



December 1st, 2015 (Tue) 16:00 - 17:30

[Attendees]

Masayuki Mitsuka, President & Representative Director, CEO

Takashi Kobayashi, Board Director, Managing Executive Officer, Division Manager of Sohyaku. Innovative Research Division

Yoshiaki Ishizaki, Board Director, Managing Executive Officer, Division Manager of Sales & Marketing Division

Seiichi Murakami, Board Director, Managing Executive Officer, Division Manager of Ikuyaku. Integrated Value Development Division

Eizo Tabaru, Board Director, Executive Officer, General Manager of Finance & Accounting Department

[Overview of Medium-term Management Plan 16-20]

Q: Will the majority of your operating income come from royalties in FY2020?

A: That is correct in comparison with current Japanese standards.

Q: Regarding the royalty income for FY2020 on slide 13, is this based on the assumption that you will still be posting royalties on Gilenya in the US?

A: We plan to offset the Gilenya cliff with an increase in royalty on INVOKANA and also with contribution from running royalty/milestone on MT-1303 and other pipeline.

Q: What is your development policy for MT-3995?

A: We are currently determining the direction of our development based on the results of clinical trials in Europe and Japan.

Q: Are there any plans for licensing out of MT-3995 in the next Medium-term Management Plan?

A: We are looking at a variety of possibilities to determine what course of action we should take.

[Four Strategic Priorities to Open Up the Future]

1. Maximizing pipeline value

Q: Regarding slides 19-21, in aiming to achieve a group headcount of 5,000 employees in Japan, do you plan to expand R&D area? Will you be able to achieve optimal competitive strength in each domain given the competitive environment growing more intense without selection and concentration?

A: We do not plan to inject resources into antibody therapies for rheumatoid arthritis other

than Remicade Simponi. The goal we are stressing in slides 19-20 is to expand our market share by injecting resources into areas of strength where we already have sales channels and development knowhow, and in related diseases with high medical needs. This is also the case for central nervous system diseases. Moreover, slide 21 indicates our plans for expansion by integrating medicinal chemistry, which is our strength, with the strength of our alliance partners.

Q: How do you plan to undertake drug development research given that you currently do not possess basic biotechnologies, including antibodies, proteins, and nucleic acids?

A: Slide 22 illustrates our challenges for new drug discovery research with opportunities. In the development of new therapeutic antibodies that utilize antibody drug conjugate technology mainly at TRL, we have reached the stage where we close to non-clinical studies. In addition, we are now able to make compounds using the bispecific antibody technologies licensed from Covagen. We are also working with Osaka University in the field of nucleic acid therapeutics to discover technologies for developing compounds that will overcome the issues of stability in blood and membrane permeability. As this shows, we acquire new various technology formats by collaborations with other companies. Going forward we aim to develop these compounds into pharmaceuticals that we can deliver to patients.

Q: Will your cooperation with AnGes MG, Inc. be a move toward undertaking regenerative medicine?

A: Our collaboration with AnGes MG is about Collatogene in gene therapies being developed by AnGes MG. Regenerative medicine in slide 22 includes radical therapies, the recovery of functions, and tissue regeneration.

Q: When you say preemptive medicine, do you mean an approach using Big Data based on a gene analysis database?

A: Our approach does not involve Big Data. We are looking for drug seeds related to the early diagnosis and early discovery of diseases by exploring changes in the proteomics and genomics of specific patient segments. We are also embarking on collaboration with an academic institution.

2. Strengthening IKUYAKU and Marketing

Q: Did you achieve your sales goal for Remicade?

A: Our plan factors in the impact of biosimilars and government policies. We plan to achieve our sales goal by further boosting the product value of Remicade and also achieve sales goal of Simponi.

Q: In Slide 30, what upside catalysts do you forecast from 2018 onward?

A: We are planning to launch sales of new drugs, including MP-214 and MT-2412.

Q: How many MRs do you think you will need to achieve your domestic sales goal for new drugs and priority products in FY2020?

A: Reflecting changes in the domestic market environment, we redefine the role of MRs, and allocate MRs in the diabetes and kidney diseases, and autoimmune diseases area, which are our priority disease areas. We are not disclosing the number of MRs we plan for 2020 at this time.

Q: Some of competitors separate their long-listed drug businesses. What direction do you plan to take going forward?

A: At this stage, we are not planning to separate the considerable portion of long-listed drugs. Our 1,800 MRs are concentrating on our priority items. This covers the cost of MRs for long-listed drugs. We plan to maintain this system for the time being.

3. Accelerating U.S. Business Development

Q: Can you give us details on how you came up with the figures for your ¥200 billion US strategic investment, which is earmarked for creating a business foundation and strengthening your product lineup?

A: In our US strategy, we plan to launch MCI-186 for ALS (domestic product name: Radicut) in FY2016 on our own. Pivoting on MCI-186, we plan to acquire companies that possess drugs in neurology to quickly maximize sales in this domain. The figures we presented are based on specific methods for their achievement.

Q: Do you plan to prioritize the acquisition of a company with products and a development pipeline in neurology, in addition to the launch of MCI-186?

A: Yes. Ideally, we want to acquire a company, and then launch of MCI-186.

