

Mitsubishi Tanabe Pharma

Monday, October 29, 2012 from 6:00pm to 6:45pm

[Attendees]

Ken-kichi Kosakai, Board Director and Managing Executive Officer, Corporate Management

Masayuki Mitsuka, Board Director and Managing Executive Officer, Division Manager of **Development Division**

Tetsuo Yoshikawa, Executive Officer, Division Deputy Manager of Sales & Marketing Division

[Business results for second guarter of FY2012 and forecasts for FY2012] Tenelia

- Q: What were the actual sales of Tenelia for the first half of FY2012?
- A: Tenelia made a good start. Based on NHI drug price, its sales for the first month of launch, September amounted to 2.2 billion yen, which is the sum of the contribution of Daiichi Sankyo and MTPC.

Telavic

- Q: Why did the sales of Telavic for the second quarter from July to September decrease compared with the first quarter from April to June?
- A: As we endeavor to arouse cautions against possible renal dysfunction, it causes a slowdown in prescription of the drug. In addition, the percentage of its use at reduced doses is increasing. These are the major factors.
- Q: You have revised the full-year sales forecast for Telavic downward to 8.5 billion yen. Please explain the background?
- A: We now are implementing all-patient post-marketing surveillance. However, with the permission of the Pharmaceuticals and Medical Devices Agency (PMDA), we have made a switch to surveillance only on patient registration without filling out of survey sheet for new cases from September 26 forth. We therefore expect that the patient registration pace will increase in the second half of this fiscal year. It should be noted that the ratio of dose reductions is increasing; so the difficult conditions will persist. For this reason, we expect the sales peak to be reached in FY2013 or later.
- Q: We heard that the second protease inhibitor would be filed by a competitor in the first half of 2013. What do you think about the possible influence?
- A: We suppose that the competing product will be launched in 2014, and we will continue

to promote the proper use of our Telavic, and safely provide as many patients as possible with therapeutic opportunities for triple drug regimen.

Radicut

- Q: Due to the NHI drug price reduction and the increased influence of generics, the sales amount of Radicut had a dramatic decline by 45.4% year-on-year. What is your current forecast?
- A: The most recent volume-based market share erosion rate by generics was slightly more than 30%, within our expectation. We see the pace of erosion to tend to decrease, and expect that the sales decline due to the influence of generics will stop in the second half.

Licensing fee etc. (Gilenya)

- Q: You have raised your full-year forecast for licensing fee etc. by 1.5 billion yen from the figure at the beginning of the period. What is the reason for this?
- A: This is mainly because the royalty income from Gilenya is making a better-than-expected contribution.

Sales cost ratio and SG&A expenses

- Q: Despite the fact that the sales for the first half nearly cleared the initial target, and that the royalty incomes exceeded the forecast at the beginning of the period, the sales cost ratio was worse compared to the forecast. Why?
- A: This is because the sales amounts of Radicut and other products with lower ratios of cost of sales did not reach the expectations in the beginning of this fiscal year.
- Q: Approximately 6 billion yen of SG&A expenses for the first half was not spent. What is your forecast for the second half?
- A: The non-consumption in the first half was attributed to a time lag in the use of R&D expenditures, including licensing-in cases. For some SG&A expenses, time lags to the second half and beyond occurred because of the lower-than-expected operating cost, diversified spending of IT-related expenditures and other factors. Regarding the second half, we expect SG&A goes as initially planned, provided that part of the budget, mainly for R&D expenditures, that remained unconsumed in the first half, will be used in the second half.
- Q: As a result of the integration of plasma fractionation operations on October 1, the number of employees decreased significantly. Despite this, the total labor cost for the second half will not be so smaller than for the first half. Why?
- A: We are planning to change the account settlement term for our overseas subsidiaries, and have compiled a budget for 15 months for the current term. Our forecasts for the

second half include the labor cost for overseas subsidiaries for a period of 9 months, and this will lessen the reduction of the total labor cost.

