Revenue

Revenue	YoY Change
¥ 288.6 billion	+ 10.2 %

Breakdown of Revenue

(Billion yen)

	FY 2017	FY 2018	YoY Change
Revenue of Goods and Products	205.9	208.9	+ 1.5 %
Royalty & other revenue	55.9	79.7	+ 42.4 %
(Opdivo)	(39.8)	(58.5)	(+ 46.9 %)
Total	261.8	288.6	+ 10.2 %

ONO PHARMACEUTICAL CO.,LTD.

First of all, revenue was 288.6 billion yen, an increase of 10.2% from the previous fiscal year. Revenue of goods and products increased 3 billion yen. In addition, royalty and other revenue increased by 23.8 billion yen, as shown in the slide. The growth was 10.2%, but in addition to the increase in revenue by 26.8 billion yen, the application of IFRS 15, had a positive impact of approximately 8.9 billion yen. The actual revenue is the amount subtracting that portion. Royalty income from BMS (Bristol-Myers Squibb) increased 18.7 billion yen to 58.5 billion yen. The royalty from Merck increased by 6.1 billion yen to 12.8 billion yen.

Revenue

Sales of Major Products

(Billion yen)

	FY 2017	FY 2018	YoY Change
Opdivo	90.1	**90.6**	+ 0.5 %
Glactiv	27.4	**26.9**	- 1.8 %
Orencia SC	14.1	**17.4**	+ 23.3 %
Forxiga	11.1	**14.5**	+ 31.0 %
Emend/Proemend	9.9	**10.6**	+ 6.6 %
Rivastach	8.9	**8.9**	+ 0.2 %
Kyprolis	5.5	**4.9**	- 11.1 %
Parsabiv	3.4	**5.7**	+ 66.8 %
Onoact	5.6	**4.6**	- 18.5 %
Staybla	4.1	**3.7**	- 10.6 %

ONO PHARMACEUTICAL CO.,LTD.

This is revenue by product. As you can see, sales of Opdivo were 90.6 billion yen, up 500 million yen from 90.1 billion yen. On a volume basis, there was an increase of nearly 40%, but the NHI drug prices were revised in April 2018 and then in November 2018. We had expected that the November revision would not have a significant impact, but actually the effect was felt as a result. Furthermore, products contributing to increased revenue include Orencia SC, Forxiga, and Parsabiv.

Revenue

Sales of Long-term Listed Products

(Billion yen)

	FY 2017	FY 2018	YoY Change
Opalmon	14.4	**10.4**	- 27.9 %
Recalbon	10.9	**7.3**	- 32.8 %
Onon capsule	5.5	**4.4**	- 20.0 %
Onon dry syrup	3.3	**2.7**	- 19.1 %

Regarding long-term listed drugs, as you can see here, there has been no change in trends over the past several years. There was 20% to 30% decline by product. Four items had a total decline of more than 8 billion yen.

Operating Profit

Operating Profit	YoY Change
¥ 62.0 billion	+ 2.2 %

Costs, etc.

		(YoY Change)	
・Cost of sales	¥ 83.8 billion	(+ 28.2%)	
・R&D expenses	¥ 70.0 billion	(+ 1.7%)	①
・SG&A expenses	¥ 70.0 billion	(+ 2.9%)	②
①+② Total	¥ 140.0 billion	(+ 2.3%)	
・Other income	¥ 0.6 billion	(- 80.1%)	
・Other expenses	¥ 3.4 billion	(+ 58.9%)	

ONO PHARMACEUTICAL CO.,LTD.

Operating profit increased by 1.3 billion yen to 62 billion yen. Cost of sales was higher due to the impact of IFRS and a temporary cost to receive stable supplies of APIs. R&D expenses were 70 billion yen, up 1.2 billion yen. Excluding R&D expenses, SG&A expenses were also 70 billion yen. This is an increase of 2 billion yen. Considering other items, operating profit is as shown below.

Profit before Tax

Profit before Tax	YoY Change
¥ 65.1 billion	+ 1.9 %

Net financial income

+ ¥ 3.1 billion (- ¥ 0.1 billion)

Finance income :	**¥ 3.3 Billion**
(Interest and dividend income received, etc.)	
Finance costs :	**¥ 0.2 billion**
(Interest expense arising from lease obligations and employee retirement benefit, etc.)	

ONO PHARMACEUTICAL CO.,LTD.

The trend of profit before tax remained unchanged from the previous fiscal year. There was an addition of 3.1 billion yen.

Profit for the Period
(Owners of the Parent Company)

Profit for the Period (Owners of the Parent Company)	YoY Change
¥ 51.5 billion	+ 2.5 %

Income tax expense

¥ 13.5 billion	(YoY Change - 0.5 %)	
Statutory effective tax rate	30.6 %	(30.8 % prior year)
Actual av. burden tax rate	20.7 %	(21.2 % prior year)

(Major change factors)

Various tax credit

This is profit for the period. We saw an increase of 1.3 billion yen from the previous fiscal year to 51.5 billion yen.

Revenue (Forecasts)

Revenue	YoY Change
¥ 290.0 billion	+ 0.5 %

Breakdown of Revenue

(Billion yen)

	FY 2018 (Result)	FY 2019 (Forecast)	YoY Change
Revenue of Goods and Products	208.9	202.0	− 3.3 %
Royalty & other revenue	79.7	88.0	+ 10.4 %
Total	288.6	290.0	+ 0.5 %

ONO PHARMACEUTICAL CO.,LTD.

Next is the forecast for the current fiscal year. Revenue is forecast to increase 1.4 billion yen year-on-year to 290 billion yen. This is an increase of 0.5%. Revenue of goods & products is expected to go down 6.9 billion yen. We expect royalty and other revenue to grow 8.3 billion yen. As in the previous year, we will not disclose our forecast on the breakdown of royalties from BMS and Merck, but will report the results on a quarterly basis.

Revenue (Forecasts)

Sales Forecasts of Major Products

(Billion yen)

	FY 2018 (Result)	FY 2019 (Forecast)	YoY Change
Opdivo	90.6	**85.0**	- 6.2 %
Glactiv	26.9	**26.5**	- 1.5 %
Orencia SC	17.4	**19.0**	+ 9.0 %
Forxiga	14.5	**16.5**	+ 13.8 %
Emend/Proemend	10.6	**11.5**	+ 8.4 %
Rivastach	8.9	**9.5**	+ 6.8 %
Parsabiv	5.7	**7.0**	+ 22.4 %
Kyprolis	4.9	**5.5**	+ 11.8 %
Onoact	4.6	**4.5**	- 1.8 %
Staybla	3.7	**3.5**	- 5.3 %

ONO PHARMACEUTICAL CO.,LTD.

By product, sales of Opdivo will decline from 90.6 billion yen to 85 billion yen, or 6%. The decline in NHI drug prices will have a major impact. The NHI drug price revision from April 2018 no longer has an impact, but the NHI drug price devaluation from November 2018 will continue to affect this fiscal year.

I won't say that there will be no impact from the planned reduction in NHI drug prices in May this year, but we assume it will be small, and we do not take into consideration this October drug prices at all. On a volume basis, it is expected to increase by nearly 20%. There is a handicap for lung cancer in first-line treatment, so it may be difficult, but we'd like to expand in the areas of renal cell cancer, gastric cancer, and head and neck cancer. As I will explain later, we expect that to happen.

For products other than Opdivo, please check the table. We expect Orencia, Forxiga, Parsabiv, and so on will continue to contribute to sales.

Revenue (Forecasts)

Sales Forecasts of Long-term listed products

(Billion yen)

	FY 2018 (Result)	FY 2019 (Forecast)	YoY Change
Opalmon	10.4	**9.0**	**- 13.1 %**
Recalbon	7.3	**5.0**	**- 31.9 %**
Onon capsule	4.4	**3.5**	**- 19.9 %**
Onon dry syrup	2.7	**2.0**	**- 25.9 %**

Regarding long-term listed drugs, we anticipate that Recalbon, which has recently become a long-term listed product, will have a significant negative impact. The negative impact of long-term listed products will gradually be smaller over time, but the trend remains unchanged. We expect a decline of more than 5 billion yen with 4 products.

Operating Profit (Forecasts)

Operating Profit	YoY Change
¥ 67.0 billion	+ 8.0 %

Costs, etc.

		(YoY Change)	
・Cost of sales	¥ 77.0 billion	(- 8.1 %)	
・R&D expenses	¥ 72.0 billion	(+ 2.8 %)	①
・SG&A expenses	¥ 72.0 billion	(+ 2.8 %)	②
①+② Total	¥ 144.0 billion	(+ 2.8 %)	
・Other income	¥ 0.5 billion	(- 22.6 %)	
・Other expenses	¥ 2.5 billion	(- 26.5 %)	

ONO PHARMACEUTICAL CO.,LTD.

Operating profit is forecast at 67 billion yen, an increase of 5 billion yen from the previous fiscal year. Cost of sales is due to improve. Although this figure rose to 29% in the previous fiscal year, we expect this figure to return to the 26s% level in the current fiscal year. There was a one-time expenditure in the previous fiscal year, which ceases to exist. R&D expenses will increase 2 billion yen to 72 billion yen. Other SG&A expenses are also to increase 2 billion yen to 72 billion yen. We will still be spending some R&D expenses in development tests for Opdivo. We try to manage within a 2-billion-yen increase.

As for SG&A expenses, in the second half of the current fiscal year, we are scheduled to obtain approval for three drugs: the cancer cachexia treatment Adlumiz (anamorelin), the chronic heart failure treatment Coralan (ivabladine), and the Parkinson's disease treatment Ongentys (opicapone). We hope that the three products will be approved promptly, but since we will engage in sales promotion for all three products at once, we anticipate that the costs will be considerably higher. While we expect costs, we do not anticipate sales yet. Other revenue is also expected to improve slightly.

