy. Regarding the timing of the application, the date shown is the earliest schedule, assuming progress is made as planned. Of course, the situation may change.

Next, I will explain mainly the changes from the previous financial results announcement in October. First is the results for FY2019 on the left column. The five elements from the top are those we have already received approval for, namely those from Opdivo for esophageal cancer at the top to combination therapy of Opdivo/Yervoy for MSI-High colorectal cancer. These have been approved, as previously reported.

With regard to the first-line treatment of non-small cell lung cancer with Opdivo, there are two trials, CheckMate-227 and CheckMate-9LA which are shown at the sixth from the top and at the bottom. We submitted applications for three combination treatments: Opdivo and Yervoy, Opdivo and chemotherapy, and Opdivo, Yervoy and chemotherapy. These were approved in November last year.

The fourth from the bottom in the blue column is ONO-5704, and this is a product composed with diclofenac, an anti-inflammatory analgesic, with hyaluronic acid, in-licensed from Seikagaku Corporation. Last week, on January 29, it was discussed at a subcommittee, and approval was recommended.

In November, we completed the procedure to revise the package insert for Kyprolis in combination therapy with Darzalex for multiple myeloma. Furthermore, we received an approval in November for an application for Braftovi and Mektovi for BRAF-mutant colorectal cancer.

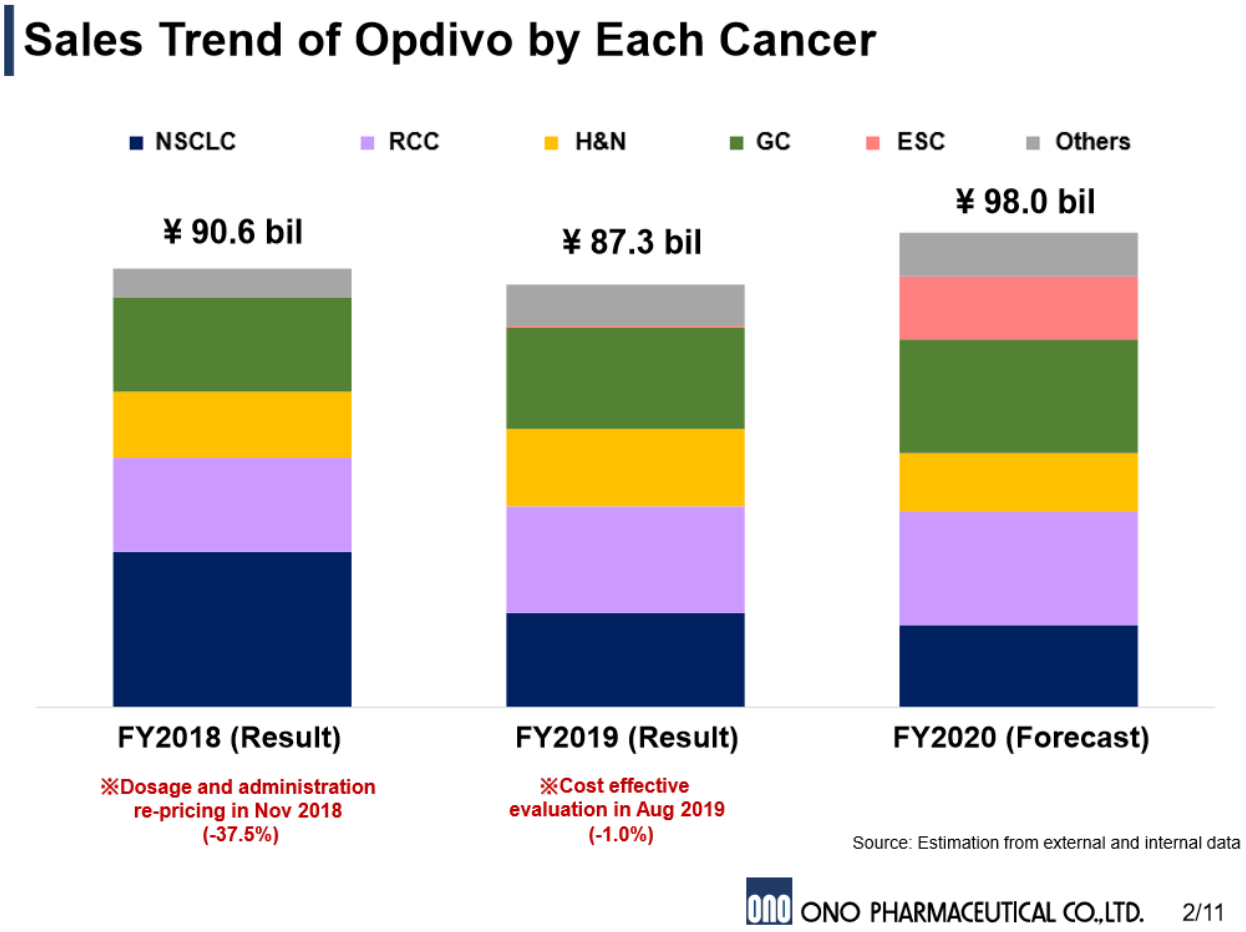
Next, I will explain the updated portion in the second column from the left, for the second half of FY2020. First, regarding CheckMate-649, for the Opdivo-chemotherapy combination treatment for first-line gastric cancer, we filed an application in December with the results from CheckMate-649, together with those of ATTRACTION-4, described at the top of the same row.

Regarding ONO-4538-52 trial conducted with combination treatment of Opdivo, Avastin and chemotherapy for first-line treatment of non-small cell lung cancer, we have started a discussion with the authorities on the revision of the package insert of Opdivo.

In addition, the application for Opdivo for pediatric Hodgkin's lymphoma shown at the bottom was filed an application last week, on January 28.

The application schedules for combination with Yervoy for first-line treatment of gastric cancer, CheckMate-649, the adjuvant treatment of renal cell carcinoma, CheckMate-914, as well as the adjuvant treatment of hepatocellular carcinoma, Checkmate-9DX have all been revised to FY2022 and removed from this list.

