

# Otsuka Holdings Co., Ltd.

## Financial Results Presentation Q1 FY2015 (Three Months Ending March 31, 2015)

**Q&A**

**May 13, 2015**

Q1: Is progress for both the Pharmaceutical business and the Nutraceutical business in line with projections excluding the portion of the development milestone payment for Brexpiprazole that was scheduled to be recorded in the second half of 2015 which has already been recorded pro rata?

A1: The consolidated figures for Avanir Pharmaceuticals are provisional, but progress is basically in line with projections.

Q2: Progress for R&D expenses is lagging behind projections. Are there any changes to the full-year projections?

A2: There have been cut-off errors for some trials with R&D expenses lagging behind. SGI-110, Nalmefene and TAS-118 have already commenced Phase III trials this fiscal year and commencement of Phase III for AVP-786 is planned within the year, so no changes have been made to full-year projections at the current time. A review of projects is also scheduled, so we plan to reconsider, including changes to the full-year outlook, at the end of the first half.

Q3: What is the current status of sales of *Abilify* in the United States? Have sales declined dramatically since the approval of generic drugs on April 28, 2015?

A3: We are currently analyzing the sales status. We will explain about the sales situation after patent expiration at the 2Q result announcement in August.

Q4: What is the impact of the nine-day delay in the approval of generic drugs of *Abilify* in the United States after the expiration of exclusivity?

A4: At the moment, there is no major deviation from projections.

Q5: Why have the exchange rates had little impact on operating income when the sales of *Abilify* in the United States have not declined yet?

A5: This is due to the effect of the increase in the proportion of co-promotion expense payments to Bristol-Myers Squibb compared to the previous fiscal year, as fiscal 2015 annual sales of *Abilify* in the United States will decline.

Q6: What progress has there been in discussions with the FDA on Phase III trials for AVP-786? What is the timeframe for commencement?

A6: Discussions with the FDA are making steady progress. The trials are scheduled to commence in fiscal 2015.

Q7: Regarding *Samsca* in Japan, prescription share of 30mg tablets for ADPKD patients is around 2% according to IMS data. Is this a slow start even during the period of implementing all-patient surveys? Are there fewer ADPKD patients in Japan than previously expected?

A7: In our view, this is because we are promoting *Samsca* for ADPKD patients carefully by limiting to the physicians who have undergone the e-learning program provided by Otsuka Pharmaceutical.  
We do not think that ADPKD patients in Japan are fewer than expected.

Q8: It is stated that approximately ¥380.0 billion in goodwill of Avanir will be amortized over 20 years in the financial results. Was the consolidation of Avanir originally included in the full-year projections for the current fiscal year?

A8: It has already been included in the projections for the current fiscal year. All Avanir's assets are provisionally recorded under goodwill at present, but the period of amortization and other details could change in the future after scrutiny of other asset categories is finalized.

Q9: What is the state of progress in the Nutraceutical business? Net sales have improved, but has operating income been progressing in line with the projections?

A9: The main season for Nutraceutical products is summer, from June onwards. During the first quarter of 2015, sales outside Japan outperformed projections due to such factors as strong sales at Pharmavite, and the Nutraceutical business overall is generally progressing in line with projections, including in Japan.

Q10: What is the sales performance of *NUEDEXTA*?

A10: The sales results of *NUEDEXTA* are not disclosed. According to IMS data, cumulative sales for January – March 2015 were US\$ 39 million.

Q11: Do you plan to disclose the interim analysis data for Phase I trial of Lundbeck's amyloid beta vaccine Lu AF20513 that is stated to commence in March 2015 and end in December 2016 in *ClinicalTrials.gov* website?

A11: There are no plans for interim analysis.

Q12: Under which item are co-promotion fees for *TAKECAB* stated?

A12: The co-promotion fees for *TAKECAB* are stated under Japanese pharmaceutical business sales and are not disclosed individually.