



October 30, 2015 (Fri) 19:30 - 20:15

[Attendees]

Seiichi Murakami, Board Director, Managing Executive Officer, Division Manager of Ikuyaku, Integrated Value Development Division

Minoru Muramatsu, Managing Executive Officer

Eizo Tabaru, Board Director, Executive Officer, General Manager of Finance & Accounting Department

Tetsuo Yoshikawa, Executive Officer, Division Deputy Manager of Sales & Marketing Division

[Earnings Results for the 2nd Quarter of the Fiscal Year Ending March 31, 2016]

Q: You upwardly revised your earnings forecasts at the end of September but since then your earnings performance has further improved. Can you explain the catalysts behind this improvement?

A: There was a gap between sales and SG&A costs. Royalty income increased because sales of Gilenya and INVOKANA at licensees were brisker than our expectations. SG&A costs were ¥3 billion lower than planned as R&D expenses were unused and R&D expenses at Medicago Inc. shift to the second half.

[Earnings Forecasts for the Fiscal Year Ending March 31, 2016]

Q: Why did you increase your full-year forecast for SG&A costs? Is this due to an increase in costs for expected business developments in the US or spending for business developments in and after FY2016? Also, do you forecast a change in R&D trends for business developments in the US?

A: The increase in our SG&A cost forecast includes US business development costs such as a review of US business developments and the transfer of employees from Japan to the US. Also, we factored in a one-off increase in SG&A costs in the second half.

Q: Will you use your entire SG&A costs?

A: We think we have a little room in our R&D expenses but costs are likely to be fully in line with forecasts in others.

[Radicut / additional indication of ALS]

Overseas

Q: When will you file Radicut for ALS in the US? Will it be in 2015 or in FY2015?

A: We aim to submit our regulatory application as soon as possible. It might be difficult to accomplish this by the end of this year. At this stage it is unclear whether we will be able to submit it by the end of the current fiscal year or not.

Q: Have you come to an agreement on the application package in your discussions with the FDA?

A: We are currently in talks so we cannot discuss the details.

Q: Radicut also received an orphan drug designation for the treatment of ALS in Europe. How do you plan to proceed?

A: We are moving forward first in the US. We will begin making plans for Europe once our goal is in sight for the US.

Q: Regarding your US regulatory application for Radicut, have conditions changed in your meetings with the FDA? What is the reason this is requiring so much time?

A: There has not been any change in particular. The application process just takes time. Our meetings and other interactions with the FDA are going smoothly.

Domestic

Q: Please give us a rundown of current trends.

A: The number of patients being administered the drug is around 800 cases.

Q: Can you give us a breakdown of the level of severity of the 800 cases for which you are currently administering the drug?

A: We do not have a breakdown right at this moment.

Q: You upwardly revised your full-year earnings forecast from ¥5.4 billion to ¥6.2 billion. Does this reflect the expanded administration of the drug to ALS patients?

A: We cannot discuss the amount but we have factored this in.

[Sales]

Q: Is the decline in Remicade sales due to impact for the biosimilar?

A: The impact from the biosimilar is minimal, about 1% on a volume basis. Intensified competition in the rheumatoid arthritis and inflammatory bowel disease markets is one factor for the decline in sales. However, we are not concerned about the recent slowdown in sales.

Q: Please give us details on the new scheme for Tenelia.

A: Since October 1, Daiichi Sankyo became the sole distributor. However, we are still conducting co-promotion.

Q: What are the details for the sales planned in the new Tenelia scheme?

A: The sales consist of sales to Daiichi Sankyo and the promotion fee we receive from Daiichi Sankyo. This is the first time we are disclosing these sales. The details can be

found in the supplement material of financial results.

Q: What is the objective of changing the sales method for Tenelia?

A: The main objective for changing our sales method is to fortify our sales channel to general private practitioners by implementing wholesale policies that integrate sales. The profit structure will remain the same regardless of changes to the sales method.

Q: Domestic sales of ethical drugs outperformed your initial forecast by ¥6.5 billion yet your upward revision to full-year sales was a mere ¥2.0 billion. Does this reflect impact from the change to your sales method for Tenelia?

A: There is no impact from the change in the sales method.

[Development]

MT-1303

Q: The efficacy of MT-1303 has shown to have benefit over existing products. How do you plan to position the drug?

A: MT-1303 is very safe owing to its high S1P receptor subtype selectivity. S1P receptor antagonists have become a typical method of treatment for multiple sclerosis. Other than this, for example, when we develop it for treatment of digestive diseases, a high level of safety would be an important issue.

Q: So you do believe there is benefit from the efficacy of MT-1303?

A: We believe that in the treatment of multiple sclerosis the efficacy of MT-1303 is equivalent to or better than peer drugs. We also plan to prove its efficacy in treating other diseases going forward.

Q: What time of day is the drug administered?

A: During the a.m.

Q: The data you released at the conference in this October, after the fourth week of administration there was a decline in the heart rate of patients in the control group versus those in the placebo group. Is this a problem?

A: The slowdown in heart rate, at least according to the data, is minimal. At this stage, we do not believe this is a major impact.

Q: Is there a possibility that it will be unnecessary to monitor the patient's heart rate?

A: Biogen will be handling development in the US and we plan to look into this together.

Q: Can you guide us through the economic terms of joint promotion you reserved?

A: We cannot answer at this moment.

Q: Looking at the slides presented by Biogen at its earnings briefing, it appears that priority is on the development of the drug for use in treating diseases other than multiple sclerosis, such as ulcerative colitis and Crohn's disease. What is your take on this?

A: Biogen is placing priority on ulcerative colitis and Crohn's disease. However, multiple sclerosis is also a major franchise for Biogen so we believe they will firmly carry out development also in multiple sclerosis.

Fasinumab

Q: Fasinumab, developed by Regeneron, is on partial clinical hold by the FDA because of other agent. What is the current status?

A: Regeneron is working to have the partial clinical hold lifted. We are licensed for fasinumab based on this premise.

Canadian government and Medicago enter contract on development of ebola antibodies

Q: What impact will this have on earnings?

A: The goal is to indicate that ebola antibodies can be produced in a short period of time. In light of this, we do not anticipate any major impact to our earnings.

Cancer drugs

Q: Will cancer drugs become a core domain into which you invest your resources?

A: Thus far we have been in the research stage for cancer drugs. The new organizational structure which took effect October 1 positions cancer drugs as a frontier business domain. We will have to monitor how things go before deciding whether cancer drugs will become an earnings pillar in the future.

[Early retirement]

Q: How many people do you plan to retire under the early retirement program?

A: We have not decided.

Q: Is the purpose of the early retirement program to close the generation gap among employees?

A: The goal is to transition to a new management structure so that our domestic ethical drug business can withstand a harsh business environment, including NHI drug price revisions and market penetration by generics.

Q: Will the early retirees consist mainly of MRs?

A: Although there are age limits, divisions/departments are not limited.

Q: How many employees do you expect to retire based on the amount factored in your estimate for extraordinary losses?

A: We cannot answer at this moment.

[Next medium-term management plan]

Q: Do you plan to roll out specific policies to fortify business operations in the US, including M&A, in the medium-term management plan you plan to release on November 30?

A: We cannot discuss this at this moment.

Q: Although you forecast favorable earnings for the current fiscal year, I think that earnings going forward are likely to be weak, including a decline in sales and profits in the first two or three years of the next medium-term management plan, and an expiration of the Gilenya patent. Do you have plans to overcome this?

A: We will refrain from commenting until we release the medium-term management plan.

End