Profit before Tax (Forecasts)

Profit before Tax	YoY Change
¥ 70.0 billion	+ 7.5 %

Net financial income

+ ¥ 3.0 billion (YoY Change - 4.2 %)

Finance income :	¥ 3.1 Billion
Finance costs :	¥ 0.1 billion

ONO PHARMACEUTICAL CO.,LTD.

Profit before tax is forecast at 70 billion yen, up 7.5%.

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

Profit for the Period (Owners of the Parent Company)	YoY Change
¥ 53.0 billion	+ 2.8 %

Income tax expense

¥ 16.9 billion (YoY Change + 25.5 %)

(Major change factors)

Increase in profit before tax	¥ 4.9 billion
Increase in corporate tax	¥ 3.4 billion

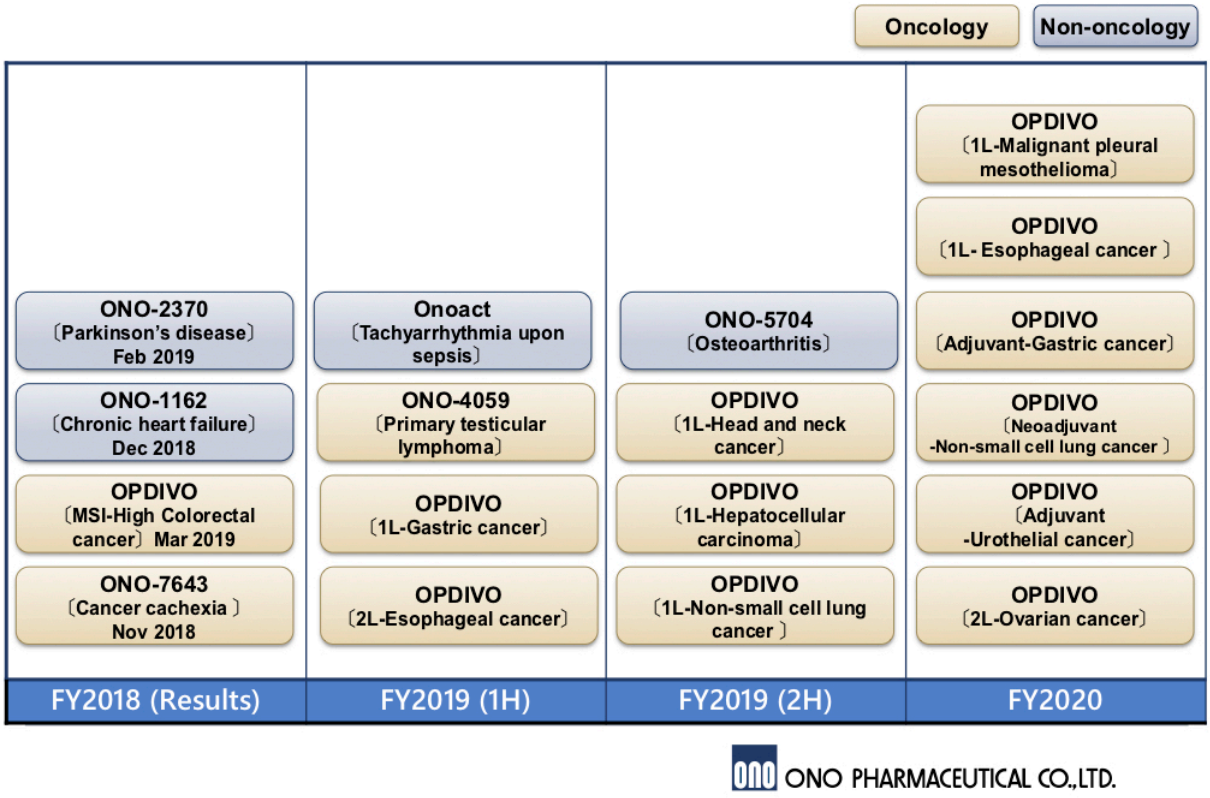
Profit for the period is projected to increase 1.5 billion yen to 53 billion yen. We expect the corporate tax burden rate to rise slightly this year. The percentage of R&D deduction may decline, as one of the criteria to determine the rate is the increase against results in the past three years. Our R&D expenses have increased from around 40 billion yen to 70 billion yen over the past few years, but the growth has slowed down towards 70 billion yen in the past two years, so we expect there might be a rise in the tax burden ratio.

The annual dividend is expected to remain unchanged at 45 yen per share.

Status of Cross-shareholdings

	March 2018	March 2019	YoY Change
Number of listed brands	111	**86**	**(- 22.5%)**
Balance sheet amount	¥ 167.1 billion	**¥ 148.1 billion**	**(- 11.4%)**

Next, I would like to touch on the state of cross-shareholdings. Last November at the briefing on interim financial results, we announced that we would gradually reduce the number of cross-held shares. We are currently aiming for a 30% reduction from the March 2018 level over three years. Half a year has passed, and we are steadily advancing both in terms of stock and sold amount; the monetary amount has decreased by 11%. We are currently proceeding in line with the plan and will continue the reduction. The number of stocks has been reduced by 25.



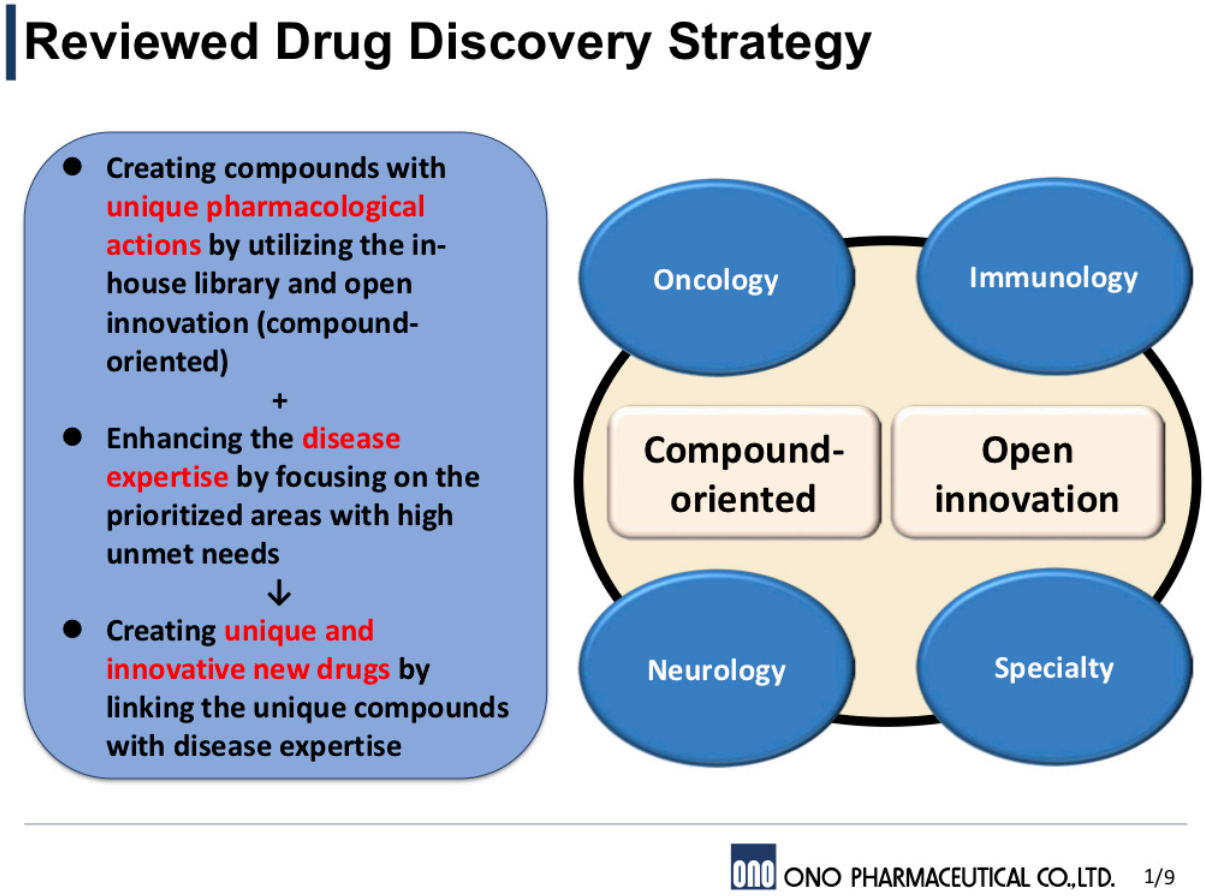
Today we introduced the pipeline from the Development Division, but this is not planned for this event, so I would share the outline. On the left is FY2018, the previous fiscal year. Then there is the first and second half of the current fiscal year, and FY2020, the next fiscal year. The orange parts indicate products in the field of oncology. The gray parts show the products outside of the oncology field. The ones for FY2018 on the left have already been applied. This table is all shown on an application basis, not approval. ONO-2370, this is Ongentys for Parkinson's disease. Then there is ONO-1162, Coralan for chronic heart failure; MSI-High for colorectal cancer; and Adlumiz for cancer cachexia, which have completed their application. Three of these are new products, so if they go smoothly, we will be able to obtain approval in the second half of the fiscal year.

Next, applications to be submitted in the first half of the current fiscal year: an additional indication for Onoact, for tachyarrhythmias associated with sepsis; ONO-4059 for primary central nervous system lymphoma; with Opdivo; 1-L gastric cancer and 2-L esophageal cancer. An application for 2-L esophageal cancer will be made soon. In the second half of the year, we have ONO-5704, for which we are proceeding with clinical trials for osteoarthritis in the knees and other locations. We expect to be able to submit an application in the second half of the year. We also expect that we can submit applications for Opdivo for 1-L head and neck cancer, 1-L hepatocellular cancer, and 1-L non-small cell lung cancer.

