Financial Results

Revenue

Revenue	YoY Change
¥ 149.0 billion	+ 3.2 %

Breakdown of Revenue

(Billion yen)

	FY 2018 Q2	FY 2019 Q2	YoY Change
Revenue of Goods and Products	105.0	106.8	+ 1.6 %
Royalty & other revenue	39.4	42.2	+ 7.3 %
(Opdivo)	(28.1)	(30.7)	(+ 9.3 %)
Total	144.4	149.0	+ 3.2 %

Product sales increased 1.8 billion yen to 106.8 billion yen, and royalty and other revenue increased 2.8 billion yen to 42.2 billion yen. Total revenue was 149 billion yen, up 3.2%. The breakdown of royalties is as follows: Royalty from Bristol-Myers Squibb increased by 2.6 billion yen to 30.7 billion yen. The royalty from Merck was 8.5 billion yen, an increase of 2.9 billion yen.

Revenue

Sales of Major Products

(Billion yen)

	FY 2018 Q2	FY 2019 Q2	YoY Change
Opdivo	45.4	**46.8**	+ 3.1 %
Glactiv	13.7	**13.3**	- 3.3 %
Orencia SC	8.6	**10.0**	+ 16.0 %
Forxiga	7.0	**8.7**	+ 24.4 %
Emend/Proemend	5.3	**5.9**	+ 10.4 %
Rivastach	4.5	**4.4**	- 3.7 %
Parsabiv	2.7	**3.5**	+ 28.4 %
Kyprolis	2.6	**2.9**	+ 13.5 %
Onoact	2.2	**2.4**	+ 12.6 %
Staybla	1.9	**1.6**	- 15.4 %

This table shows a sales breakdown by product. Opdivo sales increased by 1.4 billion yen, to 46.8 billion yen. There have been many changes including an NHI drug price of Opdivo. The price was revised in November last year, and decreased by 1% in August this year. A shift towards 240 mg flat dosing has made it a little difficult to determine how much is moving on a quantity basis. However, roughly speaking, taking into account the number of patients treated and other factors, we can estimate that volume increased by around 20%.

This may come up in the Q&A section, but the preliminary demand for Opdivo before the consumption tax hike in September was estimated to be around 2 billion yen.

As you can see, the products that contributed most to the increase in sales are Orencia, Forxiga, and Parsabiv.

Revenue

Sales of Long-term Listed Products

(Billion yen)

	FY 2018 Q2	FY 2019 Q2	YoY Change
Opalmon	5.5	**4.5**	- 19.2 %
Recalbon	4.4	**2.6**	- 41.1 %
Onon capsule	1.9	**1.6**	- 18.3 %
Onon dry syrup	1.2	**1.0**	- 14.2 %

This slide shows long-term listed products. As you can see, sales continue to be substantially negative, and for these four products sales are down about 3.5 billion yen. Incidentally, sales of long-term listed drugs make up about 10% of our domestic sales.

Operating Profit

Operating Profit	YoY Change
¥ 41.9 billion	+ 19.1 %

Costs, etc.

		(YoY Change)	
・Cost of sales	¥ 41.7 billion	(+ 0.1%)	
・R&D expenses	¥ 30.9 billion	(- 6.4%)	①
・SG&A expenses	¥ 33.7 billion	(- 1.4%)	②
①+② Total	¥ 64.7 billion	(- 3.8%)	
・Other income	¥ 0.4 billion	(- 22.7%)	
・Other expenses	¥ 1.2 billion	(+ 33.9%)	

Operating profit was 41.9 billion yen, up by 6.7 billion yen, or 19%, from the previous fiscal year. Cost of sales was 41.7 billion yen, almost the same year-on-year. The cost ratio is 28%. This is expected to decline in the second half of the year, and it is expected to be around 26.6%.

Regarding R&D expenses, we are planning to spend 72.0 billion yen over the full fiscal year. As of the end of the first half of the fiscal year, we have spent 30.9 billion yen, so we are a little behind schedule. There were many delays that occurred and have affected our schedule for the second half of the fiscal year. However, the full-year R&D expense forecast remains unchanged at 72.0 billion yen.

Selling, general and administrative (SG&A) expenses, excluding R&D expenses, are progressing at 33.7 billion yen, compared with the 72.0 billion yen planned. This is also a little behind schedule, but we originally planned to make large expenditures in the second half of the fiscal year. In the second half of the fiscal year, for example, Opdivo will have an additional indication for esophageal cancer, and there will be the launches of Coralan, Adlumiz (slightly behind schedule) and Ongentys, concentrated in the second half of the fiscal year and the first half of the next fiscal year. The full-year SG&A expenses remains unchanged

Profit for the Period
(Owners of the Parent Company)

Profit for the Period (Owners of the Parent Company)	YoY Change
¥ 32.8 billion	+ 13.8 %

Income tax expense

¥ 10.1 billion (YoY Change + 26.0 %)

(Major change factors)

Increase in profit before tax	¥ 6.1 billion
Increase in corporate tax	¥ 2.1 billion

Profit for the period was 32.8 billion yen, or +13.8%. The actual tax burden for corporate tax was 20.7% last year, but this time it is expected to be around 24%. Deduction amount of R&D expenses will decrease, or the R&D ratio will slightly change. R&D investment has been steadily rising so far, so the tax deductions have been quite large. This year, however, the ratio of R&D expenses and sales will shift slightly, so the tax deductions will reduce a little.

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 %

The sales forecast for 2020 is 290.0 billion yen, with no revisions to sales or profit forecasts. The sales figures are in line with the initial targets.

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 %

There is no change in sales forecast by product.

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 %)	

There is no change in operating profit forecast either.

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

There is no change in profit forecast with final profit for the period with 53.0 billion yen.

Status of Cross-shareholdings

	End of March 2018	End of September 2019	YoY Change
Number of listed brands	111	**84**	**(- 24.3 %)**
Balance sheet amount	¥ 167.1 billion	**¥ 146.1 billion**	**(- 12.6 %)**
the market price at the end of March 2018	¥ 167.1 billion	**¥ 147.2 billion**	**(- 11.9 %)**

Next, strategic shareholdings. Going back to last year, I would like to talk about the Company's cross-shareholdings policy. As I mentioned about this time last year, we would reduce 30% of the Company's policy-based stockholdings, which we had as of the end of March 2018, over a three-year period. The number of stock names has declined from 111 to 84. On a mark-to-market basis, we have reduced approximately 12%, going from 167.1 billion yen to 147.2 billion yen. We will proceed as planned over the next two years.

External Evaluation of ONO's ESG Initiatives

Index for Socially Responsible Investment	
Listed in December 2018 **FTSE4Good Index Series** **FTSE Blossom Japan Index**	FTSE4Good FTSE Blossom Japan
Climate Change A List Company in 2018	
Selected in January 2019 **As a global leader on Climate Change A List in CDP 2018**	CDP A LIST 2018 CLIMATE CHANGE
MSCI Japan ESG Select Leaders Index	
Selected in May 2019 **As a company with outstanding ESG performance**	MSCI
Science Based Targets (SBT) Initiative	
Approved in August 2019 **Mid- and long-term targets for greenhouse gas reduction based on SBT initiative**	SCIENCE BASED TARGETS DRIVING AMBITIOUS CORPORATE CLIMATE ACTION

For the first time, I would like to talk about ESG. We have been strengthening our ESG initiatives for several years. Until then, we had been far behind other major Japanese companies in the industry. Over the past few years, however, we have moved forward one step at a time, and received a lot of positive feedback.

We are one of 20 companies in Japan given an A-list rating in the CDP carbon dioxide disclosure system. We have been successful so far in raising our CO2 rating, as can be seen in this report.

In summary, the second quarter has seen steady progress with respect to these targets. The annual target will be left unchanged in the mid-term.

We are planning to launch new products, and the general manager of the Development Division will speak about the status of the application later. I would like to explain about the prospects for the launch of Coralan, a treatment for chronic heart failure, which is expected to be launched during the current fiscal year. Ongentys is expected to be launched in the first half of next year. In addition, although discussions are taking place at the moment, I look forward to the launch of Adlumiz in the first half of the next fiscal year.

