



Friday, November 1, 2013 from 2:00pm to 3:00pm

Michihiro Tsuchiya, President & Representative Director, CEO

Kenichi Yanagisawa, Board Director and Senior Managing Executive Officer, Division Manager of Sales & Marketing Division

Kenkichi Kosakai, Board Director and Managing Executive Officer, Corporate Management

Masayuki Mitsuka, Board Director and Managing Executive Officer, Division Manager of Development Division

Seiichi Murakami, Managing Executive Officer, Global Product Strategy Department, Business Development & Licensing Department, Vaccine Business Development Department

**【Q2 FY2013 financial results】**

Sales cost ratio

Q. Please explain why you revised your sales cost ratio forecast from a previous 39.1% to 40.6%.

A. Although additional revenue (roughly ¥4.0 billion) on licensing fee, etc. pushed down our sales cost ratio, the following factors outweighed this positive benefit and triggered a rise in our sales cost ratio.

1. Impact from product mix. Sales rose for purchased products, such as vaccines, Remicade, and Simponi, but declined for Telavic, an in-house product, and long-term listed drugs.
2. Forex impact on foreign current-denominated licensed-in products (mainly Remicade).
3. The arbitration agreement on Remicade had a positive impact, which lowered our sales cost ratio. We initially estimated the sales cost decline of roughly ¥5.0 billion but the actual decline was around 60% of this amount, in part due to impact from foreign exchange translations. We note that in addition to a decline in purchasing price, we posted an extraordinary income of ¥11.0 billion to reflect the settlement we received for past purchases. These factors are all the outcome of the arbitration ruling.

Q. Will the lower sales cost ratio for Remicade due to the arbitration ruling be the same in and after FY2014?

A. Yes, it will.

Remicade (rheumatoid arthritis, etc.)

Q. Even in Japan, Nippon Kayaku has filed for approval of a biosimilar. Are you implementing sales measures in response to this?

A. We do not implement measures that particularly focus on competition from biosimilars. We believe that making it well known that Remicade works rapidly and it has reliable data will ultimately counteract biosimilars. Remicade has an 11-year track record for its use as a treatment for Crohn's disease and a 10-year track record for its use in treating rheumatoid arthritis. Consequently, we have accrued ample evidence. Recently, to remain drug free after remission, we are implementing tight control. We have earned high praise from the market. Conversely, we anticipate that doctors with no experience in administering biologics are likely to be very careful when they use biosimilars.

Q. What is the level of usage at DPC hospitals? If the use at DPC hospitals is high, we are concerned that the impact of biosimilars is likely to be substantial.

A. Remicade is mainly administered on an out-patient basis. Currently, it is administered to hospitalized patients at around 40 DPC hospitals.

Gilenya (multiple sclerosis)

Q. What is your estimate for Gilenya royalties?

A. We upwardly revised our 2H forecast for licensing fee, etc. including Gilenya royalties by ¥4.0 billion to ¥33.2 billion, taking into account the actual for 1H and the impact of foreign exchange rates.

Q. It appears sales of Gilenya are continuing to trend smoothly. However, with the impact from Tecfidera, has the positioning of Gilenya or any other factors changed in Q2?

A. We understand that the positioning of Gilenya has not been changed. We believe sales of Tecfidera are also brisk but the market for MS injection drugs is mainly dominated by Gilenya and Tecfidera.

Q. Is there additional information on the occurrence of progressive multifocal leukoencephalopathy (PML) as a side effect of Gilenya?

A. At this stage, we do not possess any information other than contained in the press releases from Novartis.

Q. Is my understanding correct that the press release covered a special case in which PML occurred as a side effect when steroids and immunosuppressants suppress the immune system excessively?

A. Yes, that is correct.

Q. What will the impact be when Tecfidera is approved in Europe?

A. Actually, Novartis posted a larger growth in Europe, as opposed to the US, in Q3. Unfortunately, there is no sufficient data to answer your question on the level of impact.

Invokana (Type 2 diabetes)

Q. How much in royalties will you receive in 2H?

A. The amount is not very large.

**【Development pipeline】**

MT-4666

Q. Will the clinical trial test a combination drug therapy using MT-4666 and Donepezil?

A. We plan to announce details after coordinating with EnVivo Pharmaceuticals.

Q. Will the improvement to cognitive functions from MT-4666 be on a par with Lundbeck and Otsuka's LuAE58054?

A. The mechanism of action is different but we understand the benefit should be equivalent based solely on the paper.

Q. Will patients develop gastrointestinal disorders as a side effect of MT-4666? Will there be impact from the combined administration with Donepezil?

A. The activation of acetylcholine mainly results in mild constipation but we believe that the gastrointestinal side effects are mild in comparison with those of Donepezil. There are no signs of aggravated symptoms due to the combination therapy.

TA-7284

Q. Will you develop a weekly dosage form of TA-7284?

A. I am unable to answer that at this moment.

**【Medium-term Management Plan】**

Q. Are you going to review the numeric targets in the medium-term management plan?

A. We should be able to discuss this on the announcement of financial results for FY2013.

Q. When will you achieve the ¥50.0 billion target in the generics business?

A. We look at various options during the remaining two years.

**【Other】**

Q. What was the administrative action on September 30? Can President Tsuchiya answer this question?

A. We were manufacturing and selling a product that had an added ingredient that had not

been specified in our approval documentation. We apologize to related parties for the concerns we caused. The misconduct that resulted in the administrative action was not a recent incident but occurred in the past, during the period when Medway was being sold. We reported this on our own to authorities when the issue came to light while we were implementing plans to improve operations. We believe this is evidence that we are steadily making progress in operational improvements.