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Otsuka Holdings Co., Ltd.

Financial Results Presentation Q1 FY2014
(Three Months Ending June 30, 2014)

Q&A

August 8, 2014

Q1: We get the impression that research and development expenses are underspent, so will this have any impact on the full year forecasts?

A1: Although there is an impact of timing differences between recording and spending for some expenses, progress itself is moving ahead steadily. We are also conducting reviews of products under development, so the underspending could persist for the whole year.

Q2: The progress of sales promotion expenses in the pharmaceuticals business seems ahead of schedule. Do you plan to use the expenses at the same level for the full year?

A2: There was an increase of ¥6.9 billion in sales promotion expenses for the pharmaceutical business. The exchange rate and an increase in co-promotion expenses due to the sales growth for Abilify account for just under 80% of this. We do not believe that sales promotion expenses other than co-promotion expenses will increase that much in the future.

Q3: With regard to the global sales structure for Lonsurf (TAS-102), I understand that partners have not been determined at this stage, but have you decided on the sales structure?

A3: Basically we are considering a direct sales structure based on Taiho Pharmaceutical.

Q4: With regard to TAS-116, all the forerunners of heat shock protein 90 (HSP90) inhibitor are facing difficulty in their development, so what are the differentiating points from those forerunners?

A4: Retinopathy is an issue with the forerunners, but, based on the results of our preclinical studies, we expect the risk of retinopathy with TAS-116 to be low. We are going to confirm the safety profile in clinical trials.

Q5: What are the U.S. sales for Abilify Maintena? Based on the 70-80% capture rate of the IMS data, would it be correct to interpret the figure at ¥4 billion - ¥5 billion?

A5: According to the IMS data, the U.S. cumulative sales from April through June, 2014 were $36 million. I hope you will understand that I am not able to answer with specific figures.

Q6: What is the sales status for Abilify Maintena in Europe?

A6: As of June 30, 2014, Abilify Maintena had been launched in five European countries. Subsequently, the number of countries increased steadily to eight as of July 31, 2014. This includes countries without medical reimbursement. Sales are yet to come, but the number of countries where it is on sale is increasing steadily.

Q7: Regarding the approval review for the additional indication of autosomal dominant polycystic kidney disease (ADPKD) for Tolvaptan in Europe, is it correct to understand that you have responded to the questions from the EMA in the Day-120 primary evaluation?

A7: We have received some questions, but I am not able to respond to the questions regarding the content, schedule and other matters.

Q8: Are you going to disclose the bottom figures for sales and income in the medium-term management plan?

A8: We are proceeding with that plan.

Q9: What are the sales of Lonsurf in Japan?

A9: It has just been launched, and we are not disclosing sales at present.

Q10: TAS-116 and Astex's AT13387 are both HSP90 inhibitors, but do you think that TAS-116 has more potential?

A10: At this point, we do not make such a relative assessment as to the merit of the compounds. Retinopathy is a major point, so we can determine the potential depending on the outcome of clinical trials.

Q11: It has been disclosed that the ADPKD additional trial for Tolvaptan in the U.S. will be completed around October 2016, so is it correct to expect U.S. ADPKD sales to be included in the next medium-term management plan?

A11: Please wait for the guidance in the medium-term management plan scheduled to be announced on August 26.

Q12: You filed an NDA for Brexpiprazole in the U.S. When is the PDUFA date?

A12: It has not been decided yet. If the application is accepted in September, we will know when that date is.

Q13: The Brexpiprazole data for schizophrenia has not been published yet, but with the Phase III data, where do you think the differentiation with existing products lies? Will you be able to disclose the data when you release the financial results for the second quarter of 2014?

A13: We are currently preparing conference presentations and papers for publications. We have not determined the timing for disclosing the data. It will be difficult to disclose the data at the time of the financial results announcement for the second quarter of 2014.

Q14: How is Lonsurf received by physicians in Japan?

A14: It received a good reputation at the recent meeting of the Japanese Society of Medical Oncology. One opinion was that it is easy to use since hematotoxicity, the main side effect, has no subjective symptoms and can be managed if it is monitored properly.