

Mitsubishi Tanabe Pharma Corporation

## **Q&A, FY2009 Second Quarter Business Results Briefing**

November 4, 2009 (Wed.) 10:00 - 11:10

### **[Attendees]**

Michihiro Tsuchiya, President and Representative Director

Kunihiko Shimojuku, Representative Director, Executive Vice President

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

Masayuki Mitsuka, Board Director, Head of Global Product Strategy Department

Takashi Kobayashi, Board Director, Head of Corporate Strategic Planning Department

Seiichi Murakami, Executive Officer, Division Manager, Development Division

### **[Results for the second quarter of fiscal year 2009]**

#### **Sales and Marketing**

Q: It seems that sales have increased considerably since the approval of dose escalation in rheumatoid arthritis (RA) for Remicade. Could you tell us response and evaluation from doctors and medical institutions?

A: We obtained approval this July to escalate the dose and shorten administration intervals for RA, and also acquired an indication for inhibition of the progress of joint destruction. Having acquired this kind of full-fledged profile, we are now rolling out promotions for Remicade as the first choice drug for RA. As a result, we have felt a definite response from the results for July to September, and we also expect steady growth in the sales forecast too.

Q: I have heard that the assignment of the new influenza vaccine will be decided by the share ratios for last year's seasonal influenza vaccine. What was the company's share with last year's seasonal influenza vaccine?

A: It was about 20%.

#### **R&D Expenses**

Q: The forecast for R&D expenses in the second half of the year is for an increase of ¥4 billion in comparison to the same period last year. Are there plans to acquire licenses?

A: If the roughly ¥10 billion one-off payment to Vertex is deducted from actual expenses in the first half of the year as a transient cost, total R&D expenses for that period were ¥34.6 billion. In contrast, the forecast for the second half of the year is for R&D expenses of ¥39.4 billion so we are anticipating an increase of about ¥5 billion in comparison to the first half. Specifically, we have products in development that have moved up a stage, such as MP-513 and TA-7284, and the development of MCI-196(Cholebine) and MP-146(Kremezin) is reaching a peak overseas. The forecast for the second half is high in association with that because of things like allowances for an increased number of employees at our development subsidiary in the U.S. and Europe.

**[Development]**

**MP-513**

Q: Could you tell us the differentiating points of MP-513 (DPP4 inhibitor)? The Company is raising the long-lasting effects as a characteristic. Will that mean administration once every two days or three days rather than once daily?

A: We think at the present time there are two differentiating points. The first is that MP-513 is a once-daily drug in the true sense of the term; if you take it in the morning you can control blood glucose fully until after the evening meal. The second point is that MP-513 can be administered at all patient levels without regulating the dose because the renal excretion rate is so low.

Q: The adverse drug reaction (ADR) of pancreatitis has been reported with preceding products. Were there any serious ADRs to worry about in the results of the domestic phase 2 trial?

A: At the present time, there have been no serious ADRs such as pancreatitis.

Q: The Company is currently in negotiations over an alliance. Is that for out-licensing overseas or does it also include joint development? Furthermore, if things move quickly, could an alliance be established during this fiscal year?

A: At present, we think that marketing a diabetes drug overseas by ourselves would be difficult in view of the company size so we are pursuing alliance negotiations centered on out-licensing. We cannot discuss the timing because that is part of the negotiations, but we would like to arrange timing that is good for both parties.

**TA-7284**

Q: The current phase 3 trial for TA-7284 is scheduled for completion in January 2013 according to ClinicalTrials.gov. Is the planned timing for the application in fiscal year 2012?

A: We have heard that the application will be submitted in 2012.

**FTY720**

Q: Might the authorities warn the company about the need for data on a low dose for FTY720 of 0.25 mg rather than the development of 0.5 mg that the company is currently advancing?

A: We have heard that Novartis will submit their application with a dose of 0.5 mg. I have not obtained any information on lower doses.

**MP-424**

Q: I estimate that the daily drug price will be about ¥4,000 considered from the price of Ribavirin. What do you think?

A: It is difficult to answer your question at the present time because the drug price will be decided by a variety of factors including what the reference drug will be, and how drug prices are set overseas, where development is ahead of Japan.