We also plan to launch ONO-5704, hyaluronic acid, for the treatment of osteoarthritis in the second half of the next fiscal year. As for the additional indications for Opdivo, we expect to receive approval for the second-line treatment of esophageal cancer during the current fiscal year, and for the MSI-High colorectal cancer during the current fiscal year as well. We plan to submit an application for first-line treatment of non-small cell lung cancer during the current fiscal year, with a view to obtaining approval in the second half of the next fiscal year. Assuming everything goes to plan, that is our timeline.

Therefore, in the next year or so, four new non-oncology products will be launched, and I have mentioned the additional indications for Opdivo. Clinical trials are underway for further indications, and we expect it to return to a growth trajectory once again.

Development Pipeline Progress Status

Before I present the slides, I would like to give you an update based on the materials you have on hand. We have updated the Summary of Financial Results on page three from the middle to page four as the main progress status of the products under development. In addition, as for the Supplementary Material on the financial results, we have also updated the main progress status of products under development from pages 6 to 13.

First of all, we will update the financial results for the first quarter and thereafter, using the supplementary materials on hand. Regarding the materials, the oncology field is written first. This has Japan, then South Korea, Taiwan, Europe, and the Americas. Thereafter, we have listed the areas other than oncology in the same order of territory.

I'll start with page six first. Regarding the status of development in the field of oncology in Japan, ONO-4059/ tirabrutinib, at the bottom of the table, is a kinase inhibitor called BtK. We have submitted an application in August for the treatment of Primary Central Nervous System Lymphoma, PCNSL.

Then, on page seven, there is description about the Yervoy Injection in the second-from-bottom where you can see colorectal cancer and MSI-High. Microsatellite instability high is abbreviated as MSI-High. We have begun a phase III trial of Opdivo and Yervoy in combination for MSI-High colorectal cancer.

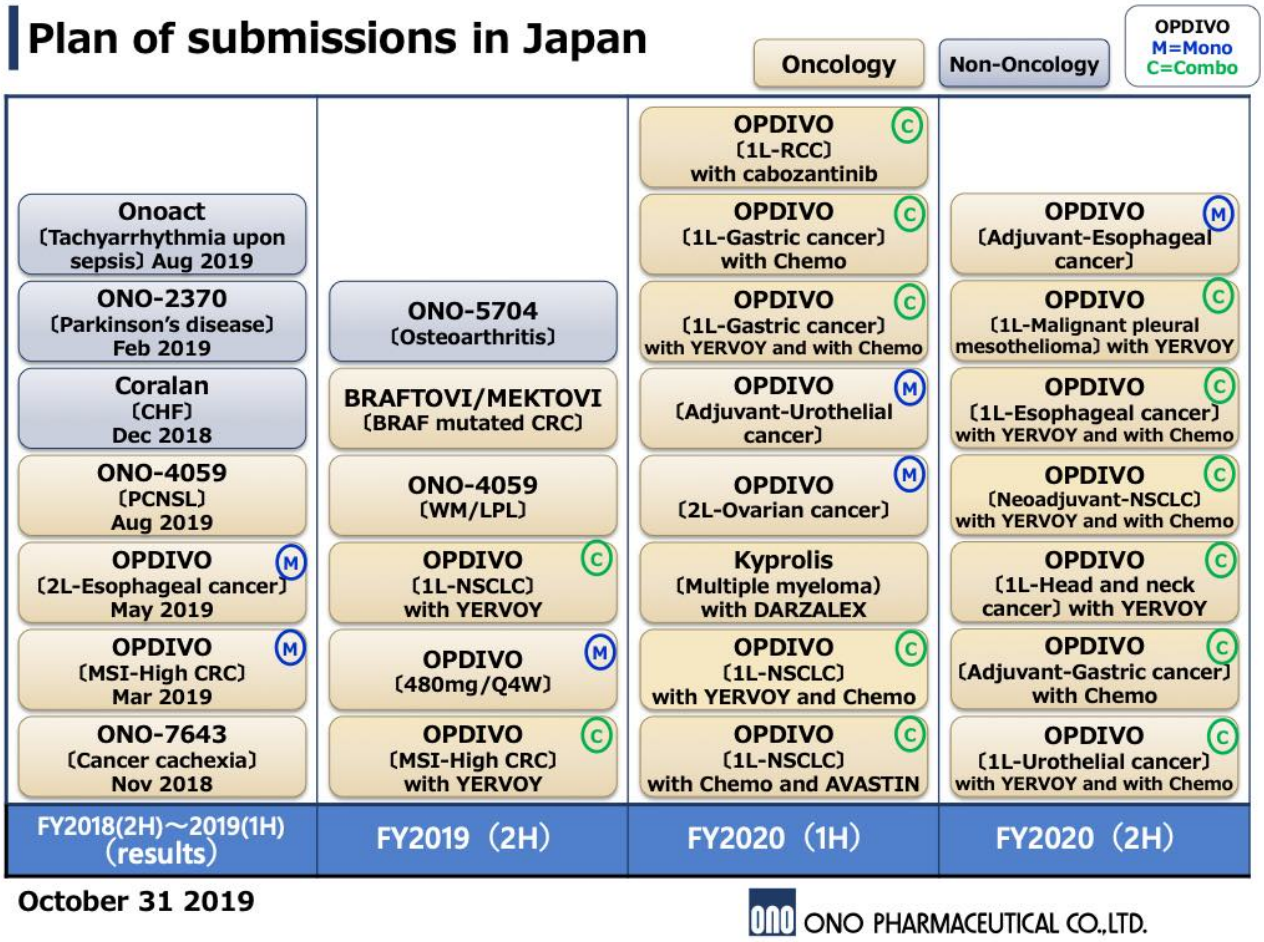
By the way, we have another mention of colorectal cancer and MSI-High, which is in the third-from-bottom row of page six. This shows an application for Opdivo monotherapy. We then started Phase III for combination therapy. In addition, the results of the combination therapy were favorable in Phase II. As the results have exceeded those of the monotherapy, we are planning to submit an application at the same time as the start of Phase III.

Below on the same page, there is an HCC. Phase III has also been launched using combination treatment with Yervoy.

Page nine: Regarding the development situation in South Korea and Taiwan, we also started Phase III of the combination therapy of Opdivo and Yervoy Injection at the lowest stage and in HCC. We also started clinical trials in South Korea and Taiwan in addition to Japan.

Continuing to page 12: This shows the progress of development in the non-oncology field. We obtained approval for Coralan/ONO-1162 in September of this year.

As for this table, in August we submitted an application for Onoact, an intravenous drip at the bottom of the table, for the indication of tachyarrhythmia caused by sepsis. That is all for the updates here.



Next, I will explain the application schedule mainly using the slides. This is the application schedule for Japan. As can be seen from the table, the results from the second half of FY2018 to the first half of FY2019 are shown on the left, and the next column shows the plan for the second half of FY2019. Next is the plan for the first and second halves of FY2020. The light orange part is oncology, and the light blue part is non-oncology. Regarding Opdivo, C or M is written on the right-hand side, where M is the monotherapy, and C is a combination therapy.

I'll start from the left side. First, Ongentys. ONO-2370 for Parkinson's disease is scheduled to be launched in the first half of the next fiscal year. As I mentioned earlier, we have already obtained approval for Coralan tablets. We submitted an application for ONO-4059 in August, as I mentioned earlier, for the treatment of primary central nervous system lymphoma. The Opdivo application was filed for the treatment of esophageal cancer in May. We anticipate that this will be approved during the current fiscal year. The Opdivo monotherapy application was filed for MSI-High colorectal cancer, and we expect that it will be approved by the end of this fiscal year as well. Regarding ONO-7643/anamorelin for cancer cachexia, which was decided to continue being reviewed at a subcommittee meeting held in August, we expect to launch this in the first half of the next fiscal year.

Moving on to the second half of FY2019: ONO-5704 is a compound combining diclofenac and hyaluronic acid. We plan to submit an application in the second half of the year for the treatment of OA. Then there is combination therapy of BRAFTOVI and MEKTOVI, which is indicated for melanoma. We will submit an application for its use in BRAF-mutated colorectal cancer.

