ONO PHARMACEUTICAL CO., LTD.

Financial Results Briefing for the Fiscal Year Ended March 2020

May 13, 2020

[Number of Speakers]	6	
	Gyo Sagara	President, Representative Director, and CEO
	Hiroshi Ichikawa	Corporate Executive Officer, Executive Director, Sales and Marketing
	Toichi Takino	Corporate Executive Officer, Executive Director, Discovery and Research
	Kiyoaki Idemitsu	Corporate Officer, Executive Director, Clinical Development
	Satoshi Takahagi	Business Unit Director, Oncology Business Unit, Sales and Marketing
	Yukio Tani	Corporate Executive Officer, Head of Corporate Communications

Revenue

Revenue	YoY Change
¥ 292.4 billion	+ 1.3 %

Breakdown of Revenue

(Billion yen)

	FY 2018	FY 2019	YoY Change
Revenue of Goods and Products	208.9	205.6	− 1.6 %
Royalty & other revenue	79.7	86.8	+ 8.9 %
(Opdivo)	(58.5)	(61.6)	(+ 5.3 %)
Total	288.6	292.4	+ 1.3 %

Sagara: Revenue increased by 1.3% YoY to JPY292.4 billion. Breaking this down, product sales are down 1.6% and royalties and other revenues increased by 8.9%.

Revenue

Sales of Major Products

(Billion yen)

	FY 2018	FY 2019	YoY Change
Opdivo	90.6	87.3	- 3.6 %
Glactiv	26.9	26.1	- 3.1 %
Orencia SC	17.4	19.8	+ 13.8 %
Forxiga	14.5	18.1	+ 24.7 %
Emend/Proemend	10.6	10.7	+ 1.0 %
Rivastach	8.9	8.5	- 4.2 %
Parsabiv	5.7	7.1	+ 23.6 %
Kyprolis	4.9	6.0	+ 21.9 %
Onoact	4.6	4.9	+ 6.2 %
Staybla	3.7	3.1	- 17.1 %

Regarding sales of major products, sales of Opdivo were JPY87.3 billion, down JPY3.3 billion. Glactive sales was slightly down. The products which contributed to the sales increase were Orencia, Forxiga, Parsabiv, and Kyprolis.

Revenue

Sales of Long-term Listed Products

	FY 2018	FY 2019	YoY Change
Opalmon	10.4	8.3	- 19.5 %
Recalbon	7.3	4.7	- 35.4 %
Onon capsule	4.4	3.5	- 21.0 %
Onon dry syrup	2.7	2.2	- 19.1 %

Long-listed products continue to see significant falls in sales. The ratio has been decreasing, but the negative trend has still continued every year. Other than these 4 products, sales of Foipan, Kinedak, and other long-listed products have declined considerably.

Operating Profit

Operating Profit	YoY Change
¥ 77.5 billion	+ 25.0 %

Costs, etc.

		(YoY Change)	
・Cost of sales	¥ 79.1 billion	(−5.7 %)	
・R&D expenses	¥ 66.5 billion	(−5.0 %)	①
・SG&A expenses	¥ 67.7 billion	(−3.4 %)	②
①+② Total	¥ 134.2 billion	(−4.2 %)	
・Other income	¥ 0.8 billion	(+27.2 %)	
・Other expenses	¥ 2.5 billion	(−26.1 %)	

Operating profit has increased by 25.0% to JPY77.5 billion. Cost of sales decreased by 5.7%. This could be because product sales have declined, by which the ratio of costs to sales has declined, and because the temporary costs associated with Opdivo (active ingredients) production facilities occurred in the previous period, but the costs have been finished in this period.

For R&D expenses, there were some development projects which had been canceled and delayed in this period, which resulted in less expenses than planned. R&D expenses were JPY66.5 billion, down 5.0%.

In terms of selling, general and administrative (SG&A) expenses, we planned to hold a number of comparatively large lectures in February and March. These have been postponed due to coronavirus. As a result, SG&A expenses were lower than anticipated.

Profit before Tax

Profit before Tax	YoY Change
¥ 79.7 billion	+ 22.3 %

Net financial income

+ ¥ 2.2 billion (- ¥ 0.9 billion)

Finance income :	**¥ 3.1 Billion**
(Interest and dividend income received, etc.)	
Finance costs :	**¥ 0.8 billion**
(Interest expense arising from lease obligations and employee retirement benefit, etc.)	

Profit before tax was JPY79.7 billion, an increase of 22.3%.

Profit for the Period
(Owners of the Parent Company)

Profit for the Period (Owners of the Parent Company)	YoY Change
¥ 59.7 billion	+ 15.8 %

Income tax expense

¥ 19.8 billion	(YoY Change + 47.1 %)	
Statutory effective tax rate	30.6 %	(30.6 % prior year)
Actual av. burden tax rate	24.9 %	(20.7 % prior year)

(Major change factors)

Increase in profit before tax
Increase in corporate tax

Profit for the period increased by JPY59.7 billion, an increase of 15.8%.

Next, we will now move on to the earnings forecast for the next fiscal year. I would like to start by talking about our underlying assumptions.

First, when a new product is scheduled to be launched or an additional indication approval is anticipated, the sales of such products were not included in the original earnings forecast. We have made adjustments when the product was actually launched. This is the pattern we have followed so far. On the other hand, costs associated with the launch of new products were included in the initial forecasts. This results in an imbalance, so from this fiscal year onward, we are incorporating both the sales forecast and the expense forecast in our overall forecast. This is the first assumption.

Another assumption is that social restrictions due to this new-type coronavirus will continue until the end of June. Although we do not expect to return to business as usual from July onward, we provide sales and earnings forecasts based on the assumption that the current situation will continue until the end of June at least. The forecast is based on these assumptions.

Revenue (Forecasts)

Revenue	YoY Change
¥ 303.0 billion	+ 3.6 %

Breakdown of Revenue

(Billion yen)

	FY 2019 (Result)	FY 2020 (Forecast)	YoY Change
Revenue of Goods and Products	205.6	210.0	+ 2.1 %
Royalty & other revenue	86.8	9.3	+ 7.1 %
Total	292.4	303.0	+ 3.6 %

Revenue is forecast to increase 3.6% YoY to JPY303 billion. The price revision had a negative impact of about 2% in the April figures. Excluding the impact on the price revision, so on that basis, sales will increase by about 5%. Product sales are forecast to rise by 2.1% to JPY210 billion from JPY205.6 billion. Royalties and other revenues are forecast to increase by 7.1% to JPY93 billion from JPY86.8 billion.

Revenue (Forecasts)

Sales Forecasts of Major Products

	FY 2019 (Result)	FY 2020 (Forecast)	YoY Change
Opdivo	87.3	90.0	+ 3.1 %
Glactiv	26.1	25.0	- 4.1 %
Forxiga	18.1	22.5	+ 24.6 %
Orencia SC	19.8	21.5	+ 8.4 %
Rivastach	8.5	8.5	- 0.3 %
Parsabiv	7.1	7.5	+ 6.1 %
Kyprolis	6.0	6.5	+ 8.4 %
Onoact	4.9	6.0	+ 23.4 %
Proemend	2.6	3.5	+ 33.3 %
Products to be newly launched	–	5.0	–

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Forecast sales are in order of large sales volume, starting with Opdivo at the top. Opdivo sales is expected to be JPY90 billion this fiscal year. Forxiga, Orencia, Onoact, and Proemend are all expected to contribute to revenue growth.

Moving on to new products, we anticipate total sales of JPY5 billion for new products. Velexbru is scheduled for launch in May, and Ongentys is scheduled to be launched in August. Joyclu is scheduled for launch in February next year. In addition, there is no clear plan for Anamorelin, but we expect that it will start to contribute in the second half of the fiscal year.

These four products are expected to generate sales of roughly JPY5 billion, and it is expected that they will gradually increase from the second half of this fiscal year and contribute significantly in the next fiscal year.

There are several filing plans for additional indications. We expect that Opdivo will gain an approval for indication of the first-line treatment of lung cancer in the second half of the fiscal year. As I mentioned, the sales for the indication is included in the product sales forecast.

Revenue (Forecasts)

Sales Forecasts of Long-term listed products

	FY 2019 (Result)	FY 2020 (Forecast)	YoY Change
Opalmon	8.3	5.0	- 40.0 %
Emend capsule	8.1	3.5	- 56.7 %
Onon capsule	3.5	3.0	- 13.1 %
Recalbon	4.7	2.0	- 57.8 %

With regard to the sales forecast for long-listed products, there is a steadily declining trend. The negative trend is especially marked in the case of Emend. The significant sales decline is because the drug price dropped significantly due to the price maintenance premium, and sales declined on a volume basis. The same applies to Recalbon. That's why revenues from these two products fell drastically from this term.

Operating Profit (Forecasts)

Operating Profit	YoY Change
¥ 80.0 billion	+ 3.2 %

Costs, etc.

		(YoY Change)
・Cost of sales	¥ 81.5 billion	(+ 3.1 %)
・R&D expenses	¥ 69.0 billion	(+ 3.8 %)
・SG&A expenses	¥ 70.0 billion	(+ 3.4 %)
①+② Total	¥ 139.0 billion	(+ 3.6 %)
・Other income	¥ 0.5 billion	(− 39.2 %)
・Other expenses	¥ 3.0 billion	(+ 19.4 %)

Operating income is forecast to rise 3.2%, to JPY80 billion. Cost of sales is forecast to increase by 3.1%. R&D expenses are forecast to return to the previous level of around JPY70 billion from this fiscal year. Selling, general and administrative (SG&A) expenses are also forecast to be JPY70 billion, based on the assumption that activities will be steadily followed up from July onward.

Profit before Tax (Forecasts)

Profit before Tax	YoY Change
¥ 82.0 billion	+ 2.9 %

Net financial income

+ ¥ 2.0 billion (- ¥ 0.2 billion)

Profit before income tax is forecast at JPY82 billion.

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

Profit for the Period (Owners of the Parent Company)	YoY Change
¥ 61.0 billion	+ 2.2 %

Income tax expense

¥ 20.9 billion (YoY Change + 5.5 %)

(Major change factors)

Increase in profit before tax	¥ 2.3 billion
Increase in corporate tax	¥ 1.1 billion

We forecast a 2.2% increase, to JPY61 billion in profit for the period.

Status of Cross-shareholdings

	End of March 2018	End of March 2020	YoY Change
Number of listed brands	111	**80**	**(- 27.9 %)**
Balance sheet amount	¥ 167.1 billion	¥ 125.7 billion	(- 24.8 %)
the market price at the end of March 2018	¥ 167.1 billion	**¥ 135.0 billion**	**(- 19.2 %)**

Next is the status of cross-shareholdings. In October 2018, we started moving forward with the plan of reducing our shareholdings by 30% over the 3 years from October 2018, against those held at the end of March 2018. Just a year and a half has passed. Currently, on a monetary basis, 19% of the planned amount has already been removed, so I think this has proceeded smoothly. If we consider 15% to be halfway, we are slightly ahead of schedule. We will continue to proceed according to the schedule.

This is our financial result for this period and forecast for the next fiscal year.

Impact of the spread of new-type of coronavirus infection

Sagara: I would like to report on the current situation regarding the impact of coronavirus.

First, production-related issues. At Fujiyama Plant and Yamaguchi Plant, we have been manufacturing as usual. Production is proceeding as usual, as we pay maximum attention to safety.