Integration of plasma fractionation operations

- Q: What is the impact of the integration of plasma fraction preparation business on business results?
- A: On October 1, we transferred our plasma fractionation operations to the Japan Blood Products Organization (hereafter the new corporation). As a result, our total inventory and fixed assets decreased by approximately 15 billion yen. Regarding its impact on our business results, we will continue marketing the products on a contract basis for a time, so the relevant sales amount will be included in our account. Meanwhile, the cost of sales and SG&A expenses are likely to change, and we expect its influence on the operating income for the second half to be slightly less than 1 billion yen. Furthermore, we have compiled a budget of extraordinary loss of 2.2 billion yen from the business integration for the first half, which includes disposal of unnecessary assets.
- Q: Will you receive money for the business transfer within this fiscal year?
- A: Although we would like to refrain from mentioning the timing of payment and other details, it is necessary to have a smooth rise of the new corporation's business operations, and we have concluded the agreement in a manner that allows the new corporation to make divided payments fitting to its profits.

[Development pipeline]

TA-7284 (canagliflozin)

- Q: Has the regulatory review for TA-7284 in the US been ongoing steadily?
- A: An approval application for TA-7284 was filed by licensee Janssen Pharmaceuticals in the US in May 2012. With the provision of an FDA standard review, PDUFA date would be March 2013. Also, it is a common process that an advisory committee meeting takes places two months before that day; we expect to see a steady progress of the review.
- Q: MTPC has both of a DPP-4 inhibitor and a SGLT2 inhibitor as their original products. Are you planning to develop a combination of these two drugs?
- A: We have begun a basic, preliminary investigation on a combination drug. If we actually proceed to develop it, a pharmacokinetic study will be implemented and be followed by a phase 3 study, but now we would like to concentrate on filing an approval of TA-7284 and its launch. Please note that the phase 3 study of TA-7284 in Japan is scheduled to be completed in May 2013, and is ongoing almost as planned.

[Others] Collategene

- Q: You have concluded an agreement for exclusive marketing rights of Collategene with AnGes MG. What is the amount of money MTPC will pay as one-time payment, milestone payment etc.?
- A: We'd like to refrain from mentioning the amount paid, time of payment and other details of the agreement. However, the amount of one-time payment is such that would make any impact on our business results. Milestones will not be paid until AnGes proceeds to a further development phase and obtained successful results from phase 3 study.

Medium-term management plan

- Q: Following the dissolution of your capital alliance with Choseido Pharmaceutical and the results of the clinical studies of MP-146 in Europe and the US, are you planning to reconsider your business strategy concerning generic drug business and overseas operations in the medium-term management plan?
- A: Although some influence may be seen, now we don't think that a major modification will take place. Regarding generic drug business, we are investigating to expand Mitsubishi Tanabe's generic business toward the numerical target of 50 billion yen for the fiscal 2015 annual sales, while taking into account strategic alliances with other generic manufacturers. As for marketing in the US, our initial plan did not include any major contribution to the sales achievements by fiscal 2015, so we are currently not planning to change the numerical targets in the medium-term management plan, i.e., a sales amount of 500 billion yen and an operating income of 100 billion yen for fiscal 2015.
- Q: Nihon Chouzai announced that it went into alliance with Choseido. Then, don't you change your plan for Tanabe Seiyaku Hanbai to continue to market Choseido's products?
- A: Regarding the handling of the products for which Choseido holds manufacturing and marketing approval, Tanabe Seiyaku Hanbai will continue to sell them for the time being, but we will consult with Choseido Pharmaceutical in the future.

Others

- Q: Your subsidiary, Benesis, received an order from the Minister of Health, Labor and Welfare to improve its business operations. How do you respond to it? Do you reconsider your efforts to restore trust for MTPC?
- A: We are very sorry about this matter. We don't think that there was any problem in our improvement plan we have so far been implementing to regain trust. It is important to implement this improvement plan as quickly as possible, and we are not planning to change our plan.