Q: It is said that there are about 20 million HCV carriers in China. Are you thinking of prioritizing development of MP-424 in China above establishing an in-house marketing system in America as Mitsubishi Tanabe strategy?

A: The Company has an operating base in the China and Southeast Asia region that includes development and production. The Company should take advantage of the superiority of that base and focus on the development of business in China. There are high hurdles in acquiring approval in China, but we have great expectations for its future as a market.

### **CNTO148**

Q: I have heard that CNTO148 is getting off to a slow start overseas. How are you thinking about things like future strategy?

A: We understand the situation overseas. As a company, we would like to consider measures that maximize the value of Remicade and CNTO148 in Japan.

### **Roflumilast**

Q: My question concerns the difficulty of a bridging application for Roflumilast. Do you have to implement a phase 3 trial in order to submit an application in Japan?

A: We consulted the regulatory authorities with Nycomed, our joint development partner. As a result, we obtained the opinions that a bridging application would be difficult with the current data and additional trials will be necessary. We will look into our development course from now on in consultation with Nycomed.

### **Kidney Area**

Q: The Company is advancing development in the kidney area, but biosimilars for erythropoietin will also enter the market in future. Does Mitsubishi Tanabe Pharma have a strategy for handling biosimilars?

A: We are carrying out a market survey in regard to erythropoietin. We are currently continuing to investigate what kinds of strategies are called for, including biosimilar products too.

### **[Others]**

#### **Overseas Business Development**

Q: Could you tell us about Mitsubishi Tanabe Pharma's M&A strategy overseas?

A: We emphasize cooperation both in Japan and overseas. We would also like to consider M&A positively after clarifying our aims. The company is aiming to become a global, research-driven pharmaceutical company, but we will select the most appropriate methods to do that on an individual basis rather than say we will market all of our products overseas by ourselves or maintain production bases. In regard to R&D as well, we would like to pursue activities in-house as far as proof of concept study and then after that, choose measures that allow us to maximize product value (in-house development, out-licensing, joint development, etc) while considering the time axis as well.

Q: Will the Company be able to achieve the target of ¥100 billion in overseas sales in fiscal year 2015?

A: That target is achievable if the products currently in development proceed as planned. Moreover, we will also license products from other companies and we would like to think about measures including M&A too, not just what we have on hand.

### **Generic Drug Business**

Q: I would like to confirm the positioning of Tanabe Seiyaku Hanbai, the generic marketing company. Some of the long-term NHI price listed products that the core Mitsubishi Tanabe Pharma handled itself were transferred to Tanabe Seiyaku Hanbai from October. Should we believe that the policy from now on will be to transfer products successively to Tanabe Seiyaku Hanbai? In addition, will Tanabe Seiyaku Hanbai also undertake sales of other companies' long-term NHI price listed products?

A: We will look at trends and investigate matters further in the future, but those products will be significant weapons for Tanabe Seiyaku Hanbai. We think that handling other companies' products would also be interesting.

Q: Could you tell us about the direction of the generic drug business? Could you tell us about future approaches - what time span is Tanabe Seiyaku Hanbai aiming for sales of ¥50 billion with?

A: The core business of the Company is new drugs and we consider generic drug business and OTC drug business as areas in support of that. We would like to develop the generic drug business into one with presence and we think that in order to do that, sales on the scale of ¥50-100 billion by about 2015-2020, level with the big generic product manufacturers, will be necessary. That will be difficult with the present growth strategy and we will have to consider options including M&A.

### **Medway Issue**

Q: Could you tell us the state of progress of the Medway matter?

A: As a pharmaceutical company, we are taking the Medway matter very seriously and before anything else, I would like to apologize for this matter as the representative of the Company. I shall refrain from talking about the situation at this moment in time because investigations by the authorities are currently ongoing. We shall provide information as appropriate when the investigations by the authorities are complete and we are able to explain.

Q: I think Medway is technology that Mitsubishi Tanabe can boast of to the world. Could you comment on the future of Medway business?

A: Medway is a very important product for us, with all-round technology concentrated within it. Demand is high round the world. There has been no change in our desire to restart sales in the future. However, we think that our first steps will be to show the world the investigation into the cause of the matter and the measures to prevent reoccurrence, and to restore the trust of society.

-End-