Next fiscal year, we currently have plans just for Opdivo, as you can see. The current plans are for 1-L malignant pleural mesothelioma, 1-L esophageal cancer, postoperative adjuvant for gastric cancer, neoadjuvant for non-small cell lung cancer, adjuvant for bladder cancer, and 2-L ovarian cancer. I will just give the outline, so please ask any questions later on. That's all from myself.

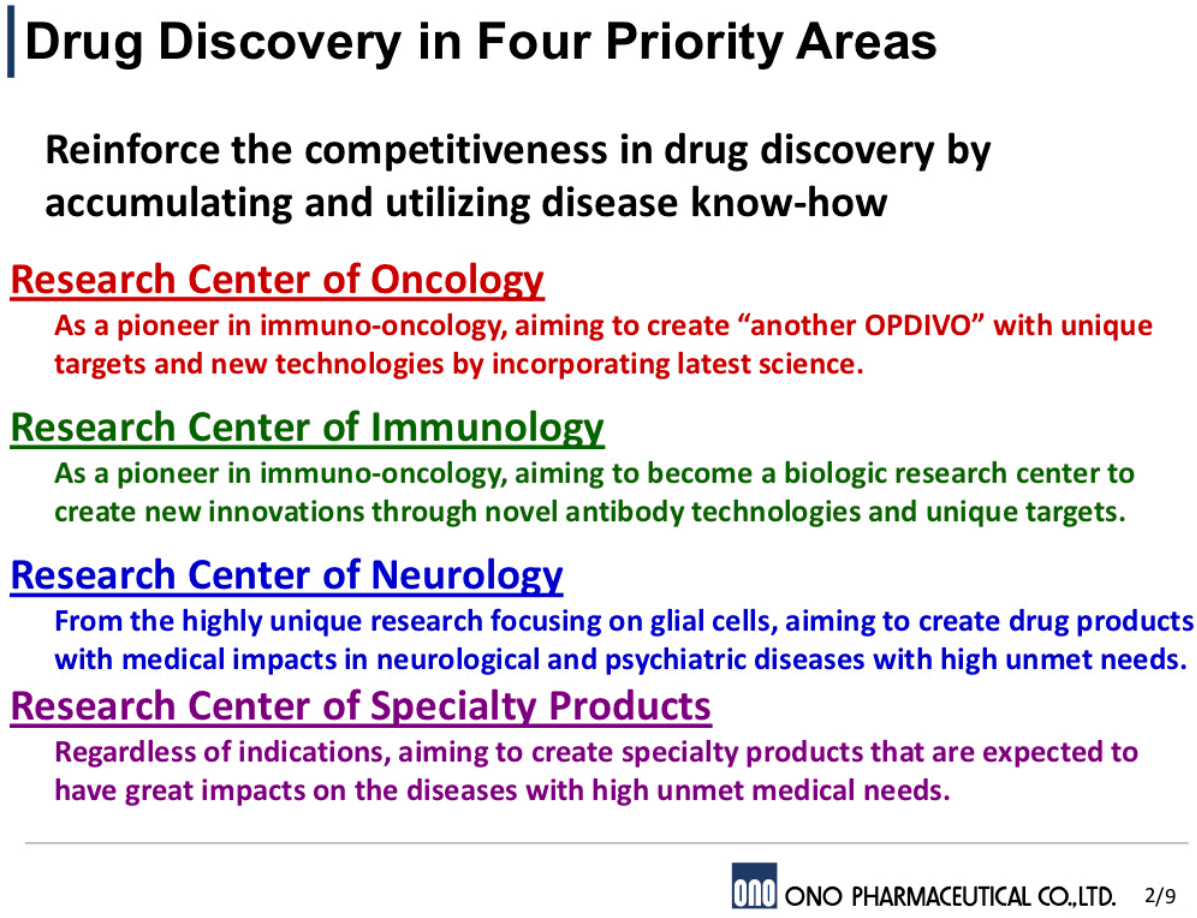
I assume you are interested in what kind of R&D is going on other than Opdivo.

Sagara has already explained the short-term outlook of regulatory approvals and applications in the development pipeline lastly. shown on the last page, so I would like to explain our current initiatives for drug discovery that are not in the development stage.



First of all, we believe that we have been successful in creating and developing extremely innovative products having a unique, characteristic physiological activities or their specific targets as drug candidates, based on “Compound-oriented” drug discovery approach, without establishing their specific disease areas through the prostaglandin history in the lipid area or the development of PD-1.

As is often said generally, low-hanging fruit has already been picked up. The difficulty of drug discovery is increasing, and as we carry out a compound-oriented approach, we consider the need to further enhance and strengthen our expertise on diseases to which it is applied. We have set the four disease areas as priority areas, and made an reorganization particularly for the biology system since this April. Through this initiative, while making good use of our unique strength in unique targets and physiological activities from the past, we will raise our expertise in these fields to ultimately lead to the creation of revolutionary new drugs.



As for the disease areas, you might think that it's the same with any competitive companies. However, we think that the unmet needs still remain in these disease fields at present. We believe that the pharmaceutical company's fundamental goal is to provide drugs with a medical impact to address unmet needs in these diseases areas. This is what we have decided to focus on these areas.

So, what is the difference from the competitive companies? I can't elaborate too much, but regarding oncology, we have many years' worth of know-how around PD-1, which is the target of Opdivo. We are aware that the oncology and immuno-oncology space in particular are constantly changing. Therefore, we are working to create a second and third Opdivo as we continually incorporate the latest science.

On the other hand, with regard to immunology, if the drug that attacks cancer by regulating the immune system is Opdivo, we can say that autoimmune diseases, where immune goes out of control, are opposite effects. We believe that our knowledge and experiences in immunology will prove to be useful in this field, and we are working with a variety of external technologies to this end.

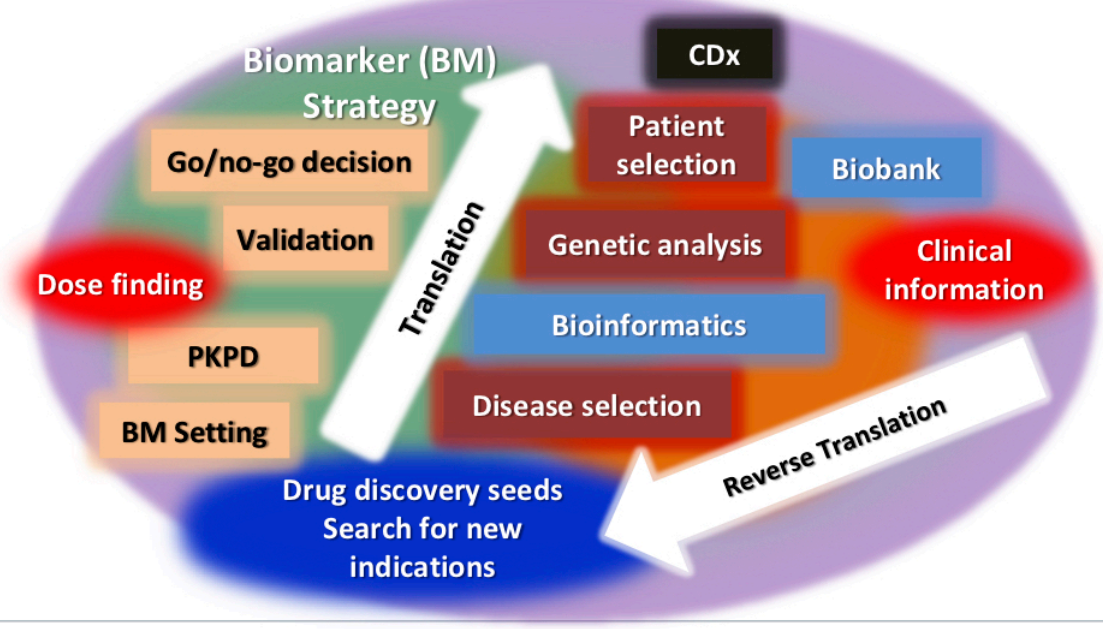
In neurology, you might remember that we had been working on a compound called ONO-2506 targeting at astrocytes for indication of strokes, Parkinson's disease and ALS. Since about a decade ago, we have focused our research on glial cells. Although we have not yet been successful in introducing any product onto the market, we would like to bring it to fruition based on our expertise and know-how developed over many years targeting at the discovery of glial cells which not only support neurons structurally, but also control various physiologies.

Other than these three areas, this might be part of our traditional compound-oriented approach, but we have also set up a specialty to work on innovative new drugs with which we can expect a medical impact on any

unmet needs, regardless of the disease area. We cannot deny that such a discovery and development approach based on physiological activity involves a high-risk drug discovery style for us.

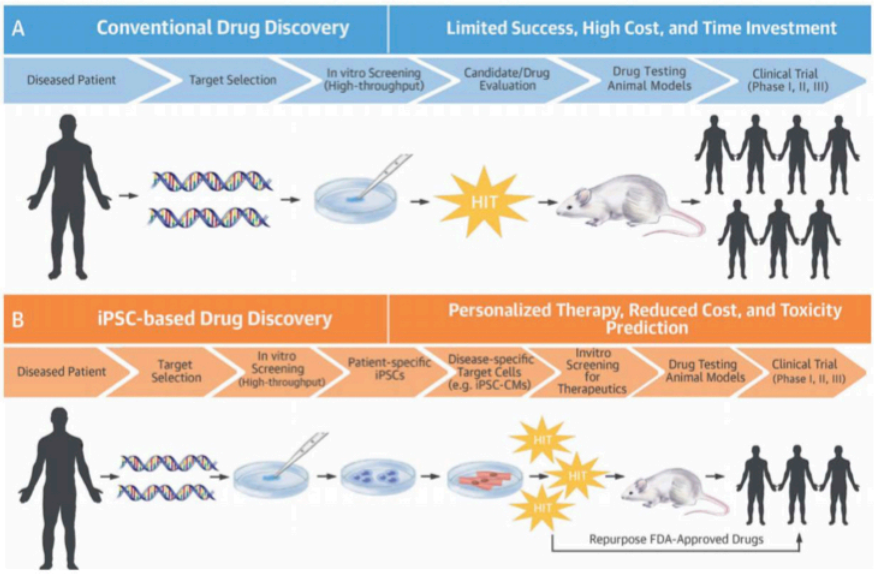
Translational Research to Increase Clinical Likelihood

Increasing the likelihood of drug discovery concepts by utilizing human data and human genetic information.



