

## **Q&A, Information Meeting**

10:00-11:30am, May 25, 2009

### **[Attendees]**

Natsuki Hayama, President and Representative Director, Chief Executive Officer

Takeshi Komine, Representative Director and Executive Vice President

Michihiro Tsuchiya, Board Director, Executive Vice President

Kunihiro Shimojuku, Board Director, Executive Vice President

Ken-ichi Yanagisawa, Board Director, Managing Executive Officer

Junji Hamaoka, Board Director, Managing Executive Officer

Seiichi Murakami, Executive Officer, Marketing & Product Management

### **[Medium-Term Management Plan Targets]**

**Q:** Several factors are expected to contribute to increases in income before R&D expense deductions towards the achievement of FY2010 targets in the medium-term management plan. It has been possible to make any preliminary calculations at this stage; I would like you to tell us what the values of these increases may be.

**A:** We have not been able to make any preliminary calculations, but when you consider that the impact of goodwill amortization was 5 billion yen in FY2007 following the merger and further expenses of 1 billion yen have been generated from FY2008, the underlying trend is certainly towards increased income. However, we are well aware that forcing an increase of 27.5 billion yen in the future on an operating income base before R&D expense deductions towards the achievement of targets will be rather difficult.

### **[Sales]**

**Q:** The Company says that it would like to acquire a 40% share of RA biological agent market with Remicade at its peak. Does this target also incorporate the impact of patients who no longer use Remicade with the realization of drug-free status?

**A:** When dose escalation is approved, approximately 10% of patients may become a drug-free status, and it is probable that we would be affected as a result. However, there would also be an increase in patients who want to use Remicade and the forecast incorporates both of these factors.

Q: Are you expecting a peak of 80 billion yen in sales at the very least?

A: Based on current NHI drug prices and not assuming drug price revisions, we would like to realize 80 billion yen in sales.

Q: What do you think in regard to Remicade of any impact on the reductions in doctor consultations and impacts on sales out of concern over infection due to the outbreak of new type of influenza?

A: MRs are trying to watch the market trend, there have been no specific impact that you mention.

Q: I think that you have about 2,400 MRs. What do you think about the current number of MRs, including the possibility that sales methods may change in the future?

A: Excluding area managers and specialists of Remicade, brain and other areas from among those 2,400 MRs, we have about 1,700 MRs. As we also have wide assortment of products, we think that we need the current number of MRs in the present circumstances and also in order to maintain sales.

#### **[Generic Business]**

Q: Are you considering releasing generic drugs of Mitsubishi-Tanabe's original drugs as part of generic business when the patents for the Company's original drugs expire? I would like you to tell us the future prospects for generic business?

A: Basically, Mitsubishi-Tanabe acquires approval for generic drugs, and Tanabe Seiyaku Hanbai markets them. One company cannot acquire two sets of approval for the same ingredients, and we would not be able to acquire approval for a generic version of our own original drugs. However, because we have retained Choseido Pharmaceutical in our Group, it is possible that approval for a generic drug could be acquired by Choseido Pharmaceutical, and it could be marketed by Tanabe Seiyaku Hanbai. We think some long-listed products that can be maintained their sales sufficiently could probably be transferred to Tanabe Seiyaku Hanbai.

Q: Do you also have the idea that, in the end, switching over to a low cost sales structure will increase the profitability of long-listed products?

A: The Federation of Pharmaceutical Manufacturers' Associations of Japan, etc. are currently investigating the new drug price maintenance system, and within their

discussions, we will consider how to handle such issues while focusing on how to develop our business in an environment involving the generic issue and in particular, their interrelationships with long-listed products.

**[Vaccine Business]**

Q: Do you have any ideas in regard to the future enhancement of the vaccine business such as licensing products from other companies or developing vaccines for therapeutic use, rather than just marketing the products that The Research Foundation for Microbial Diseases of Osaka University develops?

A: We think that the vaccine business is an important business of the Company. The business we are currently doing with The Research Foundation for Microbial Diseases of Osaka University is cooperative work that is just both a part of the development and sales work we are doing, but in the future, we want to enhance the vaccine business by strengthening our relationship with The Research Foundation for Microbial Diseases of Osaka University, including research.

**[OTC Business]**

Q: What do you think about Cholebine being included in the list of candidates for OTC drugs issued by the Ministry of Health, Labour and Welfare in this April?

A: We have been receiving requests for some time that they would like Cholebine developed as an OTC drug for lifestyle-related diseases, but at present, we are at the stage of expanding its supplemental indications as an ethical drug and evaluating its safety so we will not be converting it into an OTC drug now. However, when the safety of the drug can be confirmed properly, it is possible we might move in that direction in the future.

**[Overseas Business Development]**

Q: Do you have the idea of promoting globalization through M&A, particularly in the U.S.? In entering the renal area in American and European markets, are you thinking of buying local marketing functions?

A: Rather than looking for expansion of scale, the potential in regard to M&A is more for venture buyouts and investments in order to acquire new technology and the seeds for new drugs, aiming at strengthening R&D capabilities and enhancing the pipeline.

