

Tuesday, January 31, 2012 from 17:30 to 18:10 [Attendees] <u>Ken-kichi Kosakai,</u> Board Director and Managing Executive Officer <u>Kouji Noborihayashi</u>, Head of Strategic Sales Planning Department, Sales & Marketing Division, and Executive Officer <u>Seiichi Murakami</u>, Head of Development Division and Executive Officer

[Financial results for third quarter of FY2011]

Radicut

- Q/ Although sales of Radicut in the third quarter decreased by 26% on a year-on-year basis, what are the current sales prospects?
- A/ The impact of generic products has been expanding, particularly in DPC institutions. Therefore, the market share of those generic products at the end of December is estimated to be about 20% on a sales quantity base. This tendency is assumed to continue for the time being. However, we suppose that the particular merits of Radicut as the original product will still be valued, (for example, by providing our accumulated information on the appropriate use of Radicut), once the switch to generic products has completed and the situation stabilizes in DPC institutions. Therefore, we do not suppose that there will be sharp decline in sales of Radicut.

<u>Telavic</u>

- Q/ Are contracts and case registration for the all-patient surveillance of Telavic progressing? In addition, do you have a plan to disclose the progress data other than medical institutions in the future?
- A/ As of the end of December 2011, the number of contracted institutions was 163, and the number of registered patients was 130; the number of contracted institutions became 363 and the number of registered patients became 532 as of January 30, 2012, which shows sound progress in registration procedures. We have no plan to disclose the information on the progress of all-patient surveillance other than medical institutions at the moment.

<u>Simponi</u>

Q/ Is cannibalization between Simponi and Remicade taking place in the market for treatment of rheumatic arthritis?

- A/ A thorough investigation on this issue has not yet been conducted since sales of Simponi are still modest now. However, it is assumed that the sales derived from drug-switching from competing products will be slightly higher than those from the use of Simponi for new patients. In addition, although Remicade has been switched to Simponi in some patients who desired subcutaneous injections, no drastic cannibalization has occurred so far.
- Q/ Is there any negative impact from the fact that the indication of Simponi for self-injection has not been obtained?
- A/ Since the administration interval of Simponi is 4 weeks, which is longer than those of other subcutaneous injections, patients can undergo the treatment with a peace of mind under the doctor's supervision according to their hospital visit schedule. Therefore, we believe there are no demerits in the fact you mentioned.
- Q/ Another pharmaceutical company has made an application for an oral Janus kinase (JAK) inhibitor for approval as a treatment drug for rheumatic arthritis in Japan. What influence do you think this will have on Remicade and Simponi?
- A/ Since the information we now have is insufficient to make a judgment, we are now working on collecting information.

Imusera

- Q/ Has there been any case of sudden death in patients administered with Imusera in Japan?
- A/ There has been no such case reported, either during clinical trials or in the post-marketing period.
- Q/ The EMA and FDA started a review on the safety of Gilenya. Will the Ministry of Health, Labour and Welfare in Japan also conduct a review or issue instructions?
- A/ We have not heard any such news at the moment.
- Q/ Are any measures, for example electrocardiographic monitoring of patients for 6 hours after the first administration, being implemented in Japan as well as in the US and Europe?
- A/ In response to the news released by the EMA on January 20, we provided medical institutions with factual information and asked them to observe patients after the first administration.

Licensing fee, etc. (Royalty)

- Q/ Regarding royalties, two billion yen was recorded in the third quarter. Does this mean most of the earnings came from the royalty from Gilenya?
- A/ Although the amount includes royalties not only of Gilenya but also other earnings,

the amount of the other earnings is not so large.

- Q/ Novartis announced that global sales of Gilenya in FY 2011 amounted to about 500 million dollars. Although the expected amount of licensing fee etc. in the full business year was 6 billion yen, it may be too conservative, based on the actual amount of the cumulative third quarter being 5 billion yen. Also, have the royalty income from Gilenya surpassed the forecast?
- A/ The reason why the forecast in the fourth quarter looks rather modest is because the full-year forecast has not changed since the beginning of this year. The royalty from Gilenya have been growing above the company's expectations, thus, there is a high possibility that actual income for the full-year will surpass expectations.

SG&A expenses

- Q/ R&D expenses look higher than those of the third quarter in previous year. Is the reason the one-time payments for licensing-in? Is it possible to disclose the amount of the one-time payment for the introduction?
- A/ Although the one-time payment for the conclusion of the license agreements for TRK-820 and Hib vaccine which were licensed-in in the third quarter, and expenses related to the development in Japan such as TA-7284 increased on a year-on-year, we consider it to be still in line with the plan. We do not disclose the amount of the one-time payment since it is concerned with the contract.
- Q/ Although the progress in SG&A expenses seems to lag behind, can you spend the entire budget as planned?
- A/ We think it will go as planned at this point.

Forecast for FY2012

- Q/ Some analysts have forecast that the operating income for FY2012 will be about 80 billion yen. However, what range of operating income are you expecting?
- A/ Since the impact of NHI price revision is unknown at the moment, we cannot answer the question at this point in time.

[Development pipeline]

- Q/ Regarding additional indication of Telavic (MP-424) for chronic hepatitis C (genotype2), is it necessary to conduct phase III studies for this? If so, how long does it take?
- A/ Yes, it is necessary to conduct phase III studies, and we are now conducting such studies. We expect it takes about one year.