Q/A session (summary) (August 1, 2017)

Q 1-1

My first question is to Koshiji-san, you explained briefly against your full-year forecast. Your progress seems strong. There could maybe some differences in cost. So, in top line, there are some differences with your forecast. Could you elaborate on the differences in top line compared to your forecasts?

A1-1

Yes. In terms of the progress rate versus full year forecast our operating profit was 31%. For some cost items, there were some timing issues. So, in the first quarter some costs were not used. Now, to look at our full year forecast, on a quarterly basis, the fourth quarter includes allergy season which leads to higher sales. So, the fourth quarter, it is not one-fourth. We have higher weight in the fourth quarter. So, we cannot make a judgment just by looking at the first quarter. It is too early to make a judgment.

Q1-2

My second question. Ikervis sales are going well against your estimate, and OTC is also noteworthy. So, if you could elaborate on those two, please.

A1-2

Yes. Regarding Ikervis on a full year basis, we are on track with our plan ¥2.3 billion. Last year the NHI price reimbursement factor was there but this unforeseeable factor is now clearing. So, we are in line with the plan. In OTC, from this first quarter, the inbound demand emerged again, which is a tailwind for us. So, this is the background to sales in those areas. We are trying to analyze. But for OTC, it is too early to revise the full-year forecast. Because strong inbound demand was a factor, we need to keep our close eyes on the situation in Q2 and beyond.

Q2-1

It seems DE-117 is making progress to file in Japan in the future. If you look at sales, glaucoma treatment drugs account for the biggest portion. You have a number of products. So, going forward, what do you plan about product portfolio structure? How do you want to strengthen the glaucoma area? Would you transfer some products to other companies?

A2-1

We have a number of current and pipeline products for glaucoma. As to your question about licensing-out, we don't have any plan to transfer products to other companies. As to the positioning of DE-117, this is a new mechanism of action is different from conditional prostaglandin products. And while the Tapros patent will expire around 2022, DE-117 and DE-126 support and grow our glaucoma business. As to other products, there are non-responders to certain drugs. In that sense, we don't have any particular plan to license-out any of those products as of now.

Q2-2

And the other question I have, Dr. Shams talked about Alesion, high dose. The domestic Phase 3 study has started in Japan for epinastine HCl. As to the contract, I think this is with partner BI. Does the contract remain the same – including financial aspects? Is that a correct understanding? Because Dr. Shams said, this is going to be a very important product. So, I want to know more about this.

A2-2

There is no change to any of our relationship with BI in this case. Everything remains the same.

Q2-3

It's high dose, as compared to the existing Alesion. It's going to be have additional benefit, I believe. So, can elaborate on that side?

A2-3

I think the advantage is going to be on the dose frequency side. Meaning a longer duration of action and less frequent dosing. And that should be a significant impact.

Q3-1

My first question is the epinastine high dose. So, frequency can be reduced. Now, it is four times a day, if I'm correct. How much less frequent can you be in the study? What is the setting of the study now? And is the study design based on testing lower frequency and non-inferiority?

A3-1

So, we are hoping that we can reduce dosing frequency by 50%. So, in other words, we will have to show at least numerical superiority. Less frequent dosing and non-inferior efficacy compared to four times a day.

Q3-2

DE-117 is my second question. Whether you will develop this in Europe or U.S., has this been decided or you're still studying the possibility?

A3-2

So, we are still studying the possibility of how best to deploy this asset in the U.S. and in Europe.

Q3-3

And my last question is about sales in Asia. In ASEAN, you mentioned significant growth. In actual amount, how much sales in terms of absolute value and which products are contributing the most? Please elaborate.

A3-3

So, on a yen basis, the actual amount value was ¥1.2 billion. So, for the entire Asia, sales were ¥7.3 billion, of which ¥1.2 billion was ASEAN. The size is still small, but on a year-on-year basis, ASEAN had 75.9% growth. Cravit and Hyalein are the main products.

Q4-1

I have a question to Doctor Shams about DE-109 Opsiria. You mentioned this seems to be progressing smoothly, what do you mean?

A4-1

We have just passed them mid-cycle review. Up to this point, everything looks under control.

Q4-2

And question number two, as to Hyalein, recently, hyaluronic acid PC, I read an article about the launch of hyaluronic acid. So, my question does the right of the Hyalein belongs to you, your company?

A4-2

If you are talking about the option of switch OTC – yes, we are considering it.

Q5-1

Now if we look at China, what is the growth of China alone and in the ASEAN market, the countries you already entered and the new countries for you, if you could separate those two, then it will give me a clear idea. And the same question for European market.