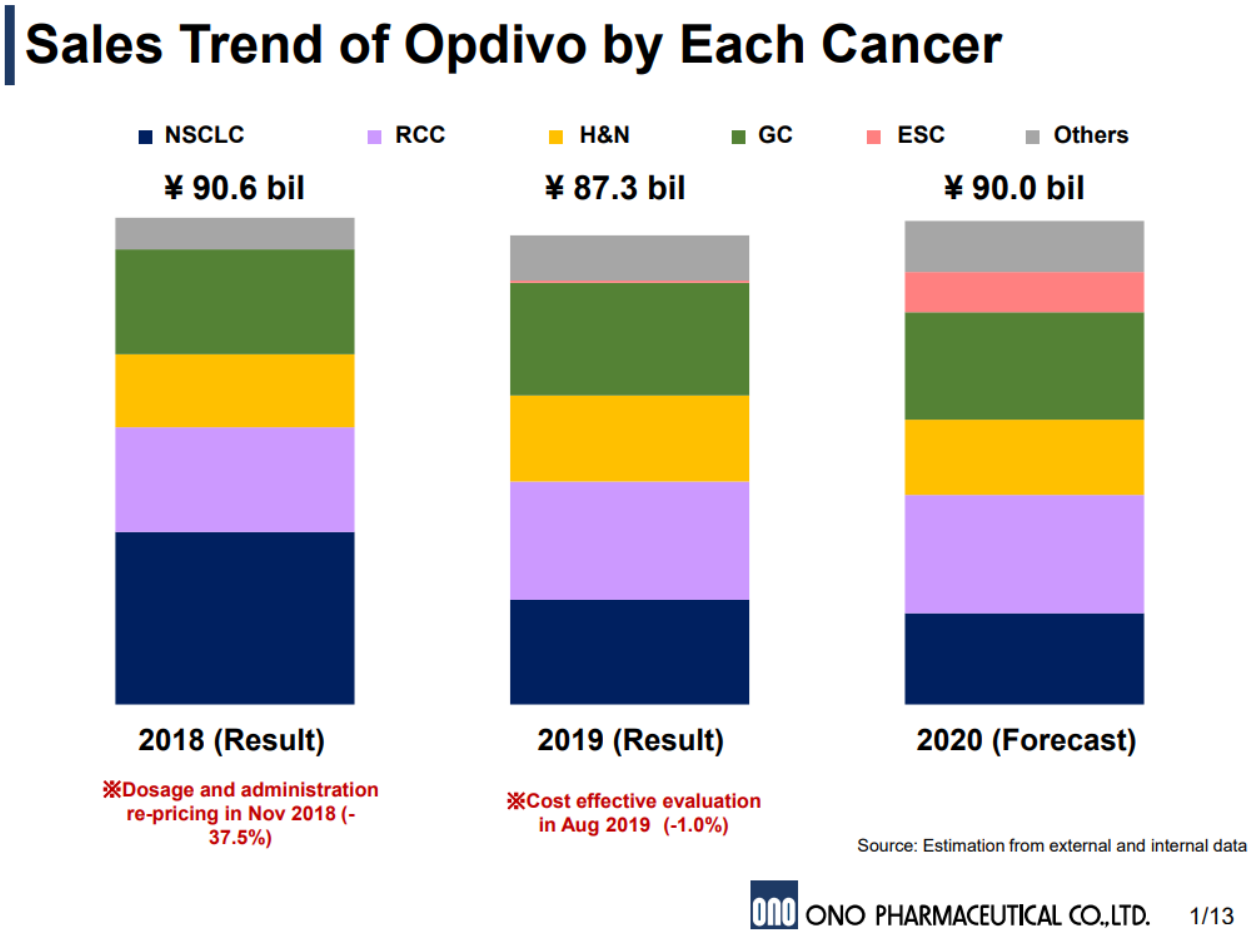
We currently have three months of product inventory and also procure raw materials for three to six months. We have a system in place to supply products for six months or more, even if all supplies are discontinued. The logistics line is currently operating as usual, so I think there are no problems.

Regarding marketing activities, we have stopped all visits and I think that this is applicable to all pharmaceutical companies. There is a concern about what effect this will have, but as of March, there was no effect. From April onward, it appears the number of clinic attendances has been decreasing. On the other hand, since prescriptions are for a long period of time, and patients who were on monthly prescriptions are being switched to two- or three-monthly prescriptions, we are not seeing any effect here.

If this continues, there are concerns about what will happen with the four new products, and with additional indication approvals. There may be a delay in market penetration.

In the US and Europe, the recruitment of clinical studies have almost stopped. In Japan, the situation is similar. Even under such a situation, clinical studies should be continued to bring a therapeutic drug to patients, in the humane and moral point of view. As you may be aware, if such a condition continues, there may be impact.

The research division is also switching to remote work, but it is taking time. Some theme and work which can be restarted immediately later on are stopped, but some projects which may cause a significant impact if they are stopped have been continued. At present, there is no impact on results, but in the future, it is unclear whether there will be any short-term impact on sales. As for R&D, there is a possibility of an impact in the medium- to long-term.

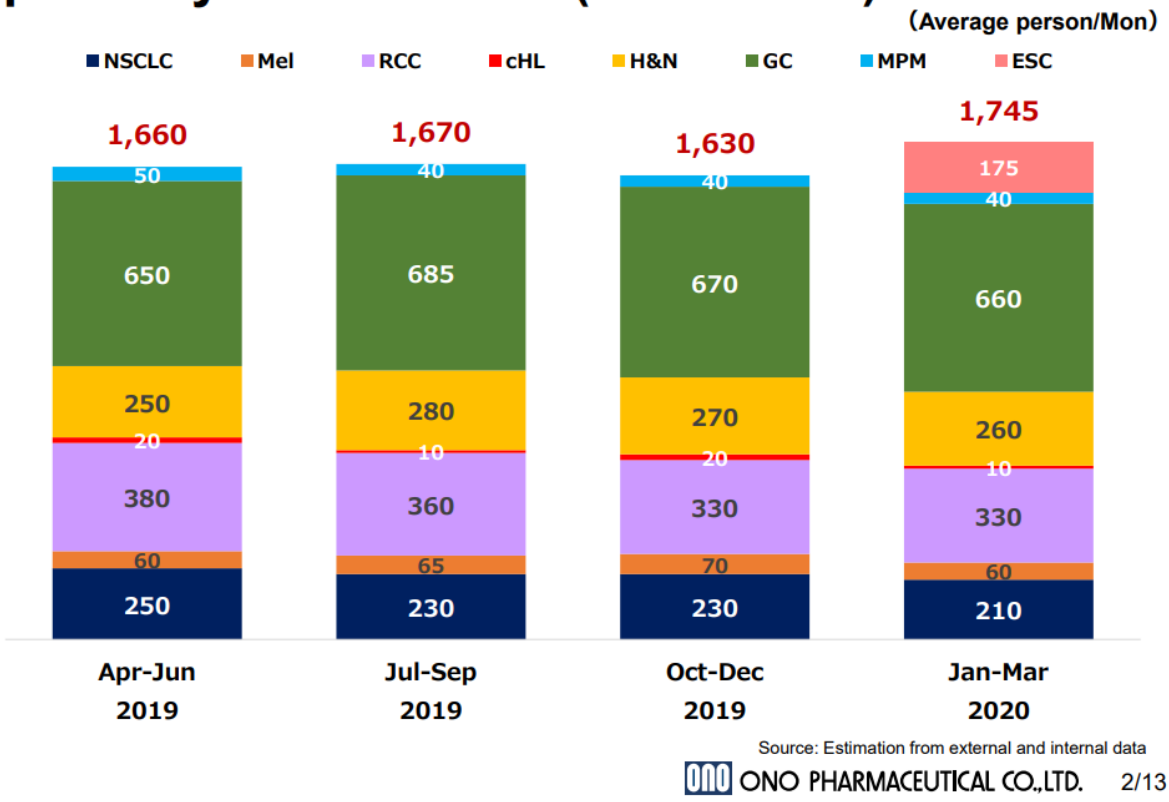


Takahagi: I will talk about the overall situation of Opdivo trends and situation of each type of cancer. I will also introduce the clinical data for esophageal cancer, for which approval was granted in February.

First, I would like to talk about sales of Opdivo. We have FY2018 results, FY2019 results, and FY2020 prospects from the left bar graph. In FY2019, we increased our prescriptions for renal cell carcinoma and other diseases. However, the net sales of Opdivo was JPY87.3 billion due to the impact of the drug price revision in November 2018, and the decline in new prescriptions for lung cance.

We forecast the sale for this fiscal year to be JPY90 billion, taking into account the positive factors to increase of new prescriptions for esophageal cancer, and to enter into the first-line lung cancer treatment, and also the negative factors of competition with competitive drugs and decrease in gaining new prescriptions for lung cancer.

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



Source: Estimation from external and internal data

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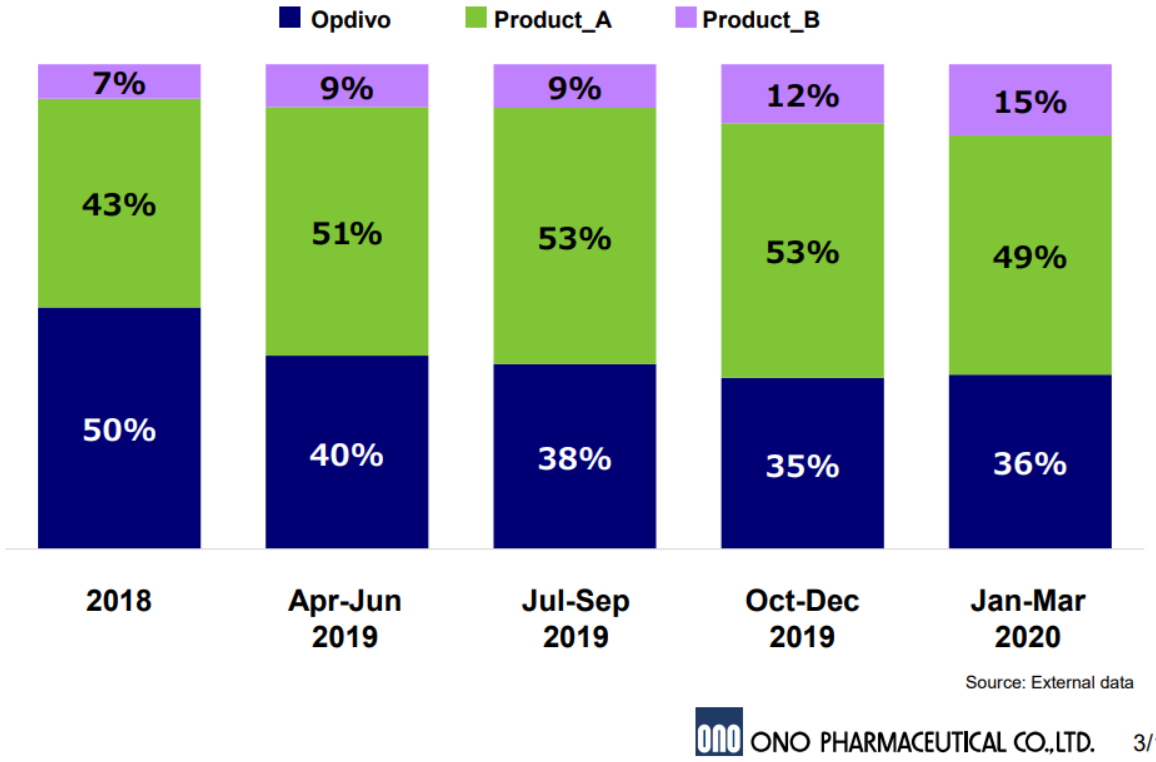
Changes in the number of new prescriptions for Opdivo by cancer type. It shows the average number of patients per month, divided by quarter from the quarter April to June 2019, to the quarter January to March 2020. Though these are our estimations, 660 patients were prescribed for gastric cancer and 330 for renal cell carcinoma in the quarter January to March 2020. In February and March, a total of 530 patients were prescribed for esophageal cancer, which was approved in February. Overall, the monthly average number of new prescriptions was 1,745.

As I mentioned earlier, I will touch on esophageal cancer later.

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



Source: External data

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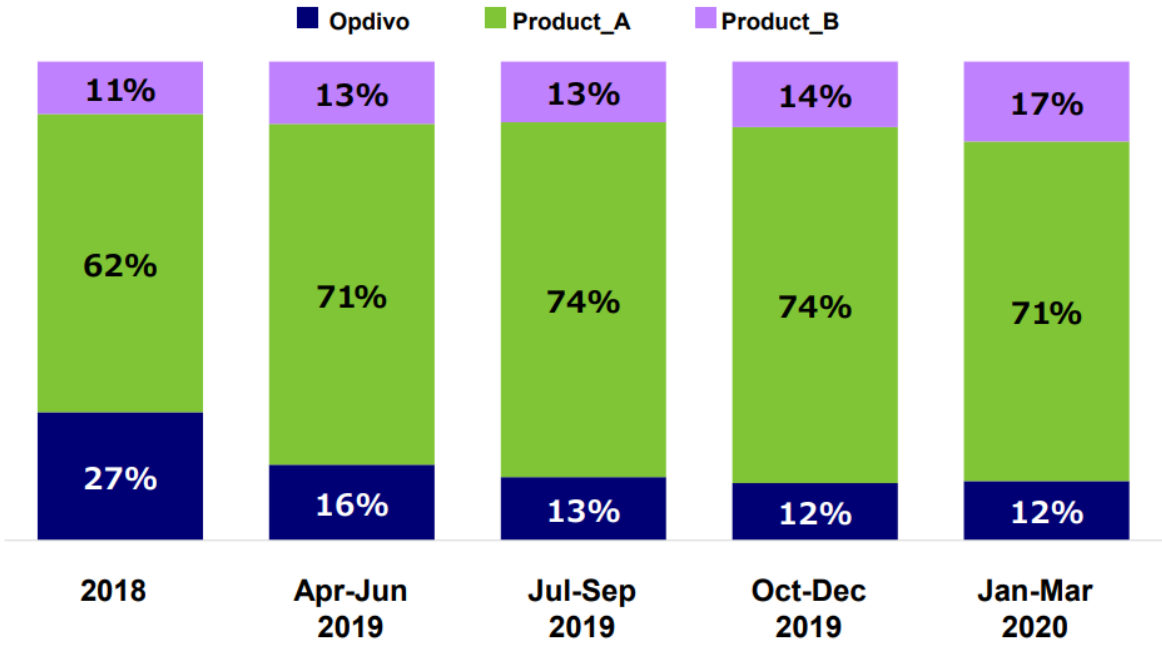
This shows sales composition ratios of the main immune checkpoint inhibitors that compete with Opdivo for all cancer types, divided quarterly from FY2018 to FY2019.