Regarding ONO-4059, in addition to the primary CNS Lymphoma application, additional indications are scheduled for primary macroglobulinemia and lymphoma. With regard to first-line treatment of non-small cell lung cancer with Opdivo, we plan to submit an application for its combination therapy with Yervoy using the results of CheckMate-227 study. In addition, we have scheduled an application for Opdivo Flat Dose 480mg regimen, which is once every four weeks. Regarding the MSI-High colorectal cancer, which I mentioned earlier,

in addition to the monotherapy mentioned here, we are planning to submit an application for combination therapy with Yervoy using the results of Phase II.

Next, in FY2020, we plan to submit an application for combination therapy of Opdivo and cabozantinib in renal cell carcinoma. We will also submit an application for combination therapy of Opdivo and chemotherapy for first line treatment of gastric cancer. We are currently waiting for the overall survival results, but if it proceeds smoothly, we will be able to file an application in the first half of the next fiscal year. In addition, we are also conducting trials for combination with Yervoy in gastric cancer, as well as another trial in combination with chemotherapy. The results of these trials are scheduled to be available sometime soon. If that goes smoothly, we would like to submit an application in the first half of the next fiscal year.

We also expect to see results for the adjuvant treatment of urothelial cancer and the second-line treatment of ovarian cancer on a schedule that means we can submit applications in the first half of the next fiscal year. Regarding Kyprolis, we were recently able to obtain favorable results in combination with daratumumab, an anti-CD38 antibody, so we are currently preparing for an application. With regard to non-small cell lung cancer with Opdivo, in addition to the trial in combination with Yervoy, the results of the interim analysis were obtained from the 9LA trial, where two cycle of chemotherapy was given together with combination therapy of Yervoy and Opdivo. We intend to apply for approval in the first half of next fiscal year based on the results.

In addition, a trial with combined Opdivo, Avastin and chemotherapy, which we call best regimen, is being done in non-small cell lung cancer. We are expecting strong results, and we are considering filing for approval in the first half of the next fiscal year. In the second half of the next fiscal year, we plan to file for approval if we are able to produce favorable results in the following phases: esophageal adjuvant, malignant pleural methothelioma in combination with Yervoy, first-line treatment for esophageal cancer, neoadjuvant treatment of non-small-cell cancer, first-line treatment of head and neck cancer, adjuvant treatment of gastric cancer, and first-line treatment of urinary tract cancer.

BRAFTOVI/MEKTOVI - BRAF mutated CRC

BEACON CRC

Patients	**Previously treated BRAF mutated mCRC**
Regimen	● **Encorafenib 300mgQD + Binimetinib 45mgBID + Cetuximab** ● **Encorafenib 300mgQD + Cetuximab** ● **irinotetecan or FOLFIRI + Cetuximab**
Endpoint	**Primary : OS、ORR**

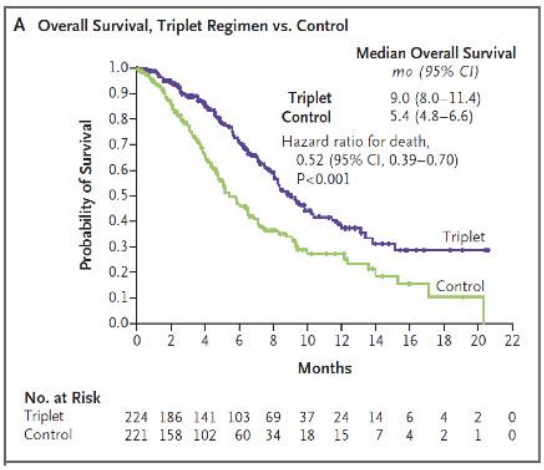


Table 2. Tumor Response in Patients with Metastatic Colorectal Cancer with the *BRAF* V600E Mutation.*

Variable	Triplet Regimen (N=111)	Doublet Regimen (N=113)	Control (N=107)
Objective response			
Patients with a complete or partial response — no. (%)	29 (26)	23 (20)	2 (2)
95% CI	18–35	13–29	<1–7
P value vs. control	<0.001	<0.001	
Best overall response — no. (%)			
Complete response	4 (4)	6 (5)	0
Partial response	25 (23)	17 (15)	2 (2)
Stable disease†	47 (42)	61 (54)	31 (29)
Progressive disease	11 (10)	8 (7)	36 (34)
Could not be evaluated according to RECIST‡	24 (22)	21 (19)	38 (36)
Clinical progression or discontinuation because of adverse event§	15 (14)	19 (17)	17 (16)
Insufficient data to assess response¶	9 (8)	2 (2)	21 (20)
Patients with duration of response ≥6 mo — no./total no. of patients with a response (%)	7/29 (24)	10/23 (43)	1/2 (50)
Patients with ongoing response and <6 mo follow-up — no./total no. of patients with a response (%)	4/29 (14)	1/23 (4)	0

S. Kopetz et al. N ENG J MED Sep 30, 2019

ONO PHARMACEUTICAL CO.,LTD.

I would like to present some of the results from our application schedule: First, the BEACON trial using BRAFTOVI/MEKTOVI for BRAF-mutant colon cancer. We are considering applying for approval in Japan using the results of this trial. This study had three groups: combination encorafenib, binimetinib and cetuximab; combination encorafenib and binimetinib; and combination chemotherapy and cetuximab.

Here you can see a result of OS and ORR in comparison of combination cetuximab/chemotherapy in green, with combination three-drug therapy in blue. Three-drug therapy showed a significant prolongation of OS. In addition, although the text is small, you can see it written as "Objective response." The response rate for the three-drug combination was 26% compared to 2% for the control, which is considered to have been highly effective. Based on these results, we are preparing to proceed with the application in the second half of this fiscal year.

OPDIVO·YERVOY MSI-High CRC

CA209142 (Phase Ⅱ)

Patients	**Previously treated MSI-High or dMMR mCRC**
Regimen	● **Nivo 3 mg/kg Q2W** ● **Nivo 3 mg/kgQ3W + Ipi 1 mg/kgQ3W four doses followed by Nivo 3 mg/kgQ2W**
Endpoint	**Primary : ORR, Exploratory : PFS and OS etc.**

Endpoints	Nivo + Ipi	Nivo
ORR	54.6%	31.1%
PFS 12m	71%	50%
OS 12m	85%	73%

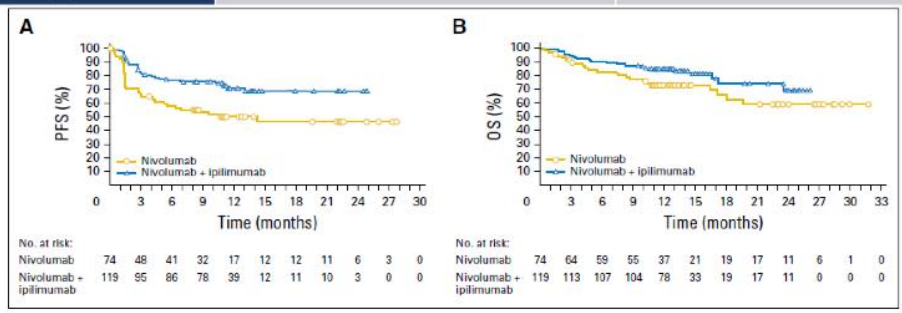


Fig 3. Kaplan-Meier plots of (A) progression-free survival (PFS) per investigator assessment and (B) overall survival (OS) in patients treated with nivolumab plus ipilimumab in the analyses presented herein or nivolumab in the monotherapy cohort of CheckMate-142 from an analysis that had a similar median follow-up (potential time on study from first dose to data cutoff, 13.4 months).[11]

Overman MJ et al. J Clin Oncol, Jan 20 2018
Overman MJ et al. Lancet Oncol, July 19, 2017

ONO PHARMACEUTICAL CO.,LTD.

Next, I would like to explain the results of an MSI-High colorectal cancer study using Opdivo and Yervoy. This study is a Phase II study, and there are separate cohorts for 3mg nivolumab and 3mg nivolumab with ipilimumab. Although it is not designed for direct comparison, each group was set up in the same study, and the results are shown here.

ORR shows a higher response with the combination compared to monotherapy. A 12-month PFS and OS have also been found to be more clearly effective than with monotherapy.

The figures are for PFS and OS. The yellow isOpdivo nonotherapy. Blue is combination therapy of Opdivo and Yervoy. We believe that higher efficacy is expected. While monotherapy will be first available in the market, we believe that the combination therapy of Opdivo and Yervoy can provide a more effective treatment.

