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Otsuka Holdings Co., Ltd.

Financial Results Presentation Q1 FY2017

(Three Months Ending March 31, 2017)

Q&A

May 12, 2017

Q1:	Millennium Pharmaceuticals is developing a drug in the same category as TAS4464. Could you explain what differentiates your compound from the competition? Are you broadly targeting both solid cancers and blood cancers?
A1:	Non-clinical studies have shown that our compound offers a wide safety margin and low toxicity of weight loss. Going forward, we will confirm these characteristics in clinical trials. As for target indications, we are currently considering both solid cancers and blood cancers.
Q2:	What are the reasons for the weak performance on sales of *ABILIFY MAINTENA* and *NUEDEXTA*?
A2:	The sales trends are in line with our forecasts.
Q3:	You just announced discontinuation of development of SGI-110 for hepatocellular carcinoma and Lu AE58054 for Alzheimer's-type dementia. Do you plan to record impairment losses relating to these?
A3:	We recorded an impairment loss for Lu AE58054 in fiscal 2016. We do not plan any impairment loss for SGI-110.
Q4:	Were there any extraordinary factors that have impact on the differences between Japanese GAAP and IFRS?
A4:	There are no major extraordinary factors, including impairment loss on R&D expenses, other than the reclassification of general line items such as the inclusion of equity investment income in operating income under IFRS.
Q5:	Regarding the discontinuation of Phase III of *ABILIFY* in Japan for agitation associated with Alzheimer's-type dementia, it was acknowledged that results for the trial would be obtained around July 2017. Have you decided to discontinue development after confirming the results already?
A5:	We decided to discontinue the development before the trial results were obtained, in order to concentrate resources on *REXULTI*.

Q6: With regard to the development of the brexpiprazole long-acting injection, Lundbeck commented in their financial results announcement that the Phase I trial will end in 2Q 2018. When are you planning to submit the application for approval?

A6: We will look at the results of the Phase I trial currently underway to confirm the clinical profile characteristics of subcutaneous injection and intramuscular injection and review the subsequent development plan.

Q7: *Lonsurf* sales made extremely significant progress in 'other' areas: other than Japan and US. Are any special factors involved in this?

A7: Servier, our alliance partner in Europe, has been steadily launching the drug in new countries. It is now available in nine European countries.

Q8: Wasn't there a plan to announce the results of the U.S. Phase III trial of Tolvaptan for ADPKD in April 2017?

A8: The timing for study completion was April 2017. We expect to be able to announce the results in 2Q or 3Q.

Q9: Are results for 1Q 2017 in line with your forecasts? I thought that the year-on-year impact of the expiration of the *ABILIFY* patent would last through the first half, but the forecast is to recover in the second half to achieve profit growth for the year overall. So, what is the progress on this forecast at the present time?

A9: We plan to generate stable profit throughout the year. At present, R&D spending is slightly behind budget, including carry-forward, but overall things are moving in line with our forecasts.

Q10: We previously heard that penetration of *Jinarc* was slow because the once monthly liver function testing created a bottleneck. Has this issue not been solved yet?

A10: We estimate that about 20% of Japan *Samsca* sales are from ADPKD prescriptions. We will continue to provide training programs for physicians and explain safety measures. Awareness and prescriptions are steadily increasing in both Japan and Europe.

Q11: What is the *Jinarc* reimbursement status in Europe?

A11: At present, insurance reimbursement has been available in 10 European countries. In two countries the drug is marketed without reimbursement. We are gradually increasing the number of countries where *Jinarc* is sold.

Q12: What is the allocation of development expenses and the development milestones in the alliance agreement with Lundbeck for the brexpiprazole long-acting injection?

A12: There will be no milestones. The development expenses are shared proportionally. The profit sharing varies depending on the country.

Q13: What are the sales you expect from the *Keytruda* co-promotion in Japan this fiscal year?

A13: We do not disclose that..

Q&A on the results of the Phase III trials of brexpiprazole for agitation in Alzheimer's-type dementia

Q14:	According to the press release, being unable to obtain consistent data from the two trials, Otsuka will discuss the advisability of filing with the FDA. Could you tell us about your prospects at the present time?
A14:	Since the release of the topline results on May 2, there has been no further progress that we are able to discuss today. We are currently analyzing the detailed data.

Q15:	The press release stated that differences in the standard of care in each country could have impacted the results, but specifically what kind of differences were there and what kind of impact they give to the trials? Does the standard of care in Russia generally have special characteristics?
A15:	The medical care environment is different in each country. We are currently analyzing the data, and we are unable to comment on the details at the present time.

Q16:	Lundbeck mentioned in the financial results announcement that even for the trial which showed no statistically significant difference in the primary endpoint for the drug group, there was a statistically significant difference when excluding Russia. In other words, was there perhaps a narrow margin that failed to show statistical significance overall? Could you also tell us the percentage of Russian patients?
A16:	We would like to refrain from commenting on that at the present time.

Q17:	Was there an agreement with the regulatory authorities on the design of the trials in advance? Also in Europe, can it be possible to get approval even with one pivotal trial?
A17:	The trial was conducted in the U.S. and Europe, but the U.S. was basically the main target. We agreed on the trial design with the FDA.

Q18:	Could you tell us the schedule for future discussions with the FDA?
A18:	That has yet to be decided. We are hoping to conduct the data analysis as soon as possible and to hold discussions with the FDA as soon as we can.

Q19:	We are informed that there was a significant difference when excluding Russia, in the trial which showed no statistically significant difference in the primary endpoint, but generally, is it possible to file for approval with data that excludes such kind of special factors?
A19:	After analyzing the data, we will discuss it with the FDA. We are unable to comment on the details at the present time.

Q20:	What is the schedule for disclosure of the data?
A20:	That has yet to be decided.