Q/A session (summary) (May 11, 2017)

Q1-1

Regarding US market entry, so far you had various discussions and you clearly stated with those two products, I don't know whether you are limited to those two items only, but you're going on your own. In terms of the infrastructure, you still need sales reps and there are some medical affairs people are available. Regarding the sales force and infrastructure investment, will that happen this year or next year, what's the size, how much money are you going to need, what's your idea here regarding the investment, the size and the timing?

A1

First, DE-109 will come to the market. Considering the number of doctors we will target, our requirement of new sales reps would be about a dozen or so to possibly increase to 30 or so in around 2020. We will focus on profitable growth. This disease itself requires long-term therapy. We will follow limited, specific doctors. For example, one MR will cover 60 sites. That would be the idea now. The sales will not jump overnight, but rather we will gradually penetrate the market with DE-109 through communication. We will look at the patients' disease status and feedback of DE-109. This is how we are planning to proceed. We hope to make the DE-109 business profitable in FY2020 and its sales peak in FY2025 / 2026, that's our rough timeline. Thank you.

Q1-2

My question is regarding R&D. You have some projects that were discontinued in this announcement, though the priority of these may not have been very high. Did you get new information or is it the case that you changed your review policy? Can you comment on your pipeline review policy?

A1-2

Yes, we use incoming data and information about our pipeline, as well as monitor information in the ophthalmology field in general, especially in areas where there may be competition or data available. Based on that data - and our in-house data as well - we then make adjustments to our portfolio. These adjustments include how we spend and allocate resources. And so that is the reason for what you mentioned is to deprioritize some projects where we think the data is not compelling enough to continue to work on, and put our resources in areas where we think we have higher probability of success and much greater differentiation from our competitors. So, in general and very briefly, this is the way we constantly adjust our work.

Q2-1

I have several questions. First question is about DE-109, the US filing. It wasn't given a priority review, why? And advisory committee may not be held, so what is the implication from that, is it going to be straightforward filing?

A2-1

I don't have a good answer for your first question, why the agency decided to give DE-109 a regular review, because that's up to them what they decide. There are guidelines for expedited reviews and the agency implements them as they see fit.
The answer to the second question is that the agency is very familiar with our data, I believe. It is very simple to understand and clear cut. There are no fancy analyses required. And such, I personally think a necessity for a panel is probably low.

Q2-2
The second is about Ikervis in Europe. There are some additional marketing costs, what kind of marketing activities do you plan? Interviewing these European physicians, I think that education to physicians and patients, may be insufficient. That is the feedback I usually get. So what kind of activities do you plan?
A2-2
The ramp-up of Ikervis revenue is behind our original schedule. One reason causing this has been challenging negotiations on pricing with regulators in France, Italy and Spain. Regarding education, we have been making efforts through our medical affairs function, but it takes longer time than we expected. The repeat rate has been increasing once patient used it. However, this is just one aspect, we, of course, also need more new patients. Therefore we need to strengthen our medical affairs efforts including publications.

Q2-3
You said that new users are very important. Where is the problem, for example, patients are not getting the prescriptions or not going to the pharmacies?

A2-3
While I do not have all the details with me today, basically, we have some struggles of obtaining prescriptions by physicians because costs and budgeting. For example Germany is going well where there is budget in the form of reimbursement. However, some people feel artificial tears are sufficient as treatment. For that to be overcome, we need education to let physicians and patients know how Ikervis improves subjective symptoms. But artificial tears continue selling well. For this reason, we'd like to strengthen our efforts to promote Ikervis.

Q2-4
And my next question is about Eylea in Japan. I think that in Japan growth estimates are very conservative. And previously, if my memory, if it is correct, tells me that the company said that it would grow more, but what's the current view?
A2-4
We are very conservative. The current plan was originated as of December. And at that time, we results

were modest and we forecasted accordingly. However, we began to see the effect of our efforts to boost demand in the market in the fourth quarter. We believe that there is growth potential in the market. Therefore, I think that probably we will be able to take a little more positive view. Thank you very much.