From January to March 2020, Opdivo held a 36% share of the main immune checkpoint inhibitor market.

Sales Ratio of ICPIs in NSCLC (Estimation)



Source: External data

I will now present information by cancer type.

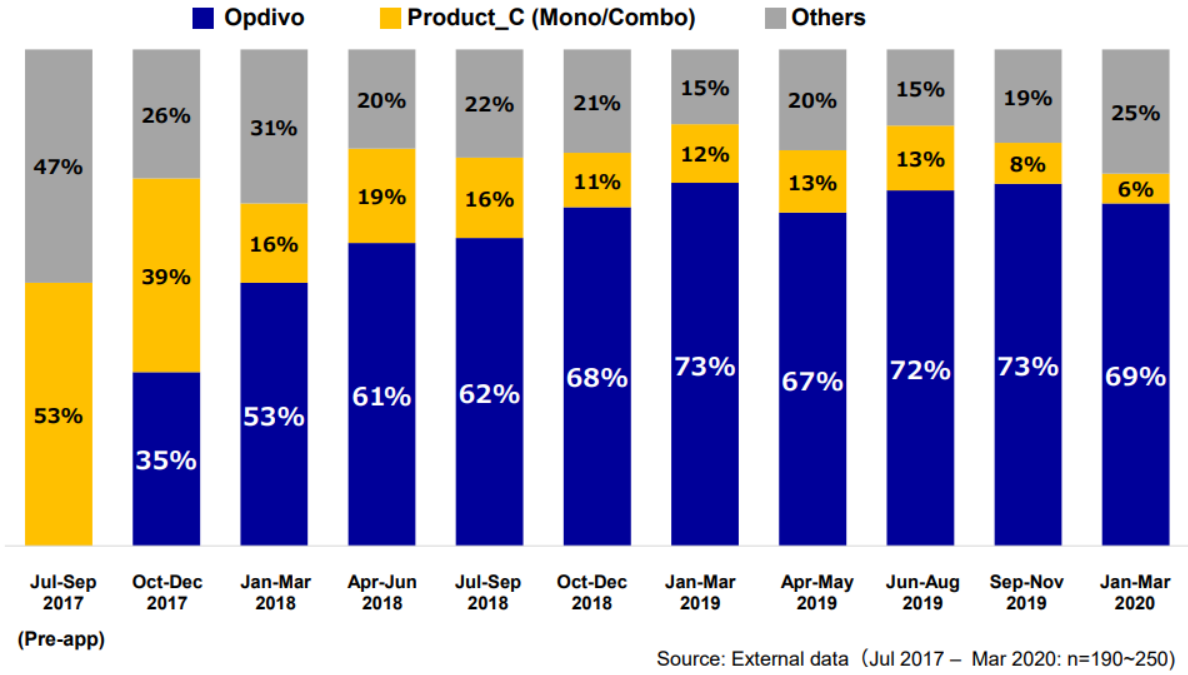
First, lung cancer. The graph shows the sales composition ratio of immune checkpoint inhibitors for all non-small cell lung cancer treatments, including first-, second-, and third-line treatments.

The market for immune checkpoint inhibitors for all lung cancer as a whole is likely to exceed JPY150 billion per year on an NHI price basis. We have divided the fiscal years 2018 through 2019 into quarterly periods and shown the changes in the market share.

Combination therapy with competitive immune checkpoint inhibitors has been approved for the first-line treatment of non-small-cell cancer, and the market share is expanding. However, Opdivo accounts for only 12% of the market, with only used for second-line or later treatment. Going forward, we will make steady progress in entering the field of first-line treatment of lung cancer in order to regain market share.

Prescription Ratio in Patients Newly Treated for 3rd Line Gastric Cancer

※ Patients starting 3rd line treatment of gastric cancer within the last 3 months



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

This graph shows changes in the share of new prescriptions for third-line treatment of gastric cancer.

We are working to acquire 70% share of new prescriptions for third-line treatment, and 65% transition rate from the second line to the third line as our goal. This slide shows the changes in the share of new patients in the third treatment. Although competitors have entered the market, Opdivo has acquired almost the targeted 70% share.

The transition rate for gastric cancer treatment, especially from the second line to the third line is around 55% to 65%. We will strengthen our activities in the gastrointestinal field including gastric cancer and esophageal cancer, without giving up our established position in this field.

Opdivo: Marketing Expansion to New Indications

Opdivo approved for two new indications on Feb 21, 2020

1. Esopahageal cancer (2nd-line treatment)

Unresectable advanced or recurrent esophageal cancer that has progressed following chemotherapy

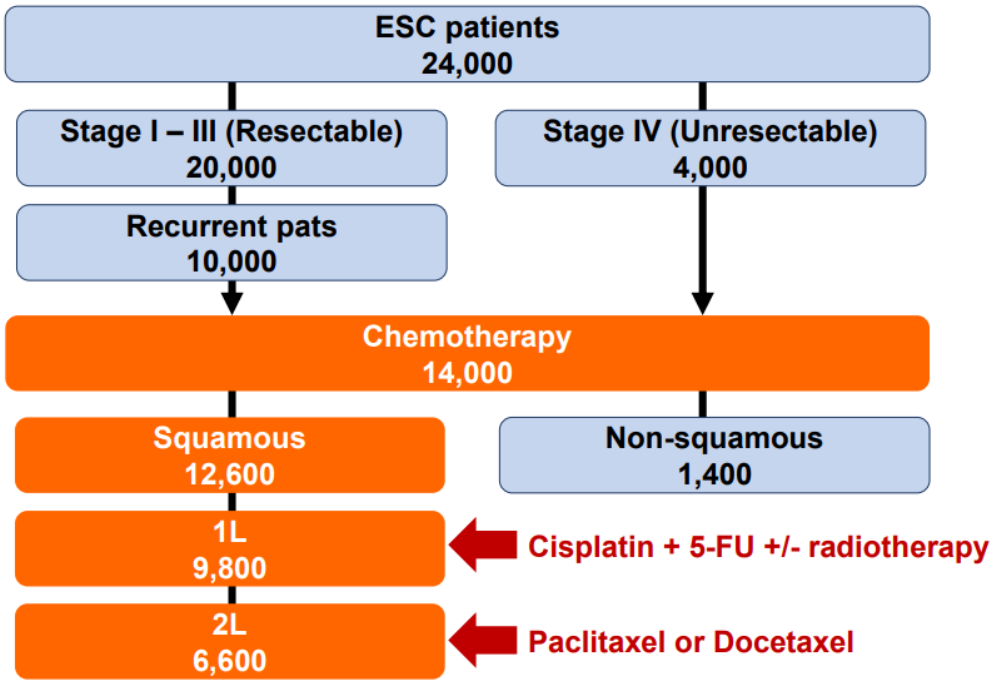
2. MSI-High colorectal

Microsatellite instability high (MSI-High) unresectable advanced or recurrent colorectal cancer that has progressed following chemotherapy

I will touch on esophageal cancer.

On February 21 of this year, Opdivo received approval for two new indications. The first is for the second-line treatment of esophageal cancer, and the second is for MSI-high colorectal cancer. Today, I will talk about the second-line treatment of esophageal cancer.

Number of ESC patients per year (in Japan)



Estimation based on internal survey (2020)

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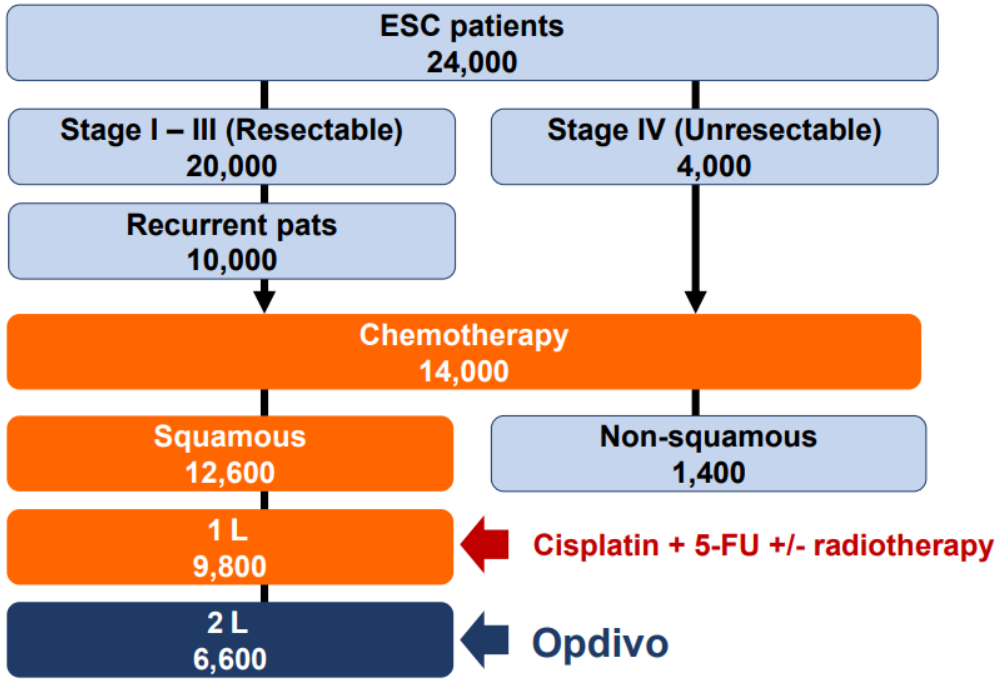
We estimate that there are 24,000 patients newly diagnosed with esophageal cancer per year in Japan, including 14,000 with recurrent or unresectable disease.

Opdivo is targeted at squamous cell cancer, which accounts for 90% of all esophageal cancer. We believe that annually, 9,800 patients receive first-line treatment, and 6,600 receive second-line treatment. The conventional first-line treatments used were a treatment known as FP therapy, which is a combination of cisplatin and 5-FU, and radiotherapy. Conventional second-line treatments included paclitaxel and docetaxel.

Number of ESC patients per year (in Japan)



Estimation based on internal survey (2020)

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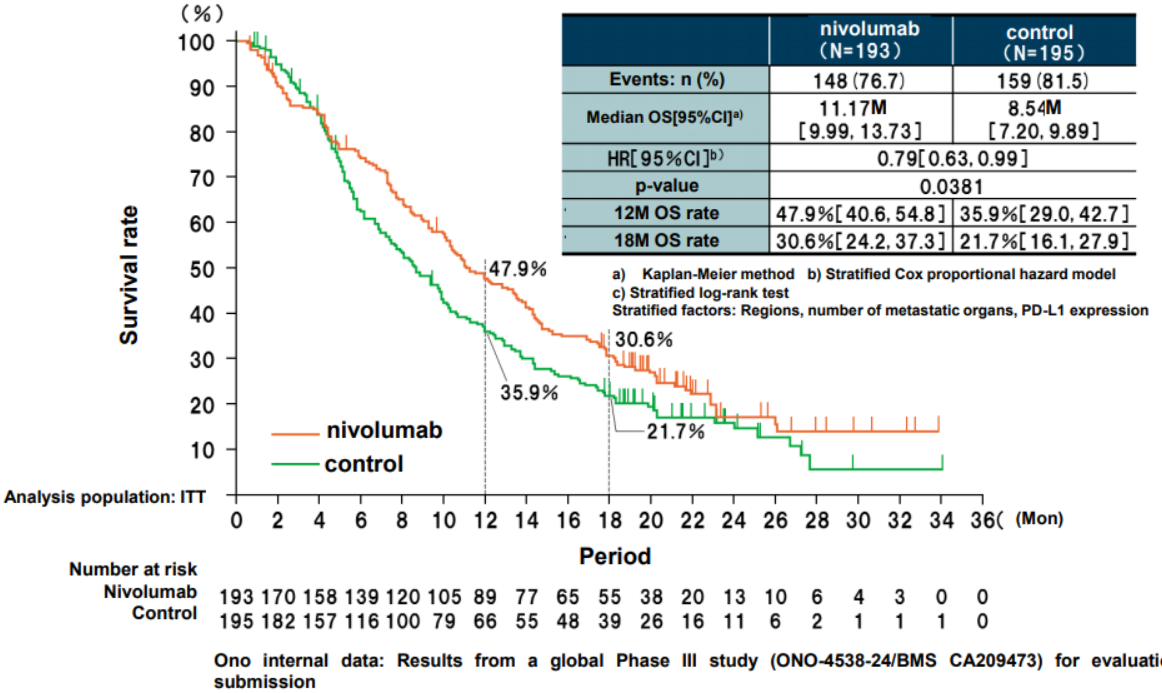
In a comparative study, Opdivo demonstrated significant extension of overall survival compared to paclitaxel and docetaxel and was approved.