Other Studies

【ONO-4538-77／CA2099LA】

Patients	1L NSCLC
Regimen	● Nivo 360mgQ3W + Ipi 1mg/kgQ6W + two cycles of chemotherapy ● chemotherapy : four cycles followed by optional maintenance therapy
Endpoint	Primary : OS Secondary : PFS、ORR etc.

The trial met primary its endpoint at interim analysis

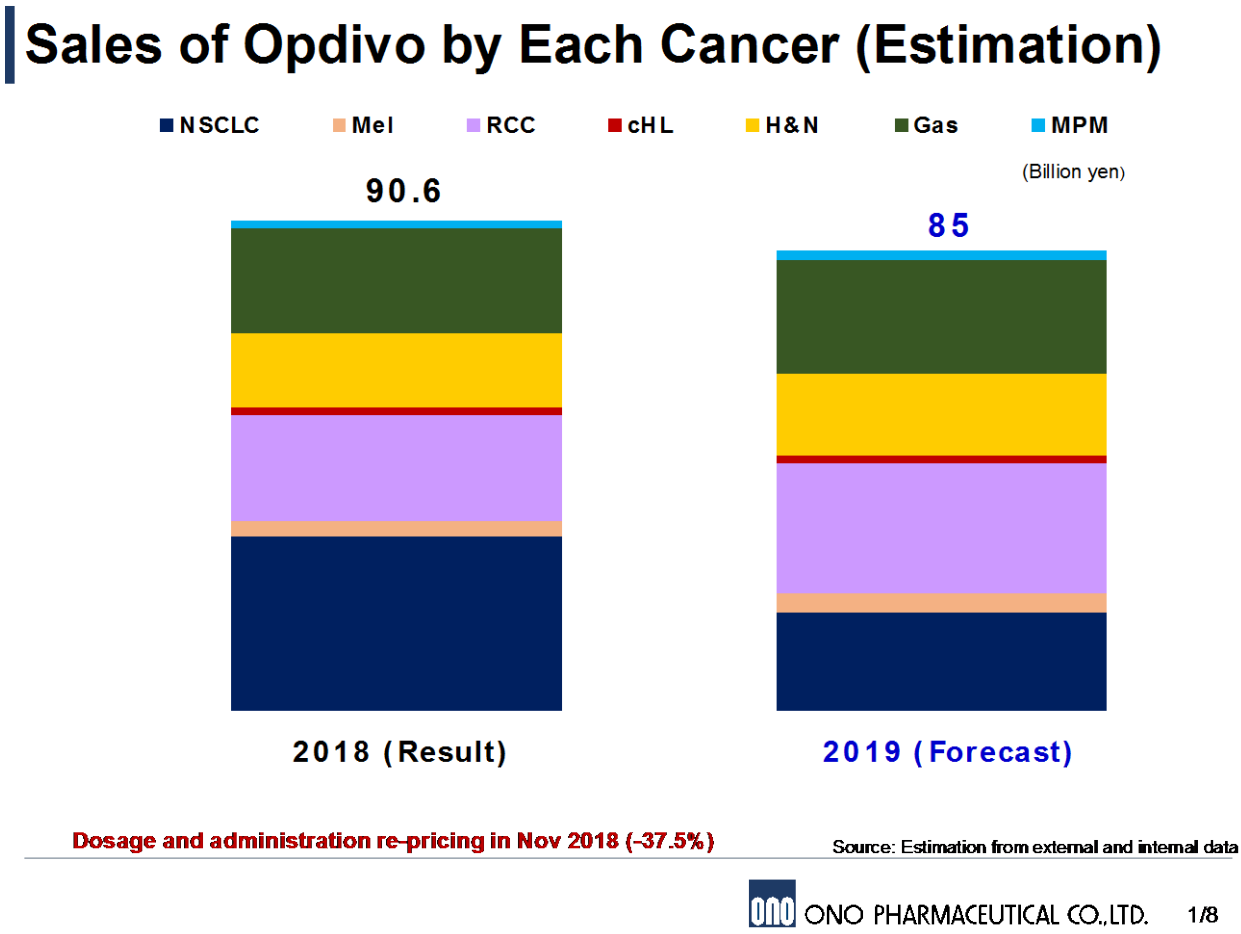
【ATTRACTION-5／ONO-4538-38／CA209844】

Patients	Resected pStage III Gastric cancer
Regimen	● Nivo 360mgQ3W (1-year) + S-1 (1-year) or CapeOX (6-month) ● investigators' choice : S-1 (1-year) or CapeOX (6-month)
Endpoint	Primary : RFS Secondary : OS

Finally, I would like to introduce some protocols. First, this is the 4538-77 study, or CA2099LA, which we usually call 9LA. In addition to nivolumab and low-dose ipilimumab, we used only two cycles of chemotherapy. This is a study that compares these treatments with existing chemotherapy. In order to refrain the first cross which is often seen in Opdivo lung cancer study, only two cycles of chemotherapy wer conducted. This is a key point of this study. This resulted in the achievement of the primary evaluation items in the interim analysis. We have not disclosed them yet, so we cannot give more detail here. However, we believe that we have achieved the results that we expected.

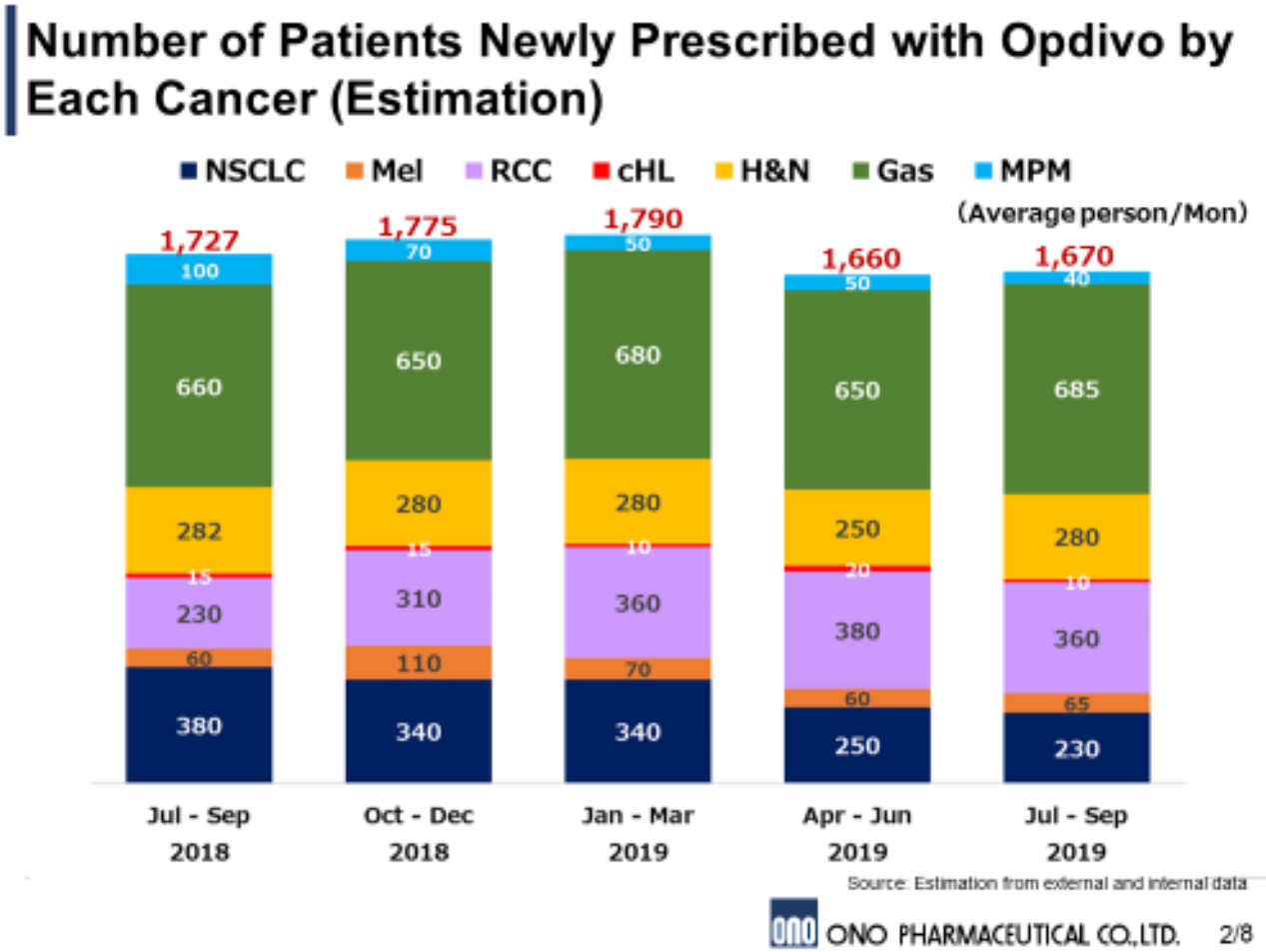
Next is gastric cancer. First-line therapy trials have been conducted. In future results for adjuvant, post-surgical trials will be coming out. I will discuss one of these, the ATTRACTION-5 study. In this study, we are conducting a one-year study to treat gastric cancer with Opdivo post-surgery together with an existing adjuvant. The primary evaluation item is RFS (Recurrence-Free Survival time), and the secondary evaluation item is OS. The result of RFS is expected to be generated first. We are pleased to introduce the results of these and other adjuvant trials for a variety of carcinomas that will be available from the next fiscal year onwards.