In order to compensate for this situation going forward, we are actively making efforts on translational research. Not only biomarkers but bioinformatics, including accumulation of human data as much as possible and big data analysis of human genes, should be utilized to increase the accuracy of the target. We are committed to taking this approach of increasing clinical likelihood.

Use of iPS Cells in Drug Discovery



Advantages of iPS cells

Patient-derived cells enable us to monitor the cells under disease condition and drug reactions.

Applications

- ✓ **Efficacy evaluation (exploration of candidate indications)**
- ✓ **Toxicity evaluation**
- ✓ **Target screening**
- ✓ **MoA Analysis**
- ✓ **BM exploration**

J American College of Cardiology, 2016:2161-76

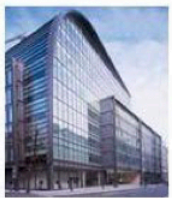
iPS cell-based drug discovery projects are in operation in neurology and cardiovascular areas.

Unfortunately, it is not possible for human samples to be used in a viable condition in all disease areas. Therefore, we are working with various academia on the use of iPS cells. The use of iPS cells in drug discovery evaluation systems still has the issue of reproducibility, and we have not yet reached to a level to establish it in terms of sufficient versatility. Nevertheless, we are working to incorporate this science in order to take an approach of increased accuracy.

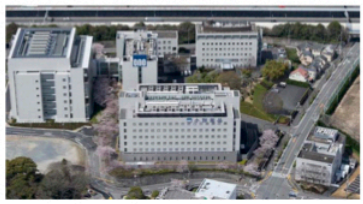
As described above, we are strengthening our expertise on diseases while making the most of our existing unique strengths. We are also maximizing efforts in translational research to fill the gap between human and fundamental research. But we will be actively committed to our drug discovery with the recognition that our activities, as shown on the past lipids and PD-1 development, are inseparable with open innovation and our lifeline.

Research Alliance/Drug Discovery Alliance

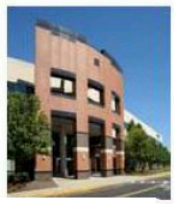
	Number of research alliances		Total
	Japan	Outside Japan	
Number of collaborations As of the end of March 2019	185	120	**305**
Number of newly initiated collaborations in FY2018			**85**



Ono Pharma UK Ltd.



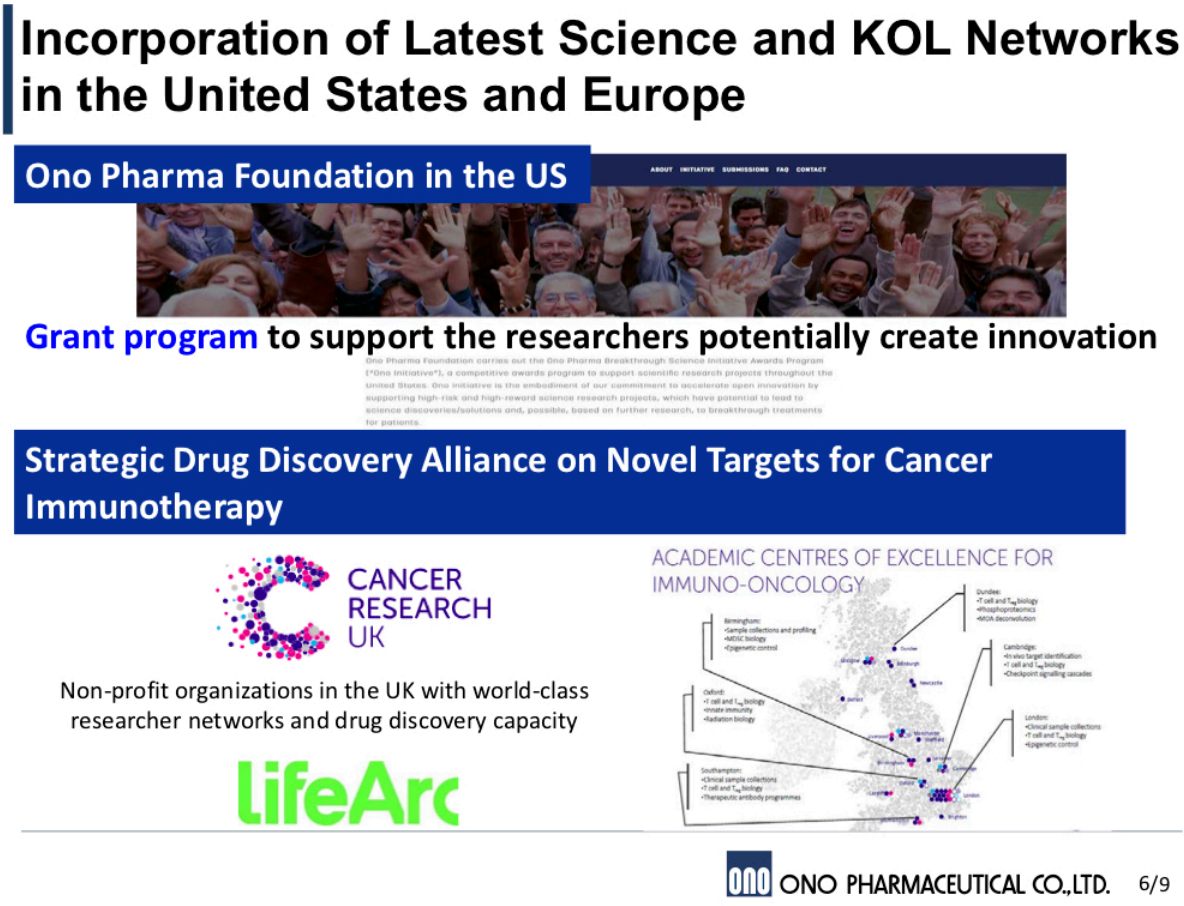
Minase Research Institute
Tsukuba Research Institute
Fukui Research Institute



Ono Pharma USA, Inc.

SCHRÖDINGER · University of Dundee · REPARE THERAPEUTICS · Fate THERAPEUTICS · twoXAR · Cancer Research UK · Ligand · Cyclenium pharma · numab Drug Innovators · neurimmune · VECT-HORUS Breaking Barriers · The University of Tokyo

We are engaged in more than 300 joint research projects in the form of research collaborations, drug discovery alliances, and a variety of other activities, both in Japan and overseas. We are involved in more than 100 joint research projects with overseas partners, and actually we have started nearly 100 research projects in the last fiscal year.

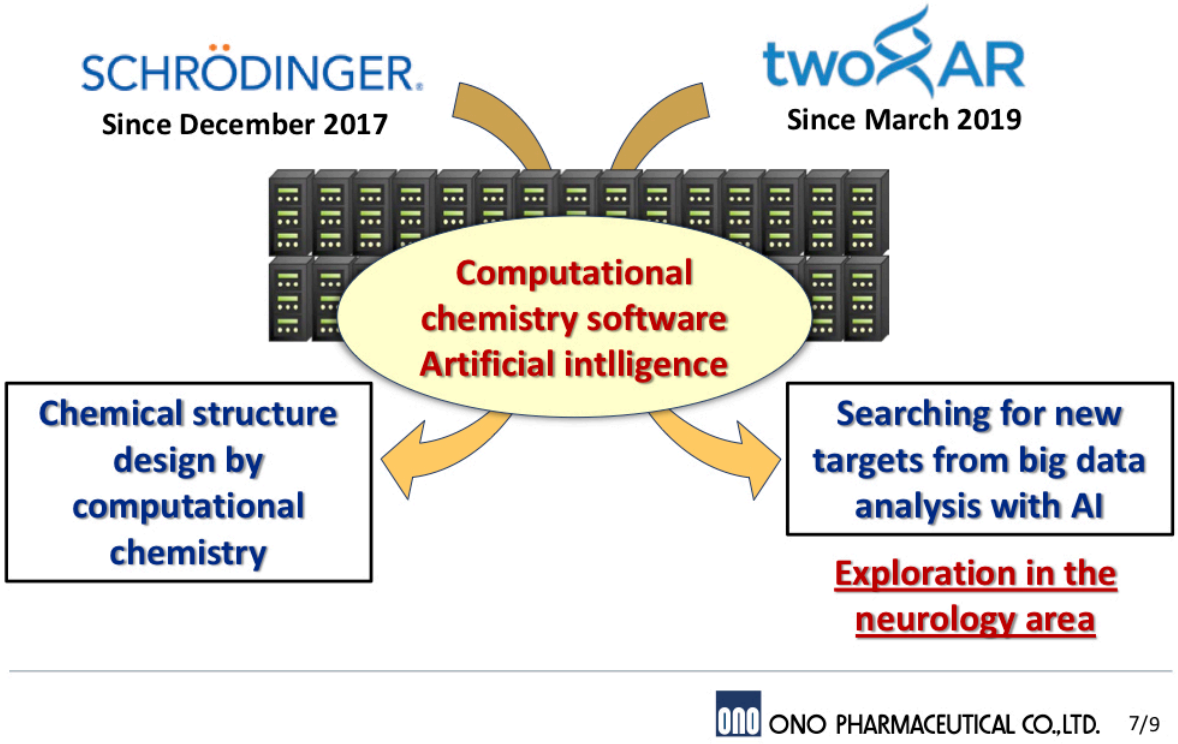


I would like to briefly discuss what we are actually doing. First of all, incorporating academic and KOL networks. We are also doing this in various forms, such as providing research grants to scientists who are engaged in cutting-edge research, though small in scale, in the United States.

