KYOWA KIRIN

News release

Regarding the Receipt of the Report on the Investigation from the Group Investigation Committee and the Recurrence Prevention Measures

It has come to light that Kyowa Hakko Bio Co., Ltd. (hereinafter, "Kyowa Hakko Bio"), which manufactures the active ingredient, has been manufacturing Mitomycin-C Kyowa, 2 mg and 10 mg (hereinafter, the "Products") active ingredient (the Products' active component Mitomycin-C) with a method that differs from the method on the approval certificate, which may have an effect on guaranteeing its sterility, and as a result, Kyowa Kirin Co., Ltd. (hereinafter, the "Company") is voluntarily recalling the product. Regarding this matter, the Company, which is a holder of marketing authorization for pharmaceutical products that is outsourcing the manufacture of the active ingredient to Kyowa Hakko Bio, as well as a group company, has decided that it is necessary to investigate the root cause of this matter, as well as provide recommendations on recurrence prevention measures. As a result, Kirin Holdings Company, Limited, the parent company, and the Company have established a Group Investigation Committee spearheaded by a third party that guarantees objectivity and independence, and have implemented the investigation.

Accordingly, the Company has received the report on the investigation from the Group Investigation Committee (hereinafter, the "Investigation Report"). Based on the opinions received from this Investigation Report, the Company has formulated a specific improvement plan to prevent recurrence.

1. Outline of the investigation by the Group Investigation Committee

(1) Outline of the Committee and Investigation

The Committee was composed of the expert of pharmaceuticals and medical devices and lawyers from Japanese Law Firm, Nishimura & Asahi. In addition, Deloitte Tohmatsu Financial Advisory LLC was hired and provided support for the forensic investigation, such as in review of the emails of the related parties.

The Committee received the minutes of the Board of Directors' meetings, the minutes of the management meetings, the quality audit reports and other in-house documents from Kirin Holdings Co., Ltd, the Company and Kyowa Hakko Bio, and examined and reviewed their contents over the period of October 8, 2019 to January 14, 2020. In addition, the Committee conducted interviews with 65 persons connected to the above three companies as well as a forensic investigation of 166 persons connected to the above companies.

(2) Fundamental Causes of the Case found as a Result of Investigation

The Investigation Report indicated that there were various causes and factors such as the weakness of the production and quality assurance units, inadequate education for quality assurance unit and production unit employees, and manufacturing plans that deviated from the actual situation, and deficiencies in the manufacturing equipment and plant infrastructure. The Investigation Report further stated that the senior management did not accurately ascertain the risks related to product quality, production/quality assurance operations and respond appropriately to determined risks.

(3) Recommendations from the Committee

From the Committee, Kyowa Hakko Bio and the Company received recommendations for recurrence prevention measures.

A. Recommendations for Kyowa Hakko Bio's recurrence prevention measures

1) Senior management's firm commitment towards GMP compliance and conveying of messages to the worksites
2) Education for Hofu Plant of Yamaguchi Production Center of Kyowa Hakko Bio (hereafter, the Hofu Plant") employees
3) Rebuilding middle management
4) Strengthening of the Quality Assurance Department
5) Clarification of reporting obligations when becoming aware of cases of impropriety
6) Clarification of the roles
7) Easy-to-use SOPs and a flexible system to manage changes for the manufacturing sites
8) Continuous monitoring by senior management

B. Recommendations for the Company's recurrence prevention measures

1) Senior management's firm commitment towards GQP compliance and conveying of messages to the worksites
2) Strengthening of the Quality Assurance Department
3) Continuous monitoring by senior management

2. Future action policies based on the investigation results from the Group Investigation Committee

First, we should fully recognize that this situation at the Hofu Plant came about as the Company did not sufficiently carry out the responsibilities as a holder of marketing authorization for the Products. The Company will sincerely accept the results of the investigation and opinions as stated in the Investigation Report, and upon sufficiently considering the details, proceed with necessary measures to prevent recurrence as quickly as possible.

As was already announced, with Kyowa Hakko Bio, the Company is not only investigating the cause of this matter regarding the Products, but also making improvements regarding production and quality control overall and recurrence prevention measures. The Company believes that it must not only strengthen manufacturing and quality assurance systems to prevent recurrence, but also address the strengthening of the corporate group's governance, following the report on the results of this investigation. In addition to the investigations and discussions that have been conducted in-house thus far, the Company has formulated a specific improvement plan that sets the three points below as important issues.

（1） Creation of a strong production and quality assurance system as management's top priority
（2） Improvement of risk management
（3） Reformation of corporate culture

Regarding the first issue, the Company established a global quality assurance system from April 2019, and started increasing the number of quality assurance employees globally, as it recognized that it is necessary to strengthen the quality assurance system further as a holder of marketing authorization for pharmaceutical products. However, this initiative has just begun to commence, and to strengthen this quality assurance system into an effective system, the Company recognizes that sufficient resources are necessary to enhance the quality assurance function. The Company has already begun recruiting highly experienced personnel from external sources, and planned a further increase in staff, but it is also important to enhance the overall skills of the production and quality assurance units at the same time. The Company will enhance the new education program for audit members, and develop personnel to support the quality assurance system in order to not only ensure they possess the necessary knowledge for quality audits, but also develop audit members who have the ability to proactively collect information on-site and to collaborate with

other departments.

Furthermore, in line with the opinions received from this investigation report, problems pertaining to manufacturing and quality assurance have become apparent as a result of this matter, and the Company recognizes that it is important to strengthen the governance of the corporate group. As stated in the second point, the Company will reexamine risk management processes in order to identify and analyze risks that will impact management, and appropriately handle these risks as management issues. The Company will develop a strong risk management system that can prevent risks before they occur by accurately assessing not only quality issues, but also new management risks and potential risks on-site, and executing necessary measures or investments without delay.

In addition, management is seriously reflecting on the fact that this situation was not able to be discovered and corrected at an early stage. Because of this, the Company believes that it is important to continuously take action to earnestly understand and instill the spirit of compliance observation throughout the company, with the firm determination to observe compliance. Management, being at the head of all employees, sincerely accepts this matter as their problem, and is fully aware that the prevention of recurrence and compliance observation are management issues of the highest priority, and thus will reform their conduct. One aspect of that measure, the reformation of corporate culture, is raised as the third point of the important management issues, and while collaborating with an external advisor, which will be the most important measure directly controlled by the President, the entire Company will make any necessary reformations in awareness in order to grow into a global specialty pharmaceutical company in the future.

These improvement measures have already begun to be considered in-house after the detection of this matter, and the Company will further assure the quality assurance of products and work to prevent the recurrence of an incident of this kind by fully accepting the opinions regarding recurrence prevention from independent and external sources, and thoroughly executing the necessary improvement measures in order to sufficiently fulfill responsibilities as a holder of marketing authorization for pharmaceutical products.

Once again, we should sincerely recognize this situation, and going forward, efforts will be made to prevent recurrence by thoroughly observing GMP regulations, ensuring the reliability of the quality assurance system, and observing all pharmaceutical regulations not only within the Company, but also for each company within the group and related contract manufacturers. The Company will also put its greatest efforts into recovering the trust from everyone by having all employees devote their utmost energies to sincerely working on activities that prevent recurrence.