Trend of Opdivo



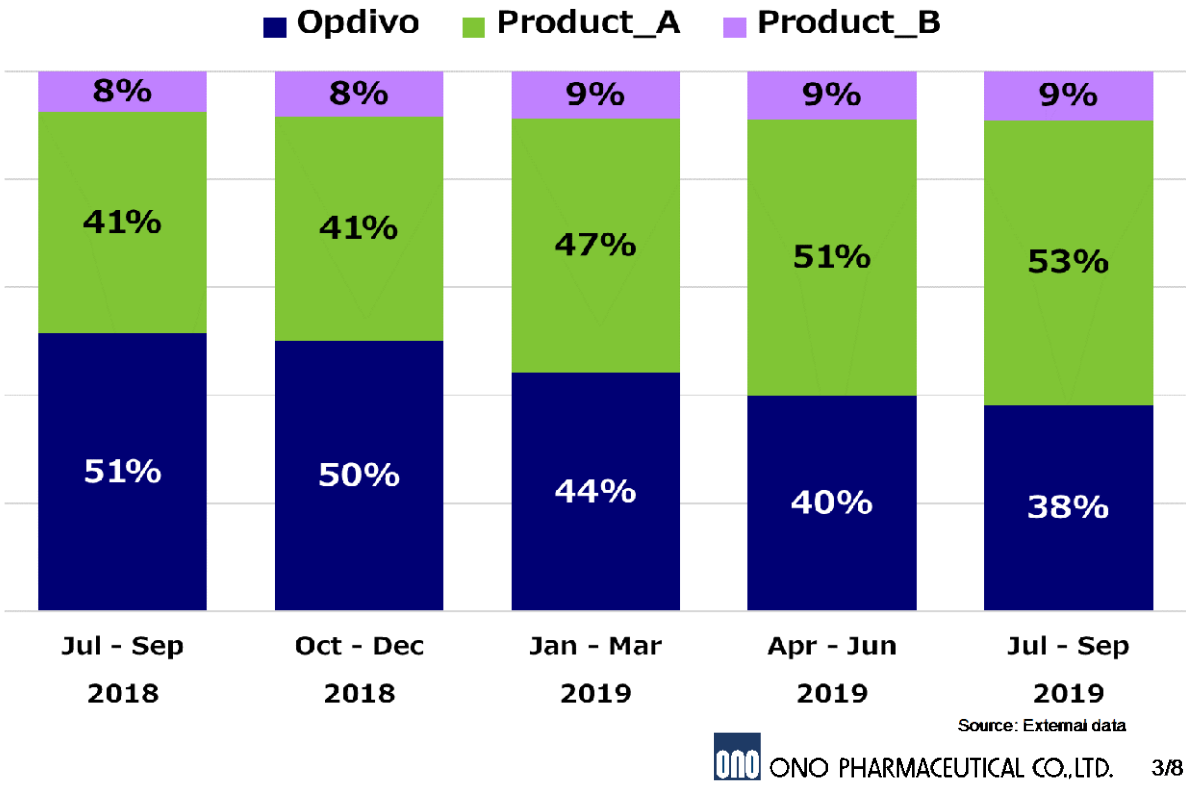
I would like to report on the general status of Opdivo, the current status of lung cancer, gastric cancer and kidney cancer. Finally, I would like to talk about Opdivo's future.

First, I will talk about Opdivo sales. The left-hand bar graph shows FY2018 results, and the right-hand graph shows FY2019 sales forecast. Sales for 2018 were 90.6 billion yen. In the current fiscal year, given the impact of the NHI drug price revision in November last year and the decrease in the number of new lung cancer prescriptions, we expect sales of 85.0 billion yen in this fiscal year.



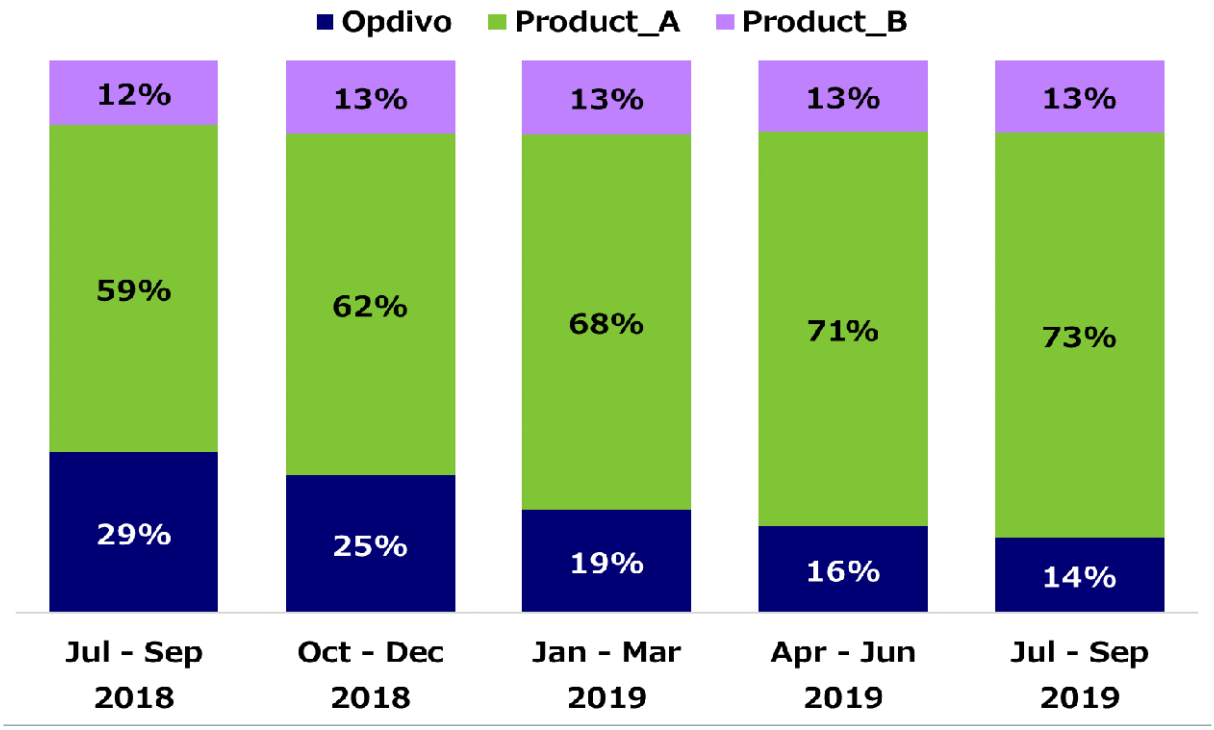
This slide shows the estimated number of new Opdivo prescription patients by cancer type. The average number of patients per month is shown on a quarterly basis in the bar chart, starting on the left at July-September 2018 and going until July-September 2019. Estimates show that in July to September 2019, 685 patients with gastric cancer and approximately 360 patients with renal cell cancer have recently received prescriptions, with an overall average of 1,670 new prescriptions a month at present.