We are incorporating the progress of front-line research, new technologies and new ideas.

The lower part shows a partnership we formed this spring. As I mentioned a little at the beginning, as innovation in oncology is proceeding at a very rapid pace, we are working to make the most of strategic use of our network with KOL scientists in Europe, so that we can discover the highest quality seeds and attractive seeds.

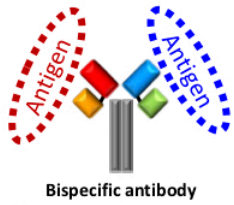
Use of AI Drug Discovery



On the other hand, regarding AI-drug discovery, we cannot deny that it is still at the trial-and-error stage. However, for improving efficiency and productivity, we hope to incorporate the use of big data and advances in computational science and are also trying to incorporate artificial intelligence approaches into our own efforts, while making a small start in the U.S. with SCHRODINGER and twoXAR.

In terms of modality, we can't just keep saying any more that we are a specialist in small molecule drug discovery. As shown in the above, we are engaged in multivalent antibody research, as well as antibodies for the central nervous system. We are working on various projects while considering how to establish our uniqueness in aspects like targets.

Application of Novel Modalities



Bispecific antibody

Antibody technology

Merus (NL)	Bispecific antibodies (Abs) in the area of autoimmune diseases	April 2014
Numab (CH)	Bispecific Abs in immuno-oncology area	March 2017
Neurimmune (CH)	Human Abs in neurology area	November 2017

Merus

numab Drug Innovators

neurimmune Promised antibody therapeutics

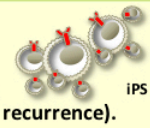
iPS-derived CAR-T Cells: Cancer-killing T cells with forcefully expressed chimeric antigen receptors

Fate THERAPEUTICS

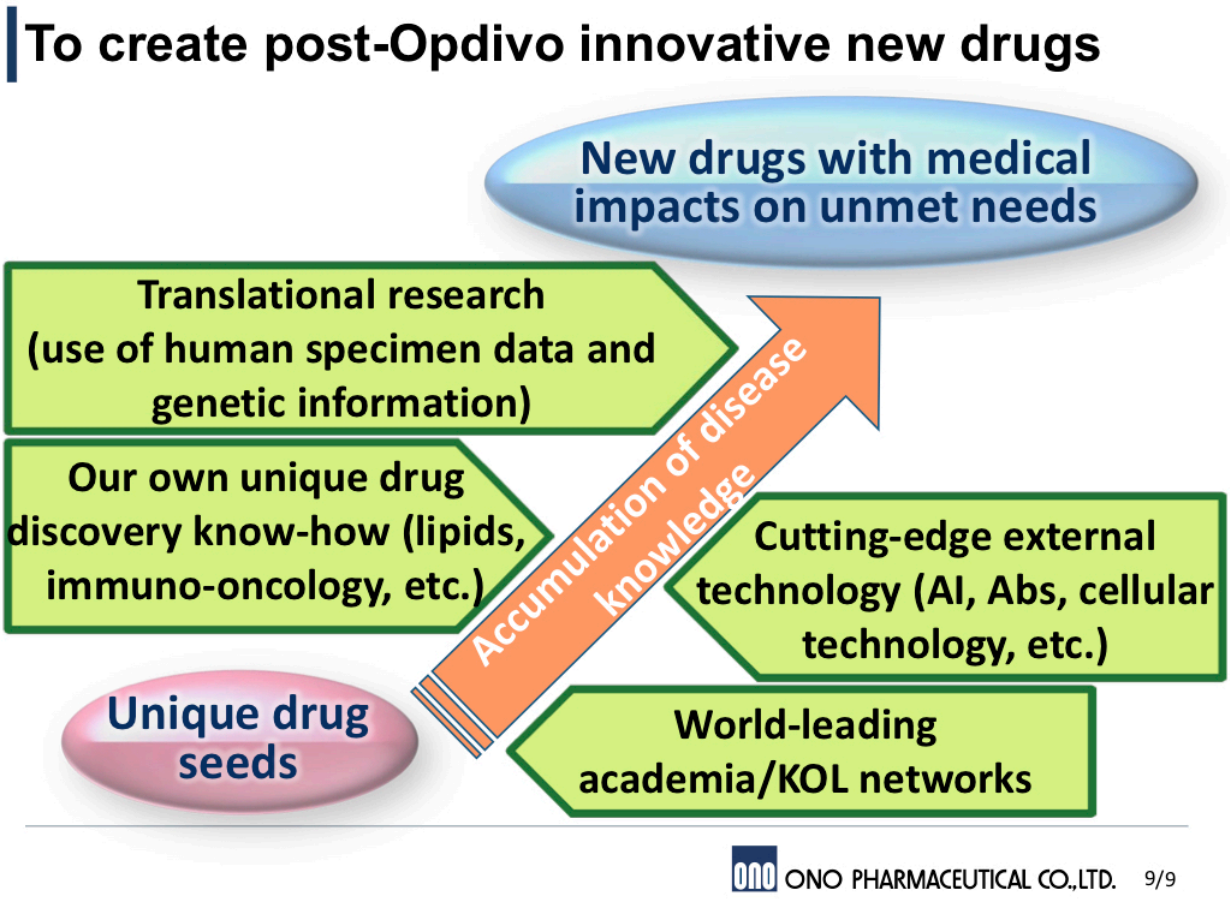
Drug discovery alliance for cellular immunotherapies (Since September 2018)

Target Product Profile

- Mass-producible uniform cells.
- Can be administered to anyone.
- Has a sustained effect (prevents recurrence).
- Has improved safety.


iPS CAR-T

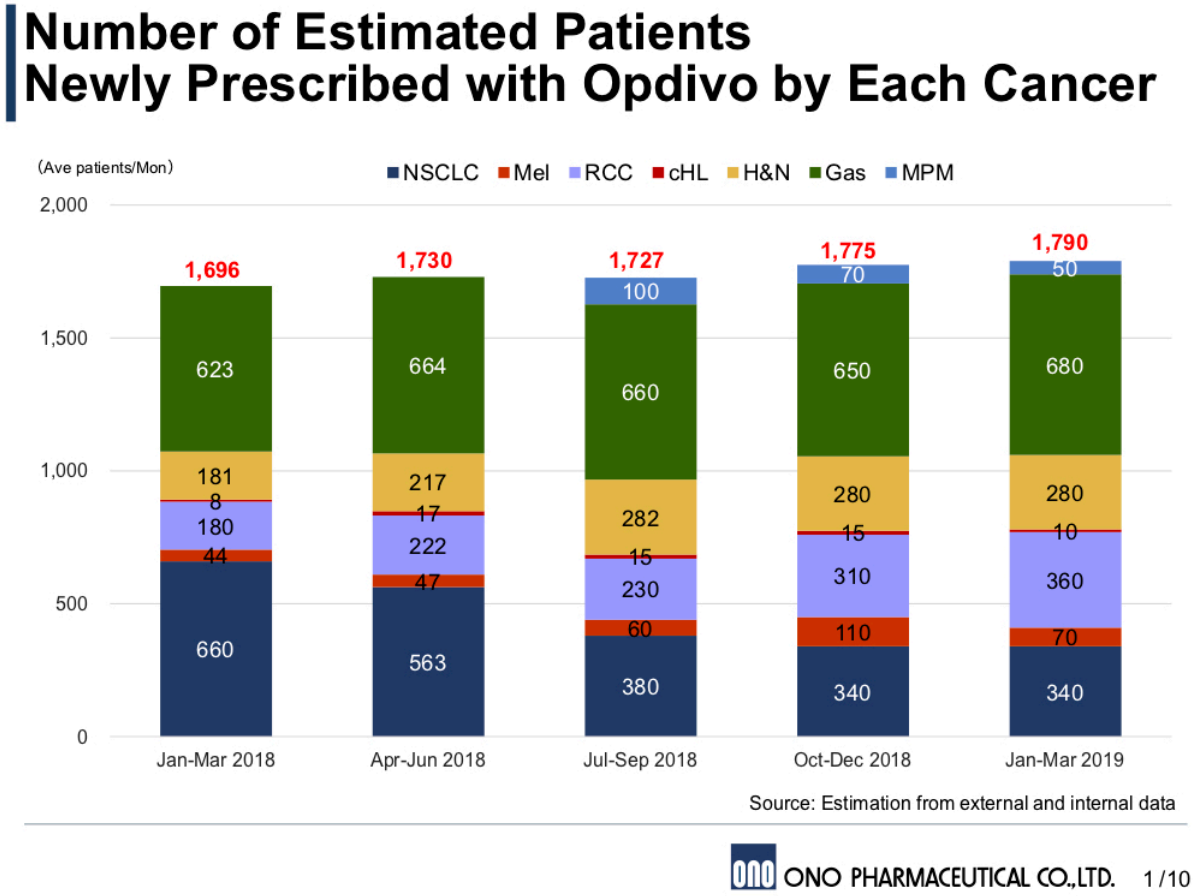
Next is CAR-T therapy, which is attracting attention recently. With regard to this CAR-T therapy, as next-generation CAR-T, we are making steady progress in preparing to enter the field of cell therapy by partnering with the U.S. company Fate for CAR-T using iPS-derived cells.



