

Thursday, May 10, 2012 from 4:00pm to 5:00pm

# [Attendees]

Michihiro Tsuchiya, President and Representative Director

<u>Ken-ichi Yanagisawa,</u> Board Director and Senior Managing Executive Officer, Division Manager of Sales & Marketing Division

<u>Ken-kichi Kosakai</u>, Board Director and Managing Executive Officer, Business Management

<u>Masayuki Mitsuka,</u> Board Director and Managing Executive Officer, Division Manager of Development Division

### [FY 2012 business forecasts]

#### Remicade

- Q: Despite intensifying competition, the Company expects sales of Remicade to increase by 14.6% year-on-year in FY 2012, a solid increase from a 9.8% growth in FY 2011. What is the factor behind the increase?
- A: Sales in our financial statements refer to sales from the Company to wholesalers. Sales in FY 2011 did not show the real picture of our Remicade business, because we saw a rebound from the temporary increase in orders due to the earthquake at the end of FY 2010. Sales on an actual consumption base (sales from wholesalers to medical institutions) grew steadily by 13% to 14% year-on-year in FY 2011. We expect similar growth in sales of Remicade in FY 2012 to what we saw in FY 2011. We forecast its sales to increase due to the lifting of all-patient post-marketing surveillance for psoriasis and an additional indication of ulcerative colitis. And, a new option to shorten infusion time of Remicade is expected to solve a problem in medical institutions, long bed occupancy. This will also contribute the increase in its sales. In addition, the price of Remicade was raised in the NHI price revision in April 2012 because the usefulness premium was applied to the drug because of an additional indication of rare diseases.

#### Telavic

Q: When would the Company expect to see the requirement for all-patient post-marketing surveillance of Telavic to be lifted?

- A: The Authorities requires us to conduct all-patient post-marketing surveillance to collect data on 3,000 cases. We have been conducting the surveillance with a target of 3,500 cases. We expect the number to reach our target by the middle of May 2012. We then expect the requirement for all-patient post-marketing surveillance to be lifted around 2014, because a one-year observation period is set for each case and we need to submit the surveillance data to the authorities for their review.
- Q: Sales of Telavic are forecast to be 10 billion yen in FY 2012. What is the Company's expectation for achieving the target?
- A: During the all-patient post-marketing surveillance period, we have strictly controlled case registration by limiting administration of the drug only to medical institutions that can cooperate with dermatologists. Although Telavic has been administered only in limited medical institutions, case registration has progressed steadily. We believe we can achieve the target.
- Q: The notice concerning potential risk of severe renal impairment including acute renal failure was posted on the website of the Pharmaceuticals and Medical Devices Agency (PMDA) yesterday (May 9, 2012). What impacts does the Company assume this to have on sales of Telavic?
- A: We started distributing to medical institutions a document concerning this issue from today (May 10, 2012). We are reminding medical institutions to perform renal function tests twice a week within the first seven days after initiating the treatment. We have already placed a warning in the package insert since adverse events such as aggravation of renal functions, especially increased creatinine, were reported in the clinical trial stage. All-patient post-marketing surveillance of the drug is under way and medical institutions have carefully administered Telavic by paying special attention to side effects such as anemia and skin problems. Therefore, we believe that they will also respond to this issue appropriately.

# MP-513

- Q: The Company and Daiichi Sankyo have agreed to conduct joint sales of MP-513 and TA-7284, diabetes treatment drugs. This is a new style of sales alliance. What merits are there for the Company with this alliance?
- A: Under a new sales alliance scheme, medical representatives (MRs) of each company will share plan information and results with each other and use any advantages to make up for weaker areas. It is quite important for us to increase the number of medical institutions that adopt our drugs for diabetes treatment. 4,000

MRs of both companies will visit as many medical institutions as possible to raise our brand recognition promptly and produce good results with cooperation from marketing specialists (MSs) of wholesalers.