As esophageal cancer is relatively common in Asia, there are no drugs highly recommended for second-line treatment. As a result, KOL in Japan had high expectations for Opdivo additional approval. Three weeks after obtaining approval, the Japanese Esophageal Society guideline preliminary report was issued. Opdivo is highly recommended for the second-line treatment for esophageal cancer, with evidence A. In addition, we had a strong recommendation for use of Opdivo, regardless of PD-L1 expression status, which is a very favorable tailwind for Opdivo. As of the end of March, 530 patients, including those on standby, had been prescribed with Opdivo, indicating a favorable start of the launch.

Going forward, we will aim to expand the use of this drug for the treatment of esophageal cancer, and in conjunction with gastric cancer activities, we will work to strengthen our presence in the gastrointestinal field.

ATTRACTION-3 Esophageal cancer (2nd-line treatment)

- Kaplan-Meier curves for overall survival (OS)　OS（primary endpoint)



	nivolumab (N=193)	control (N=195)
Events: n (%)	148 (76.7)	159 (81.5)
Median OS[95%CI]a)	11.17M [9.99, 13.73]	8.54M [7.20, 9.89]
HR[95%CI]b)	0.79[0.63, 0.99]	
p-value	0.0381	
12M OS rate	47.9%[40.6, 54.8]	35.9%[29.0, 42.7]
18M OS rate	30.6%[24.2, 37.3]	21.7%[16.1, 27.9]

a) Kaplan-Meier method b) Stratified Cox proportional hazard model
c) Stratified log-rank test
Stratified factors: Regions, number of metastatic organs, PD-L1 expression

Ono internal data: Results from a global Phase III study (ONO-4538-24/BMS CA209473) for evaluation at submission

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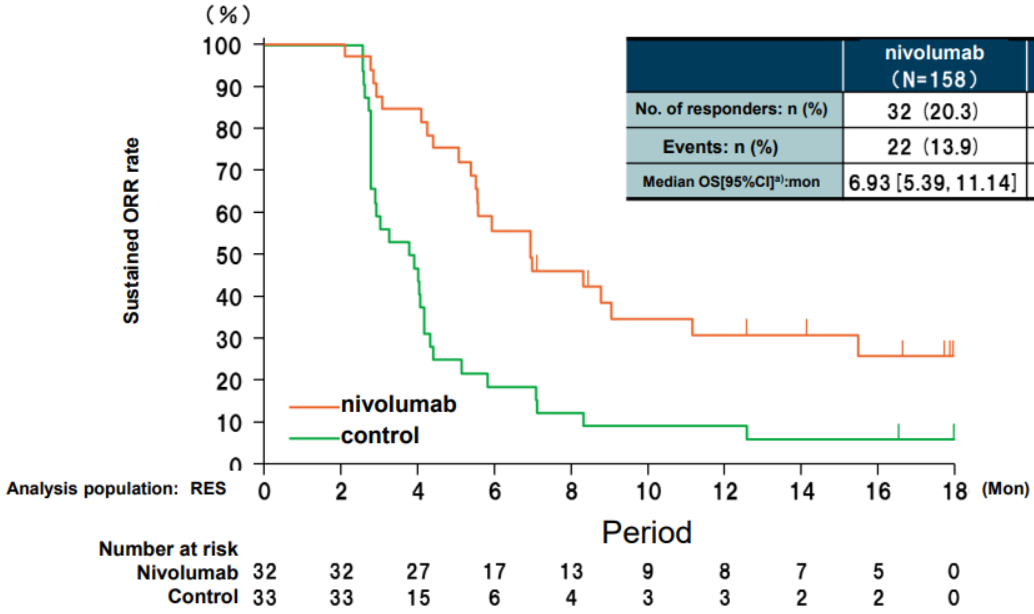
I would like to briefly talk about data from the Phase III ATTRACTION-3 study, which approval was gained.

This study is a comparative study evaluating Opdivo and taxanes such as paclitaxel and docetaxel, a standard treatment. Asian people were the focus of the study: 70% of the enrolled patients were Japanese.

Opdivo a significant extension of overall survival (OS), a primary endpoint, compared to the control group.

ATTRACTION-3 Esophageal cancer (2nd-line treatment)

● Kaplan-Meier curves for duration of response (DOR) in responders (Doctor's assessment in medical institutes



	nivolumab (N=158)	control (N=149)
No. of responders: n (%)	32 (20.3)	33 (22.1)
Events: n (%)	22 (13.9)	30 (20.1)
Median OS[95%CI]a):mon	6.93 [5.39, 11.14]	3.84 [2.79, 4.17]

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a) Kaplan-Meier method

Ono internal data: Results from a global Phase III study (ONO-4538-24/BMS CA209473) for evaluation at submission

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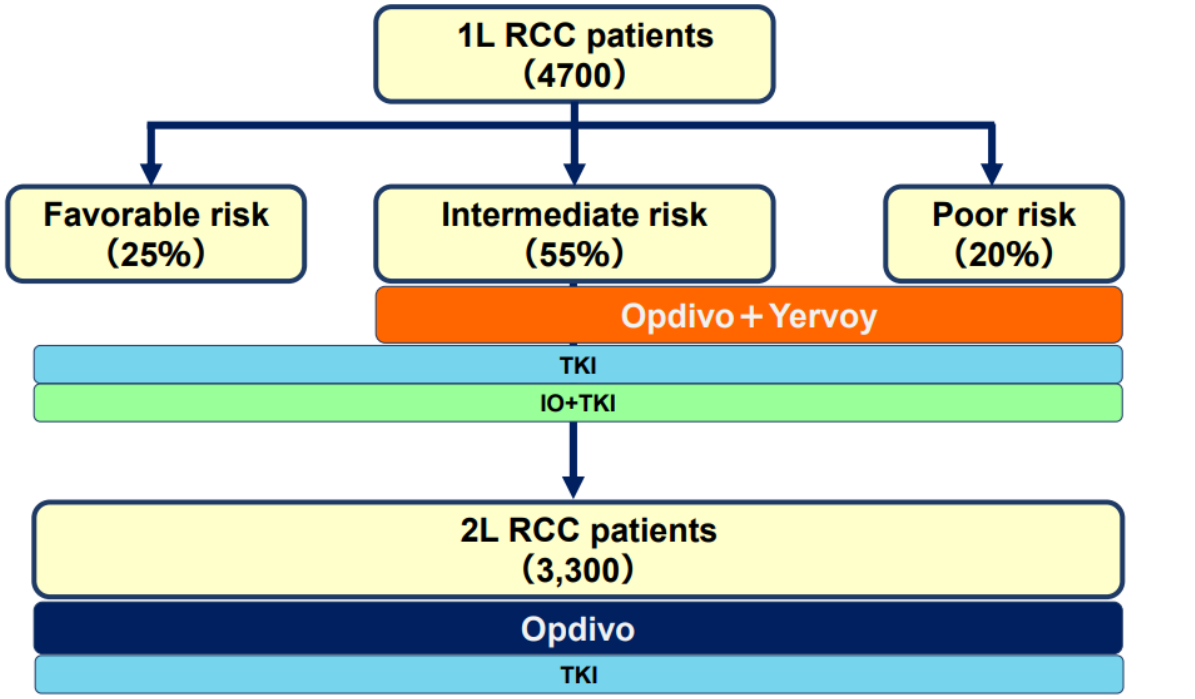
Opdivo showed an extremely high sustained overall response rate (ORR) in responders compared to the control group, in Kaplan-Meier curves as the characteristics of Opdivo, an immune checkpoint inhibitor, as observed in other types of cancers.

The usefulness of Opdivo has been highly evaluated by KOL, and we believe that it will become a standard second-line treatment of esophageal cancer in the future. In the gastrointestinal field, we are steadily developing our activities in gastric cancer, esophageal cancer, and colorectal cancer. We will proceed with our activities for the first-line gastric cancer to greatly expand a potentiality of Opdivo in the future.

Number of Patients Treated with Drugs for Advance or Metastatic Renal Cell Carcinoma (per Year in Japan)



Estimation based on internal survey (2020)

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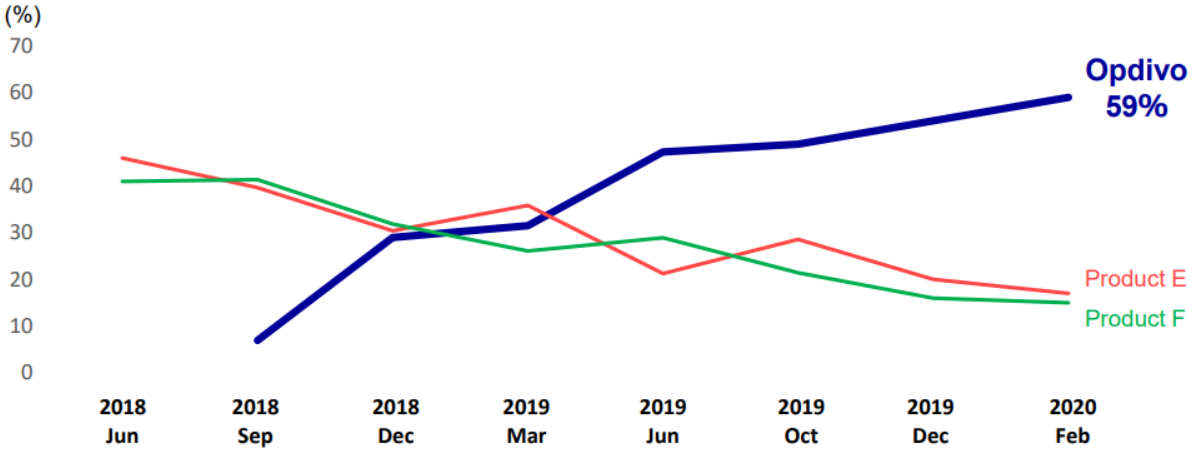
Regarding renal cell carcinoma, there is evidence for Opdivo in first-, second- or later line treatments of renal cell carcinoma. We are currently working to deliver Opdivo to all patients with renal cell carcinoma.

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

	2018 Jun	Sep	Dec	2019 Mar	Jun	Oct	Dec	2020 Feb	
Opdivo	**-**	**7**	**29**	**32**	**47**	**49**	**54**	**59**	(%)
Product E	46	40	30	36	21	29	20	17	(%)
Product F	41	41	32	26	29	21	16	15	(%)



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

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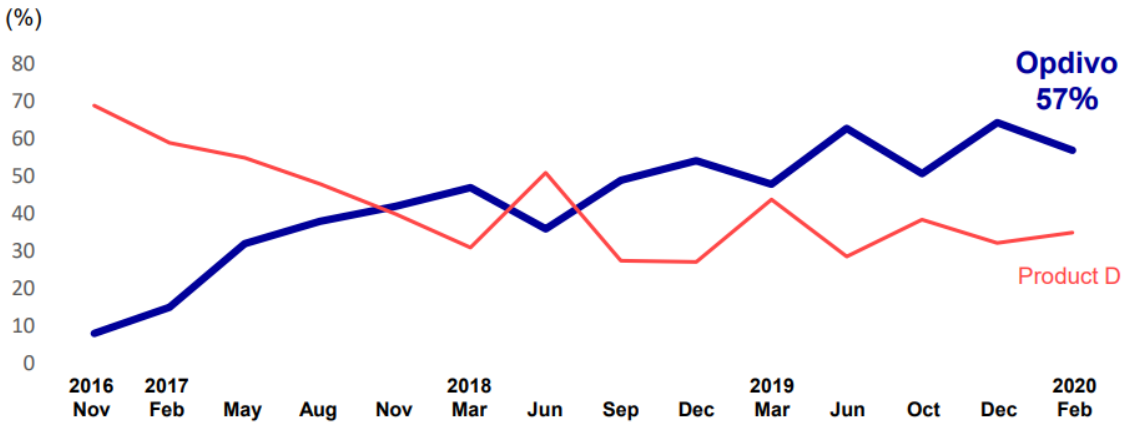
This table shows changes in the prescription ratio in patients newly treated for the first-line treatment of renal cell carcinoma.

This shows the new prescriptions share of Opdivo, including anti-cancer drugs, molecular-targeted drugs and kinase inhibitors, which are widely used for the first-line treatment. Following approval of combination therapy with Opdivo and Yervoy, the share of prescriptions of Opdivo and Yervoy has been rising steadily, reaching to 59% today.

In particular, looking at intermediate-to poor-risk patients, who are subjects to Opdivo and Yervoy combination therapy, we have captured 70% of prescription share in new patients. We will continue to acquire further share in this field.