A5-1

For China, on a yen basis revenue grew 12.6%, and 15.4% on local currency basis. On a yen basis, sales were ¥4 billion in China. So, of the ¥7 billion Asian sales, ¥4 billion came from China. In ASEAN, there are many countries. Large sales countries include Vietnam, Thailand, Singapore and Malaysia. So, local subsidiaries or the representative offices exist in these countries. Smaller, but also included are Pakistan, Indonesia and Sri Lanka. So, the remaining countries are smaller, less than ¥100 million, those are the emerging countries, this is our distribution.

Q5-2

So, of the total growth, majority of the growth are Vietnam, Philippines, Singapore, Malaysia, these countries, majority of the growth comes from the countries that you've already entered?

A5-2

Yes. The big contribution comes from Vietnam in terms of the amount of sales. In Europe, the top are Italy, Germany and France. These are the big drivers. We've had a sales base in Germany for some time. However, the acquisition of the MSD products has helped Italy and France become the new drivers since 2014. And an important emerging country for us is Russia. Last year, we established our local subsidiary and now they have the same level of momentum as Italy and same level of growth.

Q5-3

Could you give us the result of Oftan-Catachrom?

A5-3

For this first quarter, ¥772 million, 141% up, year-on-year. On a full year basis, it is ¥2.5 billion.

Q5-4

Now the inbound doesn't seem to have declined but the tourist from China is fluctuating. As of now, do you feel the slowdown, that is, a deceleration of inbound sales?

A5-4

According to our analysis, our sales are exactly proportionate to the number of tourists. So, as the purchasing behavior, inbound is still strong. The purchasing behavior will remain strong. That is our forecast.

Q6-1

I have two questions about Europe. The growth of Europe was very high. Besides the announced products, what products are growing? It looks like others must be growing fast – maybe it was Oftan-Catachrom?

A6-1

Yes, the impact of Oftan-Catachrom was very high.

Q6-2

And the second question is to Dr. Shams, DE-117. Regarding overseas development - Going forward, what do you see as the biggest issue in development overseas? Up to Phase 2, when I look at the data as compared to Xalatan, the onset may be faster. But the ocular pressure, lowering pressure is almost the same. In Phase 3, the biggest thing maybe how to treat non-responders. So, in European development of this product, what is going to be key?

A6-2

As far as the development in Europe or elsewhere, there are no major technical issues. The probability of success, in my view, is quite high. But as you've heard today, we have a very robust portfolio of IOP-lowering drugs. And so, we need to pace the development of these products, so we don't cannibalize our own product pipeline. Those kinds of things, are some of the additional things we have to discuss when deciding how fast to move both in Europe and the U.S. So, we have six or so products, innovative products in the pipeline. And we also have to manage our resources adequately so that all products get a fair share in the development effort.

Q6-3

For DE-117, you started in Asia and Japan first but development elsewhere was suspended. Japan is a strong market for Santen. And there is the issue of the patent expiration of Tapros. Is it possible that this product may not be strong enough to develop in overseas markets. That's my impression, is it true?

A6-3

No, I don't think so at all. I think the product is probably one of the best differentiated products in the IOP-lowering space. It's just development sequencing that can slow things down. You are absolutely right

about Japan and Asia. Yes, there will be an expiry of Tapros and we must protect the Japan market where we are very, very strong. So, that is naturally prioritized. But, for example, in U.S. the product could do quite well. In Europe, reimbursement and market access are challenges that have to be dealt with. It is important that the product is very well differentiated.

Q7-1

So, as mentioned in the previous question, growth in Asia and Europe in Q1 was strong. And, I recall that a lot of SG&A was used in Q4. But, in Q1 SG&A has not increased much. So, guessing from this, Asia, Europe, sales investment was completed in March and now, you are reaping the harvest from April and this trend will continue July and onward? Is my understanding correct?

A7-1

Now we are controlling our expenses - that is correct. However, the cost increases in Q4 of last year will have longer term benefits beyond Q1 which emerge over a longer period of time. On a full-year basis, the sales and profit growth trend from Q1 should continue to Q2. However, in Q3 and Q4, China has New Years and National Foundation Holidays which lowers productivity falls somewhat. So, the second quarter is the peak. And for Europe, Ikervis and Taptiqom are new products that should increase towards the end of the year – with sales and cost increases that are basically in line with each other in Europe. That is our view on a full-year basis.

Q7-2

Next, in the U.S. there was $30 million cost included as U.S. prelaunch costs. But on page 6, U.S. is negative and costs increased by ¥600 million. So, is this being used on schedule or is it front loaded, that is, being used a bit quicker than scheduled?

