

Mitsubishi Tanabe Pharma Corporation

**Q&A, FY2010 First Quarter Business Results Conference Call**

July 29, 2010 (Thu.) 18:00 - 18:40

**[Attendees]**

Ken-ichi Yanagisawa, Board Director, Managing Executive Officer and Division  
Manager, Sales & Marketing Division

Kenkichi Kosakai, Board Director, Managing Executive Officer and General Manager,  
Finance & Accounting Department

Seiichi Murakami, Executive Officer and Division Manager, Development Division

**[Settlement of Accounts for the First Quarter of Fiscal Year 2010]**

**Influence of the administrative action**

Q: To what extent did the administrative action have the influence on the results for the 1<sup>st</sup> quarter? Also, you have made no revisions to the results forecasts for the entire fiscal year ending March 31, 2011. What sort of risks do you specifically anticipate, going forward?

A: We are not able to provide any specific influence-related values. As of now, however, no major impacts are seen on the results.

After submitting a business improvement plan to the Ministry of Health, Labour and Welfare on June 11, we explained the content of the plan to various medical institutions and are making efforts to have them gain an understanding of our measures aimed at preventing similar incidents from recurring. It is possible, however, that some medical institutions may implement some sort of responses. As seen, the influence remains uncertain, making it extremely difficult for us to forecast the results for the latter half of the fiscal year and beyond. This is why we have not revised our results forecasts for the entire fiscal year.

Q: Could you tell us about the measures you will take, now that you have submitted a business improvement plan?

A: We intend to set up an in-house committee to follow up on the Medway business improvement plan, and confirm and evaluate the plan's execution status. We will voluntarily report the implementation status to the authorities.

**Results Forecasts for the 1<sup>st</sup> Half of Fiscal Year 2010**

Q: Are you using a different premise for making calculations between the results forecasts for the entire year announced in May, and the results forecasts for the 1<sup>st</sup> half of the fiscal year, which you have released anew on this occasion?

A: The results forecasts for the 1<sup>st</sup> half of the fiscal year were calculated by incorporating the impact of the administrative action to the extent possible at the present stage, based on the results of the 1<sup>st</sup> quarter. On the other hand, the results forecasts for

the entire fiscal year are numerical values that were predicted while the influence of the administrative action was still uncertain at the beginning of the fiscal year. We therefore ask you to understand that the premise of the results forecasts differs between that for the 1<sup>st</sup> half of the year and that for throughout the year.

Q: If we reviewed your sales both the results for the 1<sup>st</sup> quarter of the year, and the forecast for the 2<sup>nd</sup> quarter, we have the impression that the latter is somewhat weaker than the trends seen in the usual years. To what extent have you incorporated the impact of the administrative action?

A: We do not incorporate the impact of the administrative punishment too greatly. We feel that the higher-than-usual sales ratio of the 1<sup>st</sup> quarter is attributable to factors including a backlash to the reduced warehouse inventory prior to the NHI price revisions seen in the fiscal year ended this March, and the increased demand deriving from the administrative action. We expect to see the backlash of the increased sales appear in the 2<sup>nd</sup> quarter.

### **Sales and Marketing**

Q: Can you please tell us the number of ulcerative colitis patients targeted for Remicade whose approval was obtained in June?

A: There are about 100,000 patients in Japan. Of these, about several ten thousand patients are expected to be targeted for Remicade therapy. They are patients who suffer moderate-to-severe ulcerative colitis and could not obtain sufficient effects from existing treatments.

Q: What are the reasons why your sales of generic drugs have grown about 60% from the same period of last year?

A. The sales for which we disclose as “generic drugs” are items handled by Tanabe Seiyaku Hanbai. Besides sales increases posted for various products, the growth in sales includes increases resulting from the transfer to Tanabe Seiyaku Hanbai of a part of the long listed drugs which we have been handling.

Q: Were generic drugs also targeted for the administrative action? Has its impact appeared?