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

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



Source: External data（Nov 2016 – Feb 2020: n=32~57)

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With the spread of Opdivo and Yervoy combination therapy in the first-line setting and a slight and gradual decrease in immune checkpoint inhibitor-naïve patients in the second-line setting, the share of new prescriptions gained is 57%. Going forward, we will continue our efforts to provide Opdivo treatment opportunities to all patients with renal cell carcinoma, in both first- and second-line treatments.

While we are developing our activities in renal cell carcinoma, 42-month follow-up data was presented at ASCO GU this year for a Phase III CheckMate-214 trial with Opdivo and Yervoy combination therapy in the first-line treatment of renal cell carcinoma, supporting our activities.

This data presented brought the Japanese KOL a necessity to think about a 6-year treatment period in Japan. We had a strong opinion from the KOL that this data is extremely useful to patients. As far as I know, this long-term data is not available for competitive products. I believe that this data can exert a significant competitive advantage for Opdivo.

Even in the 42-month follow-up data, Opdivo and Yervoy combination therapy showed a sustained superiority in OS compared with the control group.

In progression-free survival (PFS), the Opdivo and Yervoy combination group achieved a tail plateau in 35% of patients at 30 months, which showed I-O/I-O characteristics.

Going forward, we will continue to steadily develop our activities, maintaining our position established with Opdivo in intermediate- to poor-risk patients for the first-line treatment of renal cell carcinoma.

In the future, we will expand the market share of Opdivo. In particular, we expect to see significant growth in the area of first-line treatment of lung cancer and gastric cancer, which is most common type of cancer in Asia.

Our competitors have the lead in the area of first-line lung cancer treatment. There are still market needs remained for those who are PD-L1 negative or weakly-positive. These individuals account for two-thirds of the total market. Therefore, we would like to regaint this market share with the three regimens of the CheckMate-9LA and 227. In addition, we would like to expand the share in the largest first-line gastric cancer treatment market after receiving its approval.

Going forward, we will continue to deliver benefits to cancer patients, with the combination therapy of Opdivo and Yervoy. In particular, we will work to further expand the Opdivo market through communication with healthcare professionals about its benefits, such as long-term survival and sustained response.

I presented the overall situation and the trends of Opdivo by cancer type. We will continue our efforts to meet the unmet needs of cancer patients.

Development pipe-line

Idemitsu: I would like to present the progress of development products. First, I will make comments on the presentation materials.

The development progress since April last year is described on pages 3 to 5 of the financial results.

In addition, we have provided explanations on pages 7 to 14 of the Financial Results Supplementary Materials, focusing on the updates since the announcement of the financial results for Q3 on January 31.

Then, I will update the status of applications using the other materials.

I. Main Status of Development Pipelines (Oncology)

As of April 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	Colorectal cancer *1 (MSI-H)	Injection	Japan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer *2*3	Injection	Japan *2 S. Korea*3	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Primary central nervous system lymphoma *4 / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	Japan	In-house

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

*1: An application for Opdivo was approved in Japan for the treatment of microsatellite instability-high (MSI-H) unresectable advanced or recurrent colorectal cancer that has progressed following chemotherapy.

*2: An application for Opdivo was approved in Japan for the treatment of unresectable advanced or recurrent esophageal cancer that has progressed following chemotherapy.

*3: An application for Opdivo was approved in South Korea for the treatment of unresectable advanced or recurrent squamous cell carcinoma of esophageal cancer which is refractory or intolerant to prior fluoropyrimidine- and platinum-based chemotherapy.

*4: An application for Bruton's tyrosine kinase inhibitor (ONO-4059 / Tirabrutinib) was approved in Japan for the treatment of recurrent or refractory primary central nervous system lymphoma.

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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	Waldenstorm 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 *5 / BRAF inhibitor	Capsule	Japan	In-license (Pfizer Inc.)
Mektovi Tablet / Binimetinib	New chemical entities	Colorectal cancer *5 / MEK inhibitor	Tablet	Japan	In-license (Pfizer Inc.)

★: Combination with Opdivo.

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

*5: An approval application for Braftovi Capsule (BRAF inhibitor) and Mektovi Tablet (MEK inhibitor) was filed in Japan for the treatment of unresectable advanced or recurrent BRAF-mutant colorectal cancer in combination therapy with cetuximab (EGFR monoclonal antibody).

As shown on page 7 of the Financial Results Supplementary Materials, Opdivo has obtained an approval for the treatment of MSI-High colorectal cancer.

Next, we have obtained an approval for esophageal cancer in Japan and South Korea.

Then, Velexbru (ONO-4059/generic name: tirabrutinib) has been approved for the treatment of primary central nervous system lymphoma.

I will update the products under applications, which is on the bottom table on page 7. As you can see, we have submitted an application for combination therapy of Braftovi and Mektovi for the treatment of BRAF-mutant colorectal cancer, in combination with cetuximab.

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
ONO-7703 / Binimetinib	New chemical entities	Colorectal cancer / MEK inhibitor	Tablet	S. Korea	III	In-license (Pfizer Inc.)
	New chemical entities	Melanoma / MEK inhibitor	Tablet	S. Korea	III	In-license (Pfizer Inc.)
ONO-7912 (CPI-613) / Devimistat	New chemical entities	Pancreatic cancer / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, Inc.)
	New chemical entities	Acute myeloid leukemia / Cancer metabolism inhibitor	Injection	S. Korea	III	In-license (Rafael Pharmaceuticals, Inc.)
ONO-7475	New chemical entities	Acute leukemia / Axl/Mer inhibitor	Tablet	USA	I	In-house
ONO-7913 *6 / Magrolimab	New chemical entities	Solid tumor / Anti-CD47 antibody	Injection	Japan	I	In-license (Gilead Sciences, Inc.)

★: Combination with Opdivo.

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

*6: Phase I of anti-CD47 antibody (ONO-7913) was initiated for the treatment of solid tumor.

* Phase I of XPO1 inhibitor (ONO-7705 / Selinexor) for the treatment of multiple myeloma and non-hodgkin lymphoma was discontinued due to strategic reasons and the rights were returned to Karyopharm.

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

At the bottom table on page 10, ONO-7913/Magrolimab is now in Phase I for solid tumor. We are considering the development both solid tumor and hematological cancer for this compound, but have decided to first conduct Phase I for solid tumor.

Although not shown in this table, we had implemented Phase I with selinexor, licensed from Karyopharm Therapeutics. However, for strategic reasons, we have discontinued the development and returned the rights to Karyopharm.

II. Main Status of Development Pipelines (Non-Oncology)

As of April 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
Orencia IV Orencia SC / Abatacept	Additional indication	Prevention of the structural damage of the joints in rheumatoid arthritis *7 / T-cell activation inhibitor	Injection	Japan	In-license (Co-development with Bristol-Myers Squibb)

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

*7: An application for selective T-cell co-stimulation modulators Orencia IV and Orencia SC was approved with Bristol-Myers Squibb K.K. for the addition of prevention of the structural damage of the joints in the previously approved rheumatoid arthritis.

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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-2370 / 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 / Short-acting selective β_1 blocker	Injection	Japan	In-house
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.

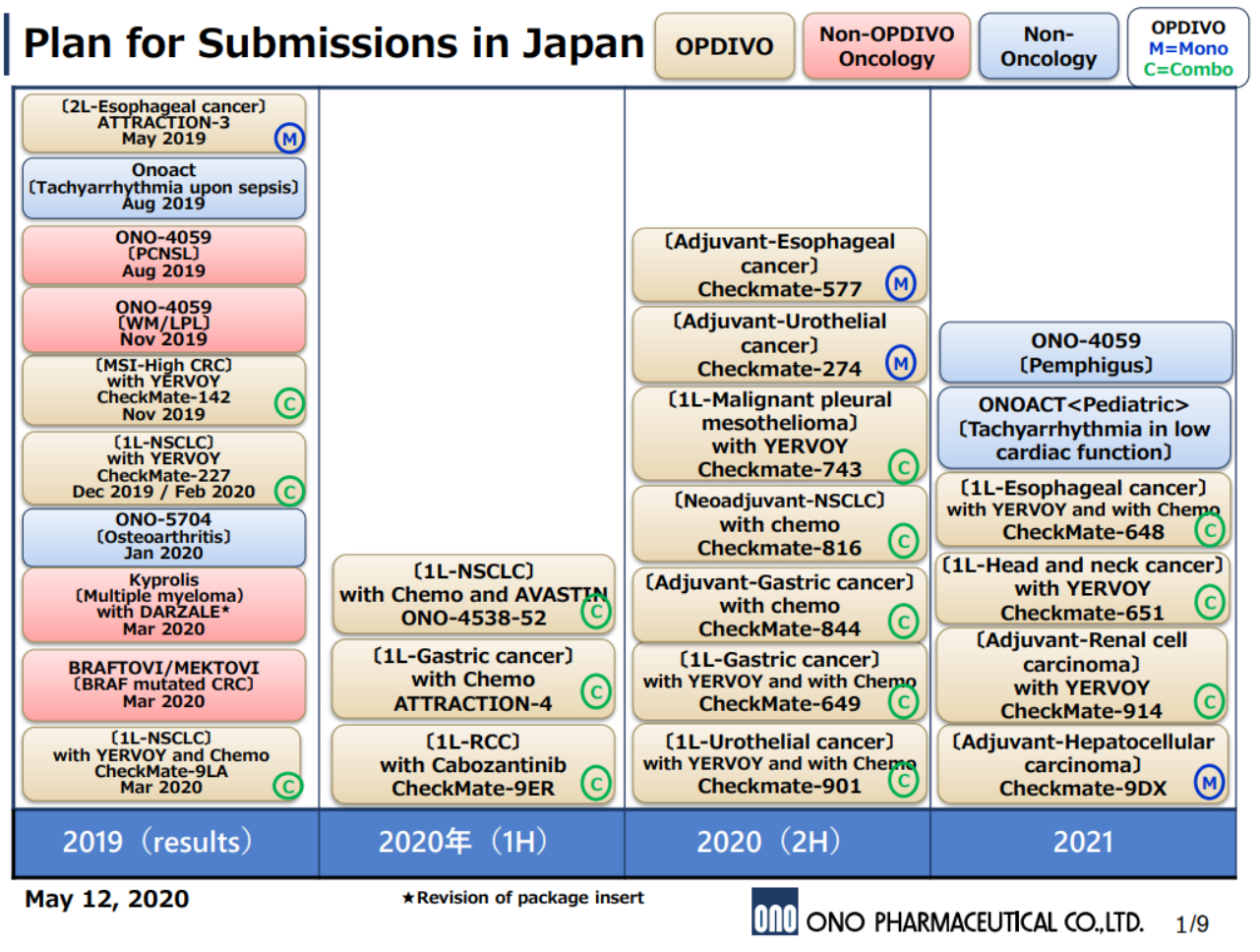
Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	Phase	In-house*) / In-license
Orencia SC / Abatacept	Additional indication	Polymyositis / Dermatomyositis / T-cell activation inhibitor	Injection	Japan	III	In-license (Co-development 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)
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

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

* Phase III of the selective T-cell co-stimulation modulator Orencia SC for the treatment of untreated rheumatoid arthritis and primary Sjögren syndrome was discontinued due to the results not being able to confirm anticipated efficacy.

Continuing on page 11, in the Non-oncology field, Orencia i.v. and s.c. have been approved for rheumatoid arthritis. In addition to the indication, Orencia was approved to include the phrase "prevention of the structural damage of the joints" in the currently approved indication.

As described on page 11, we continued to implement Phase III for Orencia for the treatment of untreated rheumatoid arthritis and primary Sjögren's syndrome. Unfortunately, however, we were unable to confirm the efficacy, and discontinued the project.



Next, I will move on to the slide for application schedule.

This shows current and future applications within Japan. Regarding the view in the table, the left-hand side shows the results of applications in FY2019. Then, we can see the first half of the current fiscal year, and then the second half. In addition, we have added some projections for FY2021.

Orange represents the Opdivo project. Red is classified as oncology compounds other than Opdivo, and blue is classified as non-oncology compounds.

In addition, in terms of Opdivo, M is monotherapy, and C denotes combination therapy.

First, on the left, about the uppermost esophageal cancer, Opdivo was approved for this indication in February. Furthermore, Velexbru (ONO-4059) was approved in March, and is now under preparation for launch.

Subsequently, for non-small-cell lung cancer with CheckMate-227, we have applied for Opdivo + Yervoy combination treatment in December 2019 and Opdivo + chemotherapy combination treatment in February 2020. The Yervoy application was submitted in December, and the chemotherapy application in February.

For non-small cell lung cancer, an application was also submitted in March 2020, using the results from CheckMate- 9LA for the first-line treatment of non-small cell lung cancer in combination with Yervoy and two cycles of chemotherapy regimens and the results of.