Q3-1

I have two questions. First, the US outlook. I would like to ask further about US market. You are going to the market with two items, DE-109, so you will start this and make profit by 2020. What's the size of sales at that point and peak sales would be FY2025 or FY2026, what's the peak sales size? And what's your forecasted scenario regarding that? Can you give us an idea about the sales size, please?

A3-1

As for sales, of course, it depends on pricing. So we need to set some assumptions. So rather than the sales, as Kurokawa said, we want to have early returns and we want to make the business profitable as soon as possible. Just for your reference, annual revenue of about JPY3 billion by 2020, that's our breakeven revenue assumption. Thank you.

Q3-2

There have been some cases in which Japanese pharmas have developed products, prepared infrastructure, and tried to sell in US market, but the development did not go very well and the sales infrastructure is not fully utilized. In ophthalmology area in the past 10 years, if you look at the statistics, one-third of the applied products were not approved. So you start with those two items and you don't really know whether they will be successful or not, there are some risks. So if development does not work very well, what's the contingency plan you have in mind?

A3- 2

Of course, it is true that there are such risks for any pharma company. We want to establish our presence in the US market, and that's very important for us and we prepare. However, if product development fails and we can’t actually launch products there is a worst case scenario in which we must stop and withdraw quickly. As of now, I don't think this is very likely. We are confident DE-109 will be launched. Also for MicroShunt, based on the data and other information we have, the probability of success is rather high. Our plans are based on these two products being launched and we don't really have to consider other products very seriously.

Regarding expenses related to DE-109 we suppress spending in the beginning of the year. As the project PTS increases, we will have higher spending. So, this step-wise spending approach is already included in our plan. This is one way we can mitigate the financial risks. The 2020 sales expectation I mentioned for your information is only from DE-109.

Q3-3

And the question is Japanese sales plan. The Eylea sales forecast you mentioned is conservative and

that's also my question. On the other hand, you have high margin products, Cravit or Tapros. Even including the NHI price revision and looking at the actual, the plan for the growth is relatively high in my impression, Tapros, without price revision and the 4% growth last year, but this year, you have a plan for 10% growth. So what is your sales plan regarding your high margin products ?

A3-3

Last year there was NHI price revision and we were impacted by 7% overall. Because of this, you can't really have an apple-to-apple comparison. In this year, there is no revision, therefore the growth can be expected as we have forecasted. Regarding Cosopt, the PMS (post marketing surveillance) period is completed and a generic will come out into the market in the late phase of this year. That is reflected in our plan. For other high-margin products, Tapros, Tapcom and Diquas, Alesion, we think forecast numbers are achievable. Thank you.

Q4-1

I have two questions. The first question is regarding costs. R&D costs and SG&A from the fourth quarter of the fiscal year ended was increasing and are higher during the coming fiscal year too. And how much, proportionally were just one-time increases and how much are your new current ordinary levels? And what is the allowable limit for R&D and SGA including investment in the US market. So for each R&D and SGA, what are your specific forecasts, could you give us more details?

A4-1

First about R&D expenditure. Currently, our R&D spending plan is JPY25 billion in FY17. Looking at our current pipeline, we have been strengthening our pipeline including MicroShunt as well as DE-117 which will be launched in Japan next year, and our DE-126 glaucoma treatment. In the glaucoma area, we have been focusing so there will be higher spending. Costs relating to DE-122, for AMD, will also increase. In total, R&D costs are expected to increase in line with sales growth from the current FY17 level of 25 billion yen to about 27 billion. We are seeking sales growth and gross margin improvement. Investments beyond these would additional cost control. Currently investments for US market entry preparation are running at about USD30 million will be invested. And in Asia, which has been showing double-digit growth in the market, especially China and Asian countries, so we'd like to make active investment there. Profit in Asia has been growing. So looking ahead to the future, and thinking about the next mid-term plan, we are growing substantially in Asia where we expect to gain top market share. This will give us an even better operating position there – allowing us to further invest in sustainable growth in the region. In Europe, we will be controlling SG&A strictly.