Q: I believe that you were approached by other companies to create alliances for the drugs which meet unmet medical needs, such as MCI-186. Do you have any business partnering plans at this stage?

A: We do not plan a straight license given that this is the core product for our US business development.

Q: Do you view your ¥80 billion goal for US sales in FY2020 as a challenge or a goal that you are fairly confident you can achieve?

A: The figures were calculated based on specific measures. We aim to achieve our goal of ¥80 billion by employing alternative measures should we be unable to succeed with our current measures.

Q: What is your estimate for MCI-186 sales?

A: The sales for MCI-186 are not disclosed. The breakdown of our ¥80 billion sales goal in

US in FY2020 includes MCI-186, vaccine, and businesses and products in which we plan to make strategic investments.

Q: What hurdles do you foresee in developing your ALS therapy in the US?

A: We believe that relationships with patient groups are very important. In addition, we think that our relationships with regulatory authorities and relationships with insurance companies that shoulder drug price reimbursements are also very important.

Q: What response do you expect when the results of your clinical trial for a group of around 60 cases which will be presented at a conference in December 2015?

A: The data has been presented and we believe the response has been very positive.

Q: Can you discuss your commitment to the expansion of business in the US? Why did the three kidney drugs in your current medium-term management plan fail? Taking these failures into account, what are you doing differently?

A: Regarding BindRen, we obtained data that makes it possible to acquire regulatory approval and it was approved in Europe but we withdrew from the market given issues with business prospects. The development of Kremezin was a disappointment as we did not obtain a statistically significant efficacy. As for MCI-186, we do not expect FDA to request additional data. We believe that FDA accepts our data of MCI-186 obtained in Japan.

Q: In the current medium-term management plan, plans were abandoned due to the failure of three drug products. Will this change your commitment to the ¥80 billion US sales goal in the next medium-term management plan?

A: We plan to achieve our goal by implementing various measures.

Q: How do you envisage Medicago in 2020?

A: We plan to generate sales in the US and Canada during the latter half of our next medium-term management plan.

Q: Regarding the ¥200 billion US strategic investment, looking at your balance sheet, it appears there is capital of ¥400 billion available, including deposits to the parent company. Will the remaining ¥200 billion in deposits be left untouched?

A: We have cash on hand of around ¥380 billion. Deposits to the parent company are about ¥190 billion. In the next medium-term management plan, our investment of ¥200 billion or more indicates our investment to build a pipeline in the US and to establish a sales base. We plan to continue to make investment to expand our business in the US in and after FY2020. We plan to utilize deposits to the parent company.

[Financial guidance]

Q: Does your shareholders return include the buyback of shares?

A: This does not include the buyback.

Q: Is the buyback one of options to achieve ROE of 7.5%?

A: We plan to place priority on investments to increase our core operating and net incomes.

Q: Do you not plan to reduce costs by more than ¥20 billion given the changes in the external environment?

A: We believe any cost reductions above this level would be difficult.

Q: Does your consolidated dividend payout ratio of 50% (IFRS) indicate the return to shareholders of 50% of core net profit on an IFRS basis, excluding special factors?

A: Yes, 50% of net income on an IFRS basis.

Q: In this case, if you conduct structural reforms, your net income will fluctuate. Does this mean that your dividend payout will also fluctuate?

A: Our FY2020 net income goal is ¥70 billion. We plan a dividend payout ratio of 50% at that point. IFRS sees impairment losses as a risk so we plan to move forward with our next medium-term management plan in a manner that will allow us to sustain a stable dividend.

Q: So it is correct to understand that you do not plan to reduce your dividend payout?

A: Yes, that is correct.

[Conclusion]

Q: The concepts and the plans in the next medium-term management plan look good to me. What do your employees in the field think of it as they that have to carry it out? For example, the plan to frontload POC, is there actually a system in place that sets goals for employees in the field that will give them a place to start from? Can you please tell us what efforts the president has made to create a sense of unity with employees?

A: I believe there is unity in the company. To reform the R&D process, the R&D reform office is analyzing issues of the Company and competitors to accelerate R&D, and we are already embarking on process reforms to achieve new goals. In sales reforms we are currently redefining the roles of MRs but we have already begun enhancing our speed and forming alliances with other companies.

We plan to promote our conventional drug discovery process for the developmental candidates we aim to commercialize under the next medium-term plan. Under the new R&D process, we believe it may be difficult to commercialize the early development pipeline by FY2020. However, we aim to speed up our R&D and produce solid results by FY2020. Each department has set KPIs and established a project management system to shorten the R&D process. Moreover, in areas where we do not have proprietary platforms, we plan to actively move forward with alliances with other companies to speed

up our R&D process, and improve quality. This is part of our open shared business, where partnerships are already taking shape with academic institutions and with AstraZeneca in the field of kidney therapies.

In sales, we plan to achieve our numeric goals for priority products and new drugs, and via alliances with other companies. This should offset the decline in sales of long-listed drugs due to the several drug price revisions we anticipate in our next medium-term management plan. In light of this, we plan to expand our MR training program, mainly for the handling of new drugs, and strengthen our sales support.

Q: Do your specific measures include conservative plans or are the plans a stretch?

A: The plans for US business development are a stretch given that growth is based on the use of external resources. The goals in other plans we plan to achieve by maximizing our efforts.

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