Otsuka Holdings Co., Ltd.

Financial Results Presentation Q2 FY2017

(Six Months Ending June 30, 2017)

Q&A

August 8, 2017

Q1: Can the full-year operating profit projection of ¥120 billion be achieved, even when impairment loss is factored in?

A1: We aim to achieve operating profit of ¥120 billion, even when impairment loss is factored in. In order to achieve the initial projection, we will need at least ¥70 billion in operating profit in the second half of the fiscal year, and we will look at the performance on sales and costs up to the third quarter, such as sales in the nutraceutical business in summer and cost control, including the progress of R&D expenses, to examine the prospects for the full year.

Q2: Regarding the future schedule for development of brexpiprazole for AD agitation, when will a meeting be held with the FDA?

A2: We submitted a meeting request to the FDA in July 2017.

Q3: Have there been any serious safety signals regarding the Phase IIIb trial of tolvaptan for ADPKD?

A3: There were no serious safety concerns in the trial.

Q4: Have you started market access preparation, including negotiations with payers, for the Digital Medicine that was filed for NDA in May 2017, and what will be the main points?

A4: As Digital Medicine is a new experiment, we are hoping to develop it seriously after confirming actual clinical uses.

Q5: In the briefing at the beginning of the fiscal year, you said that fiscal 2017 would be a key year for considering additional investment aimed at future growth based on sales growth of new drugs and the progress of drug development. Looking at the degree of progress in the half-year results, I'd like to hear about your approach to future growth investment again.

A5: At the beginning of the 2nd Medium-Term Management Plan, with the aim of achieving net sales of ¥430 billion for new drugs that will be growth drivers, 80% of them had been launched or filed for marketing approval. But there were uncertainties for 20% left. Going into the fourth year of the plan, we have seen a lot of progress on these uncertainties, such as the additional indication of bipolar disorder for *ABILIFY MAINTENA* in the U.S. and the launch of *LONSURF* in Europe and the U.S. Growth investment will be needed in the future to foster these growth drivers, and to support our in-licensed pipeline. With regards to R&D expenses for the full year, expenses for in-licensed pipeline development will increase, but there will also be decreases due to greater cost efficiency and a review of trials, so we expect R&D expenses of ¥180 billion in line with initial projections.

Q6: The atypical antipsychotic long-acting injectable (LAI) market in the U.S. has grown 12% - 15% on a prescription base, what are the factors for this growth? Also, what will be the potential for a two-monthly formulation of *ABILIFY MAINTENA* and an additional indication for bipolar disorder? Could you also explain price pressure?

A6: Because schizophrenia has a high need for medical adherence, the LAI market has continued to grow. We will develop and roll out a two-monthly formulation while monitoring the clinical environment. It is said that 1% of drug-treated patients with bipolar disorder in the U.S. are treated with LAIs, which is small percentage compared with 10% of patients treated for schizophrenia. However, obtaining the bipolar indication makes promotion possible, so this could uncover a potential market. There is price pressure in the U.S. market, but it is not limited to *ABILIFY MAINTENA.*

Q7: It is difficult to use the LAI without the bipolar depression indication?

A7: According to the clinical trial of *ABILIFY MAINENA*, the period to recurrence has been extended, so we believe that it will be used after selection of patients.

Q8: Supposing that operating profit for fiscal 2017 is within the reachable range of ¥120 billion, will operating profit of ¥155 billion for 2018 go up?

A8: At present, there are no changes to the fiscal 2018 operating profit guidance..

Q9: Do you have any plans to develop digital medicine for *REXULTI* as well?

A9: There are a variety of possibilities in the future, but first we are going to grow *REXULTI* steadily.

Q10: Do you have any plans of Rx-to-OTC switch for *Mucosta*?

A10: At present, we have no plans for that.

Q11: Could you tell us about the trials of LONSURF for second-line treatment of colorectal cancer?

A11: One study in combination with oxaliplatin sponsored by Servier, and one study with irinotecan ongoing. In Japan, study in combination with bevacizumab will be commenced.