A7-2

For now, it is basically in line with our plan. Overall, this will increase towards the end of the year. That is how we have budgeted. So, it is a YoY increase of ¥600 million but it’s not Q1 x 4. The amount will increase towards the end of the year. And this first quarter was in line with the plan.

Q7-3

My last question is about P&L. The cost ratio for the January-March quarter on a year-on-year basis, is 1.8-percentage-point worse. So, the cost ratio deterioration is rather big. Is this because of the strong Asia and Europe business or Eylea factor? Could you break down the factors please?

A7-3

There are two main factors. One is in Q1 of the prior year (2016), Eylea had a ¥700 million cost benefit. This was the adjustment of procurement cost, so that was 1.3%~1.4% of the 1.8%. Other than that, there was a change in product mix. The second is the cost ratio due to the increases of Eylea and OTC which have lower margins than our traditional pharma business and increased the cost ratio and explains the remaining about 0.3% to 0.4%.

Q7-4

One more question, if I may. So, the ¥37.2 billion is the cost ratio portfolio basis, and there's a difference between that and current level. But do I need to worry about that?

A7-4

We have not changed the forecast. In the fourth quarter, every year, Alesion and high-profit products increase. In Japan, Cosopt, Trusopt, and Timoptol will start to give the positive margin impact from bringing switching to in-house manufacturing instead of MSD manufacturing. And so, we think the cost ratio will decline over time. Now, with product mix, the cost COGS ratio may not decline as we anticipate, but we think gross margins will be maintained.

Q8-1

Overall, as you have mentioned 31% of the progress rate, it may be misleading as you mentioned. If that's the case on a core basis, sales increases of 11.9% and OP was up 10.9%. The growth of 10.9% is almost in line with the full-year forecast. So, we should look at this figure to forecast for the full year.

A8-1

Yes. That's right for the full year.

Q8-2

As to OTC, there was a talk about wholesale figures in the industry yesterday, inbound demand has been strong and eye drops are very strong because Chinese people like eye drops. So, I don't think it will decline going forward, but inbound may change going forward. Is it appropriate to think that OTC won't decline?

A8-2

Right. At this time, we basically think the same way. Now, our full year forecasts show growth of 2.8% from the previous year. But ultimately, this may be revised upward depending inbound contribution.

Q8-3

And as to glaucoma, there is a lot of talk about the patent expiry of Tapros and how DE-117 and DE-126 are kind of successors – is that still your thinking?

A8-3

But please understand that we are not expecting necessarily that patients will “switch” from Tapros to DE-117 and DE-126. Glaucoma is a chronic disease. So for those patients who are using Tapros it's not that all those patients are going to switch to DE-117. So, we are talking about success only in relation to our lineup. So, it's not about switching or cannibalization. What we want is market share and growth. This will be an additive to our market share.

Q8-4

Is DE-126 progressing on schedule and will it still be approved in 2021?

A8-4

DE-126 was in Phase 2a and now it's in Phase 2b. So, it's in line with the schedule. Yes, our expectation for approval is 2021.

Q9-1

My first question is DE-109. In the full year result briefing, Mr. Koshiji said in 2020, $30 million or ¥3 billion. I think you're entering pre-marketing phase and investigations with payers. How do you see the potential? Any changes in your forecast of sales? That's my first question.

A9-1

Yes. Preparation is underway. But there is no situation where we have to change our underlying premise significantly. So, we are on schedule.

Q9-2

So, the NHI price or the subject patient, no change?

A9-2

No. We have not changed our view.

Q9-3

My second question is for Dr. Shams. The MicroShunt, I have a question to you. So, Allergan's XEN45 was launched. What is the differentiating point if you could elaborate to put things in perspective please?

A9-3

Sure. There are several points of differentiation. Number one, the material that we use to make the device is more inert or safe, we believe, as compared to collagen or cross-linked collagen. Because of the long history of this material in man, we believe that our efficacy is going to be sustained for a much longer time. By which I mean the lowering of IOP is going to be sustained for several years. And we think that most patients will not require too many medications on top of the device. We also think that our procedure is much simpler. And most glaucoma specialists are already trained to do this type of procedure. And finally, we will start treating patients in a segment that we can compete against a much more invasive procedure called trabeculectomy.

Q9-4

And, lastly, this MicroShunt, you said that the enrollment is progressing steadily and this will complete in 2018 or 2019 but is there a more chance to complete this in 2018? And on slide 19, it takes two years from filing to launch. So, you complete the filing in 2018 and launch in 2020, so two years. So, from filing to launch, is there a chance that this can be reduced by one year? So, filing in 2018 and launch in 2019, is that scenario a possibility? Because I think so. How do you think? Any comments on that, please?

A9-4

I can just assure you that we will use every tactic to save as much time as we possibly can.