So, we have no intention to say that we are satisfied with Opdivo alone. While aiming to create something new with an impact only we can deliver, we are working to strengthen our possibly weaker areas in disease-related know-how and translational research. While improving accuracy through these efforts, we are also incorporating the latest modalities and technologies with open innovation as we strive towards the next new drug following Opdivo. I appreciate your warm support and expectations for the outcome. Thank you very much.

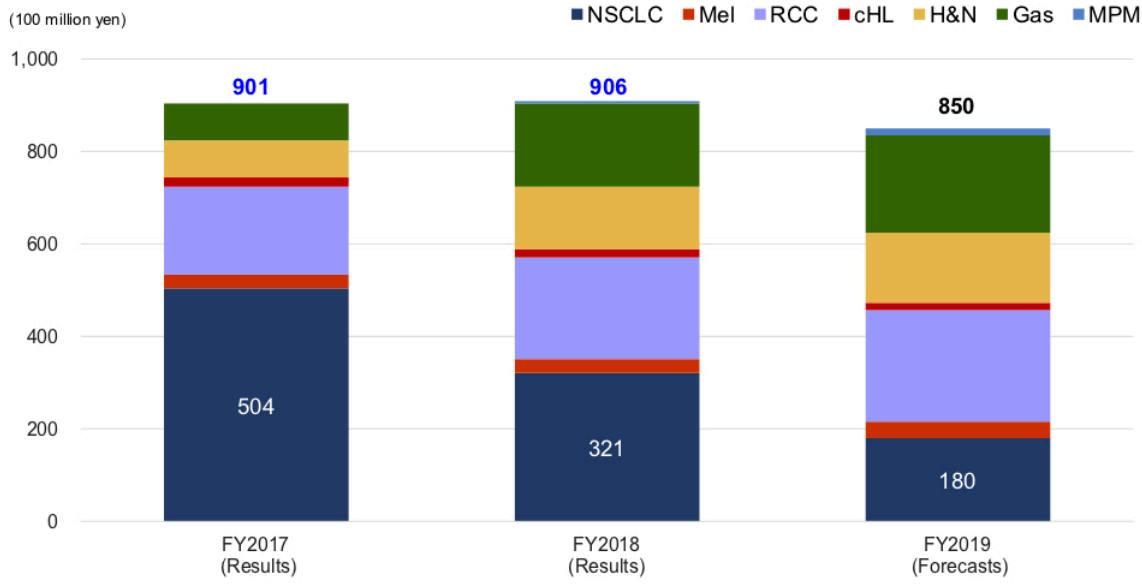
Next, Ⅰ will talk about the trend of Opdivo.

Opdivo is the world's first anti-PD-1 antibody that gained approval for indication of melanoma in July 2014. In the last fiscal year, the combination therapy with Opdivo and Yervoy was approved for the treatment of melanoma in May 2018, and 1L renal cell cancer in August 2018. In addition, monotherapy has been expanded to include adjuvant therapy for melanoma and malignant pleural mesothelioma. Now, the current status of Opdivo is that 7 types of cancers and 10 indications are applicable.



This graph shows quarterly changes in new prescriptions of Opdivo by cancer. While this is just an estimate, there were 340 cases of NSCLC and 680 cases of gastric cancer, totaling average 1,790 cases per month in the last January-March 2019 period.

Sales of Opdivo by Each Cancer (Estimation)

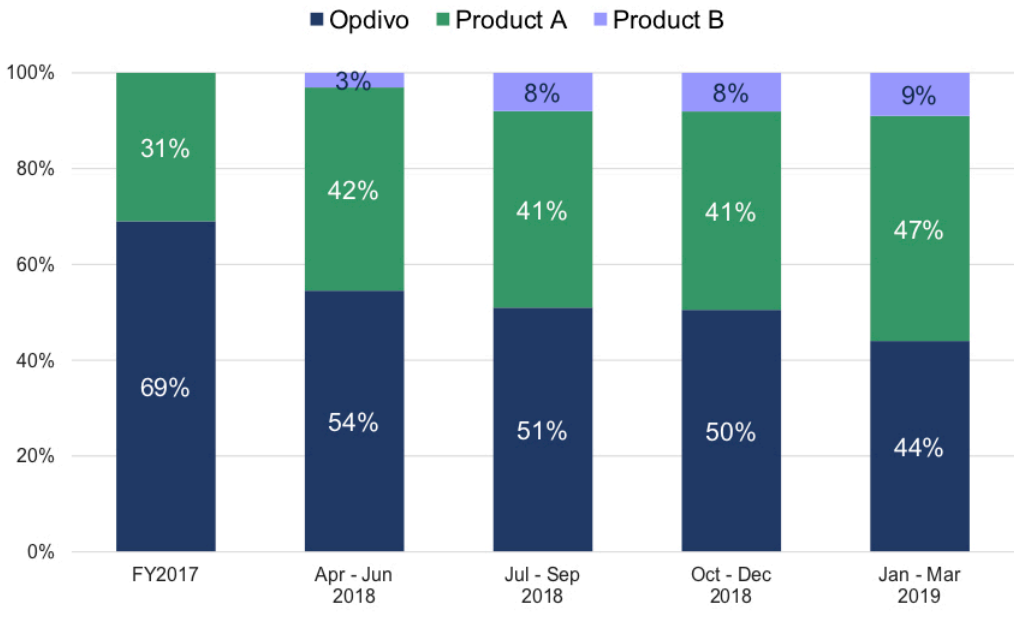


Apr. 2018	Price revision	(-23.8%)
Nov. 2018	Dosage and administration re-pricing	(-37.5%)

Source: Estimation from external and internal data

This is the estimated sales trend of Opdivo by cancer. The sales was 90.1 billion yen in the fiscal year 2017 and 90.6 billion yen in fiscal 2018, with a forecast of 85 billion yen for fiscal 2019.

Share of Sales (Estimation)
I-O Products in All Types of Cancers



Source: External data

Next is the sales breakdown of the main immune checkpoint inhibitors for all cancers. In January-March 2019, Opdivo had a 44% share of the immune checkpoint inhibitors.

Average Treatment Period of Opdivo in Each Cancer

Estimated treatment period

Average treatment period of each cancer is estimated based on Kaplan-Meier curves for PFS of each treatment line by each cancer at the clinical development stages.

Melanoma	:	5.0 months	
Lung cancer:	:	4.5 months	
RCC (2nd line)	:	9.5 months	
Hodgkin lymphoma	:	18.0 months	
H&N cancer	:	4.5 months	
Gastric cancer	:	3.0 months	
MPM	:	4.3 months	
RCC (1st line)	:	9.9 months	(Not reach median value)

Average treatment period of Opdivo for lung cancer based on DPC data

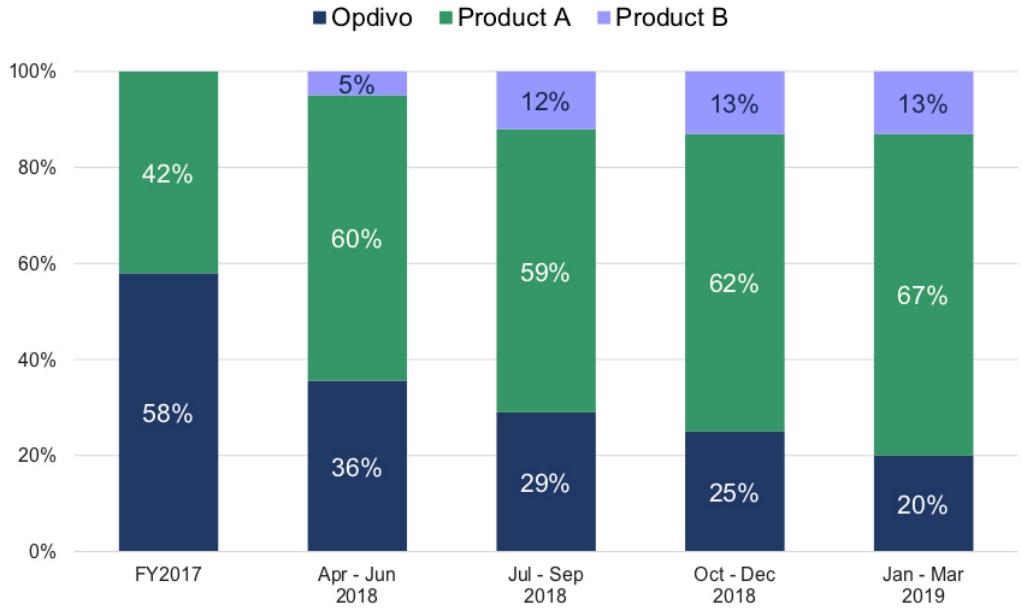
Subjects： Patients who started the treatment by December 2017

Average treatment period	2nd line	:	5.0 months
	3rd line	:	3.0 months

Note: As patients currently under treatment are included, it is anticipated that the period will be further prolonged as time proceeds.

This is the average treatment period of Opdivo for each cancer. We estimate the average dosing period based on the Kaplan-Meier curve of PFS by treatment line for each cancer at the clinical development stages. In particular, the period for 1-L renal cell cancer, with which we entered the market last fiscal year, is 9.9 months (not reached median value).