For the filing schedule for the first half of 2020, we are planning to submit an application for Opdivo + Avastin in combination with chemotherapy for the treatment of non-small cell cancer, as soon as the results of the ongoing clinical study are obtained. We are also planning to file an application for the treatment of gastric cancer using the results of a study in combination with chemotherapy.

Then, the combination treatment of Opdivo and cabozantinib. As announced in the press release the other day, the primary endpoint was met in the study. We want to prepare for the application based on the results of the study.

Regarding the second half of FY2020, we describe the schedule under the assumption that the results of the planned projects were obtained at the earliest possible time. We would like to submit an application as soon as the result is available.

One of these is CheckMate-743 study evaluating Opdivo in malignant pleural mesothelioma. As we announced in the press release the other day, in the interim analysis, Opdivo showed a significant improvement in OS. We have begun preparing an application for this indication.

In FY2021, we newly added some schedules in the table: adjuvants treatment of renal cell carcinoma and hepatocellular cancer. Regarding the first-line application for esophageal cancer and head and neck, following a review of the analysis period, we re-schedule the application timing from the second half of FY2020 to FY2021. Besides Opdivo, we are also planning to file an application of Velexbru for pemphigus and an additional indication for Onoact.

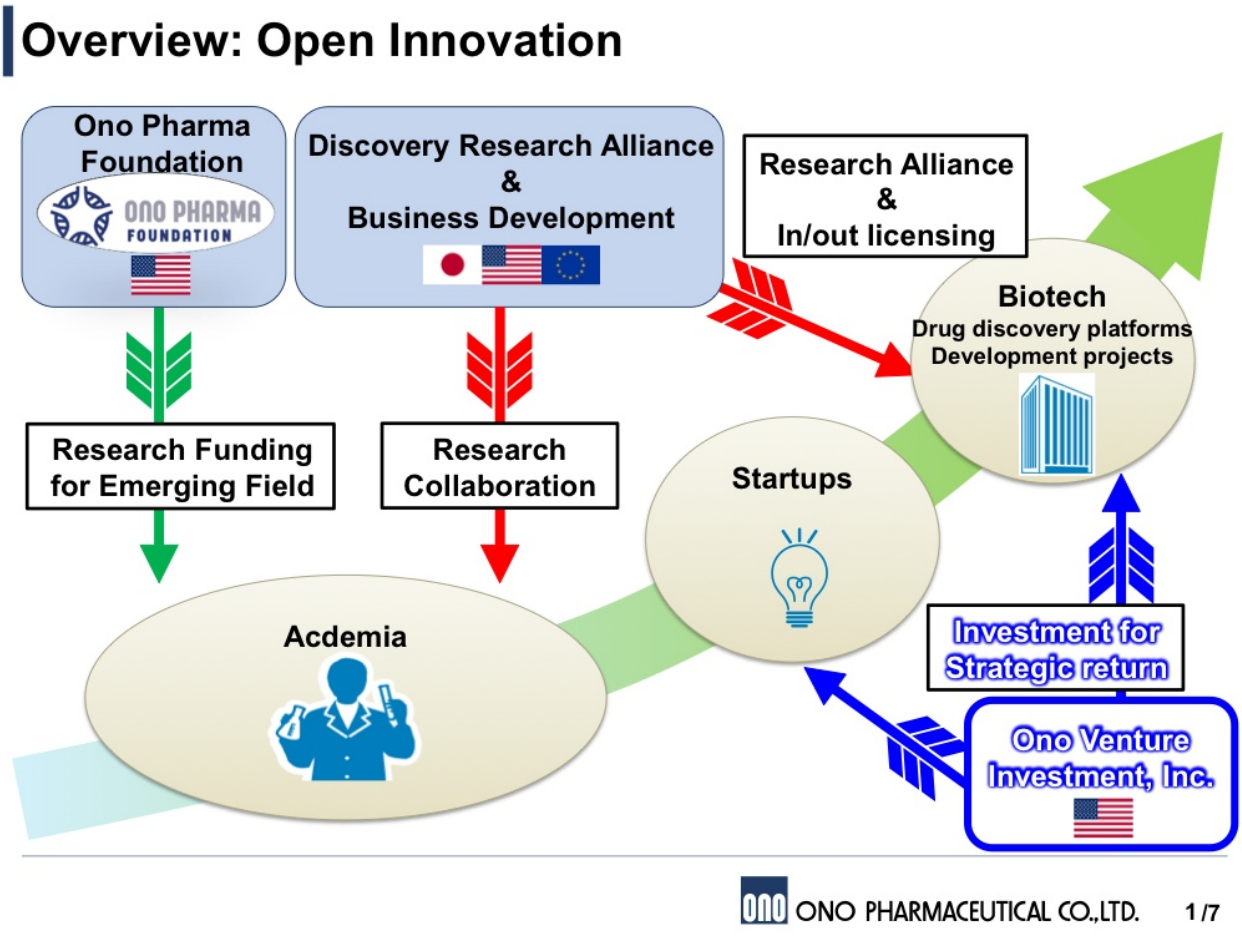
Sagara: I'd like to add a few words here.

Regarding the ATTRACTION study for first-line treatment of gastric cancer, the results of the study have been obtained, and we are currently preparing to submit an application. At the moment, we cannot tell you about the results, but we are preparing for the application.

We have been reporting that we would like to expand the scope of our activities in the gastrointestinal field, and this represents our first step for gastric cancer.

Takino:I would like to explain about the newly established Corporate Venture Capital, Ono Venture Investment, Inc., which was announced in the press release yesterday.

As is evident from our main products history, such as PD-1 inhibitor and prostaglandins, open innovation is vitally important for Ono. With that in mind, I would like to explain our motivations and R&D activities, which may be a long-term aspec,t in establishing Ono Venture Investment.



This slide shows an overall summary of our image of open innovation.

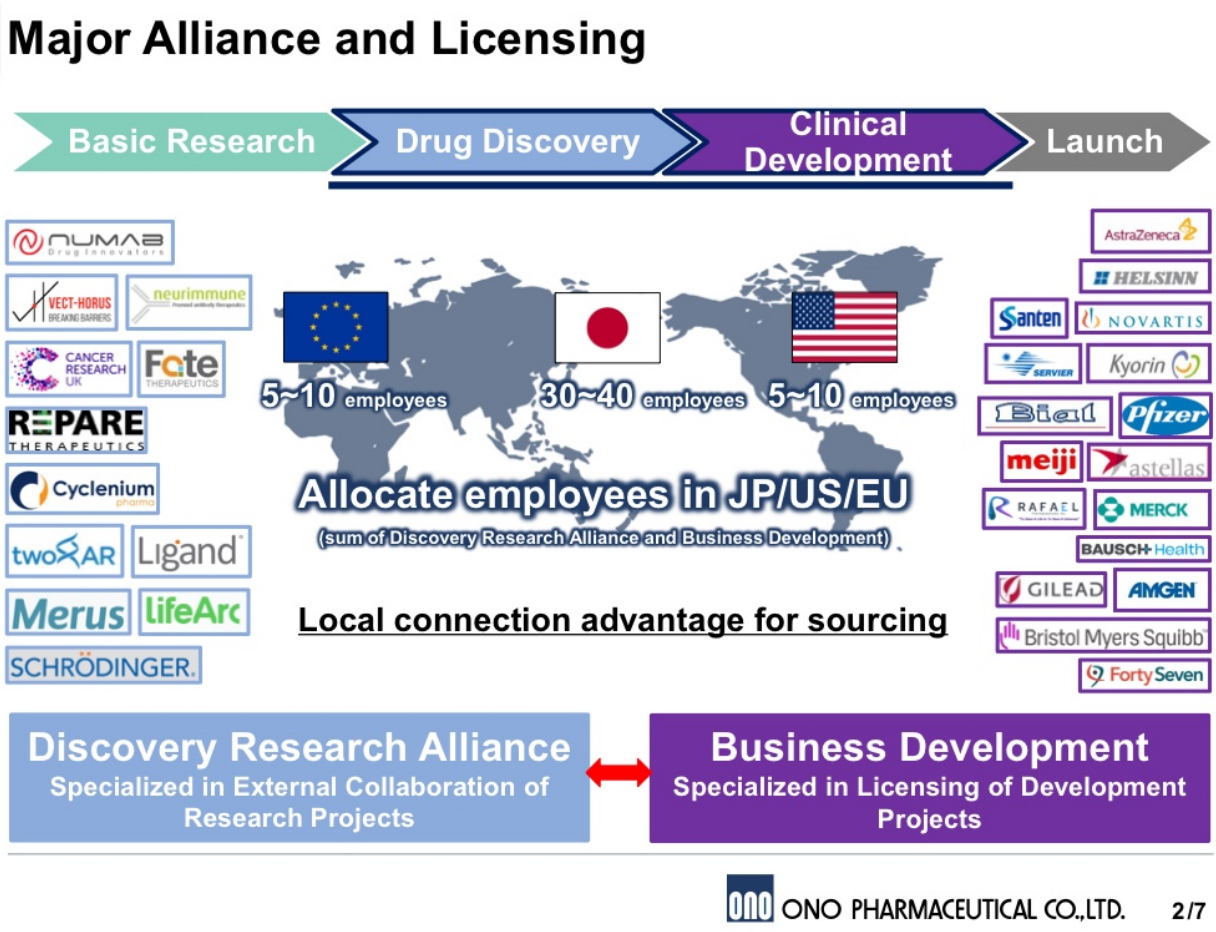
As you may be aware, we are actively engaged in compound licensing and drug discovery alliances with bio-venture companies. This is represented by the red arrow.

In particular, we are actively involved in drug discovery tie-ups not just with bio-ventures, but also through joint research with academia. In some cases, we also dispatch members of our research staff abroad in order to raise our capabilities when it comes to in-house drug discovery.

The green arrow on the left-hand side indicates our unique US foundation, which provides research grants. These grants are for academic basic research in emerging fields, with the potential to lead to future technological developments, even if the research results are not available to us.

Our Corporate Venture Capital is depicted in blue in the right bottom. This will give us a means to invest in venture companies, creating a comprehensive framework to drive open innovation.

I would like to break down the program and show you how it is being implemented.



This first slide shows our collaboration with ventures, our drug discovery alliances, and our compound licensing. In the top panel, you can see the flow from drug discovery to clinical development, and then to launch. They are distinguished here by different colors.

The blue box on the left-hand side represents our collaborative activities in drug discovery research. The Research Division's Exploratory Research Alliance Department is in charge of these activities. The Business Development Department, which is shown in purple on the right, cooperates with the Company as a whole. Both of these departments cooperate each other with the licensing of development compounds in the clinical stage.

Several staffs each from in the US and UK local subsidiaries, roughly 10 employees, are engaged in collaborative activities, enabling us to form new alliances at the forefront of new development in these countries.

The middle left and right columns show specific partner companies, but in terms of drug discovery alliances, we are also working with venture companies that are committed to bio-product technology and AI drug discovery.

Ono Pharma Foundation in the United States

Funding to Promising Researchers for Future Innovation

ONO PHARMA FOUNDATION

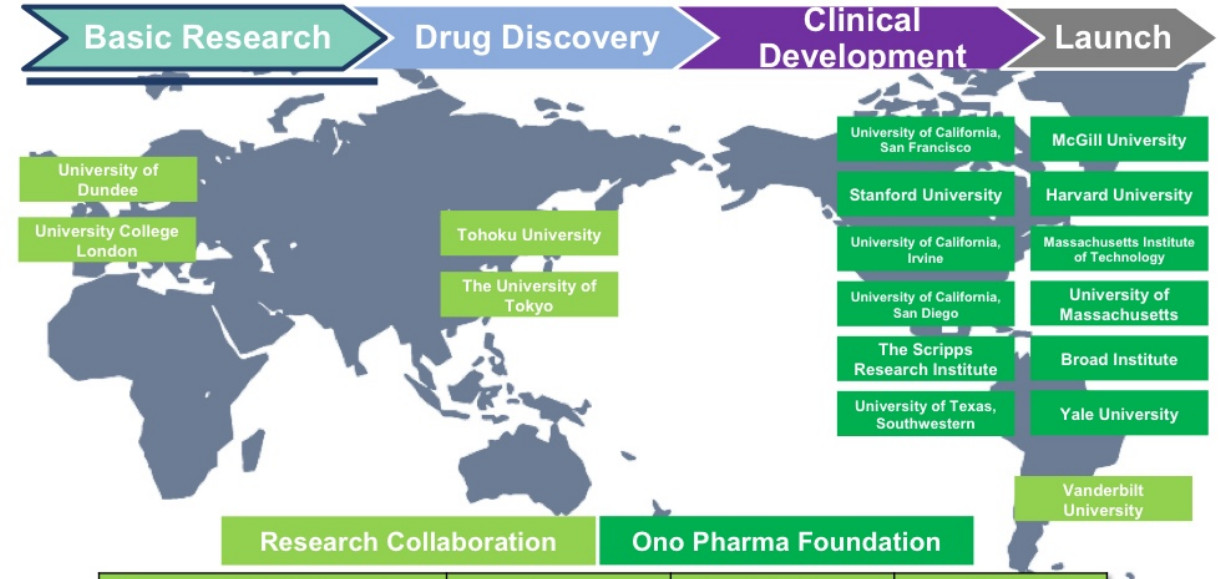
- ✓ **Started in 2017 (Funded to date with 15 Awardees)**
- ✓ **Build a Network among Awardees**

Sites of Scientific Advisors and Awardees	
University of California, San Diego	Harvard University
University of California, San Francisco	Broad Institute
University of California, Irvine	Yale University
Stanford University	University of Massachusetts
The Scripps Research Institute	Massachusetts Institute of Technology
University of Texas, Southwestern	McGill University

The second theme is collaboration with academia. As shown here, we have established the Ono Foundation in the US, which is currently functioning as a relatively unique and open innovation arm.