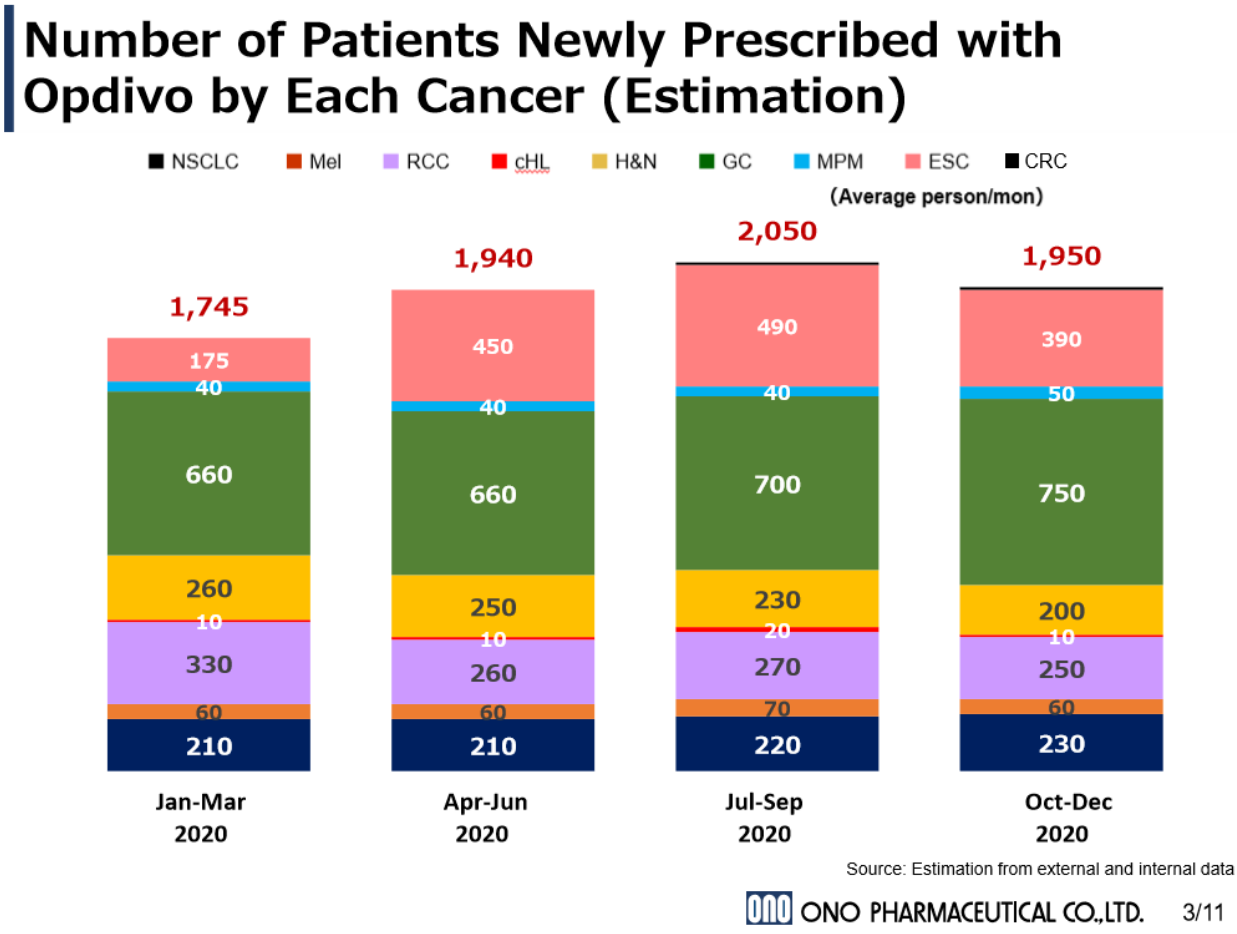
Finally, at the top right is the Foipan COVID-19 project. I explained earlier that we started Phase III study in November last year. If the trial progresses as planned, and the expected efficacy is obtained, we plan to file an application during FY2021.



Takahagi: Regarding trends of Opdivo, I will discuss general conditions, sales trends, trends in the number of new prescriptions, the composition ratio of major I-O inhibitors, conditions by cancer type, including lung cancer, gastric cancer, esophageal cancer, and renal cell carcinoma.

This slide shows the sales of Opdivo.

From the bar graph on the left, the results for FY2018, the results for FY2019, and the forecast for FY2020 are shown. We forecast sales of JPY98 billion this fiscal year.

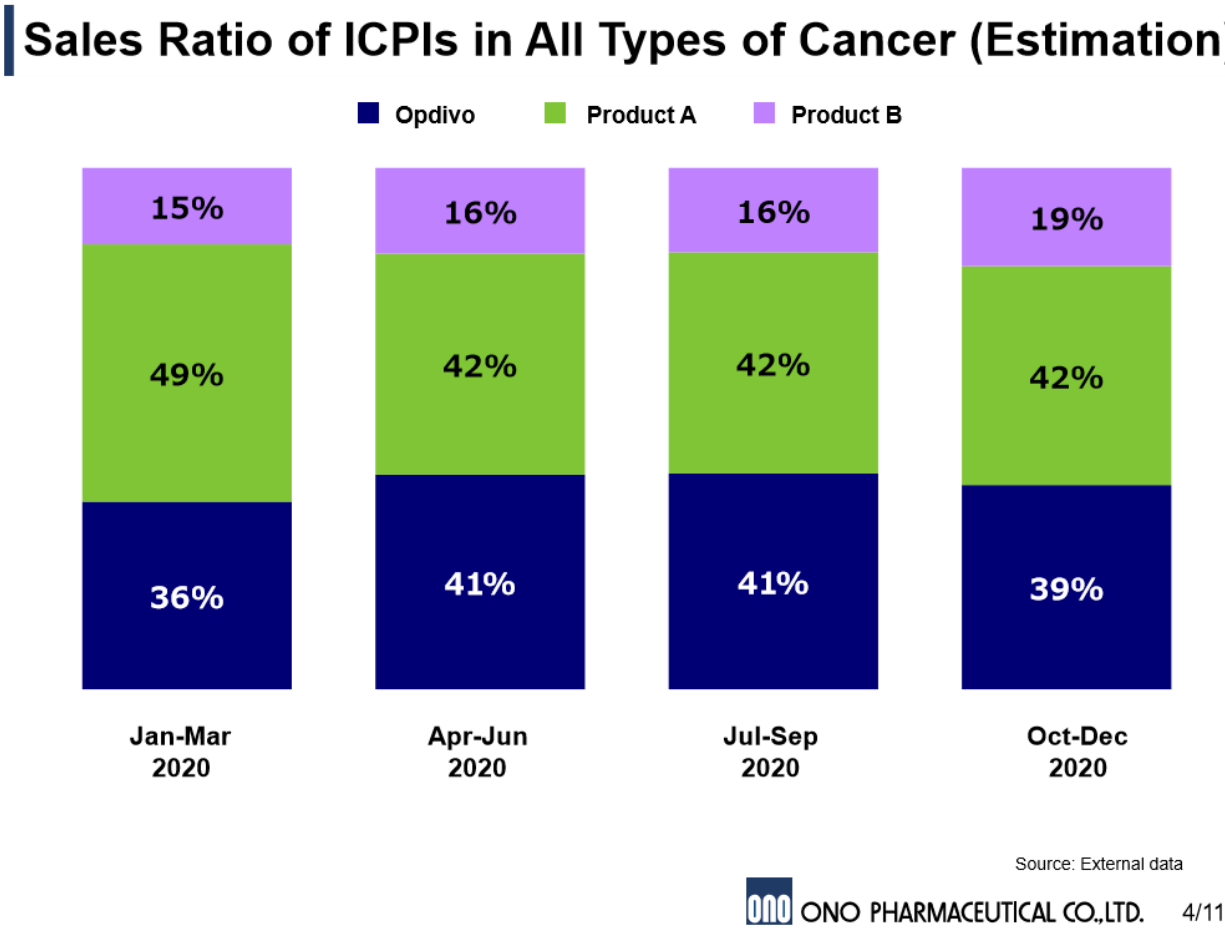


This slide shows estimated changes in the number of new Opdivo prescriptions by cancer type.

From the bar graph on the left, we expressed the average number of patients per month in the quarterly period from January to March 2020, up to the period from October to December 2020.

