

Monday, October 31, 2011 from 18:30pm to 19:10pm, JPT [Attendees]

Ken-kichi Kosakai, Board Director and Managing Executive Officer

<u>Kouji Noborihayashi</u>, Head of Strategic Sales Planning Department, Sales & Marketing Division, and Executive Officer

Seiichi Murakami, Head of Development Division and Executive Officer

[Business results report for the 1st half of fiscal 2011]

Q/ What is the status of the sales of new products, Lexapro and SIMPONI?

A/ Lexapro was launched on August 22. The competition in the SSRI/SNRI market is very harsh. In these conditions, we have conducted marketing activities with the policy to steadily penetrate the product among psychiatrists. Since the marketing effort progressed generally well, sales during the 1st half of the fiscal year were ¥400 million. As for SIMPONI, sales during the 1st half were minor since it had just been launched on September 16.

[Forecasts for the full-year results]

- Q/ Operating income for the 1st half exceeded the forecast (as announced at the time of the 1st quarter result report) by ¥4 billion. Why haven't you modified the full-year forecast?
- A/ Both net sales and operating income exceeded the current forecast for the 1st half. However, considering the product mix, expected increase in SG&A expenses and other factors, it is expected that R&D expenses and new product-related operating expenses will increase in the 2nd half. It is also difficult to forecast royalty income and the NHI price of new products scheduled to be listed in the NHI price list. Accordingly, we have not modified the full-year forecasts.
- Q/ In the briefing for the 1st quarter results, you explained that the new drugs would contribute about ¥15 billion to net sales for fiscal 2011. Is there any change in that forecast?

A/ At present, we expect about ¥15 billion.

Remicade

- Q/ Your full-year forecast for Remicade sale is ¥66.4 billion. Did you modify the original forecast? This forecast is a 10% increase from the previous year. Your forecast for the growth rate has become slower. What is the reason?
- A/ The full-year sales forecast was modified and decreased from the original forecast announced at the beginning of the fiscal year. The growth rate has become slower than previous years because the denominator for the calculation has become larger since the sales revenues have increased. We believe that this is because the competition has become harsher with more competing products introduced in the market.
- Q/ Is the sale for the indication of rheumatoid arthritis the largest contribution to the total Remicade sales? I understand that the sales increase affected by the dose escalation for rheumatoid arthritis has settled any time now. Do you believe that the growth will continue?
- A/ Sales for the indication of rheumatoid arthritis are larger than any other indications. Sales are supported not only by the effect of the increased dosage but the drug has been administered to more new patients with rheumatoid arthritis. We do not believe that sales growth will stop very soon.

Moreover, we have acquired approval for the dose escalation for Crohn's disease in August. We expect that this dose escalation for Crohn's disease will also have a positive effect on sales as well.

Radicut

- Q/ What effects do you expect from Radicut generic products? Has any bag-formulation of generic drug been introduced in the market?
- A/ In the 1st half of the year, the impact of Radicut generic drugs was relatively minor since their introduction in the market was later than expected. However, based on the latest conditions, we estimate that Radicut sales will decrease by more than 10% due to generic drugs' penetrating into the market since September. We have set the annual sales forecast assuming that this trend will be more accelerated in the future.

The bag-formulation has already been penerated in the market. We estimate that the percentage of the bag-formulation is a little higher than the ampule-formulations.

Q/ How long is the actual Radicut administration period on average? A/ Around 10 days.

Imusera

Q/ I understand that Imusera will be co-marleted with Novartis. Do you divide with Novartis

- medical facilities to visit for marketing?
- A/ We may divide with Novartis information-providing activities for certain facilities in order to ensure provision of information on proper drug use. However, we will not divide prospective customers or sales areas. This product will be sold based on two brands and two channels.
- Q/ We hear that there are 14,000 patients with multiple sclerosis. Is there any possibility that potential patients will appear after the introduction of Imusera?
- A/ Medical care certificates for specified diseases have been issued to about 14,000 patients with multiple sclerosis. With the introduction of the new drug, this number may increase.
- Q/ Is all-patient post marketing surveillance required for Imusera?
- A/ All-patient post marketing surveillance is required as a condition for approval and we will observed all cases. We estimate that it will take about two years and a total of about 1,000 cases will be tracked by the two companies.

Telavic

- Q/ When will Telavic be listed in the NHI price list? If the NHI price proposed is not what you desire, is it possible to postpone the listing?
- A/ We expect that the drug will be listed in the NHI price list in November. Since Telavic is desired by the market, we would like to proceed with the market introduction as soon as feasible.
- Q/ When listed in the NHI price list, is the subsidy for drug expenses applied to Telavic? A/ We expect the subsidy to be applied.

FTY720 (Gilenya)

- Q/ Why did net sales of other pharmaceutical drugs increase from the same period last year?
- A/ The increase was supported mainly by royalty income from licensing of FTY 720 (Gilenya) to Novartis.
- Q/ Do the revenues from technical license contracts include only royalty income for FTY 720 (Gilenya) and the milestone at the time of TA-1790 application in the U.S.?
- A/ The revenues from technical license contracts also include some royalty income and lump sum payments received for licensing of other products.
- Q/ Sales of FTY720 (Gilenya) at Novartis were very strong (Jan. Sep. 2011: \$291 million). How much royalty income do you expect for the full year?
- A/ I am sorry but the Company refrains from making any comment on that matter.

SG&A expenses

- Q/ Why will SG&A expenses increase in the 2nd half from the 1st half of the fiscal year?
- A/ Major factors for the increase are the expected increase in operating expenses relating to market introduction of new products, development expenses for TA-7284 for which Phase III trial began in the 1st half, and R&D expenses including in-licensing costs.
- Q/ R&D expenses for the 2nd half are about ¥35 billion. How much in-licensing costs are included in this figure?
- A/ Some in-licensing arrangements have not been determined and some are still in negotiation. Accordingly, we would like to refrain from making any comment regarding the amount included in this figure.

[Development pipeline]

- Q/ Why did you discontinue MCI-196 development in the United States?
- A/ In the United States, in 2014, oral agents are to be included in the new prospective payment system for medical costs of dialysis patients. At present, development has not been discontinued, but we are examining the feasibility of the agent.