A global research-driven pharmaceutical company is the company that creates new drugs to a worldwide market, and we would like to do everything we can to create new drugs. We also are thinking primarily of constructing a sales structure based on the Company, but that is one of the options that we should investigate.

Q: In regard to the Company's strategy in the U.S., a similar product to Cholebine (MCI-196) has been launched in the U.S. Including Kremezín (MP-146), do you think it is difficult with these 2 products to produce benefits and acquire market share? I think that you may be decreasing the development risks to go ahead with the market entry to begin with. It seems that the strategy and the products are not in alignment, but what do you think?

A: The reason we are placing Cholebine and Kremezín on the market first is because not many MRs are required in that area. Considering overseas business development with the current management resources of the Company, we think that these products are appropriate selections. How we roll out business after that is an issue from here on. Basically, we will develop as far as POC within the Company and after that select methods that maximize the value of new drugs and measures that allow us to move out into the world at maximum speed including licensing, self-development, co-promotion and co-marketing, etc.

Q: I would like you to tell us specifically about the strengthening of the clinical study system in Asia. Will the Company conduct phase 2 and phase 3 studies in Asia after conducting phase 1 studies in Japan?

A: In regard to countries such as South Korea and Taiwan, etc., we are thinking of a format involving joint studies with Japan. As a result of conducting surveys of products and facilities, we envisage being able to implement studies in South Korea and Taiwan at about the same level as in Japan. In areas such as diabetes, we are thinking of further expansion. We have a development company in China called MPBJ and we think that development in China is separate. What kind of data is required in each country (phase 1 data and PK data, etc.) depends on the regulatory authorities in each country. Under the idea that if we use Japanese data, almost all data can be skipped in some countries, we can develop products in Asia that we are also developing in Japan. The scheme is that those data could be used in the end for applications in Japan or all countries.

**[Development]**

Q: In regard to development strategy in the diabetes area, cardiovascular risk has become an issue in the U.S. and if it is decided that studies will be carried out in order to clear that issue, it is possible that a product that is not approved in the U.S. will not be approved in Japan either, but what do you think about this?

A: European and American pharmaceutical companies also perceived the FDA guidance on the cardiovascular risk of treatment drugs for diabetes as having a large impact and in regard to our TA-7284 as well, Johnson & Johnson, which is the licensee, is expending large costs to advance development. Because the number of patients for Cholebine (MIC-196) is limited, we think that we can develop the drug ourselves, but MP-513 will need patients on a large scale so we are planning on alliances for European and US development. We are consulting with the domestic regulatory authorities while also considering existing data and cardiovascular risk and are advancing in agreement with the protocol. At the present stage, no great issues have been pointed out by the authorities.

Q: There was an entry on the Company website in regard to the domestic development of FTY720 saying that enrolment of subjects for phase 2 would be completed soon. What is the status of the study with multiple sclerosis in Japan?

A: We are currently conducting the phase 2 study and will use overseas data so we think we can file the application using the results of the domestic study that we are currently advancing. We are having trouble with enrolments for that study because the number of patients in Japan is overwhelmingly small in comparison to Europe and US, but the fact is that there are also requests for this drug from patients as it is an oral preparation, unlike previous products, and we are promoting this study somehow and advancing development so that we can file an application with as little delay as possible after Novartis AG files its applications in Europe and the U.S.

Q: Are you considering expanding into the oncology area in future?

A: The Company is working on research in the diabetes and cerebral areas as its first and second areas, but has stayed away from the oncology, until now. At present, we are investigating candidates of the third and fourth areas; oncology is also one of the candidates under discussion.

Q: What do you think about the development schedule for MP-424 in Asia (China)? At the time of the conference call for the announcement of business results on May 8, you explained that the Company plans to make a one-off payment due to the revision of the contract for MP-424, but is that related to Asian development?

A: There are various problems in advancing development, including in regulatory terms in China, drug substance and formulation problems and how to advance development. We are currently formulating development plans accommodating all such problems. The rights in Asia were covered in the initial contract and are not related to this contract revision.

**[Other Questions]**

Q: We have heard that the main reason for the change of representative director announced on April 27 (the handover from President Hayama to President Tsuchiya) was the rejuvenation of management. Are there any other reasons?

A: I have been in office for 7 years (including President of Tanabe Seiyaku) and from the start have sought the scale and quality to survive in the world as an R&D style manufacturer. I have also done whatever I can in regard to this aim since the merger as well, but think that handing over to the next generation of management will allow us to speed up development towards becoming an international drug discovery company and so we decided to replace top management. There are no other reasons.

Q: Some mass media outlets have reported the calling off of the joint venture with Bipla. I would like you to explain the facts of the matter. If it is assumed that the joint venture will be cancelled, will Medway business be continued by Mitsubishi Tanabe alone?

A: We are aware Nipro intends to call off the joint venture with Bipla: This has been their intention since before the occurrence of Medway issue (the partial withdrawal of approval for Medway) and after that the issue occurred it has been on hold. We cannot comment beyond that. It is difficult to give you an answer as this is a hypothetical question, but if we suppose that Nipro withdraws, the Company would support Medway business.