This initiative launched about three years ago, and today it is particularly active in the new field of chemical biology. Focusing on that, we have selected academic research from the Broad Institute, MIT, Harvard, Stanford, and other famous facilities, as shown in the bottom panel. Each year, five researchers are provided with their own research grants. We have now supported a total of 15 top researchers during the last 3 years. By creating a network on state-of–the-art science among these promising awardees, we are now entering the community.

Open Innovation with Academia

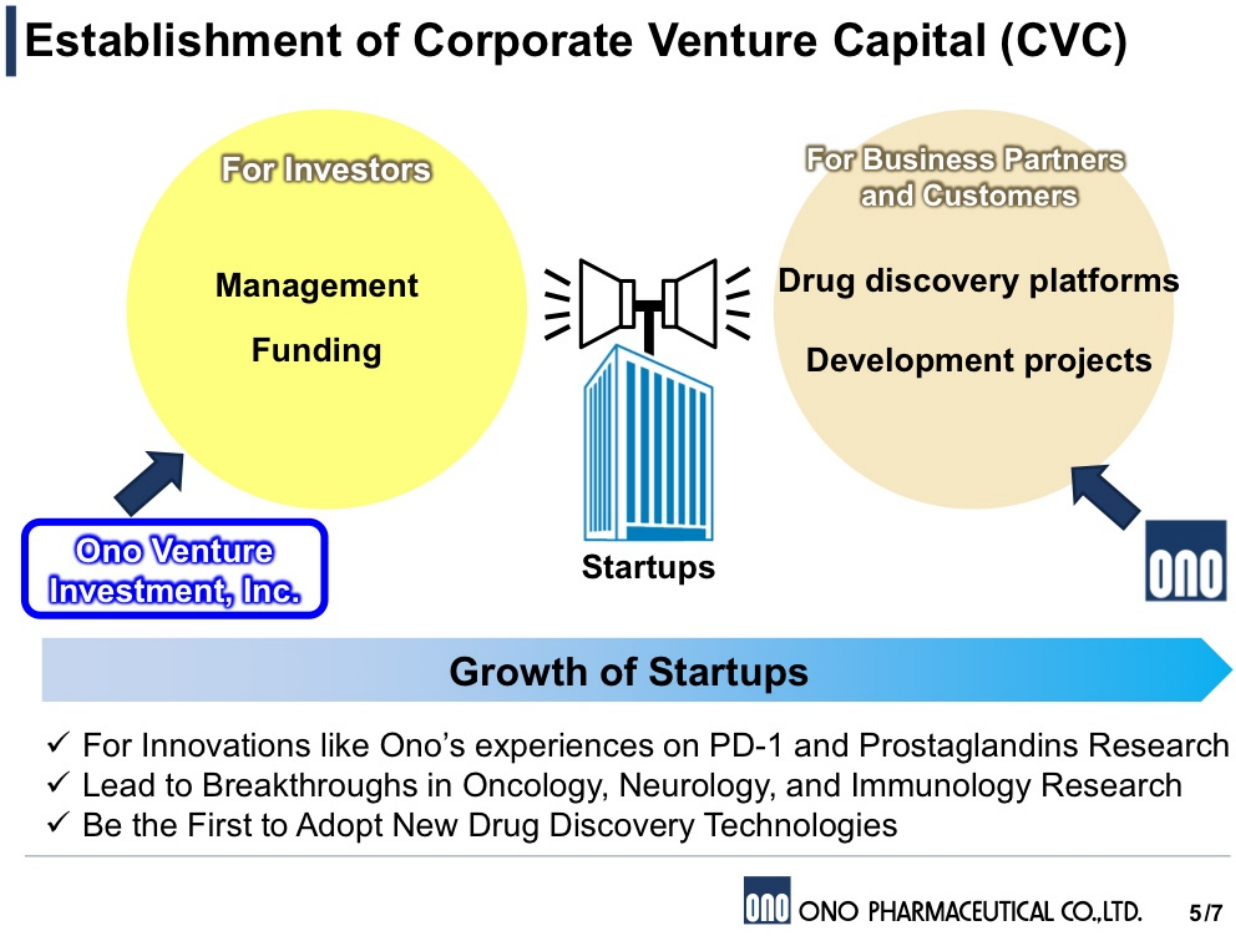


Research Collaboration	Japan	Outside Japan	Total
Number of collaborations As of the end of March, 2020	182	96	**278**
Number of newly initiated collaborations in FY2019			**54**

ONO PHARMACEUTICAL CO.,LTD. 4/7

Of course, we are also conducting joint research with academia in addition to these activities by the Foundation. This deep green color shows facilities where the Foundation has been collaborating. As well as that, we have chosen joint research collaborations, as shown on the map.

Including projects not disclosed as shown in the table below, the total number of ongoing joint research projects with academia is nearly 100 aboad. We are actively pursuing the search for seeds that will lead to drug discovery research.



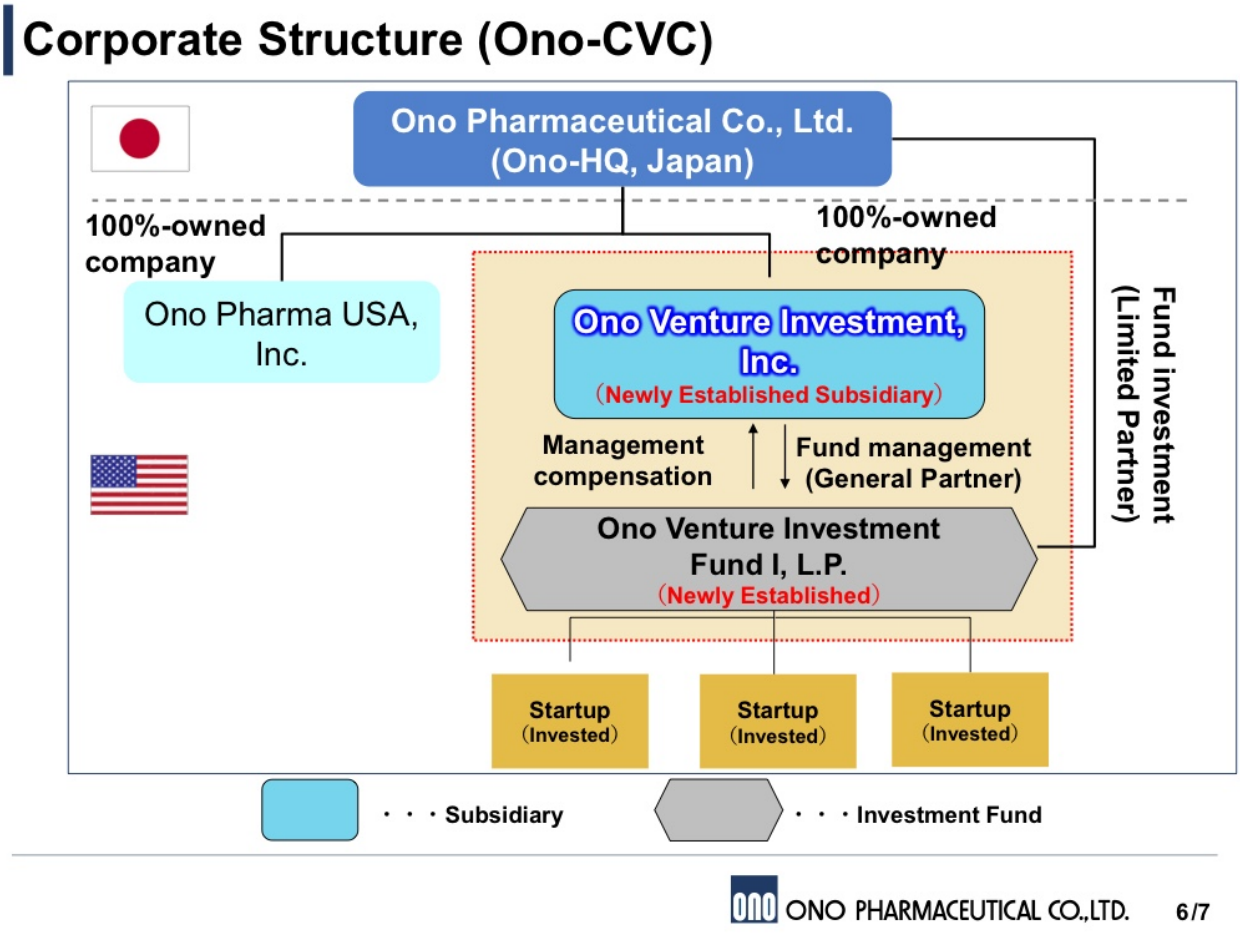
In addition to these drug discovery alliances with bio-ventures, compound licenses, and joint research and research grants with academia, I will briefly explain the role of this newly established Corporate Venture Capital.

As you are all aware, the aim of this organization, as shown on the left, is to encompass areas not covered by the previous initiatives, which are shown on the right. With this, we are aiming to enter the venture side of the ecosystem, and gather information in this way.

Our strength is the ability to make breakthroughs from open innovation, which is something we excel at. The Company is currently focusing on this strategy and is applying it to drug discovery in strategic areas such as oncology, neurology, and immunology. The aim is to bring in new technologies that will become essential and useful for this purpose.

In fact, in the course of ongoing discussions and collaborations with biotechnology ventures, there have been cases in which it was felt that, in addition to actual licensing and technology alliances, a framework capable of injecting capital would enable the realization of a more strategically wide range of open innovation.

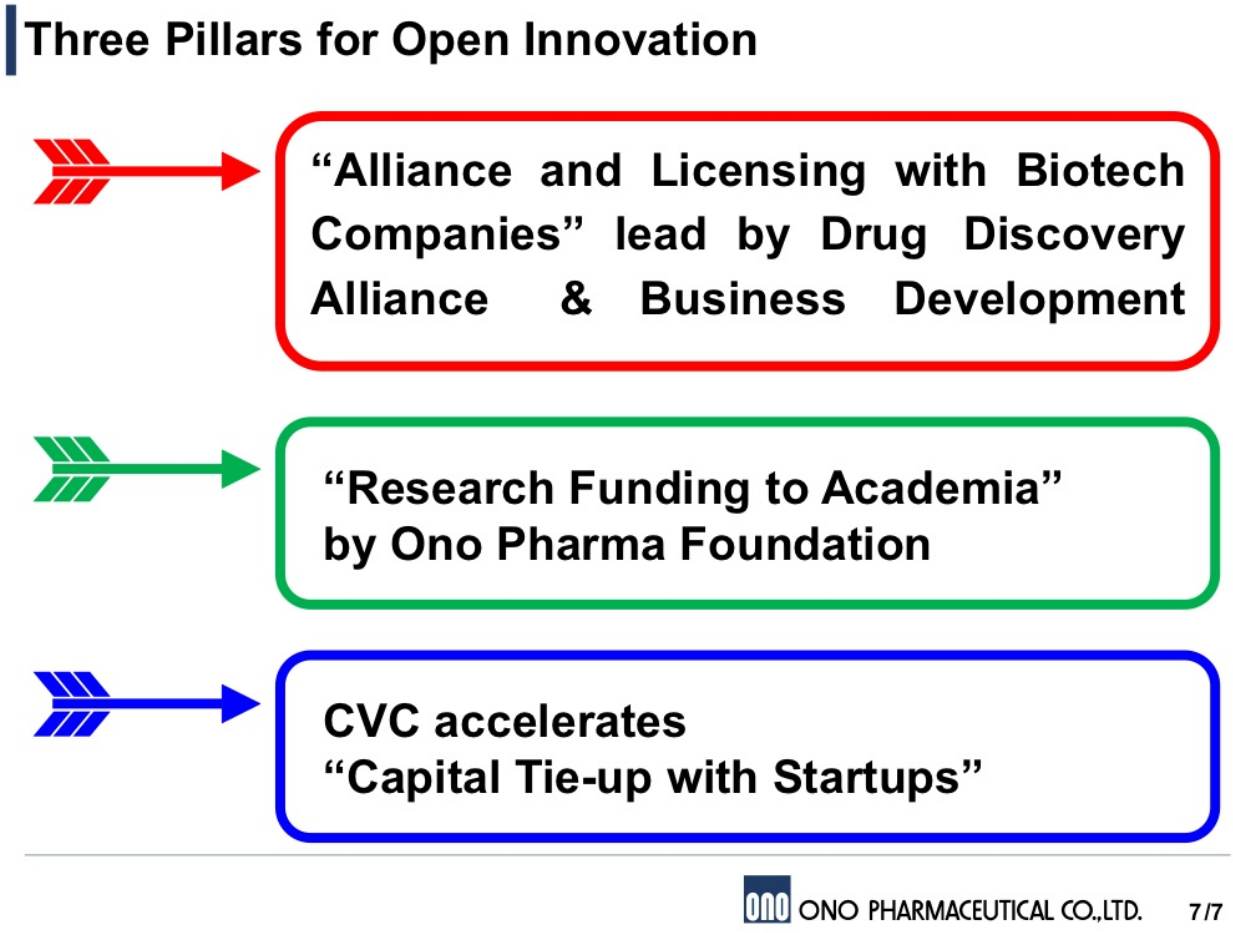
This Corporate Venture Capital will bring a number of options for different types of partnership. These may include capital injection, capital alliances, and large-scale developments. Our expectation from this is that this will lead to new forms of development.



The corporate structure of the CVC is shown in this slide. The details have already been announced in the press release, and the registration was completed yesterday. In other words, the R&D vehicle that was originally established and operated as Ono Pharma USA, Inc. on the East coast has this form of alliance with the CVC.

Ono Venture Investment, Inc. will be the fund's operating company, and will be established on the West Coast, in California.

The fund itself will be set at a total amount of USD100 million. The Company will invest 99% of that in a limited partner arrangement. Ono Venture Investment, Inc., the CVC management subsidiary will be responsible for the management and operation of the fund as a general partner. The remaining 1% of the fund will be financed by the parent Company.



To summarize, until now we have had the drug discovery alliances and compound licenses that we have been actively working on, as well as research grants to academia by the Foundation. By establishing the CVC, we are creating a new framework for capital alliances and investments with bio-ventures. This will form the third arrow of open innovation.

With the establishment of the new CVC, we intend to bring open innovation to a more competitive stage. By further expanding our open innovation efforts, we hope to bring about an increase in our Company’s competitiveness in drug discovery and research and development.

Question & Answer

Q: Regarding ATTRACTION-4 (Opdivo), although I think there were no significant differences observed with the competitor's product, I understand that the concerned company is going ahead with the application. Could you tell us about any details in terms of OS, PFS differences?

Idemitsu: We are terribly sorry, but we cannot disclose the results of the trial at this time.

Q: OK. I understand that the trial for Avastin and Opdivo finished around the end of April. Could you tell us any more about progress here?

Idemitsu: We would like to apply as per the schedule, but are waiting for the results at present.

Q: OK. Third, I think the average treatment period for each cancer type was disclosed previously. Could you tell us the planned treatment duration for esophageal cancer?

Takahagi: Given the Kaplan-Meier for PFS from the result of ATTRACTION study, we are estimating 4.2-month duration for esophageal cancer.

Q: OK. Of the JPY90 billion in the current fiscal year, it seems that about JPY9 billion would be for esophageal cancer. Of a target of 6,000 patients, you are currently at 530. Does that mean you are expecting a big increase in the number of patients in March of FY2021? This can be found from calculating backwards.

Takahagi: We would like to reach peak share and peak sales at an early stage. We are aiming at the launch start made for third-line gastric cancer.

Q: OK. Finally, I believe the president has commented at a press conference that the Company aims to achieve a target of JPY100 billion in FY2022, compared with JPY90 billion in FY2021. Is this right?

Sagara: Yes. It is not a commitment, but I made a comment yesterday that I would like to aim at that level, considering the future situation with additional indications.

Q: OK. So, if you look at it monthly, in April and May, I think that Opdivo sales will be over the Keytruda sales because the Keytruda drug price has dropped. Is that so?

Sagara: It's quite hard to tell. For Opdivo, I think it would be reasonable to aim for JPY100 billion for the next term.

Q: Regarding gastric cancer for Opdivo first, the result of ATTRACTION-4 is not out yet. If so, is it correct that there will only be a press release at the time of application? Or, is it correct to assume that the results will appear before the application at some point, or that the results will appear in the release at the time of the application? Could you tell me a little more about that?

Sales of Opdivo for gastric cancer for this fiscal year appear to be flat. Regarding this, I think that the share of the third-line for gastric cancer has leveled off to some extent. What are your views on this? Is the company estimating it simply based on the flat situation? Or, is the company estimating it conservatively taking into account any possible change in competitive environment? Could you tell us more about changes in the market here?

Tani: Regarding first-line treatment of gastric cancer, if we were to provide information now, we are preparing to submit an application, so I think the timing of the application will be announced at a later date. However, we are not in a position to comment further on that at this time.

Takahagi: I will answer about the third-line treatment for gastric cancer. As you know, a competitive drug entered into the third-line treatment for gastric cancer in August last year, and that portion is gradually increasing.

On the other hand, as I mentioned earlier, Opdivo has maintained a 70% share of prescriptions for new patients. From that standpoint, we can't give up any ground at all.

Furthermore, the transition rate from the second-line treatment to the third-line treatment is still about 60% of the total. We would like to extend that part more closely, but we are currently building a high prescription share of 70%, so we are working to build a wall against our competitors to maintain the status quo, and to build the sales in the current term even more robustly.

Q: OK. The second is about Opdivo in renal cell cancer. I think that the results that have come out are good, but I think that the sales forecast for this fiscal year will grow slightly, and that we do not have a strict view of the impacts of Keytruda + Inlyta combo-therapy. Please tell us about the current impacts of the combo-therapy, and your assumptions for the current fiscal year.

Takahagi: In first-line treatment with Opdivo, doctors' ratings of the combined use of Opdivo and Yervoy were positive, and the combination is achieving nearly 60% of new prescriptions.

On the other hand, in the case of Inlyta + Keytruda in the first-line treatment, they can be used in all risk groups. Opdivo is intended only for intermediate- to poor-risk, so there is a slightly different position there.

However, as a segment, there’s the possibility that the competition will have an effect on the intermediate-risk portion to the tune of about 10%. However, with the extremely long follow-up data period of 42 months shown earlier, data such as the long-term survival and success with Opdiva and Yervoy have been clearly presented. I would like to communicate these points to healthcare professionals and establish an optimal position for the Company.

Looking at the current market conditions of competitive products, the impression is that new prescriptions for favorable-risk patients are quite high.

Q: Lastly, I would like to know about the CVC. As for the impact of the establishment of this CVC on your company's pipeline, up to the present time there have been many conceivable in-licensed agreement, but would you think that we can expect a change in which the Company will acquire ventures and incorporate them in the future?

Takino: We believe that various possibilities will emerge.

Q: In concrete terms, it seems like this could be a change to a more pro-active approach in terms of M&A. Is the way of thinking changing a little from before?

Sagara: We cannot say much at the current stage, but if such a project were to appear, I certainly think there are some interesting possibilities.

Q: Although the number of outpatients is decreasing due to the impact of COVID-19, I think that the prescription durations are quite long, and that there will be no negative impact on sales.

Since Opdivo is an intravenous injection, I think it cannot be prescribed for a long period of time. What effects are you expecting, and how will this category of drug be affected?

Opdivo seems to have more two-week intervals, which are shorter than those of Keytruda and Tecentriq. Do you think this could have an impact on market share?

Takahagi: Indeed, as you mentioned, in the oncology field too, we are not able to visit institutions. I have heard about patients asking doctors whether they can increase the intervals between their hospital visits, how they should follow-up further treatment.

Accordingly, there may be cases in which Opdivo may be given at longer dosing intervals, but we do not have data on what the percentage is overall, so we are uncertain about the current situation.

There may be a case that Opdivo treatment period will be a little bit longer, but I cannot make any comment what percent of such case will arise because I have no such a data at present. The situation is not clear now.

As for the difference in the treatment intervals with competitors, as we think that there are significant differences in the indications between competitors beside dosing interval, we do not believe that there will be a major negative impact from coronavirus compared to competitors, taking Opdivo in general into account.

Q: Does an extended dosing interval mean a higher dose per injection?

Takahagi: I'm sorry. I don’t have any data about that at hand.

Q: Finally, about the impact of coronavirus on clinical trials, Opdivo has an immunosuppressive effect. As a result, are patients concerned about increased risk of contracting coronavirus?

Are you concerned about the risk that even after things return somewhat to normal, these kinds of worries will prevent patients from returning compared to projects in other areas?

Idemitsu: Opdivo enhances the immune system, rather than suppressing it, so at this point we are not concerned.

Rather, I should not talk too much about COVID-19, but I think that the drug to be treated will differ depending on whether it is in the early stages of an infectious disease or when pneumonitis becomes serious, but I am not currently thinking that it will worsen if Opdivo is given during viral infections.

Q: Regarding Opdivo ATTRACTION-4 for gastric cancer, certainly, the PFS results have already appeared in the past, and I understand that it was a condition for application in Japan to meet the OS endpoint, but under those conditions, is my understanding correct that the application was in the process of preparation this time?

Idemitsu: The trial has PFS and OS as co-primary endpoints. The result has become available to us, and we are going to make an application. I’m afraid I can’t say any more than that.

Q: I also think there was a mention of JPY100 billion for Opdivo for the next fiscal year. However, if sales in the current fiscal year were JPY100 billion, would I be mistaken in thinking you would expect sales of JPY110 billion in the year after?

Sagara: That’s not quite right. I just mentioned that we forcast it under the review of additional indications for which have been filed an application during this fiscal year. Those are the main take-away points.

The big thing to keep in mind is that in the second half of this fiscal year, we may be able to get approvals for first-line use in lung cancer, giving us three ways. If we can get them, then that leads me to say the figure of JPY100 billion. I would like to refrain from commenting further than that at this point.

Q: I understand. Finally, the forecast sales of new drugs are JPY5 billion in the current fiscal year, and it appears to be a little conservative. How would you list the drugs in descending order of expectations?

Sagara: In descending order of expectations, first of all, I think that JPY5 billion will start with costs in the second half of the fiscal year. I think it will be a little bigger next term.

In terms of existing product markets, or new compounds, if it were based on current patient numbers, I think Joyclu would probably be the highest.

Q: You mean SI-613, don't you?

Sagara: That's right.

Q: Regarding the Opdivo JPY90 billion and JPY100 billion figures, I think there were rules for re-pricing at that level and for drug prices to be reviewed every time the indications are expanded under the new rules, once the indications are expanded one after another.

Including this rule and recalculation, what is the effect on your company, particularly on costs? Could you briefly tell us about some of the relevant points here?

Sagara: There are some areas where clear interpretation is difficult, you may be aware of that.

At present, we expect the next hurdle to be about JPY200 billion for the re-calculation of special cases and the so-called huge amount. I don't know much about this interpretation, but I think what will happen when Tecentriq's sales grow. That’s maybe a little further down the road.

At present, the indications are expanding steadily, and we understand that the next big hurdle would be JPY200 billion.

Q: Are you not seeing much about specific expansions of indications?

Sagara: Correct. We are not very aware of each expansion, but rather have been aware of it in terms of volume.

Q: Understood. There was one more for heart failure, Coralan, that I heard spoken of positively. Could you tell us about sales or forecasts?

It's good that the heart rate decreases, and I think AstraZeneca is applying for an expanded indication for Forxiga for heart failure. Market needs are so high that we often hear about heart failure, pandemics, and et cetera. However, I am not aware of the figures for Coralan. What is the potential here? I seem to remember a JPY55 billion peak.

Although Forxiga seems to have increased considerably in the current fiscal year, I think that this will not coincide with the expansion of indications for heart failure, but do you plan on putting something in place? This is the final point.

Ichikawa: Coralan is expected to be JPY1.4 billion in the current fiscal year. However, you may not know, but this is another impact of the coronavirus. Typically, the dose is raised every two weeks to 2.5 milligrams, 5 milligrams, and 7.5 milligrams. However, at present, it is difficult for the patients to visit every two weeks for their doses to be adjusted by a clinician.

Regarding Forxiga for heart failure, we are discussing with AstraZeneca when this can be added, including Canibari. It is not clear. I hope that by the end of this fiscal year, we will be able to participate in the market in this area.

Then, I spoke about the issue of patients with Coralan and Forxiga, but it isn't necessarily the same group of patients to be targeted with the drugs. We will provide the information accurately to the patients who need the treatment, and hope that the prescriptions will be made to the right patients.

Q: Is it the case that both drugs can be given with beta-blockers?

Ichikawa: That's right. So far, I am thinking so.

Q: With beta-blockers.

Ichikawa: Yes.