

July 31, 2015 (Fri) 17:45 - 18:15

[Attendees]

Minoru Muramatsu, Managing Executive Officer

<u>Eizo Tabaru,</u> Board Director, Executive Officer, General Manager of Finance & Accounting Department

<u>Tetsuo Yoshikawa,</u> Executive Officer, Division Deputy Manager of Sales & Marketing Division

Kazutaka Kawashima, Division Manager of Development Planning and Coordination Department

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

Q: Is royalty for avanafil included in the royalty income other than Gilenya and Invokana? A: Royalty income does not include avanafil royalty.

[Earnings Forecasts]

- Q: You have not revised your earnings forecasts. Do you expect to outperform or be in line with targets?
- A: In the first half, we expect royalty income to be slightly higher than our forecast and some of our R&D and other SG&A expenses are somewhat lower than anticipated. We believe we are likely to outperform our forecasts but not to the extent that it warrants forecast revisions. We believe full-year earnings are likely to be in line with our forecast.

[Radicut (ALS)]

<u>Domestic</u>

- Q: Nearly a month has gone by since the approval of ALS, can you give us details on how the drug is doing.
- A: There are approximately 100 cases where the drug is being or is scheduled to be administered to patients.

Development in the US

- Q: Where are you with the FDA on using Japanese clinical trial data? When do you plan to file?
- A: We have already spoken with the FDA. We believe the FDA will allow us to use

Japanese clinical trial data for filing. We plan to file with the FDA once the data is ready. We aim to do this as soon as possible. As for the specific timing of the filing, I cannot give you an answer at this moment.

- Q: Will you be given a priority review voucher if the application is approved?
- A: I do not know any specifics at this moment.
- Q: How will you handle labeling in the US?
- A: I cannot give you an answer at this moment as we are still in negotiations with the FDA.

Development in Europe

- Q: The drug has also received orphan drug designation in Europe. How do you plan to launch and promote the drug? Will it be your first choice to license out the drug?
- A: Our first priority is to deal with the US FDA. Once things are squared away in the US, we plan to promote the drug in Europe. It would be one of our choice to license out the drug but we have not made any decisions on this.

[Development Pipeline]

<u>MT-1303</u>

- Q: Can you please update us on how you plan to proceed with drug development and business development? Are you still in negotiations to license out the drug?
- A: I do not have any new information I can share with you right now. We are still in negotiations to license out the drug.

<u>TA-8995</u>

- Q: How do you plan to differentiate this drug from those of your rivals? Also, I think you will have to form further alliances to carry out Phase 3. How do you plan to engage in this?
- A: This is currently under review so I will refrain from answering.
- Q: Does Mitsubishi Tanabe Pharma have option rights? Do you have the rights to sales in Japan? What other rights do you have? Are you planning to acquire shares in DEZIMA?
- A: I cannot talk about the details of our contract.

<u>Medicago</u>

- Q: Can you please give us an update?
- A: I do not have any new information. In the current fiscal year we plan to start P2b for seasonal influenza.
- Q: Is it necessary to do a P3 trial for seasonal influenza?
- A: Yes, we have to conduct a P3 trial.

Q: Can you create antibodies using Medicago technologies?

A: In principle, it is possible to create an antibody substance for the Ebola virus. We are moving forward with R&D as we stated in our press release.

[Business developments in the US]

- Q: Can you give us any details prior to the announcement of the medium-term management plan which is scheduled to be released on November 30?
- A: We believe that it is necessary to incorporate clear details on our business development in the US in our new medium-term management plan.
- Q: If you are going to develop Radicut for ALS does that mean you being targeting rare diseases related to the nerve system?
- A: Should Radicut be approved in the US for the treatment of ALS, it will without a doubt become a pillar in our business development in the US.

[Structural reforms]

- Q: Please tell us what you have planned for the current fiscal year.
- A: We are working toward our goal of curtailing costs by ¥8 billion or possibly more.