Share of Sales (Estimation)
I-O Products in NSCLC

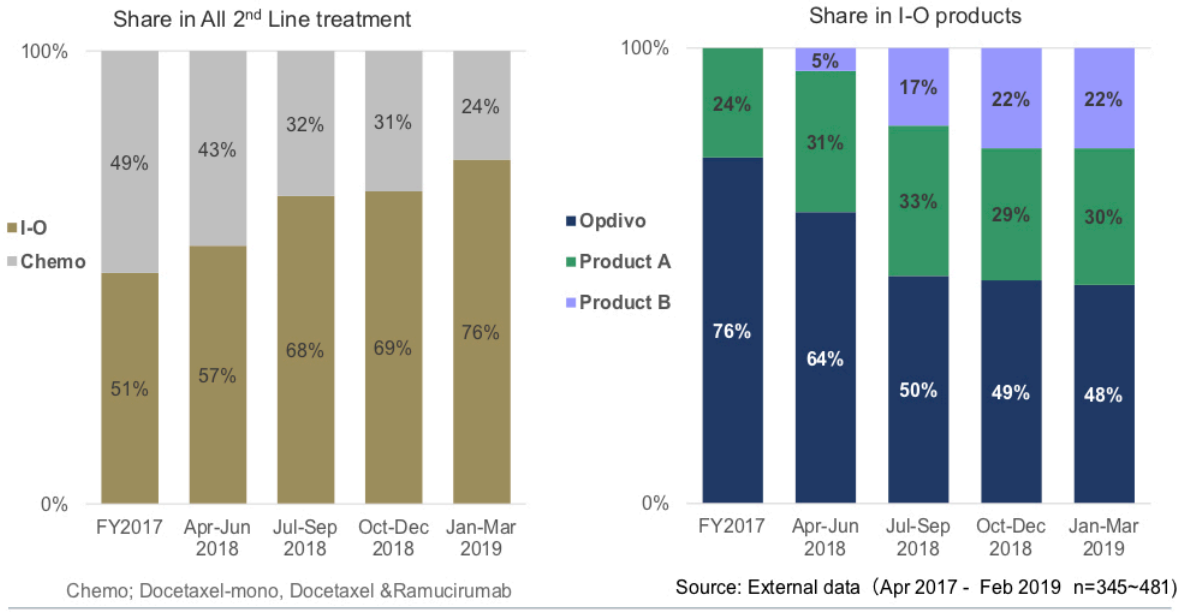


Source: External data

This is a breakdown of sales by IO drugs focused on NSCLC. In the January-March 2019 quarter, the Opdivo share was 20% including all treatment line (1st, 2nd and 3rd or more) of NSCLC.

Prescription Rate Starting Treatment for 2nd Line NSCLC (Estimation)

2nd line NSCLC (SQ+NSQ-WT)

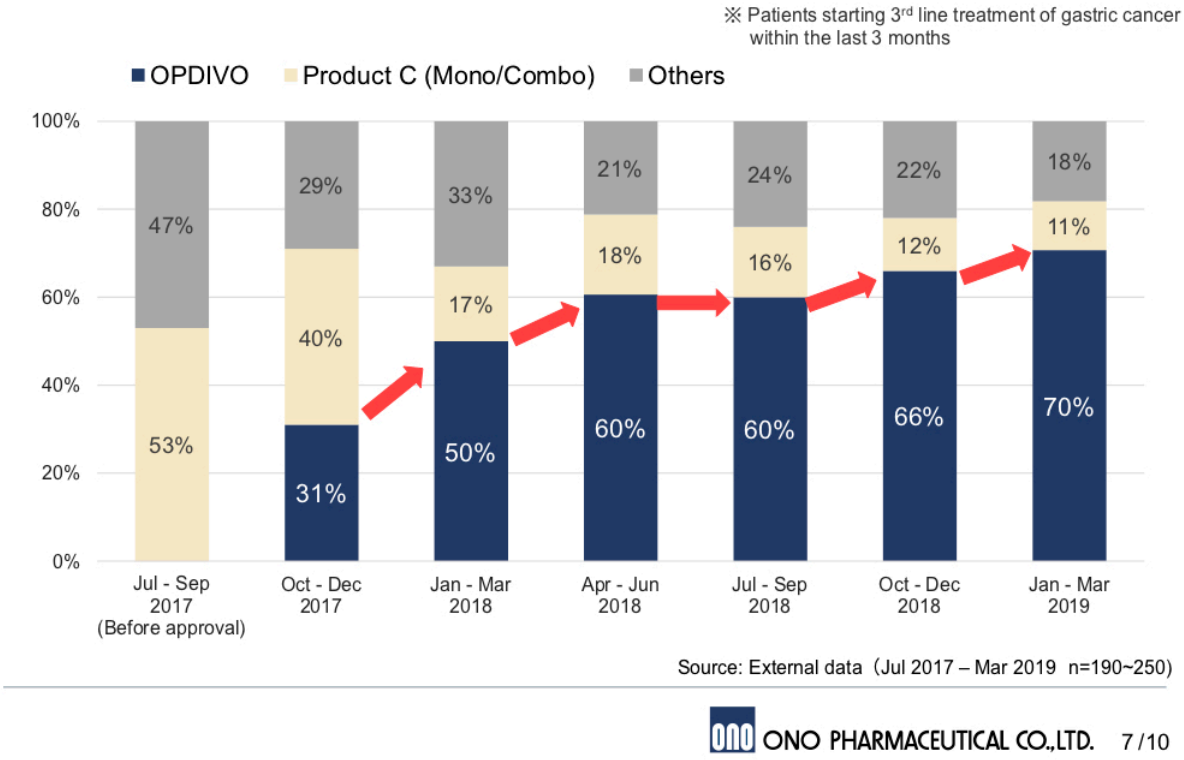


This is the breakdown of new prescriptions limited to the 2L NSCLC.

The left graph shows a prescription ratio of IO products to other chemo (Docetaxel) in 2L NSCLC. In January – March 2018, the share of IO products was 76%.

The right graph shows a prescription ration of IO products. Among IO products, the ratio of Opdivo was 48% in the period from January – March 2018.

Change in Patients Newly Treated for 3rd Line Gastric Cancer

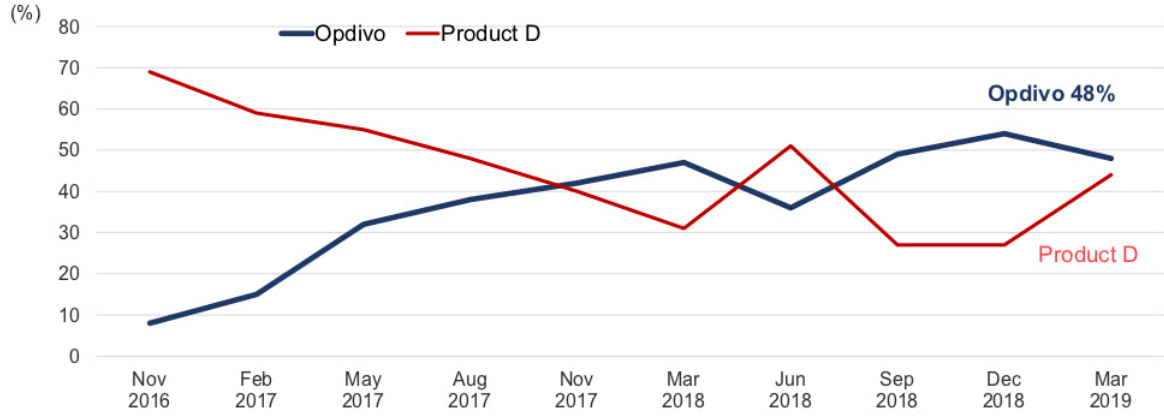


Source: External data（Jul 2017 – Mar 2019 n=190~250)

Opdivo was supplementally approved for the treatment of 3L gastric cancer in September 2017. This graph presents the trend in the share of new patients in the 3rd line. After entering the market in September 2017, we have steadily increased our share. The Opdivo share reached 70% in January-March 2019.

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

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



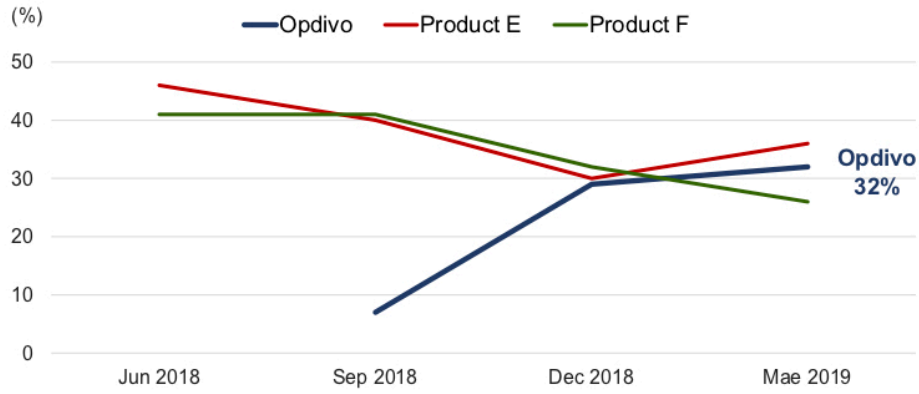
Source: External data (Nov 2016 – Mar 2019 n=32~57)

Opdivo was approved for the indication of 2L renal cell cancer in August 2016.

This shows a change in new prescription share in the 2L renal cell cancer. In March 2019, the Opdivo share was 48%.

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

	2018 Jun	Sep	Dec	2019 Mar
Opdivo (%)	**-**	**7**	**29**	**32**
Product E (%)	46	40	30	36
Product F (%)	41	41	32	26



Source: External data（Sep 2018 - Mar 2019 n=39~57）

The combination therapy of Opdivo and Yervoy was approved for the treatment of 1L renal cell cancer in August 2018.

This slide shows the trend in new prescription patients on the 1st line of renal cell cancer. In March 2019, the Opdivo share was 32%.

Question & Answer

Q: I would like to ask you a few questions about Opdivo. You issued a press release yesterday, and I had the impression that the side effects are treated differently than usual, although I don't think it is actually different. Could you give us a brief explanation of whether the handling of side effects is likely to have a clinical impact?

A: There is no difference whatsoever about the handling of side effects. Regarding the effect on the clinical practice, we have been alerting doctors about the announced side effects as already known side effects since the product launch. We will continue to promote proper use and provide doctors with accurate information.

