Otsuka
Otsuka-people creating new products for better health worldwide

Otsuka Holdings Co., Ltd.

Financial Results Presentation Q1 FY2018

(Three Months Ending March 31, 2018)

Q&A

May 11, 2018

Q1: How were sales and operating profit in nutraceutical business excluding the impact of the new consolidation of Daiya Foods Inc. and the application of IFRS 15?

A1: Nutraceutical business achieved growth in sales and profit even excluding the impact from the new consolidation of Daiya Foods Inc. and the application of IFRS 15.

Q2: I get the impression that the progress of overall business results is good. Can you tell us whether the progress is in line with your plan including special factors such as milestone payments?

A2: Sales have outperformed the initial plan. So has the operating profit. This is due in part to the impact of the progress of expenses.

Q3: Can you update us on the launch of *JYNARQUE*, which has been approved for the indication of autosomal dominant polycystic kidney disease (ADPKD) in the U.S.?

A3: At the moment, we are implementing MR education, etc. with the aim of launching the indication in May.

Q4: With regard to *JYNARQUE*, the letter from the FDA instructs you to submit a REMS plan if you launch an authorized generic. Will the same process be required for a generic application through ANDA?

A4: I understand that is the case.

Q5: With the approval of *JYNARQUE*, the label for *Samsca* in the U.S. has been changed to prohibit its use for ADPKD. Do you think this will make it difficult for *Samsca* generics to be used for ADPKD patients?

A5: As you observe, a statement on use for ADPKD (under REMS management) has been included in the Black Box Warning on the label for *Samsca* in the U.S. Given this, we believe that basically *Samsca* generics cannot be prescribed, from the perspective of appropriate use.

Q6: I think that the Phase III trial of *LONSURF* (TAS-102) for gastric cancer was initially scheduled to end in December 2018. Were the recently announced positive topline results the interim analysis?

A6: Since the trial was scheduled to end around June 2018, the topline announcement is as planned. The trial completion, including follow-up period, is December 2018.

Q7: I think that the Phase I trial of *Abilify Maintena*'s two-month depot formulation ended in April 2018. When will the results be published? Also, can you file for approval of this formulation with the results of this Phase I trial alone?

A7: The results of the Phase I trial will be either presented at a scientific conference or published as a paper. At the present time, I believe we can file for approval with the pharmacokinetic (PK) trial results.

Q8: The Phase III trial of ASTX727 for myelodysplastic syndrome (MDS) is designed to confirm PK equivalence with decitabine. I don't think the market size for decitabine itself is big. Could you give us the idea behind development?

A8: At the moment, we believe that we can file for approval with this PK data. We prioritize the launch of ASTX727 first, and then we will consider additional indications aimed at market penetration.

Q9: Does the trial design to evaluate ASTX727 imply that demonstrating differentiation on efficacy and so on compared with decitabine is difficult?

A9: If ASTX727 has the same efficacy as the existing decitabine injection, we believe that we can achieve differentiation from patient convenience perspective since ASTX727 is an oral medication.

Q10: *Deltyba* sales have not been disclosed. Is there a possibility that it will not gain market acceptance with its high manufacturing costs and safety issues?

A10: *Deltyba* sales have not yet reached the level for disclosure, but we do not believe that its costs and safety are hindering prescription. It is currently on the WHO Essential Medicines List, allowing its use in many countries. As there are multi-drug resistant TB patients who are subject to treatment with this drug in emerging countries, we are promoting patient access through agreements with various partners.

Q11: I understand that the impact of the IFRS15 application on upfront and milestone revenues was factored into the plan at the beginning of the fiscal year. Is the ¥3.9 billion recorded in the first quarter in line with the plans?

A11: Slightly less than half of the ¥3.9 billion recorded in the first quarter is related to unanticipated revenues from Astex compounds.

Q12: If PK equivalence with decitabine can be demonstrated for ASTX727, does that mean you can obtain FDA approval?

A12: At the moment, we believe that we can file with the current trial plan.

Q13: Nivolumab prescriptions have increased greatly for gastric cancer. Does *LONSURF* have any differentiation points from nivolumab other than price?

A13: We are not able to comment on that at the moment as the detailed data have not been published.

Q14: Is it correct that the increase in *REXULTI* sales comes from prescriptions for major depressive disorder (MDD)? Could you tell us the percentage of prescriptions for schizophrenia and MDD respectively?

A14: Most *REXULTI* sales are for MDD, which accounts for approximately 80% of prescriptions.

Q15: Do you have any update on enrollment of the *REXULTI* Phase II trial for PTSD?

A15: We previously conducted a Phase III trial, but enrollment did not proceed as planned, and we started a new Phase II trial under a new protocol. While the initial study had been designed for combination therapy with anti-depressants, the new study evaluates *REXULTI* monotherapy as well.

Q16: What is the share of *Abilify Maintena* in the long-acting injectable market as of March 2018? What are the U.S. sales on the local currency basis?

A16: *Abilify Maintena*'s share of sales in the market is approximately 18%. Additional indication of bipolar disorder has been driving its growth. Local currency based sales in the U.S. for the first quarter of fiscal 2018 were $100 million.

Q17: *NUEDEXTA* sales seem weak compared with the plan. Please explain the current situation.

A17: We have implemented reviews which include management changes and marketing strategy. We are also considering new marketing strategy through DTC, etc. in order to accelerate sales growth from the second half of fiscal 2018.

Otsuka
Otsuka-people creating new products for better health worldwide

Q18: Regarding the indication of *JYNARQUE*, unlike in Japan and Europe, there were no restrictions on subjects with regard to renal function and renal volume in the U.S. Is it correct to believe that all of the ADPKD patients in the U.S., which is estimated about 140,000, will be targeted? Or should we understand that the patients with advanced CKD symptoms will be the main target for prescription?

A18: The indication in the U.S. is “to slow kidney function decline in adults at risk of rapidly progressing ADPKD.” The judgement on disease progression will be determined based on various factors such as change in eGFR, family history and gene mutation. However, since there are no clear criteria, it will ultimately be decided by the physician in charge. In the REPRISE trial, many patients with Stage 3 CKD were enrolled, but we believe that the drug can also be used at an early stage if progression is determined to be rapid.

Q19: Are there any updates on the additional Phase III trial of *REXULTI* for agitation associated with dementia of the Alzheimer’s type?

A19: It is scheduled to start during the first half of 2018 as planned.

Q20: The WAC price for *JYNARQUE* is high, at approximately $13,000 per month. What is the estimated discount rate?

A20: We cannot comment on the insurance reimbursements at the moment. We will provide a range of patient support programs and consider initiatives so that the burden of patient out-of-pocket expenses does not increase.

Q21: Do you consider *JYNARQUE*'s prescription penetration for ADPKD in the U.S. will be similar to that of Japan?

A21: We will know that after the launch, but the penetration in Japan serves as a reference. It is estimated in post-marketing surveillance of *Samsca* for ADPKD in Japan that the drug was used by approximately 10% of the patients at the three-year point.

Q22: Is it correct to assume that ASTX727 filing for approval in the U.S. is your priority?

A22: That is correct. We consider filing for approval in the U.S. to be the top priority.