Mitsubishi Tanabe Pharma

R&D meeting

December 1, 2010 (Wednesday) 13:30 - 14:30

Attendees:

Michihiro Tsuchiya, President & Representative Director, CEO

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

Seiichi Murakami, Executive Officer, Head of Development Division

Yoshihiro Kobayashi, General Manager of Development Project Management Department

MP-424(Telaprevir)

< Domestic development >

Q: The proportion of patients undergoing treatment for hepatitis C who use interferon is low. Will the market expand with the introduction of MP-424?

A: There are patients and doctors who are waiting for this new drug. We do not know whether or not this will lead to market expansion (turning up of new patients), but we think it is possible.

Q: In contrast to the three times daily administration of MP-424, competing drug administered twice daily is being developed overseas. Are you considering twice daily administration in Japan?

A: We are not considering that at the present time. We will launch MP-424 as the three times daily drug first of all and see the reaction in clinical practice.

Q: In regard to PEG-interferon and Ribavirin, which are administered concurrently with MP-424, only Pegintron and Rebetol (Schering-Plough; current MSD) were used in the Japanese clinical trial. Will combined use with Pegasys and Copegus (Chugai Pharmaceutical) be possible after launch? Also, overseas, Vertex conducted combination trials with Pegasys and Copegus. Will concurrent administration be possible using the overseas data?

A: Because Schering-Plough products are used in all Japanese clinical trials, Pegintron and Rebetol will be used concurrently with MP-424, but in the end, we will consult with the regulatory authorities about this. We cannot give you an answer in regard to whether or not combined use with Pegasys and Copegus will be possible at the present time.

Q: In the trial data, hemoglobin is reduced from the 8th week of the treatment period, but sustained virologic response (SVR) of about 100% is achieved in the 6th week. Can the sufficient effects be obtained even if administration is discontinued in the event that a reduction in the quantity of hemoglobin is seen in about the 8th week?

A: The domestic clinical trial is being conducted with a 12-week administration period. Since the SVR is higher at 12 weeks than at 8 weeks in the overseas trials, the basic usage is administration for 12 weeks. However, some patients have achieved SVR even if administration is discontinued at about 8 weeks. Therefore, it would be possible that good effects can be obtained even if treatment is discontinued prior to 12 weeks.

Q: Will all-patient surveillance be required?

A: The issue of what kind of post-marketing surveillance will be required is a matter for consultation with the authorities. However, we will need to carry out a sufficient surveillance and confirm efficacy after the launch in order to increase the value of this drug.

Q: I hear that patients with hepatitis C use erythropoietin as a measure against anemia in the US. Is it possible that the same measure will also be taken in Japan too?

A: We think at the moment that anemia can be controlled with detailed dose reductions of Ribavirin so we are not considering use of erythropoietin.

Q: In regard to hepatitis C treatment, will it be possible in the future to treat hepatitis C with only oral anti-viral agent like MP-424, rather than treatment added on to interferon, which is an injection?

A: From now on, many pharmaceutical companies will probably attempt to eliminate the virus with a combination of oral drugs and such movements have already started. The Company would like to contribute to the treatment of hepatitis C in total with Urso, a hepatoprotector indicated for hepatitis C. However, it would be difficult to acquire the approval of something like a liver protecting drug overseas.

Q: The fast track review proposal for hepatitis treatment agents has been made as part of the hepatitis countermeasures recommended by the Ministry of Health, Labor and Welfare. How is the current situation?

A: We are aware of the proposal and also has expected it. However, it is not clear whether the fast track review will be applied for MP-424 at the present time. The work on MP-424 will be advanced consulting with the authorities at the time of the application.

< Competing products >

Q: I would like to be told about the development situation of boceprevir (MSD), a competing product in Japan, and the differences in its profile with MP-424.

A: It is not completely clear the situation about competing products because it concerns at another company, but we understand that the development of MP-424 is in the lead. Both of these drugs are protease inhibitors, but it is reported that boceprevir requires concomitant administration for 48 weeks, has about the same level of anemia as MP-424 and appears to have fewer skin symptoms.

< Development in China>

Q: In regard to development in China, what kind of schedule will the company conduct clinical trials with? Also, what kinds of trials are required?

A: The Company plans to start on development in China straight after the approval in Japan. PK and phase III trials will be required in order to make an application in China, but there is no answer in regard to the trial period because that is also a matter for consultation with the Chinese regulatory authorities.

Q: Will the company advance development of the drug in China itself? Or will you cooperate with another company?

A: The Company expects to advance development on its own at the moment.

<Development in the US (MCI-196, MP-146)

Q: Is there any changes in the timing of NDA for the two drugs (MCI-196 and MP-146) in the kidney area in the US?

A: The schedule is a matter for consultation with the regulatory authorities so it is possible that it will change.

Q: Could the Company carry out any large-scale M&A in the US towards sales of MCI-196?

A: The Company has not planned owning a large-scale sales network in the US and

Europe in overseas development. In addition, the Company recognizes that these drugs could be rolled out with a comparatively small sales network. The Company will aim to acquire approval overseas by itself, but our policy is to choose the method that will maximize the value of each drug. In regard to conducting overseas sales, there are some options such as on our own or in cooperation with other companies in accordance with the characteristics of each product.