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



This chart shows the percentage of sales accounted for by the major immune checkpoint inhibitors competing with Opdivo across all carcinomas, divided quarterly from July-September 2018 to July-September 2019, as before. In the July-September 2019 quarter, Opdivo had a 38% share of the major immune checkpoint inhibitors.

Sales Ratio of ICPIs in NSCLC (Estimation)



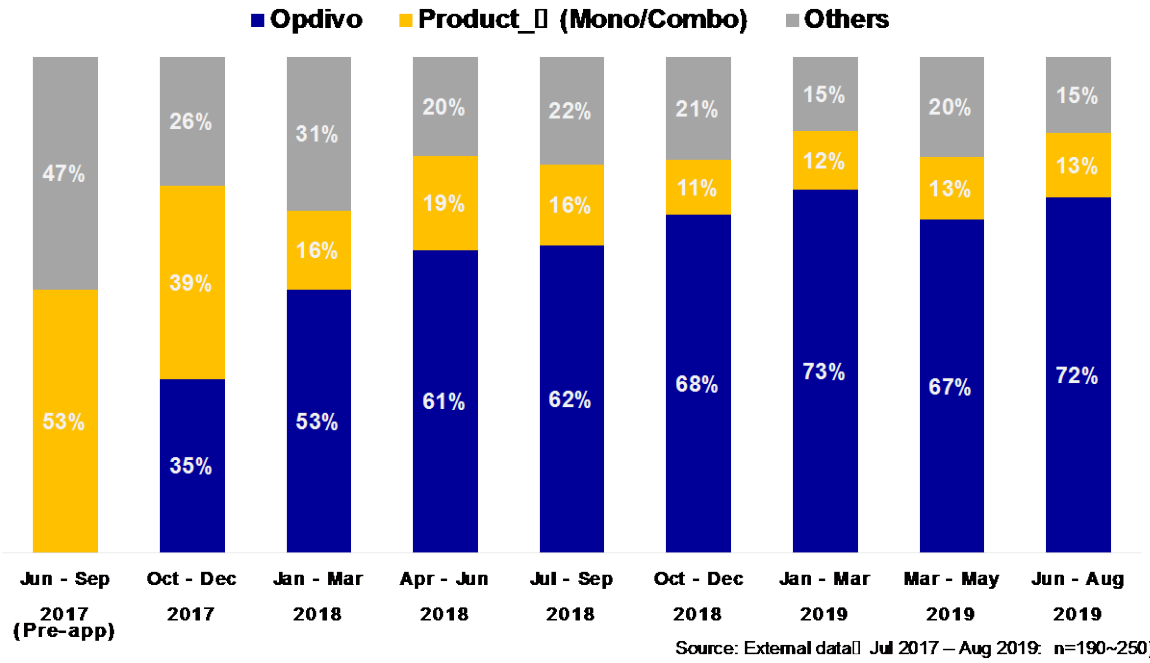
Source: External data

Next, I would like to provide a more detailed report for each type of cancer. We begin with lung cancer. This graph shows the proportion of sales accounted for by immune checkpoint inhibitors for all non-small cell cancer treatments, including primary, secondary, and tertiary treatments. This is just our estimate. We expect the total amount of immune checkpoint inhibitors for the entire cancer field to be probably around 150 billion annually on a drug price basis.

The chart is divided by quarter, starting in July-September 2018 on the left to July-September 2019. In addition to primary treatment for non-small cell cancer, the market share is expanding as a result of the addition of an indication for combination therapy with other companies' immune checkpoint inhibitors. However, most of this 14% is contributed by Opdivo's use as a second-line treatment. If we look only at the share of new patients in second-line therapy, Opdivo's market share is 30%. Based on these results, we believe that we will be able to achieve our annual plan, but in the area of lung cancer it will be limited to second-line treatment.

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

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

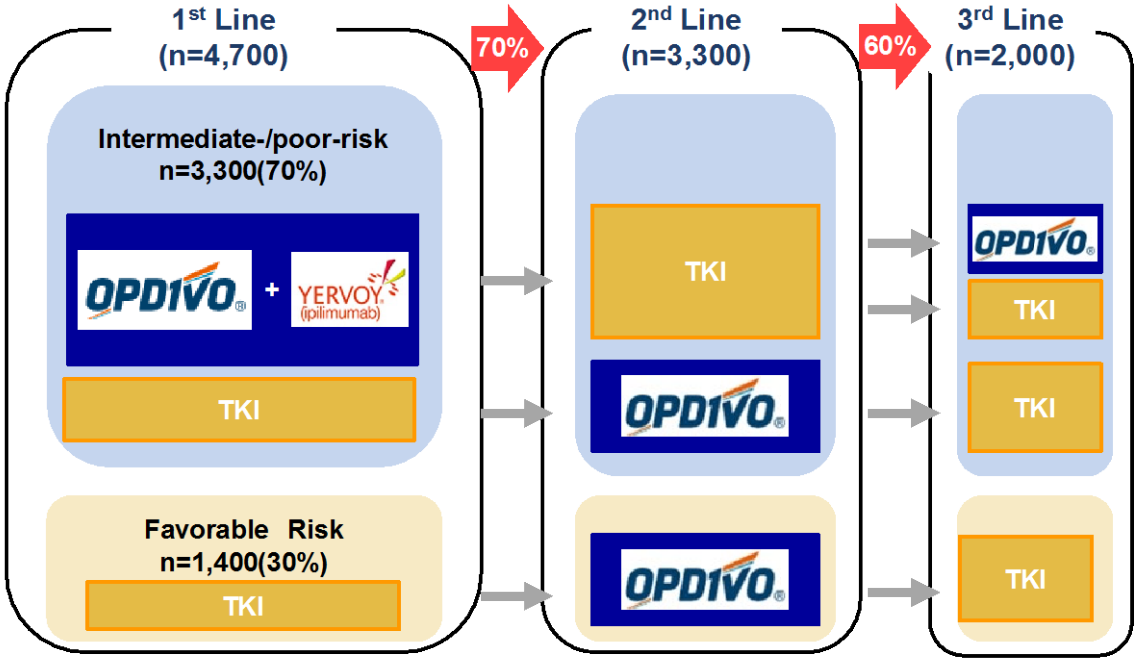


Source: External data□ Jul 2017 – Aug 2019: n=190~250)

Next, gastric cancer. Opdivo has entered the market as a third-line treatment in the field of gastric cancer. In doing so, we are working to achieve our target share of 70% for new prescriptions and 65% for shifts from second- to third-line treatments. This chart shows the trend in the share of new patients in the third-line treatment of gastric cancer. Since the approval of Opdivo, the share of new patients has been going up, and we are solidly attaining our target of 70%.

On the other hand, the transition rate has been an issue. Initially, we aimed at 65% of the total, but the rate of transition peaked out. It has risen from 55% to 60%. Since we are within sight of the 65%, we would like to make steady efforts in this area. Recently, our competitors have also entered the field of third-line treatment. With Opdivo, we intend to further increase the number of prescriptions without giving up the position we have established.

Annual Drug-treated Patients with Advanced or Metastatic RCC in Japan



Estimation based on internal survey (2018)

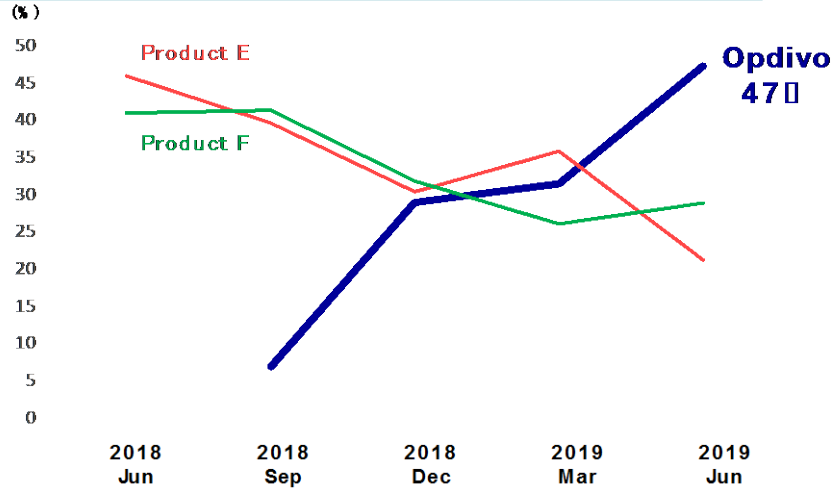
I will now talk about renal cell carcinoma. For Opdivo, the indication for second-line therapy was added in 2016. In August of last year, it also received the indication for first-line therapy in combination with Yervoy.