A. Tanabe Seiyaku Hanbai was not targeted for the administrative action. However, as the Mitsubishi Tanabe Pharma Group as a whole, we decided to voluntarily refrain from conducting sales activities on a full scale. In the 1<sup>st</sup> quarter, however, no major impact was seen, like with those drugs other than generic products.

### **Costs and Sales Administrative Expenses**

Q: The sales cost ratio for the 2<sup>nd</sup> quarter is anticipated to be 40.0%, or 4 percentage points higher than the same period of last year. What is the reason for this?

A: NHI price revision has become an aggravating factor, corresponding to a drop of 1.5 to 2 percentage points. Other than this, the reduction is attributable to the difference in product makeup, such as increased sales of Remicade. Therefore there are no

special factors.

Q: Usually each year, the tendency is that sales administrative expenses do not change that drastically between the 1<sup>st</sup> and the 2<sup>nd</sup> half of the fiscal year. So, is it safe to expect them to be around ¥90 billion for the latter half of this year also, which is comparable to the 1<sup>st</sup> half?

A: Compared to the 1<sup>st</sup> half, the latter half has no factors that would make the sales administrative expenses fluctuate dramatically. There is, however, a possibility that the amount may increase or decrease slightly, depending on the use of R&D expenses.

Q: Do you plan to implement personnel reduction measures such as early retirement programs?

A: At present, we are vigorously working to adjust the number of staff to make it appropriate, like with other cost-cutting measures, so as to attain a cost synergy of ¥24 billion (cumulative total after the 2007 merger).

#### **[Development]**

##### **FTY720**

Q: Could you tell us about situation regarding the development of FTY720 in Japan? Do you think that it is possible to submit an application within 2010?

A: At present, we have completed Phase II tests and are in the process of analyzing the data. Since favorable results have been obtained in overseas studies as well, we hope to aim at submitting an application within 2010.

##### **MP-424**

Q: Could you tell us the situation regarding the development of MP-424 in Japan? Do you plan to make public the results of your clinical tests?

A: Phase III tests are currently under way, and we plan to submit an application in early 2011. We will consider releasing the results of the clinical tests at an appropriate time.

##### **Modiodal**

Q: The scale of sales is about \$1 billion in the US. Do you think you can expand sales in Japan, comparable to those in the US?

A: The reason why sales of this drug have increased in the US is that its use for shift work sleep disorder is approved. On the other hand, no such indications have been obtained in Japan. And also, since this drug has been applied for approval as a treatment agent for excessive daytime sleepiness which occurs in the patients with obstructive sleep apnea who have failed to obtain sufficient effects from CPAP treatment during sleep, we feel that the market in Japan would not become as large as that in the US.

### **MT-3995**

Q: MT-3995 is an aldosterone receptor blocker, and there have already been some products in this class. Please tell us about what your positioning is for this product, including how you plan to differentiate it from other existing products.

A: As drugs having the same actions, there are spironolactone and eplerenone. Anti-aldosterone drugs are expected to work not only for hypertension but also for heart diseases, and new findings are also being released. We hope to release MT-3995 into the market as a new drug that is superior to spironolactone and eplerenone in terms of efficacy and safety.

### **Radicut**

Q: Regarding the additional indication of Radicut for amyotrophic lateral sclerosis, or ALS, we understand that a Phase III study has been completed. Could you tell us about the test results and the period of submitting an application?

A: Although we recently completed a verification test, we have not yet been able to verify the effects fully. From now on, we plan to proceed while consulting with the authorities. Therefore, as of now, we cannot clearly say when the application would be filed.

### **Maintate**

Q: Regarding the additional indication of efficacy of heart failure for Maintate, which is also being designated as a non-approved drug, when are you planning to submit such application?

A: If things proceed smoothly, we feel that we can submit an application about 3 years from now.

### **T-0047**

Q: Do you have any updates on the Phase II study of T-0047 which you have licensed out to GSK?

A: GSK told us that they are currently studying how to proceed from here on. At present, we have obtained no more information than this.