Q: My second question is about your future application schedule that you described. It's well known that 1-L lung cancer has become a considerable issue. You plan to apply for 1-L non-small cell lung cancer for Opdivo in the second half of fiscal 2019. Do you expect to recover your share for lung cancer in Japan after obtaining approval? There are various indications, but I think the expectations are particularly high in this area.

A: With regard to the combination therapy of Opdivo and Yervoy, we have high expectations for the clinical efficacy. We believe that we will be able to recover market share without fail by obtaining additional indications.

Q: Lastly, you mentioned that Opdivo sales for this fiscal year would be 85 billion yen, with the volume expected to grow but price to decline. Even as you have been hitting a wall of 100 billion yen sales several times in the past, given what you have mentioned, from next fiscal year, do you envision overcoming this wall and achieve another revenue growth, even if it may not be a significant increase?

A: Yes. It's a bit tough this fiscal year, certainly. We believe that if applications are approved from the next fiscal year onward, we will be able to grow again, particularly in the gastrointestinal field. We believe that the drug prices have almost stabilized, so we expect that the next fiscal year and beyond will be a time when the expansion of the volume base will be reflected in our performance, and the results of our development will also be materialized.

Q: Lastly, I would like to ask a brief question. There were some news including a press conference with a Kyoto University professor, and media quoting yesterday that you will make a comment within the month. I don't know the details of the contract, but I think it is better to solve the problem at an early stage in the sense that you should improve relationships with academia. Of course, I think there are various other aspects of the contract, but do you have a good prospect of successfully riding out this issue? I was wondering about the comments to be made from your side by the end of the month.

A: All I can say is that we will make a comment by the end of the month. We have to work well with academia. As I mentioned earlier, we are conducting 300 joint research projects, including small ones, and I believe it is important that we continue to do this steadily in the future. But that is one matter, and this is something else, so please wait for a moment.

Q: In any case, are you going to comment within the month?

A: Yes, we will.

Q: I have three questions. The first is about the schedule of applications, where you put 1-L gastric cancer in the first half of this fiscal year. Do you already have the top line or rough data, so you can submit an application at this timing, or do you just see the timing when the data will be available?

A: It reflects the timing of when data will be open. We haven't yet opened and confirmed the content.

Q: . In addition, I expect that the combination of Keytruda and Inlyta will be indicated for 1-L renal cell cancer in the near future. What are your views on the risks of competition? The impression as a layman is that you can differentiate from a safety aspect. And I wonder if Yervoy is better to use in terms of convenience. Could you tell us?

A: Opdivo targets medium- to high-risk patients with 1L renal cell cancer in the IMDC risk classification. We expect to secure a certain share of high-risk patients with Opdivo. We think the main competition might take place in medium-risk cases, but we think that we can secure a certain share based on the increasing recognition of the efficacy and safety of Opdivo. In addition, we think that Opdivo has an advantage to be used in an IO naïve patients in the 2L treatment.

Q: Finally, in explanation of R&D expenditures for the current fiscal year, I understood that certain cost will still be spent for Opdivo. Do you mean that this amount will be spent just for this period, and you are already seeing the timing of peaking?

A: Allow me to make a correction if I gave such an impression. We have a vision of how long to actively invest in development trials, based on the time when the patent expires, and that this is still a long way to go.

Q: I would like to ask about the comments made by Mr. Sagara regarding Opdivo's drug prices, including confirmation. I believe the reduction due to the change in dosage and administration last November had an impact by end of December, including the impact of inventory adjustments, but I think you mentioned that the impact has been larger than anticipated. Is there anything you confirmed in the fourth quarter? And this fiscal year, I recall you are planning a 20% increase in sales volume, which means the average drug price will be down by around 25%. I assume that the consumption tax hike in October would not have an effect on the drug price, but there should be the issue of cost performance. Can you clarify a little whether the assumption includes such factors?

A: First, we had said that the impact of the NHI drug price revision in November 2018 would almost zero. This was because the change accompanies the change in dosage and administration and is not a special reduction. Or maybe saying it's not special is misleading. The reduction is based solely on changes in dosage and administration. That's why we said there was basically no impact on sales, but that view seems to have been a little too bullish. Actually, in practical terms, the average weight of patients was just under 60 kg. But it was decided that the NHI drug price would be set based on a weight of 50 kg as a rule, and this led to a decline. We had understood this, but the impact should have been viewed mores strictly, and in reality, there was a negative impact.

Next, we expect the revision of the drug price in May this year to be in the lower single digits. It is hardly included in the assumption. Of course, the NHI drug price revision in October this year has not been decided, so it is not included. We are looking at drug prices in such a way, but does this answer your question? Is there something missing?

Q: So, the assumption of Opdivo's drug price from this April has not changed, and you haven't made any changes in the assumptions for the full-year forecast, right?

A: Yes, that's right.

Q: And you are saying that volume is expected to increase by 20%, but revenue will decline by 5%.

A: Strictly speaking, yes, that is the case. For example, suppose the impact of drug prices after November 2018 is roughly 20%. Then the 90 billion yen becomes 72 billion yen. There is a 20% increase in volume basis.

Then the figure should be slightly below 90 billion yen, around 87 billion yen, I guess. We have set sales forecast at 85 billion yen from a conservative perspective, so I hope you will understand how we came to this figure.

Q: Understood. Two more questions, including confirmation. You mentioned the impact on costs to stabilize Opdivo supplies since last year. Could you tell us what some actual figures? Have you disclosed it? This includes confirmation. Is this a payment to Bristol?

A: Yes.

Q: Could you suggest any figures or an idea of the scale?

A: No.

Q: I understand. Lastly, with regard to the combination of Yervoy and Opdivo for 1-L non-small cell lung cancer, which is scheduled for the second half of this year, there is a trial CheckMate-227 that doesn't come up much. Is your plan based on this trial, and how is the communication with Bristol, including the Tumor Mutation Burden, which I assume was dropped?

A: For 1-L non-small cell lung cancer, first the result of combination with Ipinivo for PD-1-positive will be delivered. We will make an application if the results are good. And some time after that, data on the combination with chemotherapy, called part 2 of 227, will become available. Again, we will make an application if the results are good. The explain has both in consideration. After that, there is a study on combination of Ipinivo and chemotherapy conducted in Japan, but this has not yet been included.

Q: I see. So, you're waiting to see data disclosure of 227, which would be the assumption.

A: Yes.

Q: As for the second page of the Opdivo trend, I believe you plan for lung cancer plan for this fiscal year is 18 billion yen out of 85 billion yen. Assuming that the price is 20% lower, I think your assumption is that the volume for lung cancer will decline by about 30%. With the penetration of Keytruda and chemotherapy in the 1st line, is the decline likely to be limited to 30%? Could you tell us about the current market conditions in the 2nd line, as well as how the 1st line Keytruda plus chemotherapy is used?

A: I think that the 1st line IO/chemo treatment started in January this year. We consider the impact on the shrinking market in the IO naïve patients on the 2L treatment to be seen from around June. The efficacy and safety of Opdivo has been well evaluated from doctors in clinical practice with real world data (all-cases survey) in Japanese patients. We will promote Opdivo activities in this tight 2L market, expecting 18 billion yen this fiscal year.

Q: I see. My second question is about the 227 trial. If both Part 1a and Part 2 are successful and their contents are satisfactory, with combinations with plus Yervoy and IO, I assume you will identify some points to differentiate from Keytruda. For you to capture the 1st line market, which is more important, part 1a or Part 2? I know both are important, but what is the positioning of each, and which is easier to differentiate? Could you give any comments?

A: We have to wait for the result of the 227 trial to make a comment, but we consider both Part 1 and part 2 to be important. As the IO/chemo combination therapy is currently starting in 1L NSCLC patients in clinical practice, we would like to analyze the current situation precisely. Furthermore, the combination therapy with Opdivo and Yervoy has been started for the treatment of melanoma and renal cell cancer and we would like

to accumulate clinical data to make the best use for future activity. We will prepare for the penetration into the NSCLC market once Opdivo has received its approval.

Q: I see. Lastly, you explained new initiatives for drug discovery. I understand that there have been alliances with various companies and new projects are running, although I think it will take some time before compounds start entering the clinical field. What is the potential you are feeling, and what is the expected timing when actual compounds will be coming out?

And I believe that you are working on drug discovery to pursue post-Opdivo opportunities, but I don't think the amount you are spending is particularly large. Could you tell me whether there is a possibility that you will spend a little more on this area?

A: I can't say for now what compounds will come out in the near future. R&D investment is currently planned at 72 billion yen, but this has not been enough to do what we are hoping to do. We want to do a lot more, and hopefully we will bring ourselves to be able to spend 100 billion yen in the near future. In practical terms, it is difficult to invest 100 billion yen in the current situation, but we hope to do this as early as possible. So, we will be using and increasing the amount to the maximum extent allowed by the situation.

Q: Considering the 20 billion yen in dissolution of cross-shareholdings and the current share price level, as well as the current dividend payout ratio in the 40s% range, when I asked at the earning announcement made six months ago whether you considered share buybacks, I remember the president gave a suggestive answer. What is your current concept of shareholder returns, in particular for share buybacks?

A: Our approach to shareholder returns has remained unchanged, with both dividends and share buybacks. Dividends should be stable in amount and additionally based on performance, and we will continue to buy back shares in an agile manner. These policies have not changed. I understood that in short, your question is whether we will use the 20 billion yen cash for share buybacks. As you know, we cannot answer this question at this point, but basically, there are various measures in the process of reducing cross-held shares by 30%, and we do not deny share buybacks as one option. So far, we have conducted a secondary offering, and also repurchased our own shares, so there are different measures after selling shares on the market, but there is no change that it remains an option.

Q: Aren't you very concerned about the stock price falling below 2,000 yen?

A: We'd like to watch it over the medium term, rather than making a spontaneous evaluation.