The number of patients taking Opdivo is shown. There are approximately 4,700 first-line patients per year. Among these, we are using Opdivo and Yervoy combination therapy for patients intermediate- and poor-risk groups. About 70% of the total patients, or about 3,300 people, are in these groups.

In this context, we have been promoting the efficacy and safety data of Opdivo monotherapy and Opdivo+Yervoy combination therapy to doctors since August of last year.

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

	2018 Jun	Sep	Dec	2019 Mar	Jun	
Opdivo	-	7	29	32	47	(%)
Product E	46	40	30	36	20	(%)
Product F	41	41	32	26	28	(%)



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

We apologize for the slightly old data, but as of June of this year the share of prescriptions has been changing. Since approval, prescriptions for Opdivo and Yervoy combination therapy have been steadily secured for first-line RCC treatment. As of September of this year, 1,400 new prescriptions have been obtained since the additional approval. As a result, the share of new prescriptions as of June is 47% of the total prescriptions. However, if we focus only on the intermediate/high-risk groups, we have gained more than about 60%.

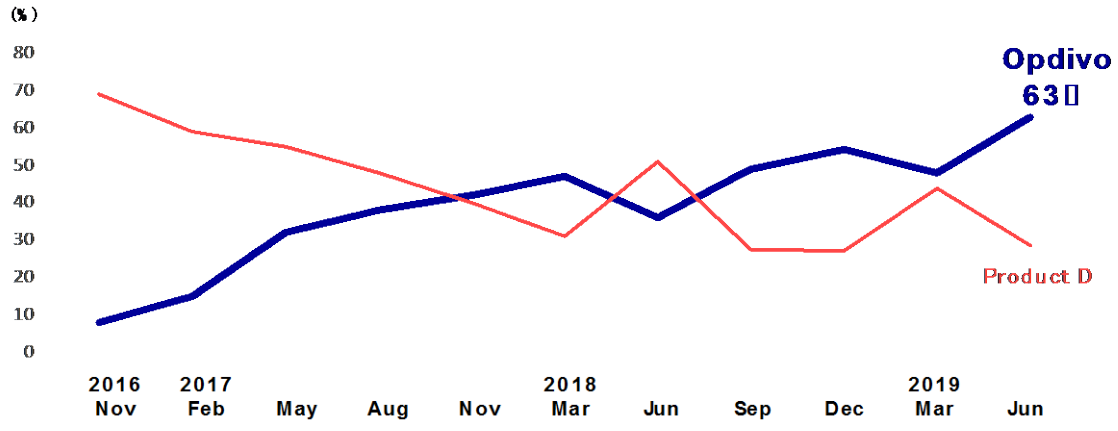
In combination therapy with Opdivo and Yervoy, at the time of approval, we received opinion from practitioners of urology, who were main doctors for this treatment, that they were extremely concerned about irAEs(immune-related adverse events). Therefore, we thought that it would be very difficult to obtain prescriptions. Nevertheless, we believe that this barrier can be overcome if we promote early detection and treatment of irAEs.

With regard to irAEs, we believe that the barriers due to irAEs have been greatly lowered by promoting in-house management and in collaboration with doctors of other different departments who are in charge of concerned irAEs, on a per-institution basis, thereby eliminating these concerns.

We expect that competitors will enter the market in the near future targeting first-line treatment of renal cell cancer. However, in the future, while competitive products will enter into this market, we intend to communicate the efficacy and safety of Opdivo and Yervoy combination therapy and aim at even higher market share.

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	
Opdivo	8	15	32	38	42	47	36	49	54	48	63	(%)
Product D	69	59	55	48	40	31	51	27	27	44	29	(%)



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

In renal cell carcinoma field, Opdivo first entered into second-line treatment. The share of prescriptions for second-line treatments increased to 60% by communicating the efficacy and safety of Opdivo to doctors. Going forward, we intend to steadily increase our presence in the urology field.

As I mentioned earlier, I-O and TKI are scheduled to enter the first line treatment market in the future. We are also proceeding with combination therapy with Opdivo and Yervoy as the first-line therapy. We assume that in the future I-O usage of the first line treatment will probably be about 90%.

As a result, we believe that the variations of treatment for second-line treatment will change considerably. We expect that TKI and molecular targeted drugs will probably be the major treatment durgs.

However, Opdivo monotherapy can be used in the third line and beyond. Opdivo is likely to be used in combination therapy with TKI in the future. Taking these factors into account, we will continue to strive to make Opdivo a drug that can be used widely, from first-line to third line treatments in the field of renal cell cancer.

We believe that Opdivo will be able to operate in more markets in the future. In particular, lung cancer and gastric cancer market shares are expected to expand.

Competitors are particularly advanced in the first-line of lung cancer treatment. However, a survey of the needs of doctors reveals that there is still a strong unmet demand in the market for cases where PD-L1 is slightly positive, 1-49% and negative, and we believe that 70% of this market is first line therapy.

In CheckMate-9LA, which was presented in the R&D presentation, and in CheckMate-227 regimen, we think that we will be able to recover in these segments.

In gastric cancer, which has a large market, we expect to be able to satisfy unmet needs sufficiently for first-line therapy with combination Opdivo and chemotherapy. We anticipate that Opdivo, Opdivo and Yervoy

combination therapy, as well as Opdivo and chemotherapy combination therapy will be expanded to other cancer treatments in the future as well. We would like to be able to deliver this benefit of Opdivo to cancer patients.

So far, we have reported on trend of Opdivo, general market conditions, as well as on lung cancer, gastric cancer, renal cell carcinoma and other points. We will continue to strive to respond to the unmet needs of cancer patients.

Question & Answer

Q: I have two questions about Opdivo.

We can calculate that the target market will triple, but since the drug price will no longer be one third, I think it will increase considerably. On the other hand, I think that there are some areas where you are slightly behind your competitors. To summarize the whole picture, if the addressable market has tripled and prices have declined slightly, and we do not know the percentage of the market share, what would be the main take-home point be?

A: First of all, although we are not currently very active in this area, we are aiming for this as a first-line treatment for lung cancer. If we can achieve that, it will be a big step.

We will not know which segments are best to aim for in the future until we see the results of CheckMate-9LA and- 227. Looking at these clinical results, we would like to judge which segments we should focus on. However, if we look at the prescription intentions of doctors, it seems that there are some patients who are not satisfied with current treatments and have unmet needs. I think we can break into that part.

A: I would like to add something to this. Opdivo is currently helping 35,000 patients. If that increases to 106,000 patients in the future, it does not mean that Opdivo would triple its current sales.

What I am thinking about now is that lung cancer is indeed the cancer type with the greatest number of patients in every region of the world, and that is why it has been lagging behind. Some people may think that Keytruda versus Opdivo has already been fought, but we do not think so. Especially in East Asia, there are many patients with gastrointestinal cancers, stomach cancers, liver cancers, colorectal cancers, esophageal cancers, and so on. With the goal of winning again in this area, over the past two to three years we have been taking the initiative in conducting multinational clinical trials where in the past we paired up with BMS. These trials are targeting the gastrointestinal system, and we will continue starting from there.

If we get good results, you will see that we can turn things around in this area, at least. This is the spirit in which we are doing business.

Q: Rather than three times higher, would it also be possible to say two and a half times higher, or two times higher? Is it difficult to put a concrete figure on this?

A: That is the figure at present. There are other ideas as well.

Q: Just one more question. There are three trials: 227, 9LA, and the Avastin trial, coming one after another. I thought that in the 227 trial there were discussions about safety issues with the I-O/I-O combination and chemotherapy.

On the other hand, 9LA is obviously in combination with chemotherapy. When we compare these three, to the extent that data is available, there does not appear to be sufficient selection to move the whole picture in the case of 9LA. However of these three, this may not be a problem in the case of the first-line NSCLC treatment trial. Could you explain the impact of this?

A: We have not made any announcements regarding this yet, so I am not able to answer your question at this time. As mentioned earlier, this test was conducted following two cycles of chemotherapy, thereby eliminating the cross that tends to be present in I-O.