Regarding R&D costs, as of the percentage of sales, but excluding Eylea sales which have been expanding, the R&D to sales ratio is about 15% and that's probably a cap. There may be some temporary ups and downs, but that is roughly the level. And SG&A in this fiscal year, it's about 40% of sales excluding Eylea revenue. And in the end, in the mid-term we'd like to control it to within 35% to 37% of sales. And for each individual items, we need to control them within the increase of gross margin. And with these two-level measurements, we'd like to control costs overall. In FY16 which just finished, we

ended up with higher costs than expected. While we started to see this increase, we also felt at the same time, that revenue would grow even more. However, certain expected upsides in revenue, such as a sales boost in Alesion sales due to high airborne pollen levels did not materialize in March. Therefore, high sales did not offset higher costs.

Q4-2

Next is about your performance and US market entry strategy. In 2020, you said you will be making profit on the bottom line. What cost control or curtailment will be done in advance? Also, there are pipeline projects in glaucoma and other areas, and you'll be probably putting those products in the US market. What is the specific strategy for you to introduce those products in the US market?

A4-2

Regarding the US market, DE-109 and MicroShunt are niche market areas in ophthalmology where we will focus. These are areas in which patients are in serious situations with the possibility of a visual loss. By 2020, we plan to achieve breakeven. Sales reps will gradually increase from 14 persons. We will follow the situations carefully – we won't try to cover all patients from day 1, but rather take a step-wise approach. However, until 2020, investments will exceed revenues. However, DE-109 and MicroShunt are expected to show high profitability and contribute to Santen's profit. These are the targets we have in mind in entering the US market.

Q4-3

I think you have been developing products like DE-117 and DE-126 for the US market. Do you plan to make major investments? What is your plan, do you also think about alliance or other partnership?

A4-3

As I explained regarding the US market entry, we are not planning a full-scale launch in the largest market segments. We plan to go into two niche markets. For these markets DE-109 and MicroShunt, we will be strategically well prepared. On the other hand, considering DE-126 which is in a major segment as an eye drop to lower intraocular pressure as a glaucoma treatment, the strategy would be different. Such a treatment area is very broad. In order to consider entering such a broad area in the US, we would need to consider additional possibilities including partnerships. Thank you.

Q5-1

First, regarding development sites, for instance, the Philippines. In which markets can you submit based on this data? Is it accepted in all the different markets in the world? Do you need additional studies? Do you have such examples? Will this study be first in the Philippines, but also in advanced countries in future?

A5-1

You are wondering if the data from Asia sites can be used for filings worldwide? Yes. OK, a couple of points. First, this is not a pivotal trial, it's an early Phase II trial to figure out the dose and regimen and how

to use it. And typically, there is no -- at least, in the big markets, especially Europe and the US -- there is no exclusion for outside data from other regions of the world as long as they are conducted in what's called a “well-controlled manner”. So that's one item. The second is that we are going to use this data to then design a global Phase III study. And so, those studies then become the basis for approval worldwide. And how we design those, and how many countries and all of that, that's pretty standard. So I think this allows us to get data quickly from good sites, good centers, patients are available, we don't have to compete for patients and the cost is controlled. So if any of those things were not true, I think we probably wouldn't do it. But right now, there is no reason that that data will not be used from safety and efficacy standpoints, and to further justify Phase III trials.

Q5-2

I have two more very simple questions. One is regarding the number of sales reps in the US, starting with 10 some people and then by 2020, you'll be increasing it to 30. Is it only for DE-109 or do you include MicroShunt?

A5-3

Yes, it is DE-109 only.

Q5-4

And you make it -- your business profitable, is it only also DE-109 business?

A5-4

Yes, in 2020 DE-109 business will be profitable.

Q5-5

And while that -- you will be also investing in the commercialization of MicroShunt?

A5-5

Yes, that's right.

Q5-6

The last one is that you have several items, currently filed in China and awaiting approval, did you see any progress?

A5-6

Our products filed in China for approval? No, we haven't seen any notable progress, but it's nothing out of routine. So, the next approval we are waiting for is Diquas. Others are not that significant.