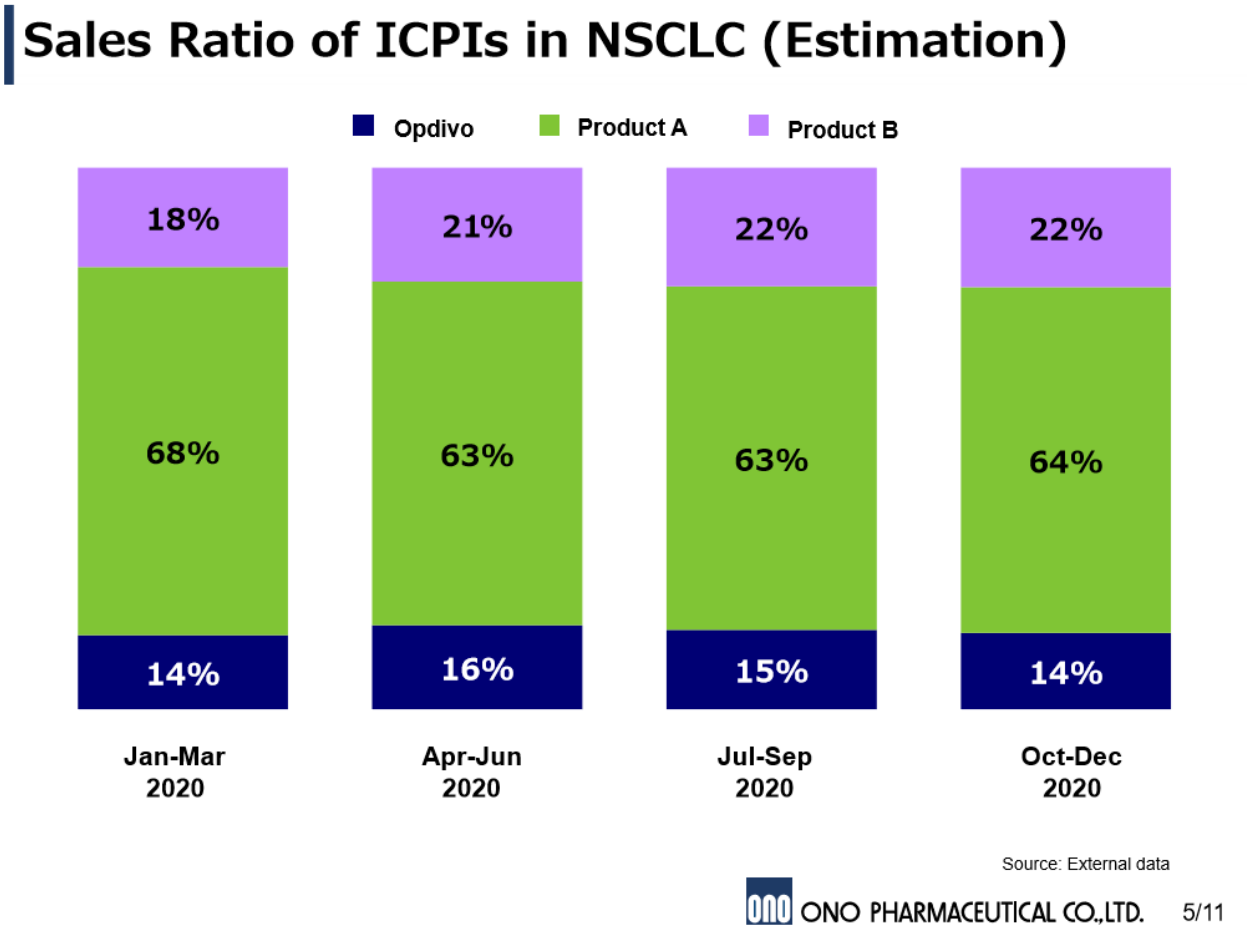
Although this is an estimate, in October to December 2020, we obtained new prescriptions for an average of 750 per month for gastric cancer, and about 250 for renal cell carcinoma. The new prescriptions for second- or third-line treatment of esophageal cancer were for 390 cases altogether. For lung cancer, we obtained new prescriptions in a monthly average of 230 cases for both first- and second-line treatments.

As a monthly average, we have acquired new prescriptions in a total of 1,950 cases. In the two months of December and January, Opdivo was newly prescribed in approximately 270 patients for first-line treatment of lung cancer, for which approval was obtained on November 27 last year. We intend to expand prescriptions in the future by promoting the benefits of immune-combination therapy, which are not available for competing products.



This slide shows the percentage of sales accounted for by the main immuno-checkpoint inhibitor products competing with Opdivo.

The sum of all cancer types is shown quarterly from January to March 2020, up to October to December 2020, from the bar graph on the left. In October to December 2020, Opdivo had a 39% share out of the major immuno-checkpoint inhibitors.

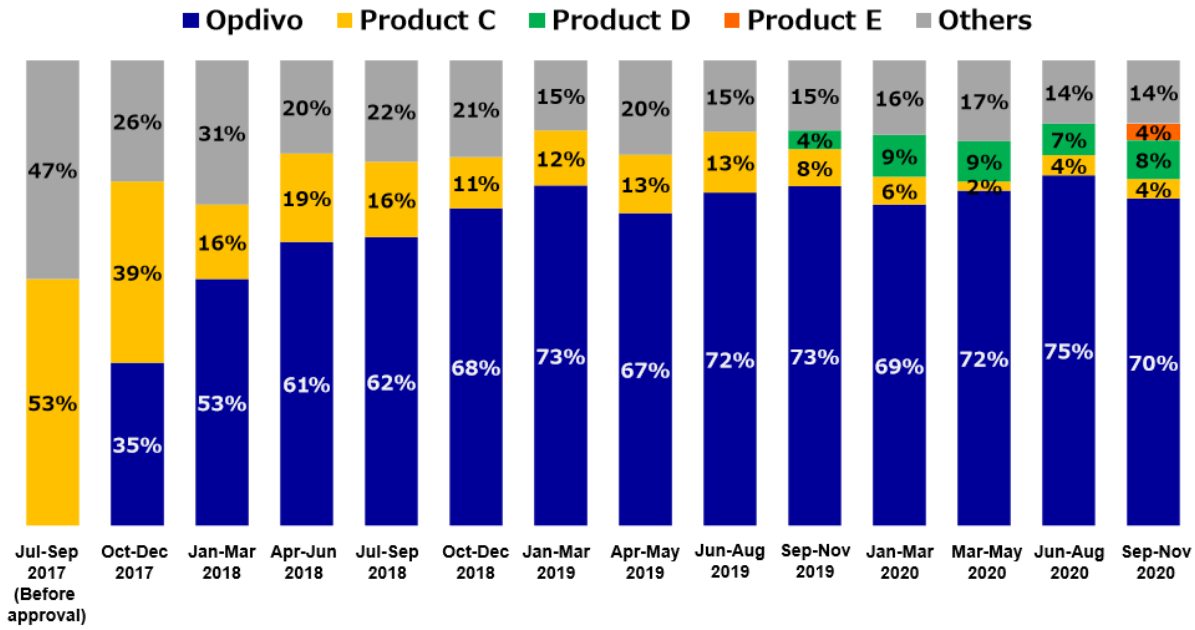


This slide covers the lung cancer segment.

The percentage of sales of immune checkpoint inhibitors in all non-small cell lung cancer lines of treatment, including first-, second-, third-line and thereafter is shown. The bar chart shows quarterly breaks from January to March up to October to December 2020 from the left.

Opdivo has 14% of the market. As we have entered the first-line treatment area of lung cancer, we will work to expand our market share.

