



November 1, 2010 (Monday): 13:00 - 14:00

Attendees:

- Michihiro Tsuchiya, President & Representative Director, Chief Executive Officer
- Kuniaki Kaga, Representative Director and Managing Executive Officer, Head of International Business
- Ken-ichi Yanagisawa, Board Director, Managing Executive Officer, Head of Sales and Marketing Division
- Ken-kichi Kosakai, Board Director, Managing Executive Officer, Head of Finance and Accounting Department
- Masayuki Mitsuka, Board Director, Executive Officer, Head of Global Product Strategy Department
- Takashi Kobayashi, Board Director, Executive Officer, Head of Corporate Strategic Planning Department
- Seiichi Murakami, Executive Officer, Head of Development Division

[Fiscal 2010 2<sup>nd</sup> quarter results and forecast for the full term]

Q: The Company revised the forecast of sales for the full term upwards from the 380 billion yen initially announced (May 12) to 401 billion yen. Can we think that this difference of 21 billion yen was the value incorporated initially as the impact of the administrative penalty?

A: The initial sales forecast was announced publicly when the impact of the administrative penalty were unclear. Therefore, it is difficult to explain thoroughly the difference in the initial forecast and the current revised forecast.

Q: The sales cost ratio has increased by 2.2 points in comparison to the same period last year. I would like to be told the contributing factors in that increase.

A: The impact due to the drug price revision was 1.4 points, making it the largest contributing factor. Another contributing factor apart from that was product mix, including increased sales of tie-up products with relatively high sales cost ratios.

Q: Have the fiscal 2010 cost synergies planned at the time of the merger been incorporated into this term's forecasts?

A: From the merger (October 2007) to the end of fiscal 2010, the company has made efforts targeting the achievement of cumulative cost reductions of 24 billion yen and we expect that we have largely been able to achieve our initial target. The value of reductions for fiscal 2010 has been incorporated in the plans for this term.

Q: The Company is expecting extraordinary losses of 3.7 billion yen in the second half of the term. I would like to be given a breakdown of these losses.

A: The main item is special retirement expenses.

Q: Sales of Remicade have increased significantly, which means the company has probably been able to enjoy the benefits of the recently strong yen. I would like to be told about the assumed exchange rate and impacts of exchange in the second half of the term.

A: Recent forecasts have been planned assuming an exchange rate of USD1 = 90 yen. In regard to the impact of foreign exchange, including purchases of Remicade, which is the largest contributing factor, we may receive a profit of 300 million yen on an operating income base for each 1 yen increase in the value of the yen against the US dollar.

[Development pipeline/ licensed-out products]

FTY720 (Novartis retail name in the US: Gilenya)

Q: How are royalties based on Novartis sales of FTY720 disclosed?

A: The Company discloses such royalties included in "Licensing fee, etc." in "Financial Results <Supplement>". Royalties based on Novartis sales each quarter are posted in company sales for the following quarter. In other words, royalties based on Novartis sales from October to December 2010 will be posted in the 4<sup>th</sup> quarter results of the Company. In addition, payments to other rights holders are not included in the disclosed results of the Company.

Q: Novartis introduced a patient support program aimed at people living on low-incomes (Novartis bears part of the patient's drug costs). Is this amount deducted when the royalties that the Company receives are calculated?

A: We have a general type of contract agreement with Novartis, but I would like to refrain from answering in regard to the details of the contract.

Q: The term of validity of the patent in the US is listed as being until 2015 in the FDA's Orange Book. Is that correct?

A: We do not disclose patent information of our products in principle, but the Company owns the basic patent and will also work appropriately as the rights holder in regard to the extension of the patent period.

#### MP-424 (telaprevir)

Q: The Company is advancing preparations for manufacturing MP-424, because the NDA filing is planned in fiscal 2010. What is happening with the schemes regarding manufacturing and the manufacturing area?

A: We are advancing the preparation of the supply chain while sharing information with Vertex. We plan to import the active pharmaceutical ingredient from a contract manufacturer.

Q: I have heard that the government will conduct priority reviews of groundbreaking new drugs as part of the hepatitis C measures that the government is promoting. Are there specific movements in regard to MP-424?

A: We are currently in consultation with the regulatory authorities, but there are no concrete discussions as yet.

#### TA-7284 (canagliflozin)

Q: When is the application for TA-7284 planned in the US?

A: We have heard that Johnson and Johnson will submit NDA filing in the US in 2012.

Q: Does the urinary tract infection, which is concerned as an adverse event, appear dose-dependently?

A: It does not appear to be dose dependent. The same event has also occurred in diabetes patients who have not been administered this drug, and the adverse events such as urinary tract infections are treatable with therapeutic agents. TA-7284 has a new mechanism and bodyweight reduction effect, and it can be used irrespective of insulin secretion ability. Taken together, TA-7284 is considered to be a new drug whose benefits exceed its risk.

#### (Next-term's medium-term management plan)

Q: There seems to be surplus in regard to the current MRs. Does the Company plan to advance MR personnel reductions in next term's medium-term management plan?

A: From next fiscal year onwards, we plan to launch new products in succession. While some of these new products will not require MRs, I think that we will be able to use the current MRs well for the promotion of products such as diabetes drugs and escitalopram, etc. that require numbers of MRs.

Q: What do you think about the China business?

A: The Company has a product line-up that promises in the Chinese market, including MP-424, etc. Moreover, the Company has production and sales bases in China and would like to

take advantage of this infrastructure to strengthen business development in China. We would like to show the details of our strategy in next term's medium-term management plan.

Q: The Company will develop business in the US centered on the renal area. Are biosimilars of erythropoietin also in view?

A: If biosimilars were the best choice as the therapeutic agent for the diseases we targeted, they would also be one of our options, but nothing specific has been determined at the present time.

Q: Is the company thinking of M&A, etc., in the US in response to the launch of MCI-196 in the US?

A: Our policy for the best method that will maximize the value of each product, not just for MCI-196. We consider in-house sales and strategic alliance with other companies carefully considering the features of each product. M&A focused on our aim will also be one of our options.

Q: Will the company proactively carry out investments on R&D enhance product pipeline, such as licensing-in, in order to make a leap forward fiscal 2016 onwards in next-term's medium-term management plan (fiscal 2011 to 2015)?

A: It is important for us to launch continually new products from fiscal 2015 onwards and the Company makes investments to bolster the product pipeline utilizing M&A and licensing-in.

Q: Is escitalopram planned to be approved in fiscal 2011?

A: Mochida Pharmaceutical Co., Ltd. submitted the application in September 2010. We have heard that they expect approval in fiscal 2011 and the Company and Mochida will co-market the product.

Q: If the Company licensed-in the drug for RA in Japanese market, is there any impact on Remicade and golimumab agreement?

A: We do not disclose the details of contracts, but I cannot say that there would be no influence at all. However, RA drug, whose mechanism is different from those products, would be possible to license-in.