# BK-4SP (quadruple vaccine)

- Q: The government will launch a routine vaccination of inactivated polio vaccine from September 2012. What is the Company's opinion on the BK-4SP schedule?
- A: The Research Foundation for Microbial Diseases of Osaka University, our codeveloper, filed an application for approval in December 2011. We are preparing now for their availability in time for routine vaccinations in fall 2012.
- Q: What is the Company's sales forecast for BK-4SP in FY 2012?
- A: We include sales of BK-4SP in our business forecasts for FY 2012, but we would like to refrain from disclosing any forecast of the drug since it has not been approved yet.

#### Licensing fees, etc.

- Q: Does the Company include royalty revenues from Gilenya in its forecasts for FY 2012 by using Novartis's sales forecasts for Gilenya as a base?
- A: We include royalty revenues from Gilenya in our forecasts for FY 2012 by using our sales estimates as a base.
- Q: Does the Company include milestone payments of TA-7284, which was licensed out, in its Licensing fee, etc. in FY2012?
- A: Yes, we include milestone payments in our plan. But, we do not disclose this figure.

# SG&A

- Q: The Company expects the SG&A and other fees for FY 2012 to increase by 6.5 billion yen from FY 2011. What are the factors behind the increase?
- A: Sales-related expenses account for about 50% of the increase. We expect sales expenses for the release of new products and the depreciation cost of distribution rights for new products that we launched last year to increase by around 2.0 billion yen and around 1.0 billion yen, respectively. In addition, we did not use up sales expenses in FY 2011 because we were not able to conduct sufficient sales activities because of the earthquake. Other than sales-related expenses, we expect temporary expenses for information systems to increase by around 1.0 billion yen and include expenses for transfer of the Tokyo head office in our budget.

#### Other

- Q: What impacts does the Company assume the transfer of plasma fractionation operations to have on business results?
- A: Our business forecasts for FY 2012 include the effects of integrating our plasma fractionation operations (Benesis) with a new organization from October 2012 (business transfer). Sales from plasma fractionation operations will be posted as our sales because we will continue selling goods under contract from the new organization for a while after the integration. We will sell inventory of finished goods that Benesis manufactures by the end of September 2012 as our group products in the second half of FY 2012 and post profits as usual. So, we think the impacts on FY 2012 business results will be minimal.
- Q: I heard that the Company has been restructuring its businesses other than the pharmaceutical business. Is the generic drug business included in the restructuring? Under the medium-term management plan 11-15, the Company sets a 50 billion yen sales target for the generic drug business for FY 2015. Is the Company keeping on target?
- A: The generic drug business is not included in the restructuring because it is part of the pharmaceutical business. We have not changed our sales target for the generic drug business for FY 2015. We believe that forming alliances with other companies is necessary to achieve the sales target, because it is difficult for us to achieve the sales target just by selling generic drugs after expiration of patents of competitors' large brand-name drugs or by transferring long-term listed drugs from Mitsubishi Tanabe Pharma to Tanabe Seiyaku Hanbai.

# [Development pipeline]

- Q: Would you please give us updated information on the development schedule of MP-424 in China?
- A: We are preparing the development in China based on the approval in Japan (approval as a third-class drug). We have prepared for the Investigational New Drug (IND) Application by obtaining a Certificate of Pharmaceutical Product (CPP) and would like to start development at the earliest possible time in 2012. Unlike the notification system in Japan, China introduces a permit system for the clinical trial. Therefore, the schedule of our clinical trial in China depends on when the Chinese authorities grant us the permit. However, we would like to make all efforts to complete clinical trials at the fastest pace so that we can set the schedule for the new drug launch before the current medium-term management plan expires.

- Q: Would you please give us updated information on the development schedule of MP-513 in China?
- A: We plan to complete the IND application after obtaining approval in Japan, because we conclude that developing MP-513 in the same way as MP-424 (approval as a third-class drug) is the fastest way to get the drug on the market.