Prescription Ratio in Patients Newly Treated for 3L GC



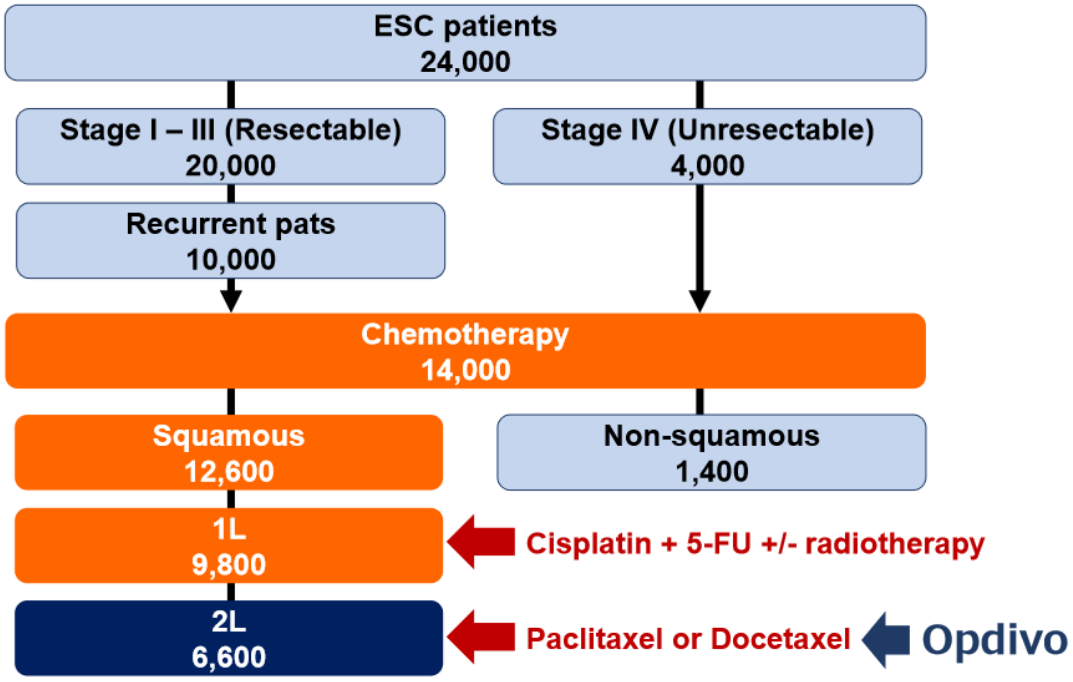
Source: External data (Jul 2017 – Dec 2020: n=190~250)

This slide covers the gastric cancer segment.

This slide presents the trends in the share of new patients in third-line treatment of gastric cancer. We maintain a target of 70% for Opdivo's third-line treatment prescription share, although competitor products have entered the market.

This is not shown in the slides here, but this is some information about the transition rate for gastric cancer treatment lines. The rate of transition from second- to third-line treatment reached the target of 65%. Going forward, we will continue to stress the significance of treatment with Opdivo in the field of gastric cancer, and extend its use for first-line treatment for gastric cancer in the future.

Number of ESC patients per year in Japan



Estimation based on internal survey in 2020

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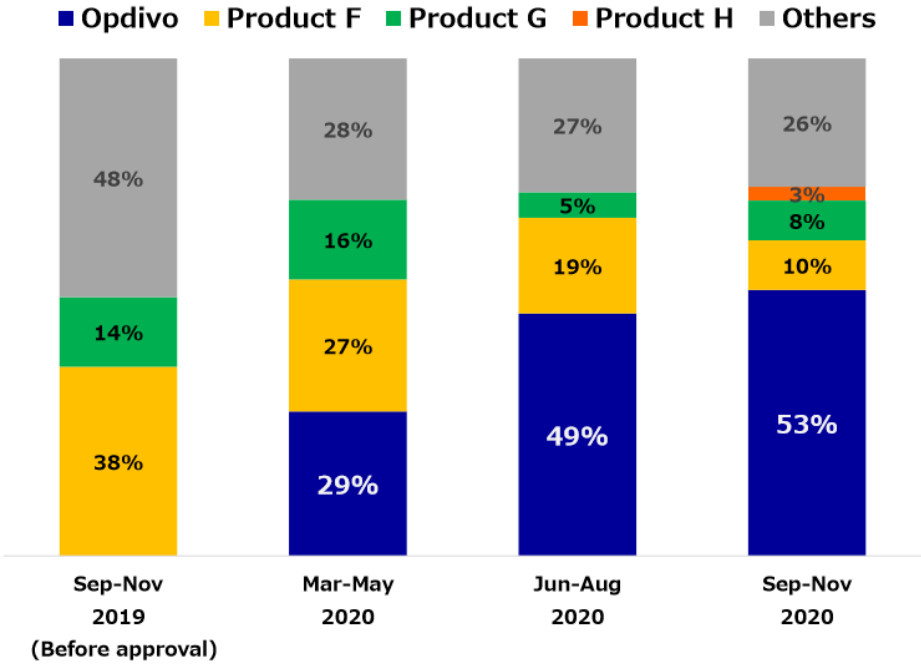
The progress of esophageal cancer activities is higher than planned.

The treatment of esophageal cancer was previously limited to treatments such as FP, S-1 and taxanes, and Opdivo has rapidly penetrated and has been used in about 4,500 cases since approval.

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

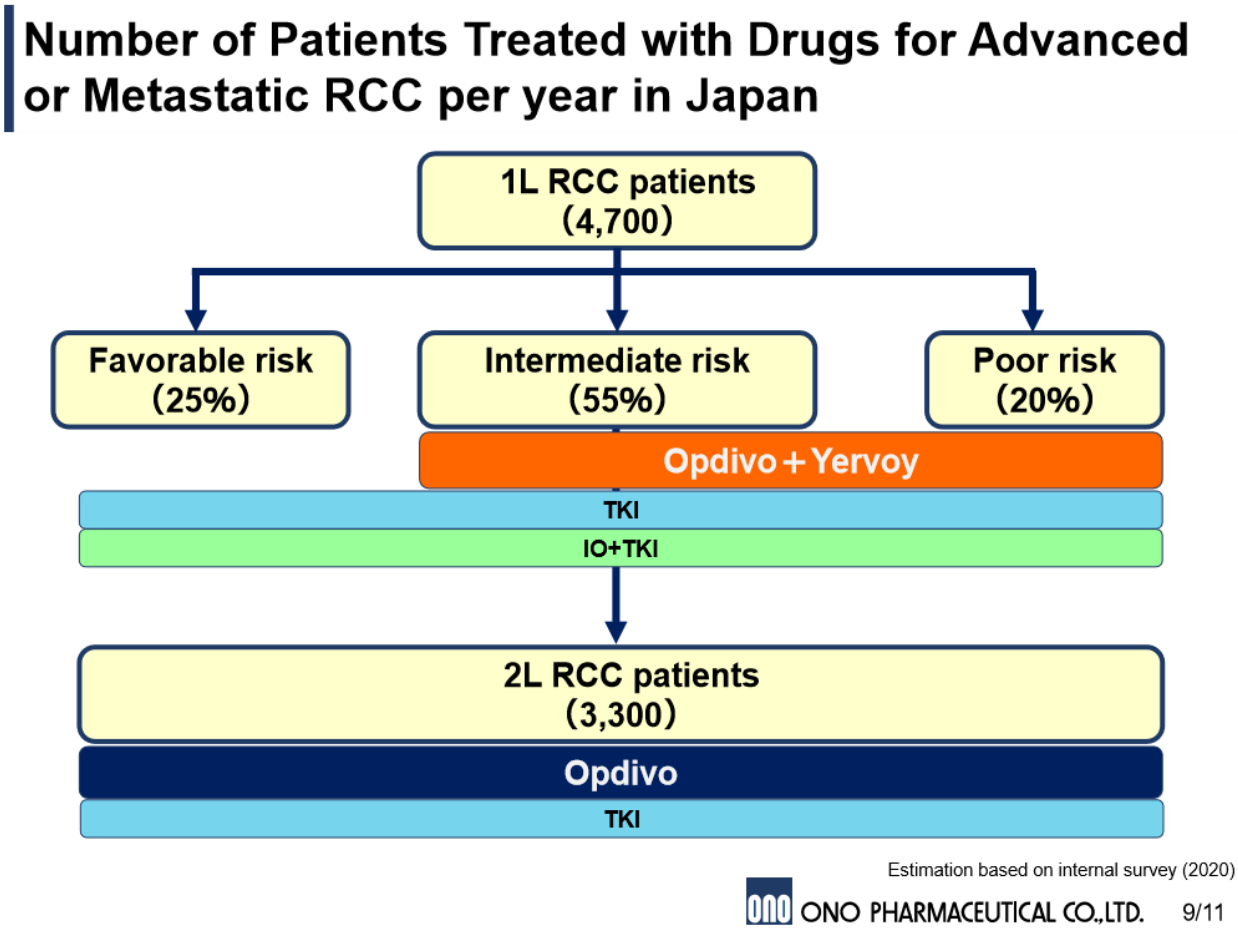
※ Patients starting 2L ESC within the last 3 months



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

The share of prescriptions for new patients for second-line treatment is 53%, showing a steady increase in market share.

