

Tuesday, July 31, 2012 from 6:00pm to 6:35pm

[Attendees]

<u>Ken-kichi Kosakai</u>, Board Director and Managing Executive Officer, Corporate Management

<u>Masayuki Mitsuka,</u> Board Director and Managing Executive Officer, Division Manager of Development Division

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

[Q1 2012 Business Results]

<u>Telavic</u>

- Q/ The number of registered patients for the all-patient post-marketing surveillance has increased steadily and the sales were strong. Given this pace, do you think that the sales for the first half of the fiscal year may exceed the plan? When do you expect the all-patient post-marketing surveillance requirement will be lifted?
- A/ The numbers of contract medical institutes and registered patients have increased steadily. We believe that the net sales for the first half of the fiscal year will move almost along the current trend. We expect that the all-patient surveillance requirement will be lifted around 2014 since we need another year of observation for each case.
- Q/ The Japan Society of Hepatology created a guideline for hepatitis C treatment and publishes it on its website. The guideline says that "a combination of two agents (peginterferon and ribavirin) and preferably a combination of three agents (telavic, peginterferon and ribavirin) should be used for aged patients (age 66 or older). Was there any impact of this guideline?
- A/ We make sure to provide complete information on proper use of Telavic to medical institutions according to the package insert. This drug is used for about 25% of treatment of aged patients.

<u>Simponi</u>

- Q/ How has switchover to Simponi from competitors' products and Remicade progressed and what is the status of acquisition of new patients?
- A/ Since we do not conduct an all-patients surveillance, we do not have statistic figures, but some time immediately after the introduction of the drug, there were more

switchovers from a competing subcutaneous injection than administrations to new patients. Recently, administrations to new patients are gradually increasing. We estimate that the switchover from Remicade to Simponi is about 10%.

<u>Imusera</u>

- Q/ In response to the revision of the package insert for Imusera, monitoring by electrocardiogram for 24 hours after the initial administration in medical institution has become mandatory. Has this revision had any impact on the market penetration of the drug?
- A/ The numbers of contract medical institutions and registered patients for all-patients surveillance have increased steadily after the revision of the attached document. There has been no significant impact of the revision.

Radicut

- Q/ Sales of Radicut decreased significantly (-44.9%) from the same period of the previous year. What affected this decrease and what is your prospect for the future?
- A/ In addition to the effect of the revision of the NHI prices in April 2012 (lowered by 18.3%), sales of Radicut was affected by generic drugs introduced in the previous year (the percentage of generic drugs on a sales volume basis was less than 30% in June 2012). Consequently, sales of Radicut decreased significantly. We expect that the situation for Radicut will remain severe as the sales percentage of generic drugs will exceed 30% in September. However, we believe that the growth speed of generic drugs has become slower.

Tenelia

- Q/ What is your marketing strategy (patient targeting) for Tenelia?
- A/ I cannot make any comment regarding our strategy, but Tenelia will be used independently or in combination with a sulfonylurea agent or thiazolidinedione as approved in June 2012.
- Q/ Can it be used in combination with a biguanide (metformin)?
- A/ The Phase III clinical trial is currently conducted for the combined use with metformin. The clinical trial has been implemented to be compliant with the clinical validation guideline for a new oral hypoglycemic drug.

Acref

- Q/ What is the status of Acref?
- A/ We have obtained a marketing approval for Acref in Japan. We would like to

introduce the drug into the market as soon as possible for patients waiting for this drug, but because we have not secured stable supplies from the overseas manufacturer, the exact introduction time is not decided yet.

Licensing fee, etc. (Gilenya)

- Q/ It seems that your plan for "licensing fee, etc" (including royalty income for Gilenya) is too conservative, considering the Gilenya sales for the second quarter announced by Novartis. Can we get disclosure of royalty amounts for individual items?
- A/ Since sales of Gilenya have grown strongly in the world, royalty from Gilenya has been slightly greater than our projection. Royalties for individual items are not disclosed presently due to restrictions under the contract with Novartis. However, we would like to consider the possibility of individual disclosure.
- Q/ Is Mitsubishi Tanabe Pharma involved in the support program provided by Novartis for monitoring of initial administration of Gilenya or in any pricing strategy for Gilenya? Will any pricing strategy for Gilenya cause impact on the royalty income?
- A/ We have not been involved in any marketing strategy of Novartis, including pricing. We cannot make any comments on contractual issues, but royalty income we receive will not be affected by their marketing strategy.

Sales cost ratio and SG&A

- Q/ You forecast that the sales cost ratio will improve significantly in and after the second quarter. What factors do you expect for that improvement?
- A/ In addition to an increase in royalty income for Gilenya, we expect that the sales cost ratio will be improved by the launch of Tenelia and sales expansion of products launched in the previous year.
- Q/ SG&A expenses for the first quarter were less than the plan. Will all remaining budget be spent within this fiscal year?
- A/ Although some expenses related to R&D and marketing were delayed, others were advanced, we expected that the total SG&A expenses for the full year shall be spent as originally forecast in the beginning of this fiscal year.

[Development pipeline]

MT-1303

Q/ What different mechanism does MT-1303 have from Imusera (Gilenya)?

A/ Like Imusera (Gilenya), MT-1303 works on S1P receptor. We cannot give you details, but it has a less side effect than Imusera (Gilenya).

MP-146

Q/ What is the development status of MP-146 in the U.S.?

A/ Phase III clinical trial has completed. Currently, trial data are being analyzed.

TA-1790 (Avanafil)

- Q/ How are the sales of TA-1790 in the U.S.? Was a marketing partner found in the U.S.?
- A/ We licensed it to Vivus, and they obtained marketing approval in the U.S. in April 2012. We heard that they are now negotiating with a prospective marketing partner in the U.S.