In reality, as mentioned earlier, we need to look segment-by-segment. There does not seem to be any area where it is ineffective.

Q: You are referring to 9LA here, right?

A: That is correct.

Q: Opdivo has strong sales in gastric cancer. Lonsurf was approved in August, which I think has not been reflected in your figures for market share. How will this affect the market share?

Keytruda had approval applied for in October. I believe that there are various interpretations of the data and the trial on which the application was based. Could you tell me how your company will look at the impact?

A: First of all, Lonsurf was approved as a third-line treatment in August, and as the results of market research have not yet been published, we only show the data for Opdivo prescription share at this time. However, based on the responses of the MRs on the ground, there are no reports that the drug was used significantly in the third-line treatment. When asked about prescription intentions of the doctors, I heard that many professionals would use Opdivo first and then go to Lonsurf. So far, we have not seen a significant impact.

However, as for our activities, we will continue to firmly solidify our third-line position.

Are you asking about the effect of Keytruda's entry as first-line treatment on third-line treatment? What the effect of this is on Opdivo?

Q: That, and also how this will affect your company's intention to put forward a first-line treatment.

A: I cannot say anything about the data itself because I do not know where the application was made and where it will be approved. First of all, I think the impact on third-line treatments would be around 10% at most.

With regard to Opdivo as a first-line treatment in the future, since the combination chemotherapy data has not yet been opened, it depends on the data. If the data is good, we will not have a major impact. We believe that we will be able to take market share as a first-line treatment.

Q: The 10% you mentioned is PD-L1, patients who saw improved overall survival compared to chemotherapy?

A: Regarding CPS, I think there will be a question as to whether or not it will be measured in all patients. Including that issue, we're considering the 10% figure.

Q: Regarding anamorelin, what are the major points of discussion for the subcommittee? In order to launch in the first half of the next fiscal year, what kind of data will you have to present, and what process is involved?

A: I would like to refrain from responding with details of the subcommittee process. At the moment, when the subcommittee was continuously deliberating in August, we have been working with the PMDA to respond to the subcommittee discussion. We do not plan to generate any additional new data at present.

Following the application for approval, a separate Phase III has been implemented since March of this year in Japan using the same endpoints employed in the United States studies.

Q: For Opdivo, three first-line regimens were mentioned today. Could you tell us a little more about the combined Opdivo, chemotherapy plus Avastin trial?

I think you mentioned it was the best regimen before. I think that the regimen you mentioned as the best one is simply because the three drugs are simply given together. I would like to confirm again why you mention the best regime. Chemotherapy will take place, and the other two agents are added. What kind of position will you take if you actually get to market?

A: As the results of 52 study are not yet available, I do not have the data I would like to back this up, but this description is based on our observations to date. We believe that the response of this regimen in an

exploratory trial combining nivolumab and chemotherapy was very good, and if it could be replicated in Phase III, it would be the best regimen in terms of responsiveness.

As mentioned earlier, chemotherapy and I-O both have good points. I-O results in long tail plateaux and reduction of the side-effects associated with chemotherapy. On the other hand, we do not know if this will be reflected in the results of 52 study. We hope that the results will satisfy both the high responsiveness and the long tail plateaux.

Moreover, the combination of nivolumab and ipilimumab was another success of adding I-O to eliminate the early cross. I am looking forward to another good result there.

Q: When we look at the results of the exploratory trials, we can see that the current data for Keytruda plus chemotherapy, or Tecentriq (atezolizumab) plus chemotherapy plus Avastin, are available. Are you saying that even in the context of these results, you feel confident about these combination regimens?

A: It is difficult to compare between different trials in different phases. Given our comparisons between nivolumab and other combinations with chemotherapy, we are confident of our direction.

Q: Understood. I believe the clinical trial will end in April 2020. If you are thinking of applying in the first half of the next fiscal year, does that mean that the data will come out at around that time?

A: I would like to refrain from making comments about when the data will come out. We are aiming to file the application in the first half of the fiscal year. This is assuming that things progress at the fastest pace, and it is not possible to be assured that this will happen.

Q: Understood. Second, Opdivo's current sales trends suggest that the second-line treatment has maintained a 30% share of the market for lung cancer. I believe that in the first quarter, market share had been rather shrinking from the first-line treatment, and been occupied in the second-line treatment. The situation is that the market share has been improving more than that for the first quarter, but is it better to see that the market for the second line treatment will shrink steadily from now on, after the third quarter?

A: As you have said, I-O and chemo are spreading fairly widely in first-line treatment, such that I think it is true that I-O monotherapy in the second line is gradually shrinking.

Q: My question is related to other companies, so I do not know how far you can answer it. I think that the drug price of Keytruda is still set about 15% higher than that of Opdivo. Is there any effect of this? I think this will probably fall next year. I think there are a number of drugs that can be taken along with it.

But Keytruda is not yet a subject of HTA, is it? Therefore, Opdivo and Keytruda have very unfair terms in this sense. What do you think about this? I would like to know whether there is any impact on actual sales on the ground.

The other is that according to the current rules, if we expand the market, we will reach 100 billion yen, 180 billion yen, and 200 billion yen. When esophageal cancer emerges, this is a new indication, so is there a so-called adjustment in drug prices?

A: I would like to answer this question by dividing it into two parts: one for esophageal cancer and the other for other cancers.

I am not going to talk about the rules for bringing together and re-pricing, because I believe you are already aware of these rules. To answer the question, I do not know. It is not yet clear whether this regular re-pricing or special re-pricing will occur, and it is not clear what will happen in the end. The situation will change for us depending on that, and the answer is that we do not know so far.

In addition, I do not think that the drug price will decline as a result t this point when the supplemental indication for esophageal cancer is approved.

Q: Please forgive my question about 9LA. So far, you have emphasized avoiding initial crossing, but I think it is probably done well. I think the concerning issue is the hazard ration of OS. It is difficult to beat or line up the figures from 0.5 to 0.6 to make a comment on this part of the report.

A: I am afraid we cannot make any further comment on this point.

Q: However, the point you would like to emphasize is the cross, isn't it?

A: What I meant is that we cannot say about the results at this point in time. The strategy of this regimen is that there is no initial cross. Other than saying that we got the results according to that, we cannot say anything else.

Q: Reducing initial cross in the Japanese market, how does this work with the specialists?

A: From the time Opdivo was originally launched, what kinds of patients cross from professors for each cancer? Therefore, I think that professors are very interested in this area.

Q: Regarding the comment on the repricing just mentioned, I would like to hear about the risks for the next fiscal year. I am pleased with the momentum of the next fiscal year, but I would like to once again understand the positive performance factors. Of course, you have talked about the risks of repricing, and several new product launches will continue. Other than that, I would like to know if there are other factors that we are overlooking, or that we should not forget about here, whether positive or negative.

A: The first line gastric cancer treatment for Opdivo is what we expect the most. I think this is the biggest. Others are within the range I have already mentioned. That is all I can say now.

Q: Is it correct to say that you do not want to increase expenses too much? SG&A expenses.

A: We will keep SG&A expenses as low as possible. This is a matter of course though.

Q: R&D expense increases to some extent.

A: I would like to increase R&D expense if possible, but since we need a financial backbone to increase it, I would like to increase it after expanding it.

Q: Opdivo, chemotherapy and Avastin are currently working well, as are chemotherapy and anti-VEGF antibodies, or TKI, and I think this is very promising.

On the other hand, when we look at atezolizumab (Tecentriq), there is a dysergy effect. It has been pointed out that the effect of paclitaxel on peripheral neurons is increased when used in conjunction with Avastin.

I would like to ask you if in treatment areas where atezolizumab is increasing, are you aware of any such dysergy problems?

I think your company has already verified the effectiveness of this combination therapy to some extent. What was the basis for this conclusion? Was it clinical or in vitro work?

A: While the risk of side effects basically rises with the addition of chemotherapy and compounds, I think the balance between their efficacy and side effects is good. Therefore, if it is said that the side effects increase when Avastin is used in combination therapy, I think it will increase slightly.

Your other question was about clinical or in vitro. As I said, impressions were good when Opdivo was used in the combination therapy. This was from a Japanese patient-based Phase I test. Various regimens were tested, and the results indicated that this regimen was the best one.