Going forward, we intend to continue to increase our presence in the gastrointestinal field, including gastric cancer and esophageal cancer.

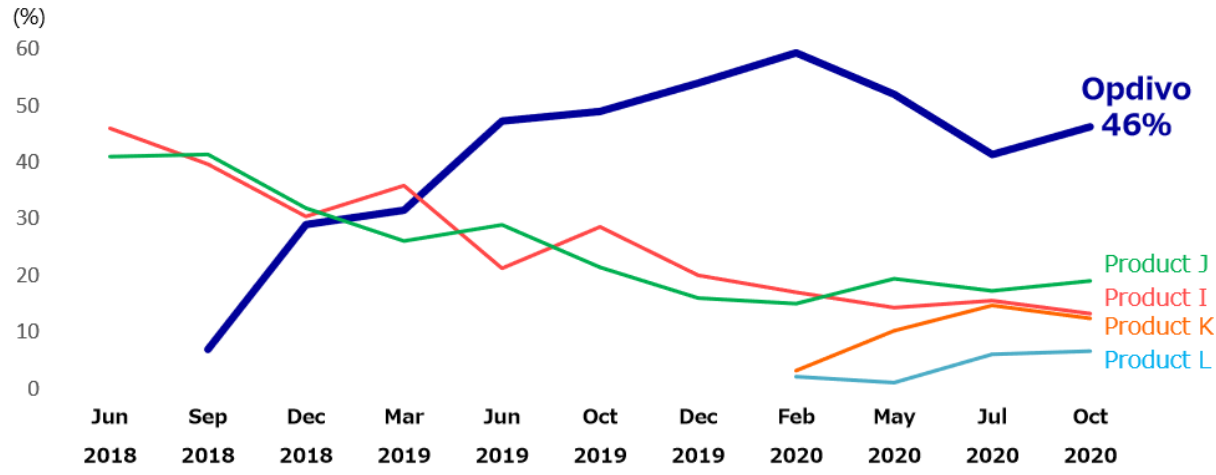


Finally, we report on the area of renal cell carcinoma.

There is evidence supporting the use of Opdivo as first-, second-line treatment and thereafter, and we are developing our activities to ensure that Opdivo is delivered to all 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	Jul	Oct	
Opdivo	**-**	**7**	**29**	**32**	**47**	**49**	**54**	**59**	**52**	**41**	**46**	(%)
Product I	46	40	30	36	21	29	20	17	14	16	13	(%)
Product J	41	41	32	26	29	21	16	15	19	17	19	(%)
Product K								3	10	15	12	(%)
Product L								2	1	6	7	(%)



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

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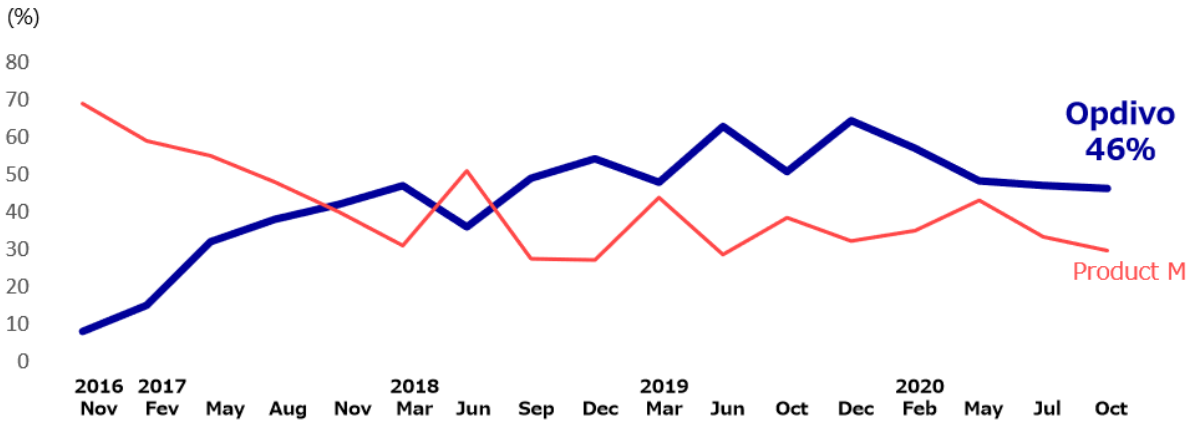
This shows the change in share of first-line treatment in newly acquired patients with renal cell carcinoma.

In first-line treatment, combination therapy with I-O+TKI has entered the market, and the prescriptions are gradually expanding. The share of new prescriptions for combination therapy with Opdivo and Yervoy is 46%. If we look at treatment of medium- and high-risk groups for the target of combination therapy with Opdivo and Yervoy, the share of new prescriptions is consistently above 50%.

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	Oct	
Opdivo	8	15	32	38	42	47	36	49	54	48	63	51	64	57	48	47	46	(%)
Product M	69	59	55	48	40	31	51	27	27	44	29	38	32	35	43	33	30	(%)



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

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While the spread of I-O therapies in first-line treatment, and the decrease in the number of patients not treated with immuno-checkpoint inhibitors in second-line treatment, the share of newly acquired prescriptions in second-line treatment is 46%. If we narrow down to I-O-naïve and untreated patients, the prescription has exceed 70%.

We have obtained approval for the first-line treatment of lung cancer with Opdivo and have applied for the first-line treatment for gastric cancer. We will promote proper use and aim to expand the market. We hope to deliver the benefits of Opdivo monotherapy and combination therapy with Yervoy, etc. to cancer patients in the future.

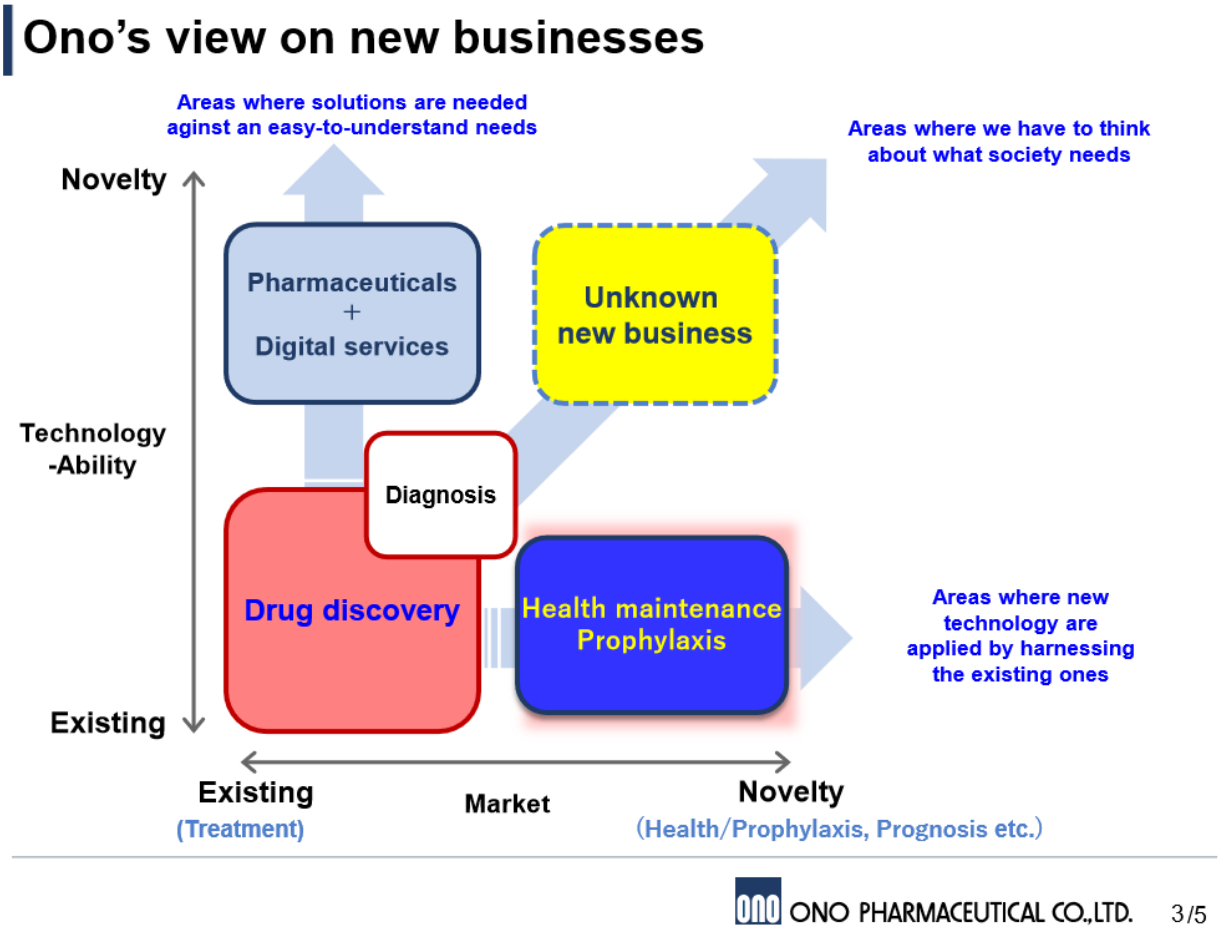
Company profile

ONO PHARMA HEALTHCARE CO., LTD.

- **Trade name** : Ono Pharma Healthcare Co., Ltd.
- **Location** : 8-2, Kyutaromachi 1-chome, Chuo-ku, Osaka, Japan
- **Founded** : February 5, 2021 (Planned)
- **Capital** : JPY 10 million
- **Representative** : Yasunari Noda, President
- **Staffs** : 4 persons
- **Business** : Solution service business in the healthcare field
- **Founder** : Ono Pharmaceutical Co., Ltd.

Tsujinaka: We have decided to establish Ono Pharma Healthcare Co., Ltd. The head office is located at 8-2, Kutaromachi 1-chome, Chuo-ku, Osaka, the same location as Ono Pharmaceutical Co. Ltd. It is to be established on February 5, 2021 and will have a capitalization of JPY10 million.

The Representative Director is Yasunari Noda, the head of our new business division. We plan to take four employees on loan. The area of the business is Solution Services in the Healthcare field. The promoter is Ono Pharmaceutical Co. Ltd.



The slide shows our approach for exploring new businesses.

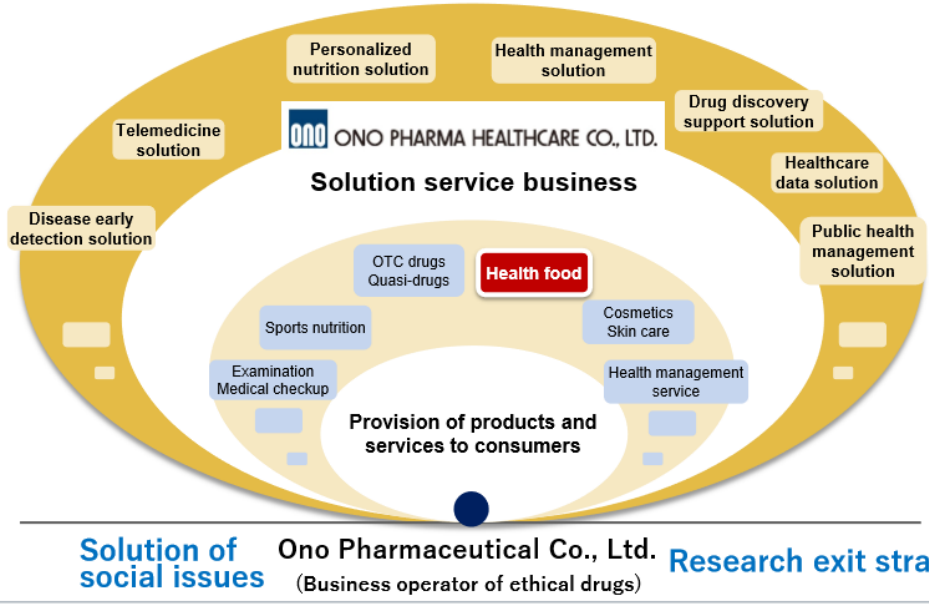
We are currently exploring new businesses in the Life Sciences field, on two axes. The first is to explore new markets by utilizing entirely new technologies and digital technologies. The other is to explore opportunities to enter markets other than pharmaceuticals and ethical drugs by utilizing Ono's existing research assets.

The former is handled by the Technovation Promoting Office within the Corporate Planning, Corporate Strategy & Planning. The latter is handled by the Business Design within the Corporate Strategy & Planning.

Today, I would like to report on the background for establishing Ono Pharma Healthcare Co., Ltd., in order to materialize the business that the Business Design is responsible for.

Target business of Ono Pharma Healthcare

Ono Pharma Healthcare is considering a business to solve various social issues in the areas from medical care to pre-illness in the pre-stage of disease and prophylaxis. Through the solution service business, we aim to enable individuals to manage their own health throughout their life course based on their own will.

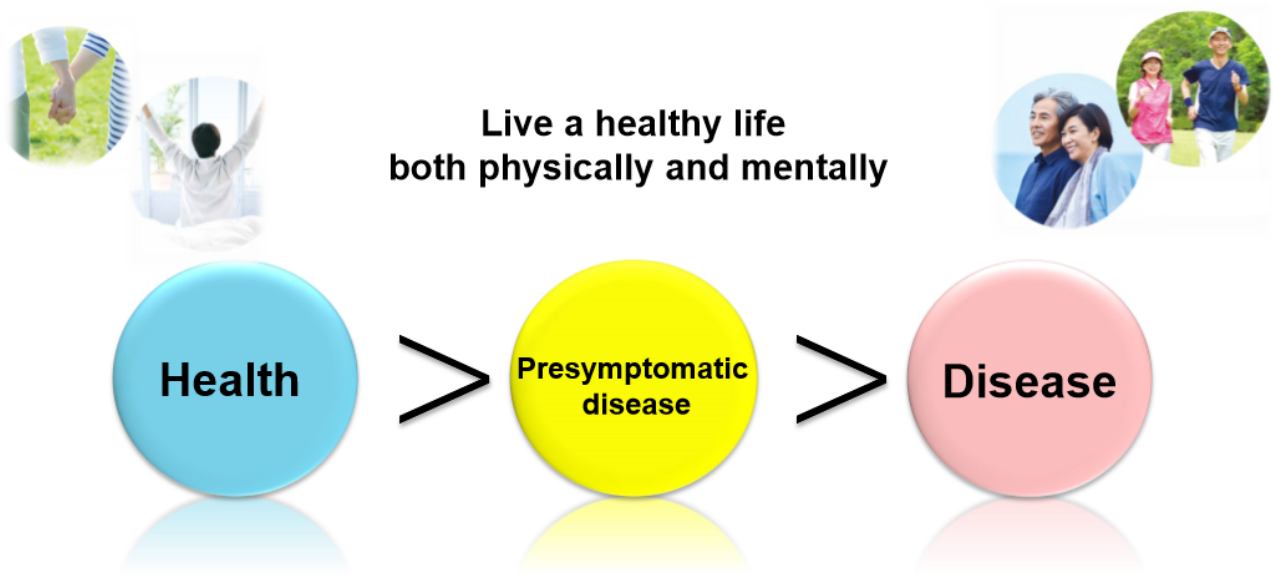


Ono Pharma Healthcare Co., Ltd. aims to develop a project to solve problems from medical care to presymptomatic disease in the pre-stages of disease and prophylaxis. Through our Solution Services Business, we aim to enable individuals to manage their own health throughout their life courses based on their own intentions.

First of all, we decided to enter the field of health foods, using our research assets cultivated in the lipid research of prostaglandins. With regard to the concept of supplements, from the viewpoint of intellectual property strategy, we will make a further announcement when we have decided on a specific launch, after consulting with a partner company.

At present, we are unable to disclose the details of the new business. We are currently working to acquire function claims for supplements derived from lipid research. In doing so, we must inform the Consumer Affairs Agency of our sales company. Based on this point, we have decided to establish a new company today.

We are currently conducting clinical trials aimed at obtaining two indications. Once the results of the clinical trials are available, I would like to report again on the details together with the collaborating companies in consideration of the intellectual property strategy.



We intend to pursue new businesses through the evolution of knowledge in existing businesses, as well as the exploration of knowledge in the Life Sciences. In addition to addressing illnesses, we aim to create a business model that can contribute to presymptomatic disease and health.

Question & Answer

Q: Firstly, it was mentioned just now that, after Opdivo was approved for first-line treatment in lung cancer, 270 new patients were treated in the two months from December to January. The total number of patients who were newly prescribed had been quoted at 230, 250 or 240 patients per quarter so far in the past, which would mean that, in the case of lung cancer, the number of prescriptions seems to have more than doubled. If so, what are your predictions for changes in February and March?

Takahagi: First, the slide shows an average of 230 patients who were newly prescribed for lung cancer in October to December.

Looking at the details, prescriptions started in December for first-line treatment of lung cancer, and we think that it was used in about 100 cases in December. The average of three months, you could think of this as about 30 cases per month, which are added to the average 200 cases per month in October to December for second-line treatment of lung cancer.

In the month of January, the number of newly prescribed patients increased to 170 cases. In the future, the number of patients newly prescribed with Opdivo for the second-line treatment of lung cancer is decreasing with a significant expansion of prescription with the I-O products for first line. Therefore, we think that new prescriptions for first-line treatment with Opdivo will more than make up for that and increase sales of Opdivo in lung cancer in the future.

Q: So, can we expect a good response to continue?

Takahagi: Yes. We intend to secure even better responses from now on.

Q: Next, regarding the first-line treatment of gastric cancer in Japan. In the end, I do not know when the clock started in the application review, either in May or December last year, but I think you mentioned previously that the approval would be in March or April at the earliest. In that case, I am wondering if it will be reviewed in the subcommittee in February. If so, would you still be looking at a subcommittee meeting in February?

Idemitsu: Given that this is a matter of discussion with the authorities on regulatory matters, I am sorry that we would like to refrain from answering.

Q: Understood. Next, regarding the figures, sales in Europe were between JPY200 - 300 million per quarter, but then it increased to JPY2.2 billion in the space of a single quarter. Is this because of the start of payment from Roche? Is this expected to continue in January to March, and is it correct to say that this is connected to the upward revision with the royalty income of JPY3 billion?

Tani: That is right. As in the press release, the royalty payment started in January 2020, so the payment for the period is included this time. Therefore, it will be in the European part, as Roche is an European company.

Q: In October to December and July to September, there was a slight downward trend in the number of new esophageal cancer patients. Are there some signs that the trend is coming to a halt?

Takahagi: I think that your understanding is fine. At the time of approval, Opdivo was prescribed for a considerable number of patients, such as waiting patients, fourth-, and fifth-line patients. Since then, the number of such patients has been decreasing steadily.

Patients are currently prescribed this medication as second-line or third-line therapy in which it was not partially prescribed. At present, I think it is leveling off for third-line treatment or thereafter. However, the share of second-line treatment prescriptions is growing steadily, so we expect to reach our target for, 65% share, by the end of March.

Q: It is reported that ankle joint has been excluded from the indication of Joyclu in the subcommittee meeting. You might suggest that I ask this of Seikagaku, but basically, I think major target is knees and hips. Can you tell us if there is any impact on the target patient number due to the ankle being excluded?

Idemitsu: I think the analysis of the details will be at a later date, but the knee joint was the biggest market, for which indication we have got an approval.

Q: Next, ONO-2909 is now in clinical trials targeting at narcolepsy, but I think prostaglandins have been said to be associated with sleep for a long time. On the other hand, development of the compounds having the effect on orexin is progressing, and I was wondering how this compound compares to orexin? Do you have any information about that, in particular with regard to efficacy? I appreciate that it is still Phase I, but I would appreciate if you would show any information, even from animal tests?

Idemitsu: Orexin and PGD_2 have completely different effects. Orexin acts on the arousal center, while PGD_2 acts on the sleep center. I think you know the effect of orexin from clinical data published from other companies, but we need to confirm the efficacy of DP antagonist in the future clinical trials. We do not know at this moment which is more effective or how they differ in terms of characteristics.

Q: Are you targeting at the domestic market only or globally? Do you think the global market, if possible?

Idemitsu: The compounds that will come out in the future are basically considered to be developed for the global market. Of course, this compound is of course considered to be global.

Q: Understood.

Q: Firstly, please tell us two things about the impact of the bribery incident. At another company where an employee was arrested on suspicion of bribery against the same university, they have announced that a considerable number of suspension measures have been imposed from the part of the customer. What impact do you think this will have on your company in the future?

When considering the impact on patients, I think that it is very unlikely that you have a substantial impact on sales and that your company's drugs will not be used, but what practical impact, if any, do you think this will have?

The second question relating to this. I think that, at present, many things are becoming a problem, but when you review other sales activities in the future, there may be cases where similarities are recognized, and you may have to change the way you sell. While this depends on the current selling method, do you think there is any risk of a slight change in sales figures if the selling method is changed?

Tani: Regarding the first question, we are now verifying the case. Although we do not offer the university name, in one case, we have received such a notice of suspension of trading. However, this involves direct business transactions between companies and universities, and as we have confirmed, there is no relationship with pharmaceutical products currently being used. I think we need to examine whether this is true of other universities, as well.

The other thing is that products are usually delivered through wholesalers, which are contracted on a six-month or three-month basis. Therefore, presumably, sales by the end of March will have almost no impact if

this trading is halted. However, I would like to keep a close watch on whether there will be any impact from April onward and report on the situation in the future.

Q: Understood.

Ichikawa: First of all, I would like to apologize for the concern and inconvenience caused. As for the second part, I think this is a question about whether there is a change in the selling method and if there is a risk of sales decrease.

As you know, the event itself was in FY2017. We began a public offering system in FY2019, in order to increase the transparency of scholarship donations. In other words, we have already shifted to a public offering system from each university by using the Web since FY2018. The case under discussion was before that switch.

Therefore, in this sense, we do not expect any impact on the method of selling. This is all.

Q: Regarding ONO-4059, Gilead still possesses rights outside the oncology field. How much is the development outside of this oncology currently moving, and what kind of motivation does Gilead show?

Idemitsu: We cannot answer any details, but we are actively considering with Gilead the development plan for areas other than oncology.

Q: I would like to ask a little about the lump-sum payment and royalty income received from Roche. In addition, there is a lump-sum payment in other income, and the royalty on Tecentriq received from Roche in royalty income. Is that correct?

Tani: That is right.

Q: I think your Company was receiving it back to January 2020. Are these figures compiled into the Oct – Dec period?

Tani: That is right. As is also written in the release, it has been occurring since January 2020, so that amount is recorded this time.

Q: You mean the payment for 12 months from January to December has been paid in the three months of this period.

Tani: Nine months instead of 12 months. Until now, Bristol royalty is directly connected to that month, but as same as Merck payments are delayed by three months, it is delayed by three months, it includes the portion from January to September.

Q: The second question is about Opdivo in lung cancer. I think there was a variety of news at the end of last year: e.g. 1) Indication was withdrawn overseas for SCLC, and 2) The combination treatment of Keytruda and ipilimumab did not show any difference in PD-L1 positive patients, compared to monotherapy.

From this data, and based on the update, how will the potential for use of Opdivo in lung cancer change? Will it be negatively impacted? Do you have any forecasts of how this will affect business performance?

Takahagi: I believe you are referring to the pembrolizumab data published at the last World Conference on Lung Cancer, is that correct?

Q: Yes.

Takahagi: First of all, I would like you to consider that the recently announced data for pembrolizumab and ipilimumab are not those with Opdivo combination therapy. First, CM-227 and 9LA regimens approved in Japan are approved in all comers regardless of PD-L1 expression.

In addition, we are currently making activities. Based on the overall survival data of competing products, our strategy now is to focus on PD-L1 expression 1 - 49%, and negative patients. Considering this point, we do not believe there will be a significant impact from the recently announced data.

In the future, with respect to the regimen of CM-9LA, I also think that we will be able to compete sufficiently in patietns with PD-L1 expression more than 50%, depending on the follow-up data. I would like to communicate this to medical professionals.

Q: I would like to ask about the one-time deposit that Roche has allocated. My calculations show that sales around the world for the year up to December last year are around JPY520 billion. Assuming a lump-sum payment of JPY6 billion, the royalty ratio would be around 1.2% to 1.3%. It seems to be a bit lower than the Keytruda royalty. I would first like to ask why you decided on that low level.

And next, I understand that they pay royalties until 2026. I think that the Keytruda royalty ratio will fall from 2024, but will the royalty ratio change even in the case of Tecentriq?

Tani: Regarding the content of the contract, we cannot give precise details. However, the circumstances of this contract are slightly different from those with Merck. The circumstances related to this anti PD-L1 are changing. I cannot be more precise than that, so I hope you understand.

Q: Other than Tecentriq, I think that other PD-1 and PD-L1 are on the market by other companies. Are you also negotiating with those companies?

Tani: Although we cannot provide details, we intend to make full use of the assets of our intellectual property.

Q: First of all, business performance is extremely strong, while it was increased by JPY7 billion between the beginning of the term and the second quarter, and this time again, it is JPY7 billion increase. However, with the revision of the increased amount in the second quarter, this is because R&D and SG&A expenses were reduced by the same amount, so I think that explains it. Can the upward revision be basically explained by JPY7.5 billion in other income including that from Roche?

Tani: That is right. As stated in the financial results report.

Nagahama: Regarding the forecast on page 4 of the financial results report, I think that the expected lump-sum payment from Roche is written in terms of the extent of the increase in profits and other income. I think the influence is big.

Q: Understood. Furthermore, SG&A expenses have been reduced by JPY3 billion in the second quarter, and the third quarter has been negative by almost JPY3 billion. However, it is difficult to operate the business in the midst of this situation, and I think there are changes from the conventional sales and marketing by introducing medical Internet and so on. How should we consider these changes?

Nagahama: Even if they are not conventional activities, we are investing in web-based lectures or promotional materials, and also in digitalization of sales contents, so it is possible to confirm the recording of expenses.

Q: Understood. Next, regarding Opdivo, in areas such as gastrointestinal cancer, and renal cell carcinoma, in the second quarter, the figure increased by JPY8 billion to JPY98 billion, and in the third quarter, by JPY27.3 billion, which is 10% increase on a quarterly basis. Given that, I felt that 4Q would be better. However, there was no change in the forecast this time. Do you have any particular issues?

Takahagi: Usually, considering the percentage and proportion of Opdivo sales annually, there was no doubt that the fourth quarter would settle around 22-23%. We have made this plan from that point of view.

Currently, we are seeing sales growth in some types of cancer, while the situation is becoming somewhat tougher in others. Especially in head and neck cancer, the sales of competing products have been considerable growths, and the figures are negative. Considering the positive and negative factors, we expect it to be largely within this level in the fourth quarter.

Q: Understood. My last question is about the transfer of Kinedak to Alfresa Pharma. There are cases in which companies either transfer generics or the products listed for long periods in bulk, or in categories, but this is just Kinedak. Or should we consider this as an opportunity to separate off unprofitable or low-profit items?

Tani: We have transferred five injectable products to Maruishi Pharmaceutical in 2018. This time, Kinedak is only transferred.

Q: Do you mean that there was a request from the other party?

Tani: I am afraid I cannot answer that.

Q: So, this does not mean that other products will be reviewed in the same way in the future. This time, Kinedak only is transferred.

Tani: That is right. As mentioned in press release.

Q: I have just one question. In considering the potential of Adlumiz, in the case of the relevant indication, what is the expected number of eligible patients? I think you also have the rights in Korea or Taiwan, so could you tell me about the development strategy with relation to this?

Ichikawa: In January 2021, we obtained manufacturing and marketing approval for the treatment of cancer cachexia in non-small cell lung cancer, gastric cancer, colorectal cancer, and pancreatic cancer. The product will be released in April. We consider that 80% of patients with cancer cachexia in advanced cancer are patients with 4 types of cancer just explained. From a variety of data, 50% to 80% of patients with non-small cell lung cancer, stomach cancer, colorectal cancer, and pancreatic cancer are eligible for the treatment.

Idemitsu: We are currently considering how to proceed with the development in Korea and Taiwan.

Q: Regarding heart failure, Forxiga and Coralan, I think there is quite a lot of potential here. Could you explain a little bit about what the situation is now?

Ichikawa: Firstly, market penetration of Coralan is very slow due to the coronavirus pandemic. We are currently implementing a variety of sales strategies by changing our operations on Web, but I think this is extremely challenging. While we are providing information on the importance of heart rate management via website, we believe that this it is very tough situation to achieve our fiscal year's target sales of JPY1.5 billion.

Regarding Forxiga tablets, as you have pointed out now, we believe that they have enormous potential. After we acquired the approval for the treatment of chronic heart failure on November 27, 2020, we have received inquiries from a very large number of medical institutions. We are looking at JPY22.5 billion, an increase of about JPY4.5 billion from JPY4.4 billion in the full year sales. In addition, we believe that there is tremendous potential for